

**THE ROLE OF A GENERAL SAFETY REQUIREMENT
IN CANADA'S HEALTH PROTECTION REGIME**

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A RESEARCH REPORT TO HEALTH CANADA

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The Role of a General Safety Requirement in Canada's Health Protection Regime

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Executive Summary/Key Findings

The Purpose of the Paper / Health Canada's Objectives

The purpose of this Paper was to consider the suitability of the General Safety Requirement (GSR) as a regulatory instrument to help to help Health Canada achieve multiple objectives under its 'Legislative Renewal Initiative', namely:

1. To promote a culture of safety as a unifying principle under a proposed *Canada Health Protection Act* by including a general prohibition against manufacturers and suppliers producing or supplying unsafe products to the public;
2. To authorize Health Canada to take timely, precautionary action, before injury occurs, against unsafe unregulated products or products that, although nominally regulated, present serious emerging risks not dealt with under existing regulations;
3. To reinforce the "front end" obligation of producers to properly assess and manage, on a life-cycle basis, risks associated with products to be supplied to the public;
4. To expedite the detection, remediation or removal of unsafe products from the market through mandatory reporting by producers and suppliers of substantial product hazards;
5. To foster an "outcome oriented" (or performance-based) product safety regime which facilitates both technical innovation and continuously improving safety standards; and
6. To promote the enhanced use and continuous improvement of voluntary standards by giving official recognition and effect to private voluntary standards and industry codes of practice, by providing that compliance with such standards will raise a legislative "presumption of conformity" with general product safety requirements.

Evolution of the GSR

The European model of the General Safety Requirement evolved in a unique set of political, economic and legal circumstances. It is premised on a "New Approach to Regulation" developed in Europe in 1985 to overcome regulatory gridlock resulting from diverse Member States trying to agree, unanimously, on the content of highly detailed product standards that were being harmonized for the purpose of establishing and improving the European Common Market. The legal and political *raison d'être* for the GSR is internal trade. Product safety is an ancillary consideration under the Treaty establishing the European Community.

Europe's New Approach to regulation makes use of voluntary standards in a manner likely to be construed in Canada and the United States as a form of "Back-door Rulemaking. Only the essential requirements (broad performance standards) are included in legislation. Responsibility for establishing technical product standards is, in effect, sub-delegated to private standard-setting committees that are usually dominated by industry experts.

Although the standards thus established are 'voluntary', they are quasi-mandatory in practice, especially for medium and small enterprises that do not have the capacity to develop acceptable alternative standards. The New Approach to Regulation was based on a regulatory framework employed in Germany and some Nordic countries that legislate only essential product requirements, leaving the matter of compliance with those requirements to the private sector based on codes of practice, standards and official guidelines.

The GSR is also premised upon absolute liability for product 'defects' based on Europe's Product Liability Directive of 1985. This concept is not generally replicated in Canada, but is a major factor in compelling positive compliance behaviour in the area of product safety in Europe, including under the GSR.

Initial Development

The European Union's policy rationale for the General Product Safety Directive was that it would *temporarily* fill out the regulatory gaps created by new unregulated products or emerging risks with the expectation that the scope for the GPSD would diminish as new product legislation was developed. In practice, the tendency for the general safety provision is to expand into a permanent form of horizontal regulation characterized by multiple layers of uncertainty. The reasons for this include: the failure of industry standards to meet safety objectives; slow progress in harmonizing European product standards due to a general policy bias against regulation if it was not rigorously justified; failure to meet the five year target for reviewing approved standards leaving more scope for the GSR and the fact that new Member States with inadequate product safety legislation or product standards employed the general safety provision as an instrument of first resort.

The GSR is a performance-based regulatory technique under which regulations are effectively replaced by voluntary specification standards, only some of which are 'approved' by government. The regime, unfortunately, is characterized by multiple layers of uncertainty, including built-in uncertainties in the definition of 'safe' product, inconsistent methodologies for assessing product risks, uncertainty about the threshold for identifying 'serious' risks, residual uncertainty about the manner of establishing conformity with the GSR and the paucity of product standards approved under the General Product Safety Directive. The GSR is not a good candidate for effective enforcement under a criminal law model. This is especially so, given the degree of imprecision in the definition of the general duty violation; the fact that Courts construe definitions of criminal offences strictly in favour of the defendant as a matter of legal principle and the

requirement that the State prove the factual elements of an offence *beyond a reasonable doubt* before the defendant is placed under any onus to disprove negligence, or otherwise mount a positive defence.

Implementation

Although “beguilingly simple” in concept, the General Safety Requirement is difficult and expensive to implement. In theory, pre-marketing duties (product development, product design, hazard assessment, risk management and production) are reinforced in law under the GSR as the responsibility of producers. In practice, the degree of uncertainty associated with the GSR’s highly flexible framework results in industry seeking comfort from the public authority on a day-to-day, product-by-product basis, concerning not only how the law will be administered but also, in effect, about what the law *is*. (ie: Is there an approved domestic standard applicable to this product? If not, what foreign standards are acceptable for the purposes of the domestic GSR? Does this product present a ‘minimal’, ‘acceptable’ or ‘serious’ risk? If we alter our production process in this or that manner, will the end product be viewed as meeting the exigencies of the GSR?)

European experience under the General Product Safety Directive confirms the need for extensive advice and guidance from public authorities, particularly on the part of small enterprises. Small enterprises seldom have the capacity for rigorous risk assessment, testing or for developing new technical standards and innovative quality management systems. If they cannot afford third party expertise, they look to government officials for advice and assistance in these matters. In some cases, local authorities have had to take over testing functions for small enterprises to make the scheme work.

Three case studies developed under this Report, and the results of interviews conducted during its preparation, illustrate the major elements of cost associated with implementing a GSR. They include: an extensive advisory program of ‘expert’ advice, scientific testing, rulings, guidelines and operational manuals; new skills training for the inspectorate (e.g. auditing quality systems vs. inspecting products); financial support for standard-setting agencies to expedite the establishment of new product safety standards; compensation for government officials and consumer representatives on standard-setting committees to maintain some stakeholder balance in the standard-setting process, research into world-wide product standards to develop a rolling inventory of standards available for the administration of the GSR; augmenting the capacity of government testing laboratories, and the cost of hiring and retaining various government ‘experts’ to sustain an effective challenge function against industry ‘experts’ under a GSR regime that is largely industry self-regulated.

The compliance and enforcement measures that a public authority must undertake under a highly self-regulatory regime like the GSR may be somewhat different from those under an inspection-oriented prescriptive regime, but do not

likely involve resource savings for government. Hodges¹, in his text on *European Regulation of Consumer Product Safety* sets out a framework for the post-marketing activities of authorities under the GSR which includes the following elements: *verification*: that economic operators have correctly and adequately carried out their pre and post-marketing functions; *market surveillance* to identify unsafe products; *taking action* to ensure that appropriate action is taken when safety issues are identified; *collaboration* with other regulatory authorities, economic operators, and consumers/users; *enforcement*, that is, imposing sanctions, or proposing to courts the imposition of sanctions on economic operators for non-compliance with legal obligations and, in addition, *providing public information* such as through vigilance information databases, answering questions from stakeholders about reporting thresholds, and possibly providing rulings on whether particular products meet the general safety requirement.

Each of above functions involves a broader subset of tasks, many of which will be resource-intensive. In elaborating on the public authority's *post-marketing verification activities* under a GSR where it must assess risks associated with potentially "dangerous products," Hodges notes that a public authority must have the ability to address a series of detailed questions associated with the prior conduct of the producer or supplier.

Examples of such questions may include: Has the producer assembled the technical documentation on the product's design and manufacture and labeling, including a risk assessment, and kept it up to date and available? Did the producer collect, record and collate safety information from users, retailers, distributors, regulators, or any other source, including scientific and technical literature, on how safe the product is in practice and whether it continues to conform to the standards of safety as these evolve in the light of new scientific and technical information? Did the producer adequately investigate negative incident information? Did the producer undertake an adequate assessment of the information thus garnered? Did the producer make appropriate use of external technical, regulatory, medical, or legal advice, or update the product's assessment, where appropriate? Was information required in law to be reported to the Authority adequately reported? Did the producer make an appropriate decision on whether any changes needed to be made or action taken as a result of the assessment, such as (i) changes in the design, manufacture, labeling, or packaging in relation to products not yet placed on the market, or (ii) action such as informing users, distributors, regulators, or others of changes in potential risks with the product, or instituting a recall of products already on the market?²

In practical terms, the Case Studies submitted with this Report illustrate how many of the above-mentioned tasks would have to be addressed under a GSR by Health Canada in relation, for example, to bicycles (an unregulated product); Konjac Jelly Mini Cups (an inadequately regulated product); and electrical household products (an area of federal-provincial regulatory overlap).

¹ Christopher Hodges, *European Regulation of Consumer Product Safety*, 2005, Oxford University Press,
² (Hodges, p. 132.)

Outcome oriented (performance-based) regulation like the GSR, though largely untested by time and the courts, is viewed by major industry and the public sector as a promising vehicle for better meeting regulatory objectives and advancing a growing convergence between business and regulatory practices. Yet the benefits and limitations of performance-based regulation, in which law, business, industry and the stakeholders relying on regulatory protection, interface, remain the subject of continuing debate and controversy. Performance measurement and enforceability will be significant challenges for Health Canada if it introduces an “outcome-oriented” GSR regime, particularly under the constraints of a criminal law model. The advantages and limitations of performance-based regulation are discussed in this Report with reference to a Harvard University seminar on the subject; a report of an Australian Commission on ‘Grey-Letter Law’; the expectations of Canada’s Auditor General when auditing performance-based approaches to regulation; and to practical considerations associated with performance-based regulation in the experience of the Offshore Oil and Gas industry.

Cost/Benefit Considerations

The cost / benefit considerations applicable to the GSR differ significantly between Europe and Canada. Cost-benefit and business impact considerations will be especially important in determining whether to proceed with a full European style GSR under the proposed new *Canada Health Protection Act*, or to incorporate only some of its features in existing legislation, or to rely on other legislative options as a ‘safety net’ for regulating emerging product risks.

The cost/benefit considerations of Europe’s ‘New Approach’ to regulation and the GSR are unique. While the regulatory costs to government and industry inherent under the European GPSD regime are significant, the financial and political benefits associated with achieving an effective European Common Market and functioning Union are enormous. In Europe the benefits of these regulatory techniques are measured almost exclusively in macro-economic and political terms. Product safety is an ancillary consideration under the terms of the Treaty establishing the European Union.

The precise effect of a *General Product Safety Directive* to ensuring safe products in Europe is far from clear. Much of the effectiveness of the European product safety regime seems attributable to the formidable market sanctions that may be imposed on producers, suppliers and exporters within the Common Market, and the producers’ absolute liability for defective products under the European Product Liability Directive. There is little case law, and Europe has had only minimal experience with the GSR in its present, substantially revised, form (The revised GPSD came into force only in January of 2004).

Effect on Compliance Behaviour

There is little evidence that the mere enactment of a General Safety Requirement (to supply 'safe' goods) has any appreciable effect on compliance behaviour in the absence of vigorous industry / government programs to promote safe practices.. The requirement to report serious product risks to public authorities is an effective element of the GSR, given the consequences that may flow from such a report in Europe such as absolute liability in damages for product defects, suspension or banning from the European Common Market, prohibition against exporting the product beyond the EC and loss of commercial reputation in the wider European Community.

With the exception of large enterprises, there is little awareness of the general safety requirement in Europe. The General Safety Requirement is a difficult concept to explain to 'regulation-centric' industries and has proven to be a significant communications challenge for European administrators. Extensive safety programming that is backed up by credible safety enforcement is the minimum requirements for bringing about a 'cultural' change in this area. Despite sectoral differences, the programming lessons learned in the Occupational Health and Safety area are likely to be helpful to Health Canada in promoting a 'culture of safety' in the consumer product sector.

However, the more mature consumer product safety programs in European Member States do seem quite effective - to the point where product safety is not regarded as a significant problem in several jurisdictions. In the UK and the Netherlands, for example, there appears to be a significant 'culture of safety' already in place amongst local industries. Some have argued that the GSR is a disproportionate response to the real product safety problem, which, overwhelmingly, is cheap imported electrical goods and toys from China and the Far East. Some argue that a more targeted solution to the problem is called for – specifically, tighter border control and education of foreign exporters about European standards. But Europe's strict product liability laws, coupled with the potential enormity of a loss of market possibilities following a Rapex Report on a dangerous product, and fear of damage to corporate reputations remain the main compliance incentives for industry.

Benefits and Disadvantages of a GSR

Health Canada should carefully weigh the benefits and offsetting disadvantages of a GSR regime before deciding to include it as part of a proposed Canada Health Protection Act.

The GSR is a form of performance-based regulation under which voluntary standards, in effect, substitute for technical regulations. The GSR's advantages and limitations are summarized in this Report: in both cases they closely parallel the advantages and limitations of any performance-based regime. The GSR's 'advantages' are expressed as *perceived* advantages because the advantages are sometimes illusory, or may be offset by corresponding disadvantages.

For example, the view that merely by enacting a GSR (in effect codifying the common law duty of care to avoid producing unsafe products) will improve industry's pre-marketing practices seems largely illusory based on the low level of industry knowledge and understanding about the GSR achieved in Europe. While the GSR seems effective as a regulatory 'safety net' to catch unregulated dangerous products, an important offsetting disadvantage is that it is difficult to contain and tends to become an expansive form of horizontal regulation characterized by multiple layers of uncertainty.

Again, though public authorities usually look for resource savings from reduced inspection costs under highly self-regulated schemes like the GSR, the reality is that industry will likely seek 'comfort' from Health Canada's advice, assistance and rulings to clarify the requirements under an uncertain law, possibly on a product-by-product basis. Industry often views regulatory flexibility and closer harmonization with industry practices as a clear benefit in terms of product innovation, or the harmonization product standards, or in terms of minimizing regulatory distortion of the marketplace. However, these advantages for industry can be offset by disadvantages for government and stakeholders in terms of undue industry influence on disputed safety issues, anti-competitive behaviour toward small enterprise and weakening of the government's 'challenge function.' This Report includes a much longer list of potential advantages and (sometimes offsetting) limitations under the GSR for Health Canada to weigh.

Legal Considerations and Impediments

There are a number of legal considerations, and some impediments, to implementing a GSR as an operative provision of the proposed Canada Health Protection Act.

The legal framework that Health Canada is constitutionally bound to utilize in implementing a GSR – a criminal justice framework - is an impediment to fully realizing the plenary administrative, civil and criminal powers (and programming opportunities) of European product safety regimes under Member States that have full constitutional and regulatory authority for product safety within their respective jurisdictions. The *administrative* recall power that is considered so important to the success of the GSR by some officials, for example, may not be constitutionally available under health protection statutes based *exclusively* on the federal authority to enact *criminal* legislation for the purpose of protecting public health and safety. Effective alternative methods for resolving complex disputes under civil processes (Is the product "safe"?) are not directly available under the criminal process; such techniques have to be carefully crafted to be compatible with the administration of criminal justice, for example, along the lines of environmental protection alternative measures developed for the *Canadian Environmental Protection Act*.

The GSR also raises important 'rule of law' issues that could emerge as serious impediments to implementing a GSR. Laws should normally be made in advance

of when they are to be applied, should operate prospectively, and should be publicized or otherwise made available to those whom they are to govern. In the case of unregulated products for which no standards exist, a “general” safety requirement leaves such an enormous charging discretion in the hands of administrators that Courts might view the Government as trying to ‘establish’ the law on a case by case basis. Alternatively, the requirements of the general duty violation may be so uncertain, or so easily circumvented by the defendant advancing alternative versions of the legal requirements (e.g. foreign standards), that the GSR will be extremely difficult or, in some cases, impossible to prosecute, given legal requirements for precision in penal processes.

There are other legal considerations, not amounting to impediments, which would have to be addressed in implementing a GSR. Mandatory reporting requirements under the GSR would have to be developed and administered in a manner that did not violate the privilege against self-incrimination in penal proceedings. In practice, Health Canada would also have to carefully manage the heightened risk of regulatory liability for negligent misstatements under an extensive program of advice, testing, and rulings that the Department would likely have to maintain (in particular, for small enterprises) in order for the GSR regime to function. Other legal considerations are discussed throughout this Report.

Summary

By way of summary, there are a number of reasons mentioned throughout this Report as to why Health Canada may wish to reconsider including a general safety requirement as a central element of the proposed new *Canada Health Protection Act*. The GSR is difficult to implement under a criminal law model and some of the remedies, such as administrative recall orders, may not be available to the Department. The need for a ‘safety net’ is not the same under the CPHA’s constituent Acts and Regulations and the Department has much closer control over emerging risks under the pre-marketing licensing and certification regimes in the *Food and Drugs Act* than it does under the *Hazardous Products Act*.

The case for implementing a GSR in Europe was based on circumstances very different from those in Canada. A GSR model imported from Europe that is based primarily on trade considerations may not be the best approach to achieving Health Canada’s *safety* objectives, or for harmonizing Canada/ United States product standards. The cost / benefit considerations associated with a GSR in Europe are highly different from those in Canada; the economic and political benefits associated with the GSR and its underlying New Approach to Regulation in Europe are potentially enormous and justify considerable administrative expense to make the Common Market and the European Union work. The resource savings that Health Canada might have anticipated under a highly self-regulatory GSR regime are unlikely to materialize under a full consideration of the cost elements inherent in administering such a regime.

While Canada’s regulatory policy encourages the use of voluntary standards to achieve regulatory goals by *supplementing* regulations and promoting a ‘best

practices' approach, it does not, on its face, go so far as to countenance the sub-delegation of *quasi-regulation-making power* to domestic or international standard-setting bodies operating outside of the domestic regulatory process, as occurs in Europe under the 'New Approach to Regulation.' In addition to raising 'rule of law' considerations, the compatibility of the GSR with Canada's evolving regulatory policy should be settled with central agencies of Government before Health Canada proceeds with the GSR initiative.

The Department's potential exposure to regulatory liability, particularly from negligent misrepresentations made under the extensive advisory program required to make the scheme work, may increase significantly. This warrants careful analysis with the Department's Legal Services Unit when and if the terms of a GSR scheme are finalized.

Alternatives

There are a number of alternatives Health Canada may wish to consider, separately or in combination, as methods for achieving the regulatory objectives outlined at the beginning of this Executive Summary. The purpose of this Paper was to consider the suitability of the GSR as a regulatory instrument for achieving Health Canada's objectives under the Legislative Renewal Initiative. Our research has led us to question the suitability of employing a GSR under the proposed *Canada Health Protection Act*. While reaching that conclusion might have been sufficient for the purposes of our mandate under this Project, we are outlining five broad options for Health Canada to consider for addressing its regulatory goals and objectives, four of which are alternatives to the GSR, namely:

1. ***The European Model*** – Attempt to adapt the European model of the GSR to the Canadian legal context for inclusion in the proposed *Canada Health Protection Act*. (This was the principle subject of this Report)
2. ***Incremental Reform*** – Import only needed elements from the GSR into the constituent Acts originally intended for consolidation under the CHPA should the Department decide not to proceed with a consolidation. (i.e. reporting requirements, data-based detection system, missing enforcement powers, etc.) This is the approach adopted by Australia following an extensive review of its consumer protection legislation completed in 2005.
3. ***Modified American Approach (HPA Only)*** – Under the *Hazardous Products Act*, Health Canada would enact a general prohibition against advertising, selling, importing etc. consumer products that *present an unreasonable risk of injury*. 'Risk of injury' would be defined on a basis consistent with the U.S. *Consumer Product Safety Act*, to mean "a risk of death, personal injury, or serious or frequent illness." 'Risk of injury' is an issue that can be determined with much greater certainty, (including by criminal courts) than the question as to whether particular products are

“safe” or “unsafe.” This Option has the additional advantage of facilitating closer harmonization of *North American* consumer product standards, injury data collection and enforcement practice.

This Option would apply only to the *Hazardous Products Act* on the assumption that there is no real need for a general prohibition of this kind under the *Food and Drugs Act* and related regulations where closely controlled licensing and certification schemes with *pre*-marketing and adverse incident reporting requirements are already in place. The GSR is a *post*-marketing mechanism that assumes little to no government oversight at the *pre*-marketing stages of product design, development and production. Moreover, an incremental reform approach is already evident under the *Medical Devices* and *Natural Products Regulations*, which now include a virtual GSR regime linked to conditions of licensing.

4. **Modified American Approach (All Constituent Acts)** – If Health Canada wishes to extend the general prohibition outlined in the previous Option beyond the *Hazardous Products Act*, the scope of the HPA could be extended to apply to dangerous unregulated products and serious unforeseen risks in product areas covered by the other Acts administered by Health Canada. While the general duty violation and related powers might be situated in the HPA, the authority would be accessible to enforcement officials administering the other enumerated Acts, as needed, perhaps without requiring significant changes to the Department’s internal organization.

While the HPA is mentioned as a possible ‘home’ for the general prohibition based on American ‘risk of injury’ terminology, it might be located in some other generic statute administered by the Department such as the *Department of Health Act*³, or the proposed CHPA if the Department proceeds with the consolidation of constituent Acts under the Legislative Renewal Initiative.

5. **Status Quo with Administrative Reform** - Under this Option, the Department would rely on the existing provisions for Ministerial Interim Orders in the *Hazardous Products Act* or the *Department of Health Act* as the main safety net for dealing with unregulated dangerous products, and unforeseen, emerging and serious risks in regulated products.

In this case, however, the focus would be on making the Minister’s existing remedy more efficient by developing internal policies for triggering the use of this power together with a fast-track process for exercising it - all in collaboration with the Minister’s Office and relevant Central Agencies of Government. The policy and fast-track process would then become a routine element of briefing for new Ministers of Health so they would be

³ S.C. 1996, c. 8

familiar with the emergency measure in advance of the need for urgent intervention.

Options two to five (i.e. the 'alternative' options) might be accompanied by a Health Canada program to encourage the development and use of effective voluntary product standards with a view to achieving levels of product safety that routinely exceed minimum legal requirements. For example, on July 10, 2006, the U.S. Consumer Product Safety Commission published a final rule on *Commission Involvement in voluntary Standards* indicating how the Commission intends to promote improved voluntary product standards in collaboration with the private sector without compromising the public authority's institutional independence or oversight role.⁴

⁴ Federal Register, July 10, 2006, Vol. 71, No. 131

1. Introduction

Objectives and Methodology

Description of the Project

This research project consists of three general components: a gathering of information; a synthesis, and a comparative analysis of the information; and an analysis and assessment of lessons learned from the Canadian perspective. More specifically, the project's scope and objectives were described in the proposal document as follows:

Following an introductory discussion of the place of the GSR as an instrument for goal-based regulation in relation to health protection, the proposed research will provide a summary and description of the legal and policy underpinnings of GSR in several jurisdictions. The project will synthesize the regulatory frameworks employed, compare the approaches adopted for defining a General Safety Requirement, and develop a taxonomy of the policy, legal and voluntary instruments used to give effect to it. In addition the proposed research will review practical experience with GSRs, including compliance and enforcement experience. This aspect of the research will involve an examination of the effects of a GSR on program administration as well as an outline of impacts on industry and business, and on the intended beneficiaries of the regulatory regime, among other stakeholders.

The analysis will be guided by reference to issues raised by Health Canada's Legislative Renewal Initiative and to the issues to be addressed by Health Canada in adapting promising GSR approaches employed in jurisdictions outside Canada to Health Canada's specific regulatory objectives, including the harmonization of regulatory approaches and standards with trading partners.

The Comparative Experience with GSR: EU and US

In order to pursue the comparative dimension of the information-gathering component of the project in a manner that would be most suited to the needs and expectations of Health Canada, a series of issues or questions intended to guide research and interviews was developed in consultation with supervision officials from the department. In the case of the European Union, members of the research team conducted in-depth interviews with government officials in Brussels and selected Member States, and consulted academic specialists. In the case of the United States, Professor Nicholas Ashford was recruited to provide information on the U.S. approach to and experience with a comparable set of issues.⁵ Professor Ashford's research paper, "Options for a Statutory General Safety Requirement (GSR): Lessons from Selected Experience in the United States," is included as Annex 12 to this report.

⁵ See Annex 12

Evolution of Instructions

In the course of ongoing consultations and discussions with Health Canada, the researchers were provided with draft legislation developed within the department and, subsequently, with an indication that internal consideration of the GSR was proceeding at an accelerated pace in contemplation of a draft memorandum to Cabinet, expected to be presented prior to the completion date for this project.

Case Studies and an Emphasis on Implementation Issues

With much of the background research (including interviews) in the European Union completed, it was no longer possible to substantially re-direct the research effort. However, to accommodate as much as possible the acceleration and intensification of Health Canada's needs for advice on the GSR, two significant changes were made in the presentation of the report. Firstly, to increase the immediate practicality of this GSR research, detailed case studies were added for illustrative purposes. Secondly, to enhance the accessibility of the overall findings, the original intention as to table of contents and organization were abandoned in favour of an approach oriented more towards specific issues arising from the research and with an increased emphasis on matters that might be expected to arise on implementation of a GSR. Much of the historic and comparative material gathered during the course of research therefore appears interspersed throughout the discussion of issues rather than in a consolidated form as background to analysis.

Overview of the Report

Following a brief review of the general context for regulatory reform in Canada and discussion of the specific objectives of Health Canada's Legislative Renewal initiative, including expectations associated with the possible adoption of a General Safety Requirement, this report proceeds in the following manner. Chapter 2 *What is a General Safety Requirement?* seeks to explain several alternative ways in which the GSR may be understood. In chapter 4 *Evolution of the General Safety Requirement*, the report reviews the evolution of the GSR within the European context where several streams of policy development contributed to the adoption and ongoing refinement of this instrument. Chapter 5 addresses in detail *The Case for Reform in Europe* with reference to the experience of other jurisdictions and in light of objectives previously identified by Health Canada. Before proceeding to analyze the *Operative Provisions* of a GSR and *Implementation Experience* (chapters 6 and 8), the report identifies a series of *Underlying Policy Considerations*, which apply generally to Canadian federal regulatory initiatives. In the context of examining *Operative Provisions* and *Implementation Experience*, we make particular reference to a series of case studies designed to illustrate the potential of a GSR to address certain generic categories of regulatory challenge. These generic challenges arise where: (1) a product is entirely un-regulated; (2) a product is subject to over-lapping federal regulatory requirements derived from two or more statutory schemes; or (3) a product is un-regulated at the federal level, but is subject to provincial

requirements. For comparative purposes the United States Experience and some existing Canadian initiatives involving GSR-type instruments or performance-based regulation are also described. The report concludes with a *Summary of Advantages and Limitations of a General Safety Requirement* (chapter 13) and a statement on Policy Options.

Background

General Regulatory Context

Modern Regulatory Reform

Before addressing the General Safety Requirement itself, it is appropriate to review the broader context within which discussion of a GSR has taken place. This is important because the GSR is but one instrument or approach to governance, and health protection is but one policy field or sector in which governments seek to promote the well-being of the societies for which they are responsible.

Western governments and their citizenry have debated extensively in the past quarter century such general issues as regulatory effectiveness, regulatory burden and regulatory reform. This has involved consideration of alternative approaches to regulation and enforcement in the context of the multiple objectives of modern governance: not only to promote health, but also economic well-being, social harmony, environmental sustainability, peace and security.

Recent discussion of the background to this evolution in the nature of governance, with particular reference to market regulation, provides an instructive introduction to the broad process of transformation in which the GSR, amongst other proposed instruments of regulatory reform, is situated:

Leaving tax policy aside, the regulation of markets was the purview of lawyers and others familiar with criminal justice. Offensive behaviour was defined by law, and transgressions were punished by sanctions. Perhaps at one time that regulatory model was perceived as effective. When the number of offences was relatively small, when industry participants could be expected to know or to be able to acquire knowledge of the legislation that defined permissible behaviours, when obedience to the law was a commonly held norm of behaviour, when social stigma existed in local markets and could be trusted to impose magnified costs for transgressions of legal norms of conduct, and when firms were more local than transnational, the criminal justice model of regulation may have worked. As well, in liberal societies, 'law' was a symbol of the appropriate role of the State - its process was conceived of as neutral, it left the market to work its wonders within the parameters set by the law, and the costs of the system were relatively low and largely private.⁶

⁶ David Cohen, "The Role of the State in a Privatized Regulatory Environment" in Kernaghan Webb, ed. *Voluntary Codes: Private Governance, the Public Interest and Innovation*, 35

Circumstances have changed in several important respects, and, consequently, attitudes towards the role and nature of regulation have also changed. Business activity now operates on a much larger scale, far removed from local markets, and increasingly involving international trade. In addition, the costs of governance have grown considerably. A line of criticism charges that traditional regulation is inefficient in that its costs exceed the value of resulting benefits. In the words of Jeremy Fraiberg and Michael Trebilcock, “We spend too much money for too little safety.”⁷ These authors attribute the sub-optimal results of existing regulatory initiatives to deficiencies in institutional arrangements, notably the undisciplined and inconsistent responses that are made to shifting public pressures. They quote N. Lind to the effect that present arrangements have a tendency towards “overreacting to small and speculative risks while leaving larger and more certain risks unattended.” Accepting for present purposes the validity of this assessment, one might imagine a GSR serving to alleviate concern around those smaller and speculative risks and allowing regulators to direct their attention and resources to more fundamental challenges.

What must be emphasized, however, is that consideration of the GSR is taking place within the context of overall re-assessment of regulation and that the Canadian characteristics of the regulatory environment are themselves in some ways distinctive. As an example, this country’s comparatively small market may be more dependent than others on the importation of manufactured products that are potentially subject to a GSR. Industrial structure may therefore be relevant to the operation of the instrument in different jurisdictions. Or, what is widely perceived as a more vigorous product litigation environment in the United States, may affect the operation of a GSR. Compensatory mechanisms and the incentives they provide “to take care” may also affect the manner in which a GSR might work. Similarly, insofar as a GSR falls within the overall category of self-regulation, the strength and sophistication of consumer organizations may be a relevant variable in assessing the level of performance likely to be achieved.

An Introduction to Smart Regulation and Precaution

It is impossible in the present context to offer a thorough discussion of industrial structure, the litigation environment, or consumer culture as factors influencing the utility and operation of a GSR. It is however important to emphasize the significance of certain current developments in federal regulatory policy, notably the Smart Regulation initiative, the precautionary principle/approach, and growing concern with compliance. While each of these will be considered more fully below, it is noted that a GSR may be viewed within the context of broader regulatory objectives associated with or emerging from the Smart Regulation initiative, and as such, the GSR might be viewed as an example of a “non-conventional policy instrument.”

Measures of this kind may be considered attractive insofar as they might achieve any of the following:

⁷ Jeremy Fraiberg and Michael Trebilcock, *Risk Regulation*, 837

- Supplement conventional regulatory approaches, thus reducing the need for regulatory enforcement action through the courts;
- Address problematic activity more quickly than conventional approaches;
- Overcome or avoid issues of federal-provincial jurisdiction;
- Address fast-moving technologies or issues;
- Address issues that fall outside the legislative scope of government;
- Allow governments to encourage activities it wishes to promote without making it a requirement; and/or
- Provide Canadians with faster, more convenient, less intimidating redress options than going to court, thereby reducing the burden on courts.⁸

Health Canada's Legislative Renewal Project

Health Canada Objectives for Legislative Renewal

Roughly a decade ago, Health Canada initiated a process of legislative review whose general objectives were to modernize and strengthen the legislation so as to help better protect Canadians against health risks, and provide policy direction in the area of health protection. Extensive consultations and research were undertaken to lay the foundations for a comprehensive health protection regime that would replace a number of existing federal health protection statutes including the *Food and Drugs Act*, the *Hazardous Products Act*, the *Quarantine Act* and the *Radiation Emitting Devices Act*. These legislative initiatives, having been implemented on a piecemeal basis, were perceived to be outdated in the context of modern technology and society.

Health Canada's legislative renewal initiative thus resembles in several respects the previous effort by Environment Canada to consolidate and enhance the effectiveness of a series of environmental statutes which had been introduced over a period of decades to address such disparate concerns as environmental contaminants and ocean dumping.

Certain general features associated with the legislative renewal initiative merit attention for they are not unrelated to the proposal for a General Safety Requirement included amongst proposed reforms. In particular, the legislative renewal initiative proposal contemplates fundamental values, guiding principles, federal-provincial relations concerning new technologies, health surveillance and research, information collection and disclosure, the enhancement of regulation-making powers, enforcement and emergency responses. These areas have been discussed with different degrees of detail in departmental documentation as the legislative renewal proposal has evolved.

Should a decision be taken to pursue implementation of a GSR, these various features of the overall legislative renewal proposal, as this report's issue-based approach underlines, would also be relevant.

⁸ Confidential: PCO, 2005 "Assessing, Selecting and Implementing Instruments for Government Action" 8-9

The General Safety Requirement Proposal

In an Issue Paper on the GSR prepared in conjunction with the overall legislative renewal agenda, Health Canada identifies certain important objectives associated with this specific instrument:

A General Safety Requirement would... clarify the responsibilities of suppliers of products with regard to health and safety and it would ensure that the health protection system has the proper legal authority to consistently and effectively address risks to health.⁹

The same document, in summarizing the department's expectations, concluded that the GSR would:

- Offer better protection to Canadians by making all products to which the Act would apply subject to a comprehensive safety standard;
- Establish a legal regime that is outcome oriented and offers more flexibility and consistency;
- Provide Health Canada with the legal tools it needs to address health risks; and
- Bring Canada up to speed with what already exists in other developed countries.¹⁰

If these are general expectations, it is also important to observe that their realization through a GSR is conditioned by a number of further assumptions. Thus, the Issue Paper suggests that the GSR impose requirements that are consistent with current practices of responsible manufacturers and that would be enforceable through prosecutions for a series of non-compliance provisions.

Another way to formulate Health Canada's objectives for the GSR is to associate the potential of this new instrument with limitations found in the current regime. Three apparent limitations were identified in the Issues Paper. Firstly, it is observed that the current regime, constitutionally anchored in criminal law authority is subject to restrictive interpretation, and some of its terms are too narrow to encompass the full range of those who might be injured, or the manner in which their injuries might occur. Secondly, it is suggested that civil law, due to procedural and remedial constraints, exerts only a limited preventive or deterrent function against a wide range of minor injuries. Thirdly, insufficient resources are available to exercise existing regulation-making power with the consequence that only a limited number of products can ever be covered by the present health protection regime.¹¹

⁹ Legislative Renewal – Issue Paper on GSR, 6 March, 2003, 17

¹⁰ Ibid, 19

¹¹ Ibid, 9

In addition to discussing existing regulatory limitations, the Issue Paper on GSR identifies a number of ways in which this instrument might operate to safeguard the public from risks to health. Some of the observations are of a theoretical nature while others take the form of empirical claims about how a GSR works. Although Health Canada's thinking has certainly evolved in the three years since this document was produced, it may still be worthwhile to highlight some of the assumptions that contributed to the department's attraction towards the GSR concept. These may provide some basis for assessing the additional information assembled in the course of research for the present report.

Assumptions and Expectations for a GSR

In introducing the concept of a GSR, it is suggested that:

- A GSR prohibits the manufacture, promotion and marketing of any product that could present an undue risk of harm to the health of a person during its manufacture, its foreseeable use or its disposal;
- A GSR requires the maker of a product to determine the risks that a product poses, and to take reasonable steps to eliminate those risks before the product is put on the market;
- A GSR compels the maker to monitor the product for risks throughout the lifetime of the product and, if a significant risk is identified, to take appropriate corrective action; and
- A GSR requires others in the chain of supply to cooperate with the maker by transmitting safety information to the end user and cooperating with the maker's corrective actions.¹²

The extent to which any of these anticipated consequences of a GSR are actually realized depends on the precise manner in which the scope of responsibilities are defined, including the nature of safety/risks to be considered, and on the manner in which obligations are implemented and enforced. Even if an elaborate system is initially established, its ongoing reliability are subject to conventional business considerations. For example, among the range of interests concerned when a manufacturer or importer faces bankruptcy, where will the interests of consumers in ongoing monitoring, reporting and corrective action pursuant to a GSR lie?

In addressing possible attractions of the GSR from the perspective of the public the Issue Paper indicates that:

A GSR will eliminate gaps and inconsistencies in safety standards, impose a clear obligation to ensure safety, authorize preventive action by Health Canada, incorporate the concept of precaution, involve consideration of risks on a life-cycle basis, ensure monitoring of adverse health incidents, and not preclude standard setting by way of regulation.

¹² Ibid, 2

Again, the specifics of drafting and implementation will greatly influence much of this, and interesting questions arise such as the applicability of the precautionary principle to the private sector and the relationship of precaution to due diligence or negligence.

The possible impacts of a GSR on industry are also addressed:

Responsible makers of products are already exercising due diligence and addressing the health or safety risks in their products, thus conforming with the General Safety Requirement.¹³

This observation combines an empirical assertion about existing levels of product safety with the suggestion that a GSR will not require different behaviour on the part of “responsible makers of products.” Industry observations may be of considerable interest in this regard. Do “responsible makers of products” anticipate that adjustments in their operations will be required as a consequence of the introduction of a GSR? Equally, if not more significantly from the perspective of enhanced safety, will those falling outside the category of “responsible makers of products” be persuaded by the creation of a GSR to exercise a more appropriate standard of care?

It is also anticipated by proponents of a GSR that this instrument offers more flexibility, eliminates barriers to innovation, facilitates harmonization, and promises a more equitable marketplace.¹⁴ These expectations are in keeping with some of the underlying goals of regulatory policy overall. However, assuming that the GSR may stimulate efforts to avoid liability for introducing an unsafe product there is an obvious legal interest in the nature or standard of behaviour to be met. Amongst the many ways to establish suitable standards some, more than others, encourage flexibility, innovation, and harmonization. It will be worthwhile to inquire whether the Europeans, on the basis of ten years experience, consider that these conditions were realized through the GSR.

An observation is also made that “Most developed countries to which Canadian products are exported and from which many products are imported into Canada have already adopted a GSR in one form or another.”¹⁵ Assuming the validity of this assessment, it offers little insight into the actual scope of the GSR in any of the relevant countries and is silent as to the volume of trade that flows under some form of GSR. More information on the distribution of product risks between developed countries and developing or emerging economy producers would seem to be of value.

A further advantage associated with a GSR is the possibility that it can permit Health Canada to take preventive action before injury or death occurs. This would appear to be a strong attraction and so it may be worthwhile to attempt to

¹³ Ibid, 3

¹⁴ Ibid, 3

¹⁵ Ibid,

identify examples where, in the absence of preventive action, injury or death subsequently occurred. This inquiry may fall outside the scope of the present report, but one would want to distinguish situations in which preventive measures, though available, were not used from situations in which such measures were not actually possible. It may also be worthwhile to look for indications of successful preventive intervention from Europe and at the circumstances in which that was made possible.

A further argument in favour of a GSR revolves around existing experience with such an instrument. Thus, it is noted that a GSR already exists in Canada in the form of certain provisions of the *Food and Drugs Act* and the *Radiation Emitting Devices Act*. Proposed legislation would extend the existing principles to all products and all risks that cause undue adverse health effects. The implication is that we are already familiar with the GSR and that the only innovation proposed is an extension of the scope of application to other sectors. The extent of that expansion is extraordinarily vast, however, and existing experience, while valuable, must be acknowledged to be very modest in comparison.

Reference is also made to “a series of limited General Safety Requirements” in U.S. legislation (eg: Food, Drug and Cosmetic Act, Consumer Product Safety Act, etc.). Although HC refers to US experience as being in the *nature* of a GSR, it will be of interest to consider the extent to which these provisions are actually viewed in this light in the US and the extent to which they are considered analogous to EU measures under the directive. It may also prove to be the case that Canadian federal reliance on the criminal law power as a source of authority for the GSR may not offer as much flexibility and scope as other jurisdictions have had available to them.

Other more detailed observations are made concerning various aspects of the background tort regime and the relationship of the GSR to formal regulations. The foregoing indicates the considerable extent of aspirations and expectations for a GSR in the Canadian context.

Health Canada’s Objectives

As part of Health Canada’s *Legislative Renewal Project*, the Department is proposing to enact a new *Canada Health Protection Act* that would consolidate and reform several related health and safety statutes and regulations. The Department proposes to include a ‘General Safety Requirement’ as part of the new *Act* with a view to achieving several regulatory goals. We have attempted to distil Health Canada’s explicit and implicit goals into the following general objectives:

- To promote a culture of safety as a unifying principle within proposed new health protection legislation by including a general prohibition against

- manufacturers and suppliers producing or supplying unsafe products to the public;
- To authorize Health Canada to take timely, precautionary action, before injury occurs, against unsafe unregulated products or products that, although nominally regulated, evidence serious emerging risks not dealt with under existing regulations;
 - To reinforce the “front end” obligation of producers to properly assess and manage, on a life-cycle basis, risks associated with products to be supplied to the public;
 - To expedite the detection, remediation or removal of unsafe products from the market through mandatory reporting by producers and suppliers of substantial product hazards;
 - To foster an “outcome oriented” (or performance-based) product safety regime which facilitates both technical innovation and continuously improving safety standards in the public interest; and
 - To promote the enhanced use and continuous improvement of voluntary standards by giving official recognition and effect to voluntary standards and industry codes of practice, by providing that compliance with such standards raises a legislative “presumption of conformity” with general product safety requirements.¹⁶

While Health Canada’s objectives for the role of the GSR under the proposed *Canada Health Protection Act* align closely with the purposes that the GSR is intended to serve in Europe, its overall effectiveness as an instrument for achieving those purposes is not yet well established.

2. What is a General Safety Requirement?

The “General Safety Requirement” (GSR) is the product of policy development in four separate areas - occupational health and safety, consumer product safety, product liability and the harmonization of technical product standards in Europe to enable the free movement of goods within the European Community.

The ‘General Safety Requirement’ (GSR) in Europe has been characterized as:

- *Target standard* setting out a broad safety requirement that prescribes no specific standard for the supplier’s processes or output, but imposes criminal liability for certain harmful consequences, or the risk thereof,

¹⁶ Health Canada Legislative Renewal Initiative, summary can be accessed at http://www.hc-sc.gc.ca/ahc-asc/activit/legren/docs/docu-7page_e.html; and *Issues Paper on The General Safety Requirement*, accessed on July 20, 2006 at http://www.hc-sc.gc.ca/ahc-asc/pubs/legren/general_e.html

- arising from the output;
- *A horizontal approach to regulation* under which voluntary standards are substituted for regulations as a means of determining conformity with essential safety requirements; and as a form of
 - *Codification of the common law* duty of care to produce safe consumer products such as to pose no foreseeable risk of harm to consumers when used in a normal or foreseeable fashion.

Under a general safety requirement, the basic regulatory objective, framed as a target standard, is included as an *operative* provision of the statute, rather than as part of the preamble or in a purpose clause as a mere aid to its interpretation.

The GSR is a form of performance-based regulation. From a policy development perspective, its advantages and limitations closely parallel those of a performance-based approach to regulation.

As in the case of performance-based regulation, Europe's 'General Safety Requirement' is given operational effect through a series of directives in the nature of performance standards (essential requirements), supplementary duties and obligations, specification standards, guidelines, codes of practice and related guidance documents, ever increasing in their operational detail.

In stark contrast with the pre-marketing approval procedures applicable to closely regulated areas such as drugs, natural health products and medical devices, the focus of regulatory effort in Europe under the General Product Safety Directive (GPSD) is on *post-marketing* measures – verifying the documentation and risk assessments of producers after production or marketing, auditing quality systems, receiving reports, and following up on complaints.

A Target Standard Linked to Europe's New Approach to Regulation

A general safety requirement is a broad safety objective, standard, or duty of care enacted as an enforceable *legal obligation* in legislation. The general product safety requirement employed throughout the European Community has also been described as a *target standard* set out in statutory format:

A target standard prescribes no specific standard for the supplier's processes or output, but imposes criminal liability for certain harmful consequences (or risks) arising from the output.¹⁷

¹⁷ Christopher Hodges, *European Regulation of Consumer Safety*, Oxford University Press, at p. 14, citing Ogus. "A target standard is to be distinguished from a performance or specification standard - A *performance standard* (or output) standard requires certain conditions of quality to be met at the point of supply, but leaves the supplier free to choose how to meet those conditions. A *specification* (or output) standard can exist in either a positive or negative form: it compels the supplier to employ certain production methods or materials, or prohibits the use of certain production methods or materials".

In the conventional approach to regulation, broad regulatory objectives, or target standards, are commonly found in the preamble or in the purpose clause of a statute as an aid to *interpreting* the legislation, rather than as an operative, enforceable provision of the *Act*. Customarily, the essential substantive requirements are set out in the statute, and detailed provisions required to give the *Act* operational effect are prescribed in regulations. Industry standards, or standards established by standard setting agencies, when referred to in regulations, may be incorporated directly into the regulation itself. In these circumstances, the standard becomes part of the regulation and is enforceable as law, but only after it has cleared the scrutiny of a democratic regulatory process.¹⁸

Under a General Product Safety Requirement, legal consequences flow directly from a breach of the target standard. Production, distribution or importing a product determined to be 'unsafe', enables the public authority to take enforcement action whether or not voluntary product safety standards exist, or are met.

The General Product Safety Directives of 1992 and 2001(it came into force in 2004) were premised on a New Approach to Regulation established by an EEC Directive in 1985.¹⁹ The purpose of the New Approach was to expedite the harmonization of product technical standards across Europe and with a view to eliminating inconsistent standards in national regulations that would otherwise constitute barriers to the free movement of goods across Europe. Prior to 1985, every European Directive had to be submitted for political consideration along with *detailed technical specifications* for unanimous approval of all Member States. This requirement slowed the creation of a harmonized system of legislation to a virtual halt.²⁰

The essential purpose of the GPSD was to ensure a minimum standard of product safety protection throughout Europe as the process of harmonizing thousands of regulations proceeded. The GPSD is thus an integral part of Europe's New Approach to Regulation. The approach adopted under the GPSD, particularly in the use made of voluntary standards, reflects New Approach thinking.

¹⁸ Occasionally standards are incorporated "as amended from time to time" to ensure currency where rapid technological change is likely to outstrip the regulatory process.

¹⁹ See Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards *Official Journal C 136*, 04/06/1985 P. 0001 - 0009

²⁰ Hodges, *European Regulation of Consumer Product Safety*, *supra* footnote 1, at p. 53

An Alternative Approach to Regulation

While Europe's New Approach to Regulation expedited the harmonization of product standards across Europe, many products were still not covered by the vertical directives. To remedy this regulatory gap, Europe enacted the *General Product Safety Directive* premised on the New Approach to Regulation with two objectives in mind:

- To establish a “final safety net” in case vertical harmonization was not fully achieved under the New Approach to Regulation and thus ensure that products were generally “safe” throughout the European Community; and
- To ensure, under the 2001 (revised) Directive²¹, that Member States had both the obligations and the necessary powers to ensure safe products in their respective jurisdictions. The expanded powers available under the revised General Product Safety Directive were made uniformly available in Member States to enforce not only the *General Product Safety Directive*, but also any of the European Commission's vertical product directives where such powers were lacking.

The European *General Product Safety Directive* is thus a form of *horizontal regulation* covering potentially dangerous products or risks not covered by Member State laws or by Europe's vertical (harmonized) regulations. Its scope is both residual and comprehensive. Its reach is extremely broad. If Health Canada were to adopt a GSR, its regulatory reach would be vastly extended the instant it was enacted. The policy, administrative, resource, and liability implications of such a development are explored throughout this Report.

A Form of Codification of the Common Law Duty of Care

A General Safety Requirement is sometimes viewed as a mere codification of an existing civil responsibility. In effect, the GSR restates the tort obligation to exercise due care in producing products so as to avoid foreseeable harm to the users of such products. Interestingly, this has also been a major argument advanced by public authorities to secure industry support of the GSR. The argument is that the GSR requires no more of industry than is required by good practice under the law. Big industry in Europe has largely been receptive to this argument, but remains concerned about compliance by smaller entities because selective non-compliance adversely affects the ‘level playing field’ for competition in that industry. On the other hand, many small industries view the GSR regime as providing a competitive advantage for larger industries that are usually better equipped to undertake complex risk assessments, testing and innovation. The regulatory ‘flexibility’ offered under the GSR may, for small industry, be largely illusory.

²¹ 2001/95/EC

In the UK review that preceded the *Consumer Protection Act, 1987*, the Review Committee acknowledged that the proposed GSR would amount to a codification of the common law in the following terms:

The Government accepts that there is a case for widening the scope of the Act to place a general obligation on the suppliers of consumer goods to achieve an acceptable standard of safety where it is reasonable to expect them to anticipate and reduce risks arising from those goods. This would induce a greater sense of responsibility on the part of those suppliers who currently regard themselves as unaffected by the legislation (*and who may not be adequately deterred by the common law duty of care*). At the same time, it would provide wider scope for swift remedial action by enforcement authorities in the case of newly identified dangerous products.²² (Emphasis added)

In the UK, the idea of codifying a general obligation under the common law, and coupling it with standards or codes of practice evolved initially from the Robens *Inquiry into Health and Safety in the Workplace (1970-72)*.²³ The Robens Inquiry Report made recommendations about how to reform and consolidate a number of piecemeal workplace safety statutes under a single Act – ultimately the *Health and Safety in the Work Place Act, 1974*. This undertaking is similar to Health Canada’s current “Legislative Renewal” initiative which proposes to reform and consolidate *The Food and Drugs Act, the Hazardous Products Act* and the *Radiation Emitting Devices Act* under a single statute: the proposed *Canada Health Protection Act*.

Until 1972, the traditional model of regulation governing safety in the workplace in the UK involved “a mass of detailed, highly technical rules under a variety of statutes. These laws lacked coherence and proved impossible to keep up to date. Exclusive reliance on detailed specification standards neither encouraged nor enabled employers to innovate in their safety practices.” Then, as with most regulation throughout the Commonwealth at the time, traditional workplace legislation “created a climate of dependence on state regulation.” There was little involvement by unions or workers in the regulatory process.²⁴

²² *The Safety of Goods*, Paper presented to the UK Parliament by the Secretary of State for Trade and Industry, Cmnd. 9302, at para. 34

²³ *Safety and Health at Work*, Report of the Robens Committee, UK 1970-72 -- “A view put to us by some legal experts – although not shared by some others – was that a statutory statement of general principles is unnecessary because it would amount to no more than a statement of the existing common law on this subject, that it would simply mean ‘writing down a duty which we all know’. Our answer to this is that few laymen are familiar with the common law on this subject, however clear it may be to members of the legal profession. (para 132)

²⁴ National Research Centre for OHS Regulation, Australia, commenting on the evolution of Occupational Health and Safety from the British Model. <http://www.ohs.anu.edu.au/ohs/index.phpa>, accessed October 24, 2005

The Robens Committee developed a new regulatory model – one similar to the New Approach to Regulation initiative advanced more than a decade later, in 1985, by the European Community. The “new style” of regulation suggested by *Robens* in 1972, which was designed to promote a culture of safety in the workplace, had the following key features:

- A more *unified and integrated system* of laws was established under *broad general duties* of care in matters affecting safety in the workplace. These duties were imposed on parties whose activities may affect safety in the workplace, including employers, employees, the self-employed, occupiers, manufacturers, suppliers and designers of plant equipment or producers of substances used in the workplace;
- The bare statutory duties were to be fleshed out” by standards and codes of practice;
- A unified inspectorate was given new administrative sanctions (improvement and prohibition notices) as alternatives to prosecution; and
- “A more effectively self-regulating system”²⁵ was created, the most important element of which was “a statutory duty on every employer to consult with ... employees or their representatives at the workplace on measures for promoting safety and health at work, and to provide for the participation of employees in the development of such measures.”²⁶

Instead of always trying to specify in minute detail how a product should be manufactured in order to be “safe” – a largely impossible task across the broad range of marketed products – *Robens* suggested that regulations be developed in a manner that required, or encouraged, producers to meet standards of safety established and kept up to date by experts external to government, or developed by experts in collaboration with government, through industry associations, or domestic and international standard-setting agencies.

The general duty of care in the workplace was viewed as a preventive regulatory measure. It was intended to reinforce the manufacturers’ common law duty to take care to supply only safe consumer goods by providing a legal framework for elaborating the voluntary or mandatory standards or desirable steps a manufacturer should meet or take to ensure he is, in fact, manufacturing safe products. It forms a separate, statutory head of authority for enforcing the manufacturers’ and suppliers’ common law duty of care - as elaborated through the standards or process measures developed under the safety regime.

²⁵ *Robens Inquiry Report*, supra, para 41

²⁶ *Ibid.*, para 70

There is a dynamic relationship between standard setting under a statutory general duty of care and the common law duty of care. The same is true under a general safety requirement, which is another form of statutory general duty of care. As safety standards evolve and improve under a general safety requirement, it is possible that the legal minimum standard of care employed by the courts in penal proceedings may also become more rigorous, though not necessarily in lock step with GPSD standards. Different principles may apply in determining an appropriate standard of care in penal proceedings. The dynamic relationship between regulatory standard setting and the common law duty of care is examined in greater detail in this Report under the heading, “Due Diligence.”

While prescriptive regulations remain an essential component of safety regulation, *Robens* viewed a standards-based approach to regulating as a promising method of achieving a better balance between the need for flexibility and precision in regulations that might otherwise have a limited “shelf life” given the pace of technological change.

The broad argument...is that many of the defects (flowing from undue reliance on prescriptive regulations) can be remedied by a switch in emphasis away from the extensive use of statutory regulations towards greater reliance on standards and codes of non-statutory origin. *In future there should be more discrimination and selectivity in making statutory regulations.* Thus the system would comprise a main Act, plus statutory regulations, plus codes of practice, but the intermediate stage of statutory regulations would often be dispensed with. (emphasis added)²⁷

Significantly, section 6 of the *Health and Safety at Work Act, 1974*, a consequence of the *Robens Report*, included a general safety requirement covering goods and substances supplied to the workplace.²⁸ A decade of favourable experience under this provision later became part of the case for including a general safety requirement in the UK *Consumer Protection Act, 1987*.²⁹

The standards-based approach to safety regulation appears to have worked reasonably well in the workplace arena, perhaps because its governing legal framework provides many extra-judicial mechanisms for making concrete decisions about “safety” - an inherently relative concept. The issue of “safety” in the workplace, for example, may be determined in the discretion of a safety representative or in the deliberations of on site safety committees, or in contract negotiations, in grievance hearings, in labour arbitrations under collective

²⁷ Robens Inquiry Report, para. 134.

²⁸ Health and Safety at Work Etc Act, UK, 1974, c. 37, s.6

²⁹ See, *The Safety of Goods*, Cmnd 9302, July 1984, para. 36. After nearly 10 years of experience under the general safety requirement imposed under section 6 of the *Health and Safety at Work Act*, “there (does) not appear to have been serious problems of interpretation of the level of safety required by the general duty for industrial goods...”

agreements, or by other informal means unique to particular employers. An overarching consideration in these proceedings is the employees right of refusal to work in an unsafe work environment.

In this Report, therefore, one key question to be addressed is how the mechanisms that seem to work well in the workplace model for making concrete decisions about the safety of particular products are replicated, or have evolved separately, under the consumer product safety regimes.

3. What Purposes Does a GSR Serve?

In Europe, the 'General Safety Requirement is thought to serve several purposes. It serves as:

- *A safety net, or emergency response mechanism* enabling a public authority to deal – temporarily - with unregulated products, or with new and emerging risks in otherwise regulated products, until the risks can be evaluated, or a regulation enacted;
- *A unifying statutory principle* designed to promote a 'culture of safety' by fixing producers, distributors, importers and others in a position to influence safety outcomes with the primary responsibility for ensuring product safety;
- *An aid to interpreting* the product safety regulations transposing the General Product Safety Directive³⁰; and as
- A legal framework for timely settlement or remediation discussions between enforcement officials and the regulated community.

Safety Net

The preamble to the *General Product Safety Directive* (2001/95/EC) sets out its essential purpose as a safety net:

"5) It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, and also to cover lacunae, in particular pending revision of the existing specific legislation, and to complement provisions in existing or forthcoming specific legislation, in particular

³⁰ In the conventional approach to regulation, broad regulatory objectives, or target standards, are commonly found in the preamble or in the purpose clause of a statute as an aid to *interpreting* the legislation, rather than as an operative, enforceable provision of the *Act*.

with a view to ensuring a high level of protection of safety and health of consumers, as required by Article 95 of the Treaty.

"12) If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks."

The *General Product Safety Directive* was designed as a "final safety net" in case product harmonization was not fully achieved in Europe, or not achieved on a timely basis under Europe's evolving vertical directives. It was to ensure, at a minimum, that products were "safe" throughout the E.U. The essential rationale for the *GPSD* was that it would temporarily fill out the regulatory gaps created by new products or emerging risks. However, it was based on the policy assumption that the regulatory gaps would be filled, over time, under vertical legislation that was continuously being developed for new products.³¹

The expectation, initially, was that the scope for the *GPSD* would *diminish* as new product legislation was developed. However, there is a growing pressure in Europe (as well as in Canada) to require increasingly rigorous justifications for new regulation. The concern is to avoid 'excessive' reliance on *formal* regulation and to encourage alternative approaches to achieving regulatory objectives where they are likely to be as, or more, effective in achieving regulatory objectives. As a result, there are fewer new legislative initiatives in the E.U., except for regulations governing high-risk products such as drugs, foodstuffs, toys, machinery, and the like. The role of the *GPSD* is thus changing from its original purpose as a 'safety net', to that of an alternative form of standards-based regulation in the model of Europe's New Approach to Regulation.'

There are several reasons for this change. Firstly, Europe's regulatory policy (as in the case of Canada's regulatory policy) has a bias against new regulation unless a strong case can be made for regulating and alternatives to prescriptive regulation are considered. Secondly, the five-year period for reviewing harmonized standards in Europe seems not to have been realistic, leaving a broader scope for application of the *GPSD*. Thirdly, new countries entering the EU that do not have comprehensive (or perhaps any) consumer product legislation, often rely on the more detailed *GPSD* as an instrument of first resort. Fourthly, some of the standards developed by the standards groups do not result in adequate safety protection due to various factors, including the overwhelming representation of industry on standardization committees, industry imperatives

³¹ Interview, November 28 2005, with Erik Hansson, European Commission, DG Health and Consumer Protection. Mr. Hansson was one of the principle architects of the General Product Safety Directive. See also Hodges, *European Regulation of Consumer Product Safety, 2005*, Oxford University Press at p. 22...."A further approach acts as a *longstop* for all consumer products not covered by a specific vertical regime, and involves a 'horizontal' basis. The focus of the *GPSD* requirements is on provision of information and, from 2004, post-marketing systems."

and the intransigent positions sometimes taken by industry on such committees.³²

Unifying Statutory Principle (Culture of Safety)

The UK, in the 1970's, - like Health Canada today - was considering how best to reform and consolidate a series of safety-related statutes under a single coherent Act with a "culture of safety" as its policy thrust. *The Robens Committee* took a comprehensive view of problems confronting the UK system of health and safety in the workplace. Just as Canada (under the "Smart Regulation" initiative) has adopted a broader view of the concept of "regulation", *Robens* took a comprehensive view of the workplace safety "system" which required reform.

By 'system', we mean here the whole complex of arrangements and activities, whether of a statutory or voluntary nature, which seek to protect and promote the safety and health of people at work, and to protect the public from hazards of industrial origin. The system can be seen as comprising two very broad elements: regulation and supervision by the state, and industrial self-regulation and self-help. The most fundamental issues before us are concerned with the relationship, balance and interaction between these two broad elements.

The Robens Committee viewed the general obligation to ensure safety in the workplace that was required of employers and others as *a unifying principle lending coherence to the new legislation*; in other words as a "statement of general principle designed to govern a conglomeration of prescriptions and prohibitions" as well as to inform a range of preventive, voluntary and self-regulatory actions.³³

In the occupational health and safety arena, therefore, *Robens* proposed a form of general safety obligation in the workplace, similar to the general product safety requirement later prescribed across Europe for the consumer product area, as the focal point of what ultimately became the *Health and Safety at Work Act, 1974*. Section 6 of that *Act*, as noted, also included a general *product* safety requirement covering equipment and substances supplied to the workplace.

The *Robens Committee* set out the new general safety obligation in the following terms:

We believe that the general principles of safety responsibility and safe working should be *embodied in a statutory declaration*, which would set all of the detailed statutory and other provisions in clear perspective. We recommend, therefore, that the *Act* should begin by enunciating the basic and over-riding responsibilities of employers and employees. This central statement should *spell out the basic duty of an employer to provide a safe working system including safe premises, a*

³² Interview with Arnold Pindar, December 9, 2005, British Standards Institution, (Consumer Policy)

³³ *Safety and Health at Work*, Report of the Robens Committee, UK 1970-72, p.41, para. 128

safe working environment, safety equipment, trained and competent personnel, and adequate instruction and supervision. It should also spell out the duty of an employee to observe safety and health provisions and to act with due care for himself and others.³⁴

The criticism quickly emerged that such a statement of basic principles might be too general to be meaningful. *Robens* rejected this, arguing that the statutory declaration was essential to establishing a ‘culture of safety’ under the new regime and that it would help to delineate a broader role for inspectors³⁵ in *promoting* workplace safety in addition to enforcing safety laws.

We do not accept the argument that such a statement of basic principles would be too general to be meaningful and helpful in practice. On the contrary, we think it would have important practical effects. A positive declaration of over-riding duties, carrying the stamp of Parliamentary approval, *would establish clearly in the minds of all concerned that the preservation of safety and health at work is a continuous legal and social responsibility of all those who have control over the conditions and circumstances in which work is performed.* It would make it clear that this is an all-embracing responsibility, covering all workpeople and working circumstances unless specifically excluded *and applying whether or not a particular matter of detail is covered by a specific regulation.* It would encourage employers and workpeople to take a less narrow and more rounded view of their roles and responsibilities in this field. *It would provide guidance to assist in the interpretation of detailed statutory provisions,* a process that sometimes created problems for those responsible for accident prevention. (emphasis added)³⁶

Robens proposed a broader preventive role for the inspectorate under the new workplace safety regime, including in-depth safety audits. The *Robens Committee* underscored the importance of inspectors taking a preventive approach to safety – an approach that many of today’s field safety inspectors might consider part of their routine responsibilities. *Robens* considered that the recommended general safety obligation would, *as an underlying general principle, reinforce the inspectorate’s preventive and remedial functions.*³⁷

³⁴ *Robens Inquiry Report*, supra, p.41, para. 129

³⁵ *Robens Inquiry Report*, supra. at para131.....”A governing statement of principles would have particular relevance to the development of the wider role for the inspectorates that we discuss in chapter 7. The limited nature of some of the present work of the safety inspectors derives from their preoccupation with – and indeed to some extent their dependence upon – a large number of detailed statutory regulations unrelated to any over-riding general requirement. The statutory framework within which they work is a constrictive one, and they have no authority to go beyond it. When an inspector visits a workplace he should be concerned with the total picture as much as with those particular details, which happen to have been made the subject of a specific regulation; and for this he needs a broad statutory mandate.

³⁶ *Ibid.* at para. 130

³⁷ *Ibid.*, at para 212.... We believe that there is great scope for experiment with new types of inspection such as safety audits in depth, and team visits. There is also scope for closer contacts with manufacturers in connection with the planning and design of new premises, plant and equipment; and for closer liaison with senior managements of very large industrial and commercial organizations.

Like the New Approach to Regulation adopted in Europe in 1985 (the regulatory model underpinning the *General Product Safety Directive*), the general safety obligation proposed by *Robens* for the occupational health and safety sector in 1972 was to be supplemented and clarified by voluntary standards and industry codes of practice.

We have advocated that statutory regulations should be simpler in style and that the procedure for formal consultation on regulations should be less cumbersome. We go further than this. *We recommend that in the future no statutory regulation should be made before detailed consideration has been given to whether the objectives might adequately be met by a non-statutory code of practice or standard.*³⁸ (Emphasis added)

Concern about the need for harmonization and avoiding unjustified regulation where industry standards suffice, resonates freshly with regulatory policy in modern Western democratic countries, including Canada. But globalization and the need for international competitiveness, rather than safety considerations, are the most prevalent reasons advanced today for product harmonization. Compelling justifications are often required before a proposed regulation will be approved. Mandatory consideration of feasible alternatives to regulation are routinely required as part of the regulatory process. In the UK, recent proposed reforms call for stricter adherence to the precepts of risk assessment and risk management in all aspects of regulation.

There is also a clarion call in Europe, and particularly in the UK, for a “light touch” to enforcement practices. Regulatory reform in the UK has been significantly influenced by two recent reports; the *Hampton Review*³⁹ and the *Less is More* Report by the UK Better Regulation Task Force.⁴⁰

Hampton Review focuses on regulatory enforcement. It proposes entrenching the principle of risk assessment throughout the regulatory system, so that the burden of enforcement falls most on highest-risk businesses and least on those with the best records of compliance. At present, not only are unnecessary inspections said to be carried out, but necessary inspections are not carried out. Under the proposals in the report, inspection rates would be reduced where risks are low, but enhanced where necessary.

³⁸ *Robens Committee Report, supra.*, para. 142

³⁹ Phillip Hampton, ‘*Reducing Administrative Burdens: Effective Inspection and Enforcement*’, March 16, 2005. Press release accessed on September 24, 2006 at http://www.hm-treasury.gov.uk/budget/budget_05/press_notices/bud_bud05_presshampton.cfm The Review itself was accessed on September 24, 2006 at http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

⁴⁰ *Regulation: Less is More Reducing Burdens, Improving Outcomes*, March 2005, accessed on September 24, 2006, at <http://www.brc.gov.uk/downloads/pdf/lessismore.pdf>

The Review speculates, based on regulators' past experience, that comprehensive risk assessment in a streamlined structure could:

- Reduce the need for inspections by up to a third, which means around one million fewer inspections; and
- Reduce the number of forms regulators send out by perhaps 25 per cent.

In addition, the Review recommends:

- Making much more use of advice, again applying the principle of risk assessment;
- Substantially reducing the need for form-filling – in practice, most businesses' most frequent and direct experience of regulatory enforcement – and other regulatory information requirements;
- Applying tougher and more consistent penalties where these are deserved;
- Reducing the number of regulators that businesses have to deal with, by merging 31 national regulators into 7;
- Entrenching reform by requiring all new policies and regulations to consider enforcement, and use existing structures wherever possible; and
- Creating a new business-led body at the centre of Government to drive implementation of the recommendations and challenge departments on their regulatory performance.

On 18 October 2004, the U.K Prime Minister asked the Better Regulation Task Force to examine:

- a. The new Dutch approach of introducing a target for reducing administrative costs to minimize the paperwork burdens faced by business; and
- b. A 'one in, one out' rule for regulation, where new regulations would have to be matched by deregulatory measures proposed by the Department promulgating the new regulatory initiative.

The Better Regulation Task Force undertook feasibility studies of these two ideas and recommended that the UK government adopt them. The Task Force suggests that the government should introduce new procedures to measure and then reduce the administrative burdens faced by businesses and other organizations in the UK. The Task Force also suggested that government should adopt a 'One in, One out' approach to regulation in order to achieve a better balance between new regulations coming in and simplify existing regulations, including the removal of unnecessary regulations.

The impact of regulations on global competitiveness was *not* a material consideration in *The Robens Committee* proposal to make enhanced use of voluntary standards and codes of practice in the occupational health and safety arena. The *Committee's* recommendation was based almost exclusively upon the conviction that 'standards and codes developed within industry and by

independent bodies are *more practical and therefore potentially more effective instruments of progress than statutory regulations*'.⁴¹ Robens was not advocating "a slacker approach to regulation", only that "the whole system should be more flexibly based and more discriminating in the use of formal regulations," especially in areas where they were demonstrably inadequate.⁴²

Today, questions still abound in the product safety area concerning the legality and the enforceability of voluntary standards, as well as their potential for undermining the democratic regulatory process due to the lack of transparency surrounding their creation. These same questions were also at the forefront of debates within the *Robens Committee*.

The question of the desirable balance between the use of statutory regulations and the use of non-statutory codes of practice and standards is a controversial one. Statutory regulations are subject to the approval of Parliament. They express unequivocal legal obligations, and can be strictly enforced. On the other hand, they often take a long time to make, technical details can quickly become out of date, and in practice once made they are seldom easy to revoke. Non-statutory codes of practice and standards are more flexible. They are easier to introduce and to revise. They are more progressive in that they need not be restricted to minimum standards, and they are less likely to inhibit new developments. *They are not, however, subject to Parliamentary scrutiny and approval, and they cannot be directly enforced.*⁴³ (Emphasis added)

The question for *Robens* was not only *how* voluntary standards should be taken into account in compliance and enforcement activity, but *which* voluntary standards deserved recognition by the public authority.

There is no simple definition of what constitutes a non-statutory or voluntary code of practice or standard. They emerge in a variety of ways and in a variety of forms. Some are prepared and promulgated by government departments, others by independent bodies such as the British Standards Institution, still others by joint safety committees or employer organizations at industry-level. They may describe desirable procedures or systems, or specify requirements in design, materials and performance. They may be concerned specifically with safety and health or with quality generally. *The constant multiplication of non-statutory codes of diverse origin and authority can be as confusing and unhelpful as the multiplication of statutory regulations. We suggest that some measure of control and co-ordination can be injected into this area without inhibiting the continued spontaneous development of good safety and health standards.*⁴⁴ (Emphasis added)

The Robens Committee identified three circumstances where voluntary standards should be taken into account in enforcement proceedings; namely:

⁴¹ *Robens Committee Report, supra.*, para. 148

⁴² *Ibid.*, para. 148

⁴³ *Ibid.*, para. 143.

⁴⁴ *Ibid.*, para. 149

- Where voluntary standards have been incorporated directly into UK regulations;
- Where the Authority has agreed to undertake, or to sponsor, the preparation of a non-statutory code as an alternative to preparing a statutory regulation on the matter in question; and
- Where the Authority has power under enabling legislation to publish lists of voluntary codes or standards '*which they regard as conforming to the general purposes of the Act*', that is, where the codes and standards in question '*are directly relevant to the Authority's specific purposes and responsibilities*'.⁴⁵ (emphasis added)

The third criterion for making use of voluntary standards under a workplace safety regime became, of course, the principle basis for using voluntary standards under Europe's *General Product Safety Directive*. Voluntary standards were to be taken into account for the purposes of administrative action in furtherance of the public authority's *injury prevention* role.

Briefly, our intention is that inspectors should have power to *issue improvement* notices in individual cases, taking into account not only any relevant statutory regulation but also any relevant voluntary code or standard that has been formally approved by the Authority *in one or other of the ways mentioned*. Such codes and standards would be admissible in evidence in proceedings before tribunals in much the same way as the provisions of the Industrial Relations Code of Practice are admissible under the Industrial Relations Act.⁴⁶

An analogous power to the UK 'Improvement Notice' exists under the compliance orders provision of the *Canadian Environmental Protection Act, (CEPA)*.⁴⁷ However, *CEPA*, like the proposed *Canada Health Protection Act*, is constitutionally grounded on the federal responsibility for substantive Criminal Law. Action under the compliance order provision of *CEPA*, therefore, is necessarily based on an inspector's reasonable belief that there has been a *contravention* of the *Act* or of a *CEPA* regulation. In the absence of an 'general' safety requirement (i.e. a prohibition against producing 'unsafe' products) linked to a significant risk of harm and reasonably precise standards of safety, an improvement notice of the kind employed under the UK *Health and Safety at Work Act, 1974* would be open to legal challenge where no law was contravened.

Aid to Statutory Interpretation

As already noted, under the conventional approach to regulation, broad regulatory objectives, or target standards, are more commonly found in the preamble or in the purpose clause of a statute as an aid to *interpreting* the

⁴⁵ *Ibid.*, paras. 150-152

⁴⁶ *Ibid.*, para. 153

⁴⁷ *Canadian Environmental Protection Act*, 1999, c. 33, s. 235

legislation, rather than as an operative, enforceable provision of the *Act*. Notwithstanding that the GSR is an operative and enforceable provision, its generality and overarching effect may serve both as a unifying principle for the governing *Act*, and also as the principle context for interpreting the intent of the legislation and the meaning and scope to be given to other, more specific provisions. This is one of the purposes it has served in the area of occupational health and safety legislation prescribing a general duty to maintain safe working conditions in the workplace.

A Legal Framework for Timely Settlement or Remediation Discussions

Because the General Safety Requirement constitutes a *legal* obligation, rather than a mere policy objective or statement of statutory purpose, an apprehended failure to meet the obligation to supply safe products may immediately trigger a public authority's use of its inspection and enforcement powers. This often provides an incentive for defendants to undertake early remediation or settlement dialogue with the public authority. It is this immediacy that makes the GSR attractive as an emergency response mechanism for dealing with unregulated products, or emerging risks in regulated products.

4. Evolution of the General Safety Requirement

Four Separate, Merging Strands of Policy Development

As noted above, the "General Safety Requirement" (GSR) is the product of policy development in four separate areas - occupational health and safety, consumer product safety, product liability and the harmonization of technical product standards in Europe to enable the free movement of goods within the European Community.

The major development thresholds for the general product safety requirement - using the experience of the United Kingdom as a Member State example, were:

- The Robens Inquiry into Health and Safety in the Workplace between 1970 and 1972 proposing an outcome-oriented regulatory model for workplace safety, the first GSR (for goods and substances supplied to the workplace) and a regulatory regime with a significant degree of voluntary self-regulation;
- The enactment of a general safety requirement for articles and substances supplied to the workplace under the *Health and Safety at Work Act, 1974* in the UK. The general safety requirement developed for workplace products was strikingly similar to the GSR developed thirteen years later

for the product safety sector, and similarly based on legislative approaches adopted in Germany and Sweden dating back to the 1960's;

- An abortive, first attempt, in 1974, to make the case for including a general product safety requirement in the UK *Consumer Safety Act, 1978*. The reasons given for the failure to implement a GSR in the 1978 *Act* highlight some of the concerns which a few stakeholders, even today, express about this regulatory mechanism (including uncertainty and inconsistency of application);
- The promulgation, in 1985, of two important European Union directives concerning the New Approach to Regulation and Product Liability which were major contributing factors in the ultimate acceptance of a GSR into UK consumer protection legislation;
- Trade-related events in Europe in the mid-1980's (stalled regulatory process) along with some high profile safety issues (Mad Cow disease, Far Eastern imports) in the early 1980's combined, finally, to make the case for including a general safety requirement in the UK *Consumer Protection Act, 1987*;
- The enactment, in Europe, of a *General Product Safety Directive* for application throughout the European Community (92/59/EEC), which the UK was required to transpose into domestic law;
- A comprehensive study of experience with the original General Product Safety Directive by the European Commission highlighting some difficult and complex implementation issues. This study led, to a revised Directive (2001/95/EC, which came into force January, 1, 2004; and
- The enactment, in 2005, of the UK *General Product Safety Regulations*⁴⁸ transposing the revised Directive.

It should be noted that Europe's *General Product Safety Directive*, even with the major revisions implemented in January of 2004, remains a work-in-progress. Various committees and working groups are continuing to examine a number of seemingly intractable implementation issues. A four-year formal review of the experience under the revised GPSD is also under way. In addition, Europe's New Approach to Regulation, which constitutes the regulatory framework underpinning the GPSD, is undergoing fundamental review.

"What may be needed, is a New, 'New Approach'," commented one presenter at the European Conference on the 20th Anniversary of the New Approach

⁴⁸ *General Product Safety Regulations, 2005*, (S.I. 2005, No. 1803)

held in Brussels on November 30, 2005.⁴⁹ Another presenter warned that it was important to consider the changes flowing from the New Approach Review “before extending the New Approach to consumer products or the environment.”⁵⁰

Occupational Health and Safety

In the United Kingdom, the first general product safety requirement was developed as an aspect of occupational health and safety reform in the early 1970’s to cover goods and substances supplied in the workplace. The idea of codifying a general safety obligation under the common law and coupling it with standards or codes of practice evolved in the UK almost a decade before Europe’s New Approach to Regulation.⁵¹ Both initiatives were modeled to some extent on regulatory practices in Germany and Sweden dating from the 1960’s.

A more comprehensive approach to safety regulation in the UK was first proposed in the seminal UK report entitled *Safety and Health at Work*, (1970-72), chaired by Lord Robens.⁵² The *Robens Committee* made recommendations about how to reform and consolidate a number of piecemeal workplace safety statutes under a single Act – the *Health and Safety at Work Act, 1974*. This undertaking, while similar to Health Canada’s current ‘Legislative Renewal’ initiative, was considerably more complex. It involved reforming and consolidating four *groups* of safety statutes and more than 500 statutory instruments.

The UK workplace safety reform addressed many of Health Canada’s key safety objectives, including the objective of creating a pervasive “culture of safety” by focusing the primary responsibility for safety on those in a position to influence safety outcomes.

The first and perhaps most fundamental defect of the statutory system is simply that there is too much law. The existence of such a mass of law has an unfortunate and all-pervading psychological effect. People are heavily conditioned to think of safety and health at work as in the first and most important instance a matter of detailed rules imposed by external agencies....This attitude will not be cured so long as people are encouraged to think that safety and health

⁴⁹ Proceedings accessed on September 06, at:

http://ec.europa.eu/enterprise/newapproach/new_approach_conference_en.htm (Two members of the Project Team attended this conference which coincided with the timing of the Interviews with European Officials.)

⁵⁰ *Ibid.*, per Han

⁵¹ See *Robens Committee Report*, para. 132: “A view put to us by some legal experts – although not shared by some others – was that a statutory statement of general principles is unnecessary because it would amount to no more than a statement of the existing common law on this subject, that it would simply mean ‘writing down a duty which we all know’. Our answer to this is that few laymen are familiar with the common law on this subject, however clear it may be to members of the legal profession.”

⁵² *Safety and Health at Work, Report of the Robens Committee*, UK 1970-72

at work can be ensured by an ever-expanding body of legal regulations enforced by an ever-increasing army of inspectors.

The primary responsibility for doing something about the present levels of occupational accidents and disease lies with those who create the risks and those who work with them. The point is quite crucial. Our present system encourages rather too much reliance on state regulation, and rather too little on personal responsibility and voluntary, self-generating effort... There is a role in this field for regulatory law and a role for government action. But these roles should be predominantly concerned not with detailed prescriptions for innumerable day-to-day circumstances but with influencing attitudes and creating a framework for better safety and health organization and action by industry itself. (Emphasis added)

While prescriptive regulations remain an essential component of safety regulation in the workplace, *the Robens Committee* viewed a standards-based approach to regulating as a promising method of achieving a better balance between the need for flexibility and precision in regulations that might otherwise have a limited “shelf life” given the pace of technological change.

The broad argument... is that many of the defects (flowing from undue reliance on prescriptive regulations) can be remedied by a switch in emphasis away from the extensive use of statutory regulations towards greater reliance on standards and codes of non-statutory origin. *In future there should be more discrimination and selectivity in making statutory regulations.* Thus the system would comprise a main *Act*, plus statutory regulations, plus codes of practice, *but the intermediate stage of statutory regulations would often be dispensed with.* (Emphasis added)⁵³

In pursuing the theme that primary responsibility for ensuring safety should be fixed on those in a position to influence safety outcomes, the *Robens Committee* noted that existing laws placed undue emphasis on the safety obligations of *users* of factory machinery and equipment and an insufficient emphasis on the safety obligations of *designers and manufacturers*. *Robens'* recommendation for dealing with this imbalance led to the UK's first general product safety requirement covering goods and substances supplied to the workplace.

We recommend, within the context of our general proposals that the approach to this subject should be along the following lines. First, there should be a general statutory obligation on those making and marketing plant, machinery and equipment for industrial and commercial use to ensure that it is in a condition enabling it to be used in compliance with all safety provisions relating to design, construction and safeguarding.

Secondly, the Authority should have powers to prepare special regulations as necessary concerning safe design and construction, and these regulations should impose direct obligations on manufacturers.

⁵³ *Robens Committee Report*, supra., para. 134.

Thirdly, *in deciding on the extent to which these regulatory powers need to be used, and how they should be used, full account should be taken of any relevant British and international standards.* Standards of specification, testing and certification will continue to be developed by the various expert bodies engaged in this work, and the *Authority for Safety and Health at Work should have power to require compliance with particular standards or approval arrangements made and operated by such bodies.*

Flexibility would be needed in exercising these powers. *In some cases the general requirement backed up by testing and inspection arrangements would suffice.* In others it might be appropriate to use regulations to spell out or refer to specific standards. (Emphasis added)

Section 6 of the *Health and Safety at Work Act, 1974* included a general safety requirement covering goods and substances supplied to the workplace.⁵⁴ A decade later, favourable experience under the GSR in the occupational health and safety arena became part of the case for reform for including the first general safety requirement for *consumer products* in the *UK Consumer Protection Act, 1987.*⁵⁵

The standards-based approach to safety regulation appears to have worked well in the workplace arena, in part, because the governing legal framework for occupational health and safety provides many extra-judicial mechanisms for making concrete decisions about “safety” - an inherently *relative* concept. Disputes about “safety” in the workplace may be resolved in the discretion of a safety representative or in the deliberations of on-site safety committees, or in management/union contract negotiations, as an incident of grievance hearings, in labour arbitrations under collective agreements, or by many other informal means of dispute resolution unique to particular employers. The right of employees to refuse work in unsafe conditions is a powerful incentive to reaching agreement on safety issues.

A key question, therefore, is how mechanisms for making concrete decisions about the relative safety of particular products or working conditions that seem to work well in the workplace model may be replicated in, or adapted to, consumer product safety regimes for the benefit of largely unorganized consumers.

⁵⁴ *Health and Safety at Work Etc Act, UK, 1974, c. 37, s.6*

⁵⁵ See, *The Safety of Goods*, Cmnd 9302, July 1984, para. 36. After nearly 10 years of experience under the general safety requirement imposed under section 6 of the *Health and Safety at Work Act*, “there ((does) not appear to have been serious problems of interpretation of the level of safety required by the general duty for industrial goods...”

Product Liability

The development most influencing the evolution of the General Product Safety requirement was Europe's adoption, in 1985, of the Product Liability Directive.⁵⁶ This Directive, which has no exact parallel in Canada, imposed virtually absolute liability on producers for defective products. The Product Liability Directive led to important changes in consumer protection legislation in Member States to account for this fundamental legal change. Subsequently, it became an important factor in the adoption of the *General Product Safety Directive* across Europe, which is largely premised on absolute liability for safety defects. The UK passed the *Consumer Protection Act, 1987* incorporating a general safety requirement applicable to consumer goods for the first time, along with provisions transposing Europe's Product Liability Directive.⁵⁷

In Europe in the 1980's, there was a lot of discussion about unsafe products, accompanied by the expectation that the Product Liability Directive would result in many claims. (This did not turn out to be the case.) The assumption at the time was that there were many unsafe products on the market. These concerns underscored the need for a 'modernization' of the consumer protection legislation to ensure regulatory order, especially in the aftermath of the Product Liability Directive.⁵⁸

The usual remedy in law for injury or loss caused by unsafe products is a fault-based proceeding in negligence, requiring proof of a duty of care, a breach of that duty, proof of damage, and proof that those damages were caused by the negligence of the defendant supplier. In Europe, under the Product Liability Directive, nearly absolute liability is imposed on producers of goods for 'defective' products. Article 6 of the Directive defines a 'defective' product to mean "a product that does not provide the safety which a person is entitled to expect, taking all circumstances into account."⁵⁹

While a producers' liability for defective products in the E.U. is nearly absolute, there are enumerated defences under the Directive, including a defence that "the state of scientific and technical knowledge at the time when (the producer) put

⁵⁶ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products; *Official Journal L 210*, 07/08/1985 P. 0029 – 0033

⁵⁷ The *Consumer Protection Act, 1987 (Product Liability) Modification Order 2000* (S.O. 2000, No. 2771)

⁵⁸ Interview with Christopher Hodges, December, 2005.

⁵⁹ Article 6 of the Product Liability Directive Provides: that "A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation. A product is not be considered defective for the sole reason that a better product is subsequently put into circulation."

the product into circulation was not such as to enable the existence of the defect to be discovered.”⁶⁰

A key objective of the Product Liability Directive, as with the GPSD, was to harmonize the laws, regulations and administrative provisions of the Member States, in this case, concerning liability for defective products. The ‘approximation’ of the Member State laws concerning the liability of the producer for damage caused by defective products was considered necessary to prevent existing divergences in the laws from distorting competition and affecting the movement of goods within the common market. Diverging product liability laws also results in differing degrees of protection throughout Europe for the consumer against damage to personal health or property caused by a defective product.

Following the enactment of the UK *Consumer Protection Act, 1987*, the Department of Trade and Industry developed a Guide, including a checklist, to help businesses meet the combined requirements of the EU’s Product Liability Directive and the new General Safety Requirement. The checklist contained a rudimentary list of production and marketing measures that should be taken by producers to ensure the supply of safe products and their financial ability to meet claims for defective products.⁶¹

Not all Member States transposed the Product Liability Directive exactly as intended. In the *Commission v. France (Approximation of laws)*, the Commission obtained a Declaration in 2002 that the French Republic had failed to fulfill its

⁶⁰ Other defences under article 6 of the Product Liability Directive include: a) The producer did not supply the product, b) The defect was caused by complying with the law, c) The defect was not in the product at the time it was supplied (e.g. careless handling by supplier d) The product was not supplied in the course of business (eg. Donation of homemade toys to church bazaar), and e)The producer of a component is not liable where the damage is caused by the product design or by giving the producer of the component faulty specification.

⁶¹ *Guide to the Consumer Protection Act, 1987, Product Liability and Safety Provisions*, UK Department of Trade and Industry, accessed on September, 19 at: <http://www.dti.gov.uk/files/file22866.pdf?pubpdfload=01%2F1438#search=%22consumer%20protection%20act%2C%201987%20uk%20s.%20%22general%20product%20safety%22%22> The checklist for business included the following advice: “a) review management procedures to ensure that all stages of production (design, manufacture, presentation and marketing) help to ensure that only safe products reach the customer, b) check whether there are any specific regulations setting mandatory requirements for the firm’s products; also check whether there are any published or proposed safety standards for its products and to what extent they meet, or could be made to meet, the standard, c)consider introducing quality assurance at each stage of the production process, d) assess whether the businesses insurance cover is adequate, including product liability insurance. The matter of insurance obtained is a matter for commercial judgment, but businesses should seek advice from their own insurance advisors, e) review any contractual arrangements with suppliers, customers or others with whom the business has relevant contracts (a business cannot contract out of liability under the Act. but might, for example, seek indemnity from others in the event of liability under the Act.), and f) decide whether the records kept by the business are adequate, bearing in mind the working life of the product, the ten year potential for liability for product liability claims, and the possible need to identify suppliers of defective products to the business in defending a product liability action (particularly relevant to ‘own branders’)”

obligations under the Product Liability Directive by varying the damage and liability provisions and the obligations of producers, ostensibly to enhance the protection of French consumers under its product liability laws beyond the protection available in other European States.⁶²

Geraint G. Howells⁶³, in the Sydney Law Review, 2006, examines the impact of European harmonization on the consumer protection laws of Member States, including under the Product Liability Directive. Howells concludes that, while Europe originally intended a minimal harmonization to provide a 'floor of protection' for consumers, EC consumer law has moved toward 'maximal harmonization' providing, in effect, a 'ceiling of protection.' "*E.C. law, under a maximal harmonisation approach,*" Howells concludes, "*is no longer a benevolent friend of the consumer guaranteeing minimum rights, but becomes the guardian of trade interests.*"⁶⁴

Minimal harmonisation was originally the dominant philosophy of consumer policy in the EC. This was combined with mutual recognition of national standards, unless receiving states could justify imposing higher standards under EC law. It was recognised that some areas needed to be totally harmonised, but for the most part Europe saw its role as creating a floor of rights on which Member States could build. Indeed for many years the European Commission encouraged States to develop more protective rules so that other Member States could benefit from these experiences. *The model was one under which European consumer rights could progressively be improved by building on best practice from the Member States. This has all changed. The Commission now believes that consumers can only be delivered the benefits of the internal market if businesses can trade with ease across borders. In their opinion this demands that no national rules be more protective than European laws.* Businesses should not be put off by the risk of being exposed to laws other than those found in their own legal system. This is not, as in the past, limited to rules which actually affect the content of the product, labelling or even advertising that might require producers to change their practice to trade in other states, *but seemingly will be extended to all consumer protection laws.*

Maximal harmonisation turns the EC rules into the ceiling of protection. Any more protective national rules are simply not permitted as a matter of EC law. EC law under a maximal harmonisation approach is no longer a benevolent friend of the consumer guaranteeing minimum rights, but becomes the guardian of trade interests. Business only has to be concerned to lobby hard for favourable

⁶²) [2002] EUECJ C-52/00 (April 25, 2002), accessed on September 27, 2006, at <http://www.bailii.org/cgi-bin/markup.cgi?doc=eu/cases/EUECJ/2002/C5200.html&query=%22general%20product%20safety%20%22>

⁶³ Professor of Law, Lancaster Law School, United Kingdom.

⁶⁴ *The Rise of European Consumer Law – Whither National Consumer Law*, Sydney Law Review, 2006. Article accessed on September 19, 2006 at <http://www.austlii.edu.au/cgi-bin/disp.pl/au/journals/SydLRev/2006/4.html?query=%22general%20product%20safety%20directive%22#fn1>

European laws and national legislators are unable to react to any remaining consumer concerns. Consumer protection has truly been integrated into other community policies as the European Economic Treaty requires in fact it seems sometimes as if consumer protection policy has become internal market policy. (Emphasis added)

Europe's enactment of the Product Liability Directive in 1985, however, clearly paved the way for both the enactment of a general safety requirement in the UK as part of a 'modernized' UK *Consumer Protection Act, 1987* and for Europe's General Product Safety Directive (92/59/EEC). Both initiatives have strong elements of 'absolute liability.' Neither fits comfortably with the Canadian defence of due diligence in regulatory prosecutions.

Consumer Product Safety in the Member States

Prior to enactment of the initial *General Product Safety Directive (92/59/EEC)*, some Member States had already included a General Safety Requirement in their consumer product safety legislation. These States included Germany, some Nordic Countries, the Netherlands and the United Kingdom (*The Consumer Protection Act, 1987*).

In Europe, national consumer product legislation must be looked at both in domestic and E.U. terms. There are different forces at work in the national and European contexts. These forces – political, economic, scientific, parochial - are sometimes parallel, and sometimes not. The United Kingdom experience serves as an example in this Paper.

Consumerism in Europe was the product of a post war industrial expansion and dates mainly from the 1960's (the thalidomide crises). It gathered substantial momentum in the 1980's (the mad cow crisis among other concerns) and continues to evolve at a quickening pace today.

Germany, France, the Netherlands, the United Kingdom and a few other European countries developed embryonic consumer safety legislation around the early 1960's. The UK the *Consumer Safety Act, 1961*, while it addressed the issue of consumer protection, was also viewed as a pro-industry statute in that it constituted a base for standardization which facilitated trade. The *Act* was administered by the Department of Trade and Industry in the UK, as is the current *Consumer Protection Act, 1987*.

UK industry is generally reputed by the Department and Trade and Industry to produce safe products because the UK developed an industry-made form of self regulation over the past forty years based on quality systems which came to form the basis for ISO 9000 standards. The standards-based approach to the regulation of consumer products and reliance on quality systems for conformity

assessment purposes under Europe's GSR is, therefore, not just familiar to UK industry, but largely integrated with industry practices.

The details of how the general safety requirement evolved under UK consumer legislation are set out in the section of this Paper entitled *The Case For Reform*, below.

Harmonizing Technical Standards for the European Common Market

Prior to 1985, Member States adopted diverse approaches to regulating consumer products. Germany defined broad safety principles in legislation and left their implementation to producers, with guidance from standards, codes of practice or official guidelines. The Federal *German Law on Technical Equipment, 1968* ('the Equipment Safety Law') required only that "all manufacturers and importers must ensure before sale that their equipment, when properly used, is safe from hazards to life and health."

France adopted a contrasting approach to product safety: it employed formal and highly detailed regulation. The French approach eventually ran afoul of the principle of free movement of goods under the mutual recognition provisions of the European Community Treaty of 1957 on the grounds of alleged protectionism. The United Kingdom faced similar challenges from other Member States under the Treaty. Germany, on the other hand, avoided the anti-protectionist features of the Treaty by the flexible approach it followed in meeting the essential safety requirements set out in its legislation.

Initially, two changes in policy helped speed up the process of integrating the numerous European laws engendered by rising concerns about product safety.

First, a mechanism was put in place to prevent Member States spontaneously adopting technical barriers to trade without prior notification, coupled with (judicial) reinforcement of the principle that products placed on the market in a Member State should be entitled to move freely throughout the Community, in accordance with the principle of mutual recognition.⁶⁵

The *Cassis de Dijon*⁶⁶ decision of the European Court of Justice was the first decision of the Court to give a clear signal that it was prepared to assist with the creation of an internal common market without barriers to trade between Member States. This decision established that a product (in this case, a French blackcurrant liqueur) sold lawfully in one member state could not be prohibited in another member state (Germany) except on public health grounds under the principle of 'mutual recognition' of Member State laws.

⁶⁵ Hodges, *European Regulation of Consumer Product Safety*., Oxford University Press, 2005, p. 53, and footnote 3. See also council Directive 83/189/EEC of March 1983 laying down a procedure for required sharing information in the field of technical standards and regulations.

⁶⁶ *Cassis de Dijon* [1979] ECR 649.

In the first meeting of the Committee struck by the Commission to facilitate information sharing on European technical standards and regulations, the German representative invited the Member State representatives present to consider adopting the German approach to regulating product safety. Only the essential safety principles developed to protect the public interest would be set out in legislation. The technical details required for implementing the essential requirements would be determined by enterprises and private standardization agencies employing standards, codes of practice and guidelines that they developed with the aid of ‘technical’ experts.⁶⁷

Immediately following this meeting, the French and British representatives examined the German approach with the Chairman, Paulo Cecchini, then Deputy Director-General of the European Commission. At an informal meeting with the German and British representatives at the Chateau de Namur in Belgium in June of 1983, Mr. Cecchini presented a paper outlining the framework of a New Approach to Regulation for Europe based on the German regulatory practice. With minor amendments, the proposal was accepted for later presentation to the Member States.

The follow up of the result of the Château de Namur meeting was embodied in a presentation by Mr. Narjes, Member of the Commission for the Internal Market, which led to Council conclusions of the 16th of July 1984, annexed later to the Council Resolution of 7th of May 1985(Official Journal of the European Communities n. C 136/1 of the 4th of June 1985). (The New Approach to Regulation)⁶⁸

The essential features of Europe’s New Approach to Regulation are that:

- Only “essential requirements” are set out in technical directives, for which the means of compliance is left to individual manufacturers;
- The technical specifications of products meeting the essential requirements set out in the directives are established through harmonized standards developed by technical experts and approved by standardization committees;
- Compliance with harmonized or other standards remains *voluntary*. Manufacturer’s are permitted to apply other technical specifications to meet the essential requirements of the legislation if they chose to do so;
- Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements – although *individual* products may still be found to be “unsafe” and acted against by the appropriate public authority;
- European New Approach directives are treated as “total harmonization directives”, that is, the provisions of these directives supersede all corresponding provisions in the laws of Member States; and

⁶⁷ Correspondence, dated February 3, 2006, from Mr. Paulo Cecchini, former Deputy Director-General of the European Commission to Lyle S. Fairbairn, Q.C., filed with this Report.

⁶⁸ *Ibid.*

- New Approach directives are ultimately addressed to Member States, which have an obligation to transpose them into their national legislation.⁶⁹

Europe has approximately 20 vertical directives dealing with such matters as appliances burning gaseous fuels, construction products, lifts, low voltage equipment, machinery, medical devices, toys, and personal protective equipment, among others.

The following examples illustrate the very general level at which “essential requirements” are struck in the vertical European directives and transposed in Member State regulations. The vertical directives are, in effect, broad ‘performance standards’.

- **Appliances burning gaseous fuels** must be so designed and built as to *operate safely and present no danger* to persons, domestic animals, or property when normally used (as defined in article 1.4)⁷⁰
- **Low voltage electrical equipment**, together with its component parts should be made in such a way as to ensure that it can be *safely and properly assembled and connected*.⁷¹
- **Medical Devices** must be designed and manufactured in such a way that when used under the conditions and for the purposes intended, they *will not compromise the clinical condition or the safety* of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.⁷²
- **Toys...**The user of toys as well as third parties must be *protected against health hazards and risk of physical injury* when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.⁷³

Under the New Approach, therefore, detailed regulations are effectively displaced by ‘technical’ specifications for products as set out in voluntary standards struck by standardization agencies and expert committees, which are submitted to the European Commission for approval and publication. If a product meets the specifications in production, it will benefit from a presumption of conformity with

⁶⁹ European Commission Guide to the Implementation of directives based on the New Approach and the Global Approach, pp. 8,11, accessed February 9, 2006, at:

http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf

⁶⁹ Ibid., para 149:

⁷⁰ 90/396/EEC, 1.1

⁷¹ 73/23/EEC, 1.22

⁷² 93/EEC, 1.

⁷³ 88/378/EEC,1.

the essential requirements of the relevant European Directive. The specification standards are numerous and certainly as detailed as any prescriptive regulation, however, compliance with them remains voluntary. *Ultimately, the onus is on the manufacturer to establish conformity with the essential requirements.* This may be done with reference to ‘approved’ European standards – or to standards developed or employed by the manufacturer that meet or exceed the ‘essential requirements.’

In the case of Toys, numerous standards have been developed by European Standards Agencies (or by Member States submitting national standards for approval by the European Commission as “European” standards”). Specification standards for toys include standards relating to flammability, the mechanical and physical properties of toys, the potential for migration of chemical elements, and age labeling warning symbols. Particular categories of toys likely to expose children to accidental injury are also covered by specification standards; including swings, slides and similar ‘activity’ toys, finger paints and chemical toys.

Despite the modest standard setting resources available in the UK in 1972, the *Robens Inquiry* anticipated that any safety regime relying extensively on voluntary standards would soon see an exponential increase in the development of standards. This had been the case in Germany under its *Equipment Safety Law, 1968*. It also proved to be the case in Europe after the New Approach to Regulation in Europe was adopted. The European Committee for Standardization (CEN), which has access to more than 60,000 technical experts, has developed more than 12,000 European standards under the New Approach. The European Committee for Electrotechnical Standardization (CENELEC) has developed over 5100 European standards.⁷⁴

Conformity Assessment Modules

The ‘New Approach’ standards are, as noted, are strictly voluntary, but the onus is on producers to establish conformity with the essential requirements of the vertical directives. In 1990, nine harmonized methods, or modules for the assessment of product conformity were laid down in Council Decision 90/68/EEC.⁷⁵ In 1993, the European Council laid down criteria for which of the conformity assessment procedures are appropriate for the particular technical harmonization directives (93/465/EEC). In some instances, producers are given a choice amongst the various modules where more than one approach is consistent with ensuring compliance with the ‘essential requirements’ of a vertical directive.

The conformity assessment modules usually address both the design and production phases of a product. Depending upon the product in question, the

⁷⁴European Conference on the 20th Anniversary of the New Approach, Brussels, November 30, 2005, presentation by Michael Kelley, Chairman of CEN/CENELEC/ETSI Joint Presidents Group, accessed on June 5, 2006 at http://ec.europa.eu/enterprise/newapproach/new_approach_conference_en.htm

⁷⁵ December 13, 1990, OJL 380/13,31,12.90.

conformity assessment module might involve a simple self-certification of the design, manufacture and operation of the product, possibly with a supplementary requirement for specified tests on aspects of the product.⁷⁶ Other modules involve the participation of “notified bodies” (independent laboratories serving a quasi-governmental surveillance and testing function); the production and assessment of prototypes; approval by a notified body of a quality assurance system covering production; final product inspection and testing; unit by unit verification by a notified body; verification of manufacturing processes or “full quality assurance”, which incorporates many of the features of other modules covering design, manufacture, and final product inspection and testing.⁷⁷

Standard Setting Under the GPSD

The European Commission has established a process to evaluate and identify standards that will provide a supplier with a "presumption of conformity" to the general safety requirements of the GPSD. A list of qualifying standards is published in the Official Journal of the European Communities. The recommendation for a standard to be included in the list of published standards may come from a number of sources including European Standards Bodies, industry, consumer associations and member states.

Before making a decision on a standard, it is evaluated by two Expert Committees with representatives from member states and stakeholders who provide advice on standardization matters.⁷⁸ Members of these committees are asked to provide their opinion on whether they consider the standard to fulfill the requirements of the GSR under the GPSD. No specific criteria are set for the process other than what is specified in the GPSD. If it is the opinion of the committees that the standard fulfils all the requirements of the GSR, the standard is deemed to confer conformity to the general safety requirements of the GPSD and is published.

The questionnaire used by the Committees in carrying out this analysis, includes criteria similar to U.S. criteria under the U.S. *Consumer Product Safety Act* (for deferring to voluntary standards) and is attached as Annex 2. To date, only one rather limited list of standards has been published under the GPSD, it deals

⁷⁶ The producer is obliged to retain supporting documentation in support of the self-certification for periods up to 10 years or the expected duration of the product.

⁷⁷ See Christopher Hodges, *European Regulation of Consumer Product Safety*, *supra* Appendix 5: Modules for Conformity Assessment Procedures Under the New Approach.

⁷⁸ Directive 98/34/EC “Standing Committee, the members of which will be appointed by the Member States with the task of helping the Commission to examine draft national standards” and “the Standing Committee should be consulted on the draft standardisation requests referred to in this Directive;”

mainly with child care articles, children's' furniture and lighters.⁷⁹ A second list is currently being developed for publication.⁸⁰

Trade-based Jurisdiction of the GPSD

The European Community's competence to legislate in relation to product regulation (including for the general product safety requirement) is limited to measures that help establish or improve trade throughout a European Common Market.⁸¹ This contrasts significantly with the jurisdictional basis for Health Canada's proposed *Health Protection Act*, founded on the exercise of the federal criminal law power for the exclusive purpose of protecting public health and safety. This difference in Europe's underlying authority for product safety is an important influence on Europe's perspective on product safety issues. In particular, it affects European approaches to setting and amending standards and the role of those standards in achieving product safety. It also affects which stakeholders occupy the ascendant role in the regime's regulatory processes, as well as the perspective of officials engaged in market surveillance, compliance and enforcement measures.

Article 95 of the *Treaty Establishing the European Community* provides:

By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. (i.e. establishing the internal market) The *Council shall*, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States *which have as their object the establishment and functioning of the internal market.* (Emphasis added)

Product safety, as such, is not within the European Community's Treaty express mandate, although consumer protection and product safety are an important ancillary consideration because the laws, regulations and technical requirements of Member States are required to be harmonized "to a high level of protection." Section 95(3) of the Treaty provides:

The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, *will take as a base a high level of protection, taking account in particular of any new development*

⁷⁹ See *Commission communication in the framework of the implementation of Directive 2001/93/EC of the European Parliament and of the Council of 3 December of 2001 on general product safety* of listed European Standardization Organizations, published in the Official Journal of the European Union, (2004/C 100/04)

⁸⁰ Personal electronic communication between Elizabeth Nielsen and Erik Hansson, Deputy Head of Directorate General Health and Consumer Protection. April 29, 2006.

⁸¹ Christopher Hodges, *European Regulation of Consumer Product Safety*, Oxford University Press, 2005, pages 28-37

based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective. (emphasis added)

The preamble to the *General Product Safety Directive*, recites the trade-based jurisdiction to make clear that a major purpose of the GPSD is to avoid differing levels of protection being accorded to like products within various Member States to avoid barriers to trade or distortions of competition in the European Community. If the European Commission's GPSD measure had been advanced to meet product safety objectives exclusively, it would clearly have been challenged on jurisdictional grounds under the Treaty establishing the European Community.

The preamble of the Directive alludes to the trade-based objective in the following terms:

(2) It is important to adopt measures with the aim of improving the functioning of the internal market, comprising an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.

(3) In the absence of Community provisions, horizontal legislation of the Member States on product safety, imposing in particular a general obligation on economic operators to market only safe products, might differ in the level of protection afforded to consumers. Such disparities, and the absence of horizontal legislation in some Member States, would be liable to create barriers to trade and distortion of competition within the internal market.⁸²

The ancillary, safety-based, objective of the GPSD (which links to the "high level of protection" terminology in the Treaty) is expressed in the following terms:

(4) In order to ensure a high level of consumer protection, the Community must contribute to protecting the health and safety of consumers. Horizontal Community legislation introducing a general product safety requirement, and containing provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and on rapid exchange of information and action at Community level in certain cases, should contribute to that aim.

While both trade and safety objectives are recited in the GPSD directive, it is important to emphasize that the trade objective is paramount in Europe and any safety measure undertaken by the EU cannot usually be divorced from its common market objectives. This is significant because trade and safety objectives sometimes conflict. It is important to keep this in mind should Health Canada decide to adapt aspects of the European model to the Canadian health protection legislation.

⁸² *General Product Safety Directive*, 2001/95/EC, preamble, section (3).

5. The Case for Reform in Europe

Europe: The General Product Safety Directive

The Case for Europe's General Product Safety Directive

The German and Nordic approach to regulation was adapted to the general duty of care prescribed under occupational health and safety legislation in the United Kingdom in the early 1970's⁸³, and to workplace safety regimes in numerous other Commonwealth countries, including Canada. These initiatives in the occupational health and safety sector were preceded by a seminal UK report⁸⁴ that made a compelling safety case for placing primary statutory responsibility for safety on those in the best position to influence safety outcomes. This was the Report that led to the enactment, in 1974, of the UK's first general product safety requirement covering goods and substances supplied to the workplace.⁸⁵

The case for a standards-based approach to regulatory reform in Europe was grounded on the compelling need to overcome regulatory gridlock in Community legislation and to expeditiously establish a viable, internationally competitive, common market by establishing harmonized voluntary product standards.⁸⁶ The case for reform in Europe was primarily trade-based; it was not predominantly a case for improved product safety.

Under the Treaty establishing the European Union, Member States retain the residual power and the European Parliament relies exclusively on the provisions of the Treaty for its authority. Under the Treaty, product safety is an ancillary issue. The Treaty requirement that product standards be harmonized *to a high level of protection* (Article 95) is only "procedural and aspirational," and would be difficult to enforce as a matter of binding policy.⁸⁷ In 2000, for example, the European Court of Justice struck down a European Community Directive on tobacco advertising because the measure was found to be concerned strictly with public health policy and did not contribute to market building.

The original GPSD underwent major revisions in 2001 and the overall role of the GSR is now undergoing a metamorphosis in Europe. Through inertia in the regulatory process, the GSR is becoming transformed from a temporary 'safety net' into a more permanent horizontal form of regulation for unregulated consumer products at the pan-European level generally. This is occurring for the

⁸³ I.e. Under the *Health and Safety at Work Act, 1974*

⁸⁴ *Report of the Robens Committee on Safety and Health at Work, 1970-72*

⁸⁵ See Annex 3 for a discussion of the first GSR in the UK under a Workplace Safety Model.

⁸⁶ See Annex 2 for a more detailed description of Europe's New Approach to Regulation and its relationship to the General Safety Requirement

⁸⁷ Christopher Hodges, *European Regulation of Consumer Product Safety*, Oxford University Press, 2005 at p. 31

following reasons:

- There is a policy bias against regulation unless the need for regulation is compellingly justified;
- Some new countries entering the E.U. do not have mature, or any, consumer product legislation and thus rely heavily on the *General Product Safety Directive* as framework legislation;
- There are vastly differing capacities and resources within the Member States for developing, administering and enforcing product safety regulations;
- Europe's targeted five-year period for reviewing standards is not always achieved, leaving additional, unintended, scope for the GPSD;
- Some of the standards developed by standards groups are simply not effective safety standards, by reason of trade imperatives or intransigent positions taken on largely industry-controlled standardization committees; and
- The capacity of new Member States for transposing new regulations is also limited due to onerous demands on their regulatory process. (New States being brought into the European Union must adopt approximately 26,000 European laws as a condition of admission.)

European community standards are moving in the general direction of international standards in the interest of enhancing international trade and competitiveness. International product standards, ironically, may sometimes provide lower safety levels than national standards due to the degree of compromise required to achieve a consensus at the international level and the general absence of consumer representation on international standard-setting bodies.

All of these factors are important considerations for Health Canada in assessing whether, or how far, to adapt aspects of the European model of the GSR to Canada's health protection legislation.

The United Kingdom – Consumer Product Safety Legislation

The General Safety Requirement in the current UK *Consumer Protection Act* was influenced by two separate policy strands, namely: the workplace safety reforms of the early 1970's and the trade-based regulatory reform in the European Union in the 1980's. Both policy strands placed an emphasis on enforced *self*-regulation and the substitution of voluntary standards for prescriptive regulation, where feasible.

The UK experience in crafting general product safety requirements in the workplace and product safety sectors illustrates key policy and practical considerations associated with this regulatory technique. The outcome-oriented reforms of UK workplace safety legislation in the 1970's - including the GSR on which the UK product safety requirement was later based - mirror Health Canada's objectives under the Legislative Renewal initiative to a remarkable degree.

In the early 1970's, the consumer safety regime was somewhat rudimentary. Its deficiencies included a significant lack of information about consumer safety issues, limited availability of operating standards, and a somewhat limited power to make regulations.

One of the deficiencies under the UK consumer safety regime in the 1970's, resonates with Health Canada's principle reason for wanting to include a general safety requirement in the proposed *Health Protection Act*:

Regulations provide a long-term safety measure by ensuring that all goods of a particular class are made to minimum safety standards. *But they cannot be invoked to take speedy action to deal with a newly discovered hazard, or against dangerous goods of a sort not covered by regulations.* Other procedures are required to enable action to be taken in such circumstances, and there is no power at present to order the immediate withdrawal from sale of dangerous goods.⁸⁸ (Emphasis added)

In the UK, the case for including a GSR in consumer product safety legislation was not easily made. In 1974, the UK first considered, and rejected, a GSR for inclusion in the *Consumer Safety Act, 1978*. Consumer groups had pointed out that, but for a few product-specific statutes, there was no comprehensive legislation which prohibited the marketing of dangerous goods; nor was there any statutory power under which a trader could be compelled to withdraw dangerous goods. The proposal to include a 'General Safety Requirement' in the legislation was clearly regarded as a radical proposal.

Some *have gone so far as to propose* that it should be made an offence for any person to supply a dangerous product which is dangerous or a risk to health.⁸⁹ (Emphasis added)

Criteria for UK Rejection of the GSR in 1976

In 1976, the GSR proposal was rejected for numerous reasons. Based on Health Canada's consultations under the Legislative Renewal Initiative, some of the reasons (those in italics) are still topical concerns in Canada.⁹⁰

⁸⁸ Ibid., para. 45

⁸⁹ *Consumer Safety, A Consultative Document*, UK February, 1976; Cmnd. 6938, para. 80

⁹⁰ Others reasons for rejection of the GSR in the UK in the 1970's are of less concern in Canada today because 'regulatory offences' have been distinguished from purely criminal offences by the Supreme Court

- “A trader might find himself at risk of prosecution for an absolute criminal offence although he had taken all reasonable care in the course of his business;”
- Even if a statutory defence of due diligence were included, this would still leave “the onus on the defendant to prove that he was not negligent;”
- *“It also leaves the main emphasis of the prosecution case on whether the product was unsafe; this could tend to underline the difficulty of establishing criteria of safety, on which opinions of experts are liable to differ;*
- Imposing a duty on any person supplying a product to ensure that it is safe, as an alternative, would amount to making it a criminal offence to fail in the common law duty of care which already rests on manufacturers and others supplying goods;
- To secure a conviction under such a provision, it would not be sufficient to for the prosecution to prove that a product was unsafe, it would also have “to show that the accused failed in his duty to take reasonable steps to establish the safety of the product;”
- *A GSR would not guarantee that unsafe goods would not reach the consumer, nor would it “adequately secure the withdrawal of any such goods found on sale;”*
- *There was doubt about whether the resulting encouragement to traders “to exercise more care” warranted the creation of a new offence, or the additional case load on the criminal courts;*
- *The problem of defining what is “safe” would become more critical in criminal proceedings than it is in civil proceedings and was “bound to raise problems of consistency”, not only in day to day prosecutions, but also in international for a like the EEC; and*
- *The GSR would only serve a purpose “in extreme circumstances”; regulations and “direct action by the Department would remain the main instruments for ensuring adequate safety standards.”⁹¹*

Factors Underlying UK Acceptance of The GSR in the mid-1980's

The United Kingdom had an opportunity to reconsider the GSR proposal in 1984 while reviewing the effectiveness of *The Consumer Safety Act, 1978*.⁹² The review was prompted, in part, by an influx into the UK in 1981 of over one hundred types of dangerous electrical hair curling brushes imported from the Far

of Canada. (*R. v. Sault Ste Marie*, 1978, CanLII 11 (SCC), [1978] S.C.R. 1299) Regulatory offences now generally carry a lesser social stigma and provide for a defence of ‘due diligence’ so as to prevent quasi-criminal liability without fault. The new regulatory offences enable a defendant to escape liability if he can establish on a civil burden of proof (beyond a preponderance of probabilities) that he exercised all due care to avoid committing the offence. However, the prosecution must still establish the factual elements of the offence on a *criminal* burden of proof, that is, beyond a reasonable doubt.

⁹¹ *Ibid.*, Cmnd. 6938, paras. 79-84

⁹² Report to Parliament on *The Safety of Goods*, by the Secretary of State for Trade and Industry, July, 1984, Cmnd 9302

East, The curling brushes lacked adequate insulation and posed a severe electrocution hazard. The expense and difficulty in tracking down these appliances and removing them from the market, together with long delays between the identification of suspect goods and their removal from the market, clearly pointed to the need to reform the 1978 legislation.

The UK Department of Trade and Industry (DTI) circumscribed its proposed reforms with two important cost/benefit parameters:

10. In safety, as in other fields, there does, however, come a *point where additional benefits begin to become disproportionately expensive. Safety policy must reflect a judgment on the degree to which the community as a whole is prepared to pay for additional safety. The Government has not pursued suggestions which would involve major interference with the normal processes of manufacture and trade and so put up unduly the prices which consumers have to pay.*
11. The Government has also *excluded options which could be implemented only by directing large additional resources to enforcement. Again consumers – as tax and rate payers – would have to meet much of the cost. The Government’s intention is to encourage more efficient use of existing resources by facilitating better identification of unsafe goods before they are distributed and streamlining the procedures for halting their supply.*⁹³
(emphasis added)

The DTI proposals involved “wider powers for enforcement authorities (which were) *balanced by appropriate safeguards* for traders.”⁹⁴ The approach to be adopted in balancing new powers with appropriate safeguards is an important policy issue for Health Canada, should it adopt a GSR. This regulatory technique involves a considerable expansion of administrative discretion in the process of determining the ‘safety’ of consumer products and in selecting appropriate actions, including prosecution, to be followed in the case of ‘unsafe’ products.

In 1984, the UK Government accepted that there was a case for widening the scope of the 1978 *Act* “to place a general obligation on the suppliers of consumer goods to achieve an acceptable standard of safety where it is reasonable to expect them to anticipate and reduce risks arising from those goods.”⁹⁵ The Government recommended the inclusion of a GSR in its consumer product safety legislation for the following reasons:

- The GSR was considered to induce a greater sense of responsibility on the part of those suppliers who regarded themselves as unaffected by the

⁹³ *Ibid.*, paras. 10 and 11

⁹⁴ *Ibid.*, para 12.

⁹⁵ *Ibid.*, para. 34

legislation (and who might not have been adequately deterred by the common law duty of care);⁹⁶

- Local authorities already dealt informally with complaints about the safety of unregulated goods and often sought to persuade suppliers to withdraw or modify such goods, or drew attention to the attention of the Secretary of State for consideration of possible use of prohibition powers. The introduction of a general duty would enable enforcement officials to take action on the basis of a legal obligation on suppliers;⁹⁷
- In ten years of experience with a general safety requirement in section 6 of the *Health and Safety at Work Act, 1974*, there did not appear to have been serious problems of interpretation of the level of safety required for industrial goods;⁹⁸
- A general safety duty was thought likely to stimulate the formulation and wider use of safety standards for consumer goods and thus contribute to the development of a more effective standards system – an objective to which the UK was already committed;⁹⁹
- While the proportion of accidents caused directly by dangerous products was thought to be small, a major purpose of safety legislation was thought by DTI to “help prevent accidents by setting new standards for reducing risks.”¹⁰⁰
- Greater enforcement at the point of first supply was thought likely to be more cost effective than the former practice of concentrating on the retail stage,¹⁰¹ and
- The powers to require production of documents or to seize and detain goods for testing would be available for new products which, in the absence of a general legal duty to produce ‘safe’ products, would only have been available where the enforcement officer had reasonable cause to suspect or believe that specific regulations, orders or notices had been contravened.¹⁰²

Proposed Use of Voluntary Standards

To address earlier concerns about how to determine what level of safety would be required to meet the new general duty to produce ‘safe’ products, the UK

⁹⁶ *Ibid.*, The hope and expectation was that a GSR would encourage or re-enforce good risk assessment and risk management practices at the pre-manufacturing stage.

⁹⁷ *Ibid.*, para 35

⁹⁸ *Ibid.*, para 36

⁹⁹ *Ibid.*, para. 36

¹⁰⁰ *Ibid* paras. 9, and 36

¹⁰¹ *Ibid.*, para. 21

¹⁰² *Ibid.*, para. 21

Government proposed to link the general duty (along the lines of the German approach to regulation) with a broadly defined reference to standards such as 'sound modern standards of safety'.¹⁰³

The purpose of this linkage would be to ensure that the level of safety which can legitimately be expected is interpreted by reference to *identifiable and accepted points of comparison* rather than simply left to more subjective assessments of safety. Such points of comparison *would have to embody established and proven technology, recognized by expert opinion in the field and already available at reasonable cost.*¹⁰⁴ (Emphasis added)

Where a published standard was accepted as a safety benchmark for the product in question, the standard would still be treated as voluntary. "Achievement of the same level of safety by compliance with equivalent standards, or by other means, would be equally acceptable."¹⁰⁵

Influence of the 'New Approach' Regulation

It is noteworthy that the date of the UK proposal to rely on voluntary standards as an aid to interpreting the meaning of 'safety' in the consumer safety area occurred at precisely the same time as Europe's New Approach to Regulation was being developed. In 1983, a British official and a German representative had collaborated with Paulo Cecchini, then Deputy Director-General of the European Commission in proposing the new, standards-based, approach to regulating the technical aspects of products as a means of overcoming regulatory gridlock on technical issues.

Europe's New Approach to Regulation was adopted by a European Council Resolution of May 7, 1985, two years before the enactment of a General Safety Requirement in the *Consumer Protection Act, 1987*. It is probable, therefore, that the 'New Approach' developments in Europe - in which the UK played an active role - made the UK rather more receptive to a standards-based approach to regulation than had been the case in 1974 when the UK rejected the GSR proposal, almost out of hand.¹⁰⁶

Canada's policy position on the role of voluntary standards in regulation is still evolving, but it does not yet reflect a commitment to using voluntary standards *in substitution for regulations* to the same extent as under Europe's 'New Approach' regulation or under the GPSD. Canada's position, over time, will be influenced significantly by the United States' position on the role of voluntary standards in regulating consumer products since the U.S. is its major trading partner. Europe's use of voluntary standards as a quasi-mandatory substitute for regulations is likely to be regarded, in the United States, as 'back door rule making'.

¹⁰³ *Ibid.*, para. 37

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.*, para 38

¹⁰⁶ Official Journal of the European Communities n. C 136/1 of the 4th of June 1985.

The role of voluntary standards in regulation in Europe, Canada and the United States is discussed later in this Paper under the heading *Implementation and Operational Experience*.

Balancing Enhanced Flexibility with Increased Accountability

Enhanced producer responsibility for verifying the safety of products was the *quid pro quo* exacted by the UK for allowing increased flexibility to producers in meeting safety requirements. Enhanced self-regulation also implied the need for increased stringency in the penalties for non-compliance, and also for limiting the excuses that constitute a defence of ‘due diligence’.

As a general rule, however, the Government considers that the first suppliers should be allowed to retain flexibility in choosing how to set about ensuring that their goods meet safety requirements. *The counterpart of that flexibility is responsibility*. There is a case for greater stringency, in both the penalties for infringements and *the criteria for defences to criminal charges*, in the case of first suppliers. First suppliers whose method of doing business leads them to rely for the specification of products, or materials for finished products, on other suppliers will need to take this into account in deciding the degree of confidence they wish to place in their sources of supply.¹⁰⁷ (Emphasis added)

The UK Government therefore proposed that a first supplier could not, in advancing a due diligence defence in a general safety requirement proceeding, rely on information supplied by another person, *unless they had taken reasonable steps to verify that information*. The wording of the due diligence defence in the *Consumer Protection Act, 1987* further restricted the due diligence defence by requiring a defendant to establish, in addition to having exercised all due diligence, that he or she had taken “all reasonable steps” to avoid committing the offence. This requirement has been carried over to the UK *General Product Safety Regulations, 2005*, transposing the revised GPSD.¹⁰⁸

29. (1) Subject to the following provisions of this regulation, in proceedings against a person for an offence under these Regulations it shall be a defence for that person to show that he *took all reasonable steps and* exercised all due diligence to avoid committing the offence. (emphasis added)

Compensation to Traders for Ungrounded Action by the Public Authority

The expanded powers given to the Public Authority were counterbalanced with upgraded safeguards for the Trader where the Public Authority exercises powers of seizure against consumer products later determined to be safe.

Expanded seizure powers and the power to require suppliers to hold goods suspected to be dangerous for six months are two of the “wider powers for enforcement authorities (which were to be) balanced by appropriate safeguards

¹⁰⁷ *Ibid.*, para 17

¹⁰⁸ S.I. 2005, No. 1803.

for traders.”¹⁰⁹ In the event that the authority’s initial suspicions could not subsequently be confirmed, the Government considered it fair that the authority be liable to *compensate* the trader for loss.

Australia’s Recent Review of Consumer Product Safety

The Ministerial Council on Consumer Affairs of Australia (MCCA) composed of representatives from the Australian Government and the Governments of the States and Territories undertook a review of the Australian Consumer Product Safety System.¹¹⁰ The main goals were to ensure that consumers could purchase safe products and that unsafe products would be readily detected, reported to the authorities and, if necessary, removed from the market. In addition to protecting consumers, they wanted to promote an efficient market for consumer products and use of limited government regulatory resources.

The main reasons for the review¹¹¹ identified by the MCCA are very similar to those behind the proposal to renew the Health Protection Legislation in Canada. They included:

- The need for a more proactive system that did not place the onus on government to identify, assess and regulate each product hazard amongst the increasing number of new and innovative consumer products on the market. As in Canada, the ability of government to address all the potential safety hazards associated with these products is affected by the resources available for regulatory development and enforcement. Also, the system suffered from an inability to detect unsafe products at an early stage since regulators did not have access to industry information on product safety problems nor did it have national statistics on product related injuries; and
- The need for a more efficient system that reduced the impact of their regulatory initiatives on consumers and businesses in the broader context. Since the Australian System includes product safety regulation not only at the Commonwealth level but also at the level of the individual states and territories, it resulted in duplication of effort, the potential inefficient use of public funds, and additional costs for business.

The MCCA identified a number of options to be considered in order to reform the system and requested the Australian Productivity Commission to assess the system’s ability to address the safety of consumer products; to examine the impacts of the options identified including the direct and indirect costs; and to evaluate the benefits of implementing the proposed options versus retaining the

¹⁰⁹ *Ibid*, para. 12

¹¹⁰ Australian Ministerial Council on Consumer Affairs, Review of the Australian Consumer Product Safety System Options for Reform, August 2004.

¹¹¹ UK *Consumer Protection Act, 1987, s. 14* (Suspension Notices).

current system. Some of the options proposed by MCCA¹¹² are the same as those in the Canadian Legislative Renewal Proposal¹¹³ such as:

- A general legal obligation for businesses to market only safe consumer products commonly known as a General Safety Requirement or General Safety Provision (GSP);
- A revised definition of unsafe goods;
- The provision of improved product safety information to businesses and consumers;
- New requirements for businesses to monitor and report on the safety of their product;
- A new requirement for businesses to recall unsafe products; and
- Measures to harmonize product safety legislation, administration and enforcement between the Commonwealth and the States and Territories.

Issues Identified by Stakeholders

Extensive consultation with stakeholders was carried out on the review of the system as proposed by the MCCA. A wide range of stakeholder groups from industry associations to consumer protection organizations responded and they identified a number of common issues needing to be addressed. Both Consumer Groups^{114, 115} and Industry Associations^{116, 117, 118} were concerned about:

- The fragmented product safety system with different rules in different parts of the country resulting in uneven protection to consumers and added costs to industry and consumers;
- The level of non-compliance with Australian standards and consistency of enforcement across the country;
- The lack of adequate data about the level of injuries associated with consumer products;
- The lack of sufficient research in the area of consumer product safety; and
- The differences between Australian and international standards.

Although Consumer Groups strongly supported the implementation of a GSP and reporting of adverse incidents, industry associations did not, primarily, because of the added cost burden and uncertainty due to the vagueness of a GSP.

¹¹² Australian Productivity Commission, *Review of the Australian Consumer Product Safety System, Discussion Draft*, August 2005.

¹¹³ Health Canada, *Health Protection Legislative Renewal, Detailed Legislative Proposal*, 2003.

¹¹⁴ Commonwealth Consumer Affairs Advisory Council, *Submission to the Review of the Australian Consumer Product Safety System*.

¹¹⁵ Australian Consumer's Association, *Submission to the Ministerial Council on Consumer Affairs Review of the Australian Consumer Product Safety System*

¹¹⁶ Australian Retailers Association, *The Position of the Australian Retailers Association in Relation to the Review of the Australian Consumer Product Safety System*, Dec. 2004.

¹¹⁷ Australian Toy Association Inc, *Submission to the Review of the Australian Consumer Product Safety System*.

¹¹⁸ Infants and Nursery Products Association of Australia, *Submission to the Review of the Australian Consumer Product Safety System*.

Results of the Productivity Commission's Research

Problem Areas Identified

In carrying out its research on the existing regulatory system, the Productivity Commission concluded that the most significant problem areas needing to be addressed appeared to be:

- Product misuse and poor product maintenance rather than faults inherent in the products themselves were found to be the most common cause of product-related injury;
- The inability to accurately define the size of the problem raised the issue of whether or not more public resources should be used to improve the safety of products or used to address other sources of hazards;
- The inadequate collection and use of evidence to help identify hazards as early as possible to permit a reasonable assessment of risks, and to fashion an evidence based response;
- Cases where the injury or death associated with a product has a delayed onset so that it is not easy to make the connection to the product; and
- Products supplied by recalcitrant and 'fly-by-night' sellers and manufacturers, rather than long-standing suppliers concerned to protect their reputation.¹¹⁹

Incentives to Achieve Adequate Product Safety or Change of Behaviour

Achieving a situation where consumer products do not cause injury or deaths is a responsibility that is shared between suppliers, consumers and governments. To achieve appropriate safety levels, the Commission suggested that a mix of cost effective incentives is required to encourage appropriate behaviours among those responsible. For suppliers, these included:

- The threat of adverse media coverage or criticism by consumer organizations and subsequent loss of reputation;
- Strict product liability rules, improved enforcement, and general legal remedies which encourage suppliers to implement measure to reduce their liability and potential damages;
- Insurance for suppliers; and
- Research into the health and safety of consumer products.

These conclusions were also identified by a number of consumer product suppliers who indicated that damage to company reputations, reduced sales and costly litigation acted as strong incentives to put into place programs to manage the safety and quality of the products they sell.¹²⁰

The factors that were found to influence the behavior of consumers and as a result the injuries and deaths associated with consumer products included:

¹¹⁹ Australian Productivity Commission, *Review of the Australian Consumer Product Safety System, Discussion Draft*, August 2005, Pg. XXVI

¹²⁰ Corporate Executive Board, General Counsel Roundtable, *Strategies for Managing Product Safety and Quality*, Catalogue No. GC157D75T, 2006.

- Provision of targeted information and education on the safe use and maintenance of products that is effective in influencing consumer purchasing decisions and behavior;
- Health care costs; and
- The potential of injury and death.

Key Findings and Related Rationales

The Productivity Commission after examining the existing product safety system in Australia did not recommend the establishment of a GSP similar to that being proposed in Canada and existing in Europe. The Commission was not convinced that a GSP would result in net benefits for Australia. The research instead indicated that in Europe, suppliers have a low awareness of the GSP requirements, are concerned about its vagueness and uncertainty and are influenced to a greater extent by liability rules. Moreover, the implementation of a GSP would be accompanied by additional transition costs lasting a number of years.

The Commission, in addition, did not recommend moving from the voluntary recall system that has worked well in Australia to a mandatory recall requirement as exists in Europe and the United States. It indicated that the incentives present to achieve product safety were sufficient for businesses to voluntarily to recall their products.

The Commission did however identify a number of areas where improvements could be made, such as:

- Harmonizing legislation across the States and Territories so that the implementation of any bans or standards were national in scope;
- Developing or improving mechanisms to detect unsafe products at an early stage¹²¹ such as a linked national system of complaints information, hospital data, mortality data, international information on injuries and hazards related to consumer products that is readily accessible to regulators;
- Including the concept of ‘foreseeable misuse’ in the definition of ‘unsafe’, as long as it is limited to behavior which is reasonably predictable and not unreasonable;
- Providing better information to businesses on regulatory requirements;
- Targeting information campaigns to consumers to influence their behavior;
- Improving data collection and research so that evidence-based hazard identification and risk management can be central to policy making, standard setting and enforcement;

¹²¹ Australian Productivity Commission, *Review of the Consumer Product Safety System, Chapter 11 Early warning and information sharing*, August 2005.

- Making greater use of cost-benefit analysis, embodying risk assessment, in determining whether and how to intervene to address identified product hazards so that public resources can be focused on the most serious product related hazards; and
- Targeting enforcement resources on the “fly-by-night” businesses that are most likely to supply unsafe products.

Response of the MCCA to the Productivity Commissions Findings

The findings of the Commission supported by the MCCA particularly as they relate to harmonizing the Australian Product Safety System and enhancing the proactive nature of the system were:

- Developing a hazard-based approach to product safety
- Undertaking a base-line study of product-related accidents;
- Establishing an internet one-stop shop to provide product safety information to businesses and consumers;
- Enhancing business reporting requirements regarding products clearly associated with serious injury or death;
- Ensuring legislative coverage of ‘reasonably foreseeable use’ in the threshold tests for bans and recall orders; and
- Enhancing the standards making process.¹²²

The Council did not, however, unanimously support the Commission’s recommendation that the implementation of a GSP would not benefit Australia. They plan to investigate this issue further.

The Ministers directed government officials to investigate how the Productivity Commission’s recommendations would work in practice and to report back at a meeting in mid September 2006.

Relevance to the Canadian Renewal Proposal

The review of the Australian Product Safety System and the detailed evaluation of implementing a GSP, a mandatory adverse incident reporting system and mandatory recalls is very relevant since these options are also being considered by Health Canada for possible inclusion in new legislation. In many cases, the findings of the Productivity Commission could apply to Canada as the issues identified by government and stakeholders are very similar. For example as in Australia, there is a need in Canada:

- To improve injury data collection, product safety research and cost/benefit analysis in order to determine whether and how to intervene to address product related hazards. This makes it possible to target public resources on the most serious problems;
- To develop or improve ways of detecting unsafe products at an early stage, particularly for consumer products;

¹²² Ministerial Council on Consumer Affairs, *Joint Communique of Ministerial Council on Consumer Affairs Meeting*, May 16-17th, 2006.

- To include the concept of ‘foreseeable use’ in the definition of ‘unsafe’, as long as it is limited to behavior which is reasonably predictable and not unreasonable; and
- To provide better information to businesses on regulatory requirements.

The Commission was not convinced that the benefits associated with the implementation of a GSP would justify the costs. They were concerned that a GSP would fail to target areas of the biggest risk and to deliver benefits beyond what could be achieved with modifications to the existing system. Similar conclusions were reached with respect to mandatory reporting and recalls mainly due to the fact that the Australian government is notified of many unsafe products due to its current voluntary recall system. A similar analysis of the Canadian situation including cost and benefits would assist Health Canada in determining whether or not to proceed with these initiatives in new legislation.

Generic Lessons Learned from Reform in the Occupational Health and Safety Sector

Employees do not occupy the same position relative to employers that consumers occupy to producers and suppliers but there are many parallels in the regulatory and safety considerations in these areas and numerous lessons for consumer product safety that can readily be extrapolated from the workplace safety regime. This is especially true when considering methods for ensuring transparency, consistency and accountability under a self-regulatory regime – all areas of observed weakness in Europe’s general product safety regime

There are remarkable parallels between Europe’s New Approach to Regulation in which voluntary standards *supplant* regulations and the justification for using voluntary standards to *supplement* regulations under generally prescribed duties of care in occupational health and safety legislation. Typically, under workplace safety legislation, everyone in a significant position to influence safety outcomes in the workplace has a duty of care toward safe working conditions. The purpose of this legislative approach, as with Health Canada’s approach under the proposed *Canada Health Protection Act*, is to displace a culture of mere compliance with regulations with a ‘culture of safety’ and injury prevention.

Europe’s general product safety requirement and the UK’s reformed occupational health and safety regime, though more than a decade apart in their inception, were both founded on a form of New Approach to Regulation under which voluntary standards were given a significant role in regulation. Both regimes are highly self-regulatory in nature. Both resonate with key elements of modern regulatory policy and ‘smart’ regulation concepts. Despite important differences between the two sectors, there is much to be learned from tapping into more than thirty years of experience in the workplace safety sector with the ‘New Approach’

principles that they share with the product safety area. There are useful lessons to be shared between the Sectors concerning:

- Formalizing participation by the intended beneficiaries of the regulatory requirements in assessing safety risks and in monitoring compliance with essential safety requirements;¹²³
- Approaches to prevention, safety training and communicating safe practices to industry and consumers;
- How to achieve an appropriate balance between flexibility and precision when regulating safety;
- Developing informal methods of dispute resolution regarding 'safety' (an inherently relative concept) and for minimizing the need for judicial intervention;
- Methods for ensuring that industry risk assessment and risk management practices in product development become routine aspects of 'good management' and part of a 'systematic' approach to self-regulation; and
- The role of good monitoring and enforcement techniques, and proportionate and appropriate sanctions, to the effectiveness of a prevention-focused regulatory regime characterized by a significant self-regulation component.

In Europe, the general product safety requirement is a 'work-in-progress' with important aspects of its implementation still undergoing careful review. The GSR has important deficiencies that are still being addressed. The *primary* focus of Europe's New Approach to Regulation - upon which the *General Product Safety Directive* is premised - is not safety, but *trade harmonization* and the effective operation of an internal European common market that is also competitive internationally.

The *Robens Committee*, in effect, developed a standards-based 'New Approach' in the occupational health and safety area more than a decade before the European New Approach to Regulation was implemented – and did so exclusively from a *safety* perspective. European experience under the *General Product Safety Directive* is much more recent than the 'New Approach' initiative and its overall effectiveness in achieving the kinds of objectives established by Health Canada for the GSR remains inconclusive. The formal use of voluntary standards was incorporated into the revised *General Product Safety Directive* only in 2001, for implementation only as of January 2004.¹²⁴

The Importance of Balancing Flexibility with Precision in Regulations
Canada's *Government Directive on Regulating* - though still a consultation document - sets out the federal Government's current policy expectations of

¹²³ Workers are the primary beneficiaries of workplace safety laws and they are formally involved in risk assessment, monitoring and risk management activities. The role of consumers and consumer organizations is equally important in the consumer product area in relation to these same activities, although the means of consumer participation is necessarily be different.

¹²⁴ 2001/95/EC

regulatory departments in their regulatory initiatives. Part of the Directive provides that when federal departments are developing or changing technical regulations, particularly regulations affecting trade, they are expected to:

- Specify, where possible, technical regulatory requirements in terms of their performance rather than their design or descriptive characteristics to ensure that regulations do not restrict trade any more than necessary to fulfill the intended policy objectives; and
- Make use of voluntary, consensus-based standards or guides when they adequately fulfill intended policy objectives.¹²⁵

While the balance achieved between regulations and voluntary standards as alternative means of meeting regulatory objectives is quite different in Europe from that in Canada, the rationale advanced by the *Robens Inquiry* in the early 1970's might well have been written as a justification for using voluntary standards as a means of introducing flexibility into regulation under Canada's regulatory policy in 2006.

If legislation is to remain current and effective, it is important to achieve an appropriate balance between rigid prescriptive regulations and a more flexible performance-based, voluntary self-regulatory approach to regulation.

Regulations which lay down precise methods of compliance have an intrinsic rigidity, and their details may be quickly overtaken by new technological developments. On the other hand, lack of precision creates uncertainty... The need is to reconcile flexibility with precision. We believe that, wherever practicable, regulations should be confined to statements of broad requirements in terms of the objectives to be achieved. Methods of meeting the requirements may often be highly technical and subject to frequent change in the light of new knowledge. They should, therefore, appear separately in a form which enables them to be readily modified.¹²⁶

The Robens Committee considered that the enabling legislation proposed to govern health and safety in the workplace should be supported by detailed provisions not only in statutory regulations, but also in voluntary standards and industry codes of practice.

We concluded that what was needed was less law and more provision for voluntary self-regulation... The broad argument in the present chapter is that many of the defects we described in chapter I can be remedied by a switch in emphasis away from the extensive use of statutory regulations towards greater

¹²⁵ Canada, *Government Directive on Regulating*, accessed at http://regulation.gc.ca/docs/smartregint/gdrfinalv4_e.pdf on June 5, 2006. lines 235-242. This part of the Directive on Regulation addresses Canada's broad commitments set out at the beginning of the Directive to support a fair and competitive market economy, to create more responsive regulation and to promote long-term regulatory cost-effectiveness. (see lines 45-70).

¹²⁶ *Robens Inquiry Report*, supra, p. 43, para. 138

reliance on standards and codes of non-statutory origin. In future, there should be more discrimination and selectivity in making statutory regulations.¹²⁷

The Limited Role of the Criminal Law in Regulation

Robens articulated something most regulatory officials know instinctively, namely, that the criminal law is a blunt and often ineffective instrument for dealing with regulatory non-compliance. Since Canada's proposed *Health Protection Act* is based on the exercise of the federal criminal law power, it is important to consider the scope for regulation under that power and how criminal processes might be adapted to achieve some of the efficiencies of civil and administrative regulatory instruments. In particular, what kind of a framework can be developed under a criminal law model to enable the negotiation of good remedial solutions to regulatory non-compliance?

In addressing some of the shortcomings of the criminal law and procedure, *Robens* noted:

Sanctions under the criminal law have only a very limited role to play in improving standards of safety and health. Truly criminal sanctions should be employed only for "offences of a flagrant, willful or reckless nature that either have or could have resulted in serious injury."¹²⁸

We found that those who took the opposite view were unable to deal convincingly with the fundamental weakness of legal sanctions in this field – that criminal courts are inevitably concerned more with events that have happened than with curing the underlying weaknesses that caused them. The main need is for better prevention. Technical problems of safety organization and accident prevention are matters for experts in the industrial field, rather than for the courts.

...It is fair to say that inspectors value the *threat* of possible prosecution as a potent sanction, and that they attach importance to the deterrent effect of the adverse local publicity which prosecutions frequently attract. Nevertheless, the weight of the evidence points to the conclusion that the lengthy process of investigation, warning, institution of criminal proceedings, conviction and ultimate fine is not a very effective way of producing an early remedy for known unsatisfactory conditions. In sum, we do not believe that the traditional sanction commands any very widespread degree of respect or confidence in this field.

The U.K in 1972, unlike Canada in 1978, had not developed a separate, less stigmatic, regulatory (or negligence) offence. The significance of this distinction is discussed later in this Report under the heading "Due Diligence." The *Robens Committee* noted, however, that most regulatory offences were the result of inadvertence or negligence.¹²⁹ The defence of due diligence still exists in

¹²⁷ *Ibid.*, para 134)

¹²⁸ *Robens Inquiry Report, supra*, para 255 et seq.

¹²⁹ *Ibid.*, para. 261 "The fact is - and we believe this to be widely recognized - that the traditional concepts of the criminal law are not readily applicable to the majority of infringements which arise under this type of legislation. Relatively few offences are clear-cut, few arise from reckless indifference to the possibility of

England, even in regulatory prosecutions brought under the General Product Safety Directive, though it is not a comfortable fit with a GSR premised on absolute liability for product defects.

The distinction between crimes and regulatory offences bears importantly on the design and implementation of any General Product Safety regime developed under the federal criminal law power. The distinction affects such matters as the burden of proof in regulatory enforcement proceedings, the choice of regulatory instruments, and the safeguards, which must attach to those instruments.

None of these developments, however, would alter the views expressed by *Robens* about the basic shortcomings of the criminal law and process when employed as the chief, or only, means of dealing with regulatory non-compliance.

The Importance of a Preventive Focus

Health Canada has a *dual* role – that of promoting and enforcing safety. *Robens* commented on this dual role after noting that a regulatory authority under Health and Safety law should seek “*to promote, as much as to control.*”

The basic function of state inspection services should be, and be clearly seen to be, the provision of advice and assistance *towards progressively better standards...* (The Health and safety administration should operate) under a framework for *stimulating and encouraging self-regulation* by industry and the exercise of individual and co-operative responsibility.¹³⁰

While criminal prosecution will remain appropriate in a minority of cases, and *the penalties available should be strengthened accordingly*, we believe that in the future much *greater reliance should be placed on non-judicial administrative techniques for ensuring compliance with minimum standards of safety and health at work*. Where advice and persuasion fails and pressure is necessary, the pressure should be exerted in a form that is positive and constructive as well as quick and effective. For the most part, as we have argued, prosecution is none of these things.¹³¹

Robens considered that inspectors had a leading role to play in promoting a ‘culture of safety’ under a safety regime premised upon individual responsibility for safety outcomes. The *Committee* expressly considered what the role of the inspectorate should be under such a regime.

What should the role be? It is not enough to think in terms of ‘ensuring compliance with minimum legal requirements. Whatever the means adopted, this concept is too narrow and restrictive. Inspectors *should seek to raise standards above the minimum levels* required by law. They should advise on

causing injury, and few can be laid without qualification at the door of a particular individual. The typical infringement or combination of infringements arises rather through carelessness, oversight, lack of knowledge or means, inadequate supervision, or sheer inefficiency.

¹³⁰ *Robens Committee Report, UK, supra.*, para. 254 et seq.

¹³¹ *Ibid.* para. 265

better organization. They should be concerned with the broad aspects of safety and health organization at the workplaces they visit, as much as with those narrow aspects, which may have been made the subject of detailed statutory regulations. We believe that, as a matter of explicit policy, the provision of skilled and impartial advice and assistance should be the leading edge of the activities of the unified inspectorate.¹³²

Under any regulatory regime with a *general* safety requirement as an operative provision, there is bound to be uncertainty - and a corresponding need for careful advice from the governing public authority. European experience under the General Product Safety Directive confirms the need for extensive advice and guidance, particularly on the part of the small business community. Small businesses seldom have the capacity for rigorous risk assessment, testing or for developing new technical standards and quality management systems. If they cannot afford third party expertise, they look to agents of the public authority for assistance in these matters. This has important training, cost and organizational implications for the inspectorate. It also has legal implications in terms of regulatory liability, and the possibility of raising grounds for defences of “official misdirection,” should negligent or erroneous advice be given.

The duality of Health Canada’s role – to promote, and enforce, safety - has implications for the design and implementation of a general product safety regime under the proposed *Health Protection Act*. For example, voluntary standards developed to meet the highest safety standards achievable under best practices may not be strictly appropriate when determining what constitutes “compliance” in *penal* proceedings.

It is not always easy to know what standards of reference a court will examine in determining whether a defendant has exercised “due diligence” in a particular penal proceeding. “State of the art” or “best practices” standards may be given modified application in penal proceedings. This matter is discussed in greater detail later in this Report under the heading of “Due Diligence”.

It is noteworthy that the definition of the term ‘safe product’ under the European Directive on General Product Safety (2001/95/EC) includes the following qualification:

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be unsafe.¹³³

The somewhat loose terminology used in connection with the general safety requirement in the consumer product area to describe levels or standards of safety may require some reconsideration if they are to be imported into a Canadian *penal* model, which requires a reasonably high degree of certainty to

¹³² *Ibid.*, para. 211

¹³³ 2001/95/EC, para. (b) (iv)

function properly. The legal issues raised by imprecise terminology are discussed in chapter 10 *Other Legal Considerations*, and more specifically under the headings *Uncertainty* and *Delegation of Legislative Authority – Back-Door Rulemaking?*

The Importance of Available Standards to Implementing a GSR

Robens emphasized that the widespread availability of effective and relevant standards would ultimately be essential to the success of the general safety regime it proposed for workplace safety. In the 1970's, the state of standards development was rudimentary compared with today. The *Robens Committee* accurately foresaw the exponential increase in standards development in the UK. This was viewed as the probable result of implementing a general obligation to ensure safety in the workplace once the obligation was placed on all of the principle actors in a position to influence workplace safety outcomes.

The constant multiplication of non-statutory codes of diverse origin and authority can be as confusing and unhelpful as the multiplication of statutory regulations.

There is no simple definition of what constitutes a non-statutory or voluntary code of practice or standard. They emerge in a variety of ways and in a variety of forms. Some are prepared and promulgated by government departments, others by independent bodies such as the British Standards Institution, still others by joint safety committees or employer organizations at industry-level. They may describe desirable procedures or systems, or specify requirements in design, materials and performance. They may be concerned specifically with safety and health or with quality generally. *The constant multiplication of non-statutory codes of diverse origin and authority can be as confusing and unhelpful as the multiplication of statutory regulations. We suggest that some measure of control and co-ordination can be injected into this area without inhibiting the continued spontaneous development of good safety and health standards.*¹³⁴

The status and potential of Canada's standard-developing capacity, therefore, is a highly important consideration bearing on the feasibility of implementing a general product safety requirement under a Canada Health Protection Act.

The Importance of "Extra-Judicial Measures" in Promoting Safety

The *Robens Committee* considered administrative and extra-judicial actions, not criminal prosecution, as playing the most important role in improving safety standards beyond legal minima. While voluntary codes and standards do not in themselves impose legal obligations, it is important to devise effective means for taking them into account in enforcement proceedings.

What we have in mind here is that the reduction we propose in the amount and detail of general statutory regulation must be coupled with new administrative procedures for enforcement....Briefly, our intention is that inspectors should have power to issue improvement notices in individual cases, taking into account not

¹³⁴ *Ibid.*, para 149:

only any relevant statutory regulation but also any relevant voluntary code or standard that has been formally approved by the Authority in one or other of the ways mentioned. Such codes and standards would be admissible in evidence in proceedings before tribunals in much the same way as the provisions of the Industrial Relations Code of Practice are admissible in proceedings under the Industrial Relations Act.¹³⁵

Voluntary codes and standards may be given an *enforcement value* by various means. They may be given evidentiary value by allowing them into evidence to establish the existence or lack of due diligence in regulatory prosecutions. They may also be given probative value in administrative enforcement decisions leading to the issuance of improvement or prohibition notices, stop work orders, banning or recall orders, or the development of compliance agreements.

Targeting Strategies, Risk Assessment & Risk Management

Robens considered risk assessment and risk management practices simply as aspects of *good management*¹³⁶ and *systematic self-regulation*.¹³⁷

The promotion of safety and health is not only a function of good management but it is, or ought to be, a normal management function – just as production or marketing is a normal function. The effective exercise of this function, as any other, depends upon the application of technique. Too many firms still appear to regard accidents as matters of chance, unpredictable and therefore not susceptible to ‘management’. Too few appear to have made serious efforts to assess the total problem, to identify the underlying causes, or to quantify the costs. Too few make use of diagnostic and predictive techniques such as safety sampling or hazard analysis, or safety audits in which each aspect of workplace organization and operation is subjected to a carefully planned and comprehensive safety survey; or systematic preventive procedures such as clearances for new equipment and processes, safe access permits and so on. (emphasis added)

Although not expressed in terms of risk assessment or risk management, the *Robens Committee* stressed the importance of adopting a *targeted* approach to safety issues and inspections based on risk assessment principles:¹³⁸

Our point is that the *resources of the inspectorate must be used selectively*. They should be concentrated on priorities and problems that have been identified

¹³⁵ *Robens Committee Report.*, para. 153

¹³⁶ *Ibid.*, para 46

¹³⁷ *Ibid.*, para. 50...”We are encouraged by the increasing interest shown by employers in the development of more systematic approaches to prevention...More needs to be done to increase industry’s capacity for this kind of *systematic self-regulation*.”

¹³⁸ *Ibid.*, para. 219 ...Inspection programs should be *oriented towards problems rather than based on periodical visits of a general character*. This would mean that some workplaces would be visited less frequently than at present. We think this is right. To the extent that a general watchdog role is necessary, occasional spot checks would be just as effective as a comprehensive program of periodical visits. Over a large part of the field *the main emphasis should be on self-inspection by employers, in co-operation with employees and representatives*. (emphasis added)

through the systematic assessment of all the available data – general technical information, local knowledge, statistics of accidents and so on. Obvious though the point may appear, we found in the major inspectorates less evidence than we had expected of *serious and sustained priority planning based on the systematic appraisal of data*. The preference for set patterns of regular inspection has tended to dominate thinking and to pre-empt resources that could be put to more efficient use. In recent years there has been some movement in the direction of a more selective approach. This movement needs to be developed and speeded up.¹³⁹ (Emphasis added)

In our visit to the United Kingdom we learned of a current example, in the consumer products area, of a routine inspection practice that was viewed as a misallocation of inspection resources. Local Authorities in the UK annually inspect about 370,000 ‘optics’ (a device which pre-measures alcohol shots in pubs and other institutions serving alcohol) although the device is designed to measure precise amounts of alcohol. While the device is not tamper-proof, it is clear that a more systematic approach to risk assessment would result in many fewer inspections of optics, thus freeing up inspection resources to focus on areas with a higher risk of non-compliance.

In March of 2005, the UK released a report under the ‘Hampton Review’ entitled: *‘Reducing administrative burdens: effective inspection and enforcement’*.¹⁴⁰ The Review proposes entrenching the principle of risk assessment throughout the regulatory system, so that the burden of enforcement falls most on highest-risk businesses and least on those with the best records of compliance. The Review estimated, based on regulators’ past experience, that comprehensive risk assessment in a streamlined structure could reduce the need for inspections by up to a third, leading to about one million fewer inspections.

Monitoring and surveillance of a broad range of consumer products in the complex consumer product safety environment presents quite different challenges from surveillance and monitoring safety issues in the workplace. To the extent that a “systems” approach to regulation evolves under a general product safety regime for consumer products, however, it is clear that different skills – including systems auditing skills – will need to be enhanced in the inspectorate. This has both cost and training implications for regulatory planners.

Auditing of management or production processes (as opposed to inspection under detailed regulations) is an activity that demands an expertise which can be in short supply when both government and industry are bidding for same available talent to meet regulatory obligations. If Government is to exercise an effective challenge function under any self-regulatory scheme, it is important that it maintain some expert capacity for independent verification.

¹³⁹ *Ibid.*, para. 218

¹⁴⁰ The Report may be viewed on the website of the UK Better Regulation Unit, accessed June 11, 2006, at <http://www.cabinetoffice.gov.uk/regulation/>

Self-Regulation Requires Effective Accountability Measures

Heightened reliance on self-regulation is a principle feature of the 1972 *Robens* approach to regulating occupational health and safety. Industry self-regulation is also the hallmark of the voluntary, standards-based, 1985 New Approach to Regulation of products in Europe, of which the General Product Safety Requirement is an integral part.

It is useful to compare the accountability mechanisms developed for the UK occupational health and safety regime, founded chiefly on *safety* objectives, with that of Europe's 'New Approach' to product regulation, based chiefly on *trade* objectives, where safety is an important but clearly ancillary consideration.¹⁴¹ European authorities remain concerned that market surveillance, enforcement practice and general accountability under the General Safety Requirement in Europe needs improvement. Several major administrative reviews and pilot projects are in place to address these concerns.¹⁴²

Christopher Hodges, in a recent text entitled *European Regulation of consumer Product Safety* describes persistent problems with market surveillance and enforcement practice not only under the vertical New Approach directives, but also under General Product Safety Directive:¹⁴³

Recent reviews of various (New Approach) Directives have consistently identified ongoing problems with market surveillance and enforcement. An approach based on mutual recognition is increasingly seen as ineffective and new initiatives are occurring sometimes based on more prescriptive integration, albeit with different approaches remaining in different sectors.

For GPSD products, the Commission has accepted that there are serious weaknesses in market surveillance¹⁴⁴ and ECOSA (European Consumer Safety Association) has said bluntly that most Member States lack even a basic enforcement structure and in those that have one responsibility is delegated to local authorities that lack proper co-ordination and funding.

Robens foresaw the need for new and to some extent, different, accountability mechanisms to ensure that a regulatory scheme with a significant self-regulatory component was effective. While much has been written about how to ensure accountability under self-regulatory regimes, *Robens* proposed the following accountability mechanisms:

¹⁴¹ Christopher Hodges, *European Regulation of Consumer Product Safety*, 2005, Oxford University Press, p. 31-32

¹⁴² European Conference on the 20th Anniversary of the New Approach, Brussels, 2005; see conference materials, accessed on October 5, 2006 at http://ec.europa.eu/enterprise/newapproach/new_approach_conference_en.htm

¹⁴³ 2005, Oxford University Press, at p. 182

¹⁴⁴ Commission Report to the European Parliament and the Council on the Experience Acquired in the Application of Directive 92/59/EEC on General Product Safety, COM (2000) 140.

- A *statutory duty* on every employer to *consult* with his employees or their representatives at the workplace on measures for promoting safety and health at work, and to provide arrangements for the *participation* of employees in the development of such measures;¹⁴⁵
- A legal obligation on all employers employing 10 or more employees to set out their safety and health policy and rules in writing and to make such statements available to all employees and, if requested, to visiting inspectors.¹⁴⁶, and to ensure interest at the corporate board level;¹⁴⁷
- A legal obligation to include in the annual directors' reports routinely lodged with the Registrar of Companies, prescribed information, including statistics about reportable accidents and industrial diseases suffered by the company's employees and about measures taken by the company in this regard;¹⁴⁸
- New administrative and "extra-judicial procedures, including improvement and prohibition notices, administrative monetary penalties, licensing provisions; and
- Strengthened criminal penalties.¹⁴⁹

Robens proposed that the form and manner of employee consultation and participation need not be specified in detail, so as to provide the flexibility needed to suit a wide variety of particular circumstances and to avoid prejudicing satisfactory existing arrangements:

Guidance should, however, be given in a code of practice outlining model arrangements, including advice on joint safety committees and the appointment of employees safety representatives. We envisage that these appointments would be through election by employees, arranged through the trade unions recognized at the workplace or through works groups as appropriate. The code

¹⁴⁵ *Robens Committee Report, supra.* paras. 68-71...The form and manner of such consultation and participation would not be specified in detail, so as to provide the flexibility needed to suit a wide variety of particular circumstances and to avoid prejudicing satisfactory existing arrangements. Guidance should, however, be given in a code of practice outlining model arrangements, including advice on joint safety committees and the appointment of employees safety representatives. We envisage that these appointments would be through election by employees, arranged through the trade unions recognized at the workplace or through works groups as appropriate. The code should deal with such matters as the qualifications, training, duties and rights of employees' safety representatives, arrangements for joint inspections, the objectives, composition and procedures of joint safety committees, and so on. ...Above all, the code should stress that simply talking together about safety and health is not enough. It is essential to ensure the active follow-through of the measures discussed. (para. 70)

¹⁴⁶ *Ibid.* para 74.

¹⁴⁷ *Ibid.* "In addition to setting out main policy objectives, the statements should include information on the firm's safety and health organization, on the duties of its safety officers, on arrangements for joint consultation about safety and health measures, and on matters such as safety training, protective clothing and so on."

¹⁴⁸ *Ibid.* para. 76...."It might be argued against this that a recital of bare statistics can be misleading. This true, but we cannot imagine that a company would quote such statistics without comment or explanation. It is precisely the preparation of such comments and explanations that would ensue attention to the subject at the highest level within the firm."

¹⁴⁹ *Ibid.* para 265

should deal with such matters as the qualifications, training, duties and rights of employees' safety representatives, arrangements for joint inspections, the objectives, composition and procedures of joint safety committees, and so on. ...*Above all, the code should stress that simply talking together about safety and health is not enough. It is essential to ensure the active follow-through of the measures discussed.*¹⁵⁰

Though the parallels are inexact, Europe has developed a framework for requiring Member States to institute a number of parallel accountability measures under the General Product Safety Directive and the New Approach to Regulation. These measures include uniform conformity assessment modules for use by Producers, the establishment of Notifying and Accreditation bodies, mandatory reporting of serious risks, shared risk reporting amongst Member States and the Commission, a duty to inform consumers of product risks, consumer participation on standardization and advisory committees; the duty of producers to adopt remedial measures to deal with identified risks and a broad spectrum of powers for governing authorities including banning, export controls, product recall and criminal prosecutions.

6. Operative Provisions of the European General Product Safety Directive (GPSD)

Introduction

In making a decision on whether or not to include a General Safety Requirement (GSR) in renewed Health Protection legislation, many questions arise that need to be resolved in terms of how such a provision would operate and its potential impact. Europe is one of the few jurisdictions that has considerable operational experience under its General Product Safety Directive (GPSD) in implementing and administering a GSR. The operative provisions that the European Commission (EC) put in place, the experience gained and the resulting revisions that were made to the directive are presented here. The main purpose of this section is to assist Health Canada in resolving the issues that have been raised with respect to including a GSR in Canadian legislation.

Regulation of the Safety of Consumer Products in Europe

Regulation of the safety of consumer products in Europe follows either directives that are sector specific and establish either technical details (old approach) or essential requirements (New Approach) within the text or a Directive such as the GPSD which is not sector specific. Sector specific directives cover such goods as food products, pharmaceuticals, children's toys, personal protective equipment, cosmetics and electrical equipment.

¹⁵⁰ *Ibid.*, para. 70

The old approach directives made assessment against the legislation relatively easy; however, the directives needed to be updated frequently as products were improved or as new products entered the market. The process of updating these specifications and legislation proved to be complicated and time consuming and often differed in member countries resulting in barriers to trade.¹⁵¹ In response to the problems identified and the need to establish a market based on the free movement of goods, the "New Approach" was defined in a Council Resolution of May 1985.¹⁵² This approach was intended to emphasize a less prescriptive and more flexible regulation aimed at ensuring the safety of each product in its entirety. The "New Approach" directives set out the essential safety requirements which a product must fulfill in order to be considered safe in general terms and to be marketed in Europe. The European national standards bodies are entrusted with the developing the detailed technical specifications. As a result, there is a clear separation of responsibilities between the legislator and the European standards bodies.

Unlike the sector specific directives, the GPSD establishes rules regarding product safety that are applied throughout the European Union (EU) and are aimed at ensuring that all consumer products placed on the market are safe. The European Product Liability Directive of 1985 described in this report paved the way for the GPSD by harmonizing the laws concerning liability of defective products and establishing the elements of absolute liability on which the GPSD is based.

The European General Safety Requirement (GSR)

The first general safety requirement (GSR) was introduced as part of the United Kingdom's *Consumer Protection Act* in 1987¹⁵³ and was followed by the adoption of a GSR in Europe's General Product Safety Directive (GPSD) in 1992.¹⁵⁴ The GPSD was revised and the current European version became effective in 2004.¹⁵⁵

Under the GPSD, member states are required to enact the laws and/or regulations necessary to implement its requirements. Therefore, businesses do not have to comply directly with the GPSD but rather must comply with the laws and regulations of member states, which should include requirements to

¹⁵¹ Nordic Council of Ministers, Guide on Market surveillance and safety of consumer products, Best Practices in Nordic countries, Temanord, 2006:511, www.norcon.org

¹⁵² Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards, *Official Journal C 136*, 04/06/1985 P. 0001 - 0009

¹⁵³ UK Department of Trade and Industry, *Product liability, defective products, unsafe products fact sheet*, URN No: 05/1728

¹⁵⁴ Commission of the European Communities, *Directive on General Product Safety* (92/59/EEC), OL L 228, 11/08/1992 P. 0024-0032

¹⁵⁵ Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), OL L 011, 15/01/2002 P004-0017

implement the GSR. It would appear that all pre-expansion EU countries have transposed the GPSD into national legislation but in different ways to accommodate local considerations and differences in legal and constitutional frameworks. This section will focus on the provisions of the GPSD in general across the EU rather than on the particular laws of any one member state.

The Purpose and Scope

The purpose of the GSR specified in the GPSD is to ensure that consumer products placed on the European Market do not present a risk under normal, or reasonably foreseeable, conditions of use and to harmonize the measures taken by Member States to impose this obligation on producers. Thus, it aims to ensure both a consistent and high level of protection of consumer health and safety through the EU and support the proper functioning of the internal market.^{156, 157} According to the preamble of the Directive, a broadly based, legislative framework of a horizontal nature was also needed to complement sectoral legislation by covering products not covered by the legislation as well as covering gaps in existing sectoral legislation.

The Directive applies to products that are intended or are likely to be used by consumers. This includes new, used and reconditioned products, with the exception of antiques and products sold with a view to being reconditioned, provided that the supplier informs the consumer of this fact. Products intended for professional use that are likely to migrate to the consumer market are also covered. The Directive requires producers to place only “safe” products on the market. When the producer is not based in the EU, the obligation applies to his representative in the EU or the importer

The Evolution of the GPSD

The GPSD was first adopted in 1992 (Directive 92/59/EEC) and included the following main features:¹⁵⁸

- Obligations for producers
 - To place only safe products on the market;
 - To provide consumers with the relevant information to assess the risks associated with a product; and
 - To adopt measures to ensure that they will be informed of risks posed by the products, which they supply, and to take action to prevent those risks, including withdrawal of products when necessary.

¹⁵⁶ Commission of the European Communities, *Proposal for a Directive of the European Parliament and of the Council on general product safety*, COM (2000) 139 final/2, Brussels, 15.6.2000

¹⁵⁷ Commission of the European Communities, *Commission Report to the European Parliament and the Council on the Experience Acquired in the Application of Directive 92/59/EEC on general product safety*, COM (2000) 140 final, Brussels, 29.3.2000

¹⁵⁸ Commission of the European Communities, *Proposal for a Directive of the European Parliament and of the Council on general product safety*, COM (2000) 139 final/2, Brussels, 15.6.2000, p 5.

- Obligations for distributors
 - Not to supply products which they know or should have presumed to be dangerous;
 - To collaborate in the monitoring of the safety of products they supply; and
 - To prevent any risks posed by such products.

- Definition of criteria for assessing product safety and deciding under which conditions a product is deemed to be safe
 - Products conforming to specific rules of national law of the Member State in which they circulate are deemed to be in compliance with the GSR of the GPSD; and
 - In other cases, the safety of a product shall be assessed having regard to European or national voluntary standards, Community technical specifications, codes of good practice, the state of the art and expectations of consumers.

- Obligations of the Member States:
 - To take measures in order to make producers and distributors comply with their obligations. This includes in particular establishing or designating market surveillance authorities empowered to adopt a range of control and enforcement measures and to impose sanctions in the event of failure to comply with the obligations of the Directive;
 - To notify the Commission of the measures they take restricting the marketing of products or imposing their withdrawal from the market; and
 - To ensure that their officials and agents do not disclose information covered by professional secrecy, obtained for the purposes of the Directive, except for information relating to the safety of a product, which must be made public in order to protect the health and safety of persons.

In addition, the European Union also expanded the informal system (RAPEX) established by enforcement officers to exchange rapidly information on products posing serious or immediate risks as required by the Directive. Under this system, when a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the marketing or use of products posing a serious and immediate risk, it must notify the Commission, which, in turn, will inform the other Member States. Details of the functioning of the system are set out in an annex to the Directive.

The Commission funded an in-depth review and assessment of the implementation and application of the GPSD before the GPSD was revised in 2002. The review undertook a critical analysis of the transposition and

implementation of the original GPSD. The review¹⁵⁹ identified a number of weaknesses in the GPSD and additional measures that were needed to meet its stated objectives. These weaknesses and needs, outlined below, were the reason that the GPSD was revised:¹⁶⁰

- Uncertainty, disagreement or lack of awareness existed about the application of certain provisions of the GPSD. Some Member States believed that the provisions did not apply to products covered by sectoral legislation, in spite of the fact that the legislation did not address the risks in question. The provisions under question included the products covered by sectoral legislation where gaps in the risks covered existed, the obligations for producers and distributors, market surveillance, notification under a rapid alert system and Community emergency measures. As a consequence, these important aspects of product safety are not treated in a consistent way throughout the Community¹⁶¹ and the scopes of the transition acts were found to be ambiguous and confusing.
- There were also uncertainties with respect to whether or not certain products were covered by the Directive. For example, some products sold for professional use and not intended for consumers were migrating into the consumer market. These products were not subject to the protective and control requirements of the GPSD.
- Producers and distributors may discover or be informed of risks related to a product. However, the authorities were rarely informed when producers and distributors discovered risks related to a product. The authorities, therefore, did not have the possibility of making checks on the product or similar products and exchange the relevant information with the other Member States and the Commission.
- In addition to withdrawing a dangerous product from the market, the study also identified a need for producers and distributors to comply with the obligation to inform consumers of the risk presented by a product already on the market or sold. The absence of penalties for noncompliance with this obligation, ignorance of its existence and the lack of guidelines as to what had to be notified and how it should be made were thought by the researchers to explain the non-compliance.
- National administrations were also unclear about when to notify and considered that the Commission was slow to react. Many only learned of a

¹⁵⁹ Centre du droit de la Consommation, Université Catholique de Louvain, *The Practical Application of Council Directive 92/59/EEC on General Product Safety*, 2000

¹⁶⁰ Also refer to Annex 12, Lessons from Selected Experiences in the US and Europe.

¹⁶¹ Commission of the European Communities, *Proposal for a Directive of the European Parliament and of the Council on general product safety*, COM (2000) 139 final/2, Brussels, 15.6.2000

measure taken by one Member State many months or even years after the measure had been taken. Moreover, the Commission was not obliged to notify all the Member States if it disagreed with a measure taken. This discouraged Member States from notifying the Commission when an action was taken.

- The review also found that the absence of a definition of “serious and immediate risks” and the exclusion of long-term risks represented a shortcoming of the Directive and it posed problems in the implementation of emergency action at Community level.
- The potential of the GPSD for ensuring a consistent, high level of protection throughout the EU and the proper functioning of the internal market was limited by the way in which conformity assessment criteria were defined and the lack of a clearly defined legal status for them.
- European standards did not confer a “presumption of conformity” under the Directive, unlike the harmonized standards under the “ New Approach” directives. Different documents that could be used to assess the safety of a product as mentioned in the Directive resulted in different interpretations. Moreover, the researches indicated that the lack of a role of European standards in establishing the conformity of products to the GPSD weakened its credibility in ensuring harmonization.
- In order to ensure that a standard provides the required level of protection, it was suggested that a “safeguard clause” procedure should be included in GPSD. This would allow Members States or the Commission to intervene if a standard did not address a risk associated with a product.
- Differences in the effectiveness of control and enforcement systems put in place by Member States resulted in uneven enforcement of the GPSD. Moreover, sanctions were often not dissuasive enough or not applied and therefore did not always represent an effective means of ensuring compliance.
- Finally, market surveillance was fragmented, with little collaboration between the relevant authorities of the Member States.

The review resulted in the Commission revising the GPSD.¹⁶² The revised version maintains the requirements included in the original GPSD, but introduced a number of new or reinforced provisions. The new or revised provisions:

- Clarify the relationship between the GPSD and other sectoral legislation;

¹⁶² Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), OL L 011, 15/01/2002 P004-0017

- Extend the scope of the Directive in order to ensure that all products supplied or made available to consumers through normal commercial retail networks and by service providers are covered by the GPSD;
- Provide criteria for assessing the conformity of a product with the GSR and allow products in compliance with European Standards established under certain provisions to benefit from a “presumption of conformity;”
- Allow for the withdrawal of standards subsequently found to provide an insufficient level of safety or “safe-guard” clause;
- Reinforce the obligations of producers to provide information to the authorities, and consumers on product risks and to recall dangerous products when necessary;
- Make a more effective use of standards in order to apply consistently the concept of safe product;
- Establish the obligations of member states to monitor compliance of suppliers with the requirements of the Directive;
- Promote a more systematic and structured approach to market surveillance and enforcement activities;
- Establish a framework for collaboration between the authorities of the various Member States on risk assessment, testing of products, market surveillance;
- Improve the Rapid Alert System for circulating and following-up information on measures and action related to products posing serious risks;
- Enable exchange of Rapid Alert-notifications with third countries, and in particular with candidate countries;
- Streamline the concepts, conditions and procedures applicable to Community-wide rapid intervention measures; and
- Ensure that products withdrawn following Community rapid intervention measures are not exported to third countries.

Definition of Safe Product and Foreseeable Use

The Directive sets out the generic definition of safe product to which products must comply. It states that:

Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the health and safety of persons, taking into account the following points in particular:

- The characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;
- The effect on other products if used with other products;
- The presentation of the product, the labeling, any instructions for its use and disposal; and

- The categories of consumers at serious risk when using the product, in particular children.¹⁶³

Products in conformity with the specific rules applicable in the Member State in which they are in circulation are deemed to meet the definition of safe product. If there are no specific national rules, the safety of a product is assessed in accordance with European standards or national standards, Community technical specifications, codes of good practice, the state of the art and the reasonable expectations of consumers. Before placing a product on the market, producers are expected to perform a risk assessment which forms the basis for determining that a product satisfies the GSR of the GPSD.

Foreseeable use is not defined in the Directive or in guidance documents produced by the EU. However the United Kingdom, in a guidance document provided the meaning of foreseeable use, stated that:

Reasonably foreseeable use should, it is considered, where appropriate, take account of the intended and potential types of user (i.e. the elderly, the unpredictable behaviour of children) and how a reasonable person might use a product in the absence of any indications to the contrary.¹⁶⁴

It is worth noting that the GPSD does not provide a specific definition and/or guidance on acceptable levels of safety, which invariably leads to Member State discretion in interpretation, and enforcement of safety requirements as well as adopting different approaches to assessing product safety.

Definition of Suppliers

Suppliers are divided into two groups under the Directive – producers and distributors. A producer is defined broadly to include the manufacturer, anyone representing himself or herself as the manufacturer, anyone representing the manufacturer, an importer (where no manufacturer or representative is in the EU), a person who reconditions a product, and anyone else whose activities “affect the safety properties of a product placed on the market. The term distributor means any professional in the supply chain whose activity does not meet the safety properties of a producer.¹⁶⁵ In the guidance provided by the UK government, the meaning of a distributors is clarified further to include wholesalers, retailers (shops), agents and auctioneers. In addition, a person

¹⁶³ Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), Article 2(b), OL L 011, 15/01/2002 P004-0017

¹⁶⁴ UK Department of Trade and Industry, *General Product Safety Regulations 2005, Guidance for businesses, consumers and enforcement authorities*, July 2005.

¹⁶⁵ Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), Articles 2 (e) and 2 (f), OL L 011, 15/01/2002 P004-0017

who makes a product available for the use of a consumer in the course of delivering a service will for the most part also be considered a distributor.

The Principle of Proportionality

One of the most important principles in the implementation of the GPSD is that any measures taken by Member States should be proportional to the seriousness of the risk. Moreover, within the European Union, the precautionary principle is considered to be a general principle of international law. Part III of the Treaty establishing a Constitution for Europe sets out the precautionary principle as a fundamental principle of decision making regarding policies and the functioning of the Union. The Directive 2001/95/EC on general product safety expressly states in Article 8 that Member States shall implement measures in a manner proportional to the seriousness of the risk and taking into account the precautionary principle.

Administration and Operation of the GPSD

Powers and Authorities

The GPSD requires that member states establish or designate authorities to monitor product safety and have the powers to take “appropriate measures, including the power to impose effective, proportionate and dissuasive penalties”. Moreover, member states have an obligation to legislate rules on penalties applicable to non-compliance within national regulations or legislation adopted as a result of the GPSD. In article 8, the Directive specifies the measures that member states are entitled to take which include:

- Requesting relevant information from all parties concerned;
- Taking samples of products and evaluating them for safety;
- Requiring that products are marked with suitable warnings;
- Making the marketing the product subject to prior safety conditions;
- Requiring that persons at risk be warned;
- Temporarily banning a product while safety evaluations are being carried out;
- Banning the marketing of a product; and
- Ordering or organizing a withdrawal or recall of the product, alerting of consumers to the risk it presents and ordering the destruction of the product.

The Directive specifies that authorities in member states should implement any measures taken in a manner that is proportional to the risk posed and one that takes into account the precautionary principle. Member states are also directed to encourage and promote voluntary action by producers and distributors in carrying out their obligations.

The United Kingdom, for example, transposed the provisions of the directive into its General Product Safety Regulations 2005. These regulations specify which organizations in the UK enforce the regulations and what powers they are given in terms of investigating problem, entering premises, making test purchasing and undertaking tests and seizing records and products from producers and distributors. In addition, the regulations set out the measures available to the authorities, the offences¹⁶⁶ that are punishable and the penalties in terms of imprisonment or fines for these offences. Under the UK regulations the penalties imposed include a maximum penalty of £20,000 or 12 months imprisonment for serious breaches of the GSR (see following table) or a safety notice, and a maximum fine of £ 5,000 or 3 months imprisonment for other offences.

In addition to the measures that may be taken by Member States, the Commission, assisted by a Committee, may adopt temporary, Community-wide measures concerning products posing a serious and immediate risk. The measures are subject to a number of substantive and procedural conditions. The Commission must consult the member states and a Scientific Committee¹⁶⁷ if scientific questions arise.

Offences under the UK General Product Safety Regulations 2005

- A producer who places a product on the market without knowing it is safe
- A distributor who supplies a product he knows or should have known is dangerous
- A person who contravenes a safety notice which includes a requirement to mark, warn, suspend, withdraw or recall a product
- A producer who fails to provide consumers (within the limits of his activities) with relevant information enabling them to assess the risks inherent in a product
- A producer who fails to adopt measures to avoid risks a product might pose
- A distributor who fails to monitor the safety of a product on the market
- A producer or distributor who fails to notify an enforcement authority of a product that he knows poses a risk to the consumer
- A person who fails to comply with a notice to supply additional information
- A person who obstructs an enforcement officer

Under the GPSD, the Member States are obliged to establish authorities that are responsible for carrying out market surveillance and enforcing the applicable national legislation. The Directive also specifies that these authorities must have the necessary resources and powers for their surveillance activities.

¹⁶⁶ Department of Trade and Industry, *The General Product Safety Regulations 2005, Guidance for businesses, consumers and enforcement authorities*, July 2005.

¹⁶⁷ Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), Article 13 O L L 011, 15/01/2002 P004-0017

Post-market inspection or inspection after the product is placed on the market, rather than pre-market assessment and approval, is the general way that enforcement is carried out. Enforcement authorities in Member States monitor the consumer products placed on the market to ensure that they comply with provisions of the applicable national legislation. The focus is on identifying potentially dangerous products and assessing compliance of the products with information provided by manufacturers, having the products inspected and tested and investigating consumer complaints. The main goal is to quickly identify consumer products that seriously infringe the provisions of the applicable legislation and take action to have them removed from the market. Minor deficiencies such as incorrect labeling and lack of documentation are handled differently, for instance, by having the manufacturers remedy the shortcomings.¹⁶⁸

Each Member State can decide upon its market surveillance infrastructure: the only requirement is that it is efficient and covers the whole territory. As a result, the legal and administrative market surveillance infrastructures differ from one Member State to another. This requires, in particular, that efficient administrative cooperation between competent national authorities is in place so that an equivalent level of protection can be ensured throughout the Community, in spite of the competence for market surveillance being limited to each Member State's territory¹⁶⁹ operations.

As with most post-market surveillance systems, enforcement authorities do not inspect every product. There are thousands of consumer products on the market and it is not possible to inspect all of them. Normally, enforcement authorities visit commercial premises on a regular basis and take and test random samples of certain product groups based on the risk they pose. Apart from random inspections, enforcement authorities also perform inspections based mainly on the following factors:

- Consumer reports, complaints or accidents in relation to consumer products;
- Reports from manufacturers and importers on dangerous products;
- Surveys (in cooperation with laboratories), where applicable; and
- European notifications - RAPEX

If an unsafe consumer product is found on the market in one of the member states, the national enforcement authority must consult the manufacturer (or distributor) of that product. Appropriate actions or restrictions must be taken and notification sent to the EU Commission. All the others are then notified of the action taken so they can check if the same product is circulating in their markets and take appropriate measures, as required.

¹⁶⁸ Nordic Council of Ministers, Guide on Market surveillance and safety of consumer products, Best Practices in Nordic countries, Temanord, 2006:511, www.norcon.org

¹⁶⁹ European Commission, *Guide to the Implementation of Directives Based on the New Approach and the Global Approach*, 2000.

According to a European Third Country Regulation relating to the safety of imported products,¹⁷⁰ customs authorities can detain goods from third countries at the external borders for up to three working days to permit checks by enforcement authorities. This is the case when products bear the characteristics suggesting a serious and immediate risk to health and safety of consumers and/or they are not accompanied by required documents assuring their safety. Given these circumstances, customs authorities play an important role in market surveillance activities.

Enforcement authorities have to make available to the public any information about specific consumer products that pose risks to the health and safety of consumers and the measures that the authorities have taken to remove those risks. In Figure 1, (following page) the overall approach to ensuring product safety in the EU is presented.¹⁷¹

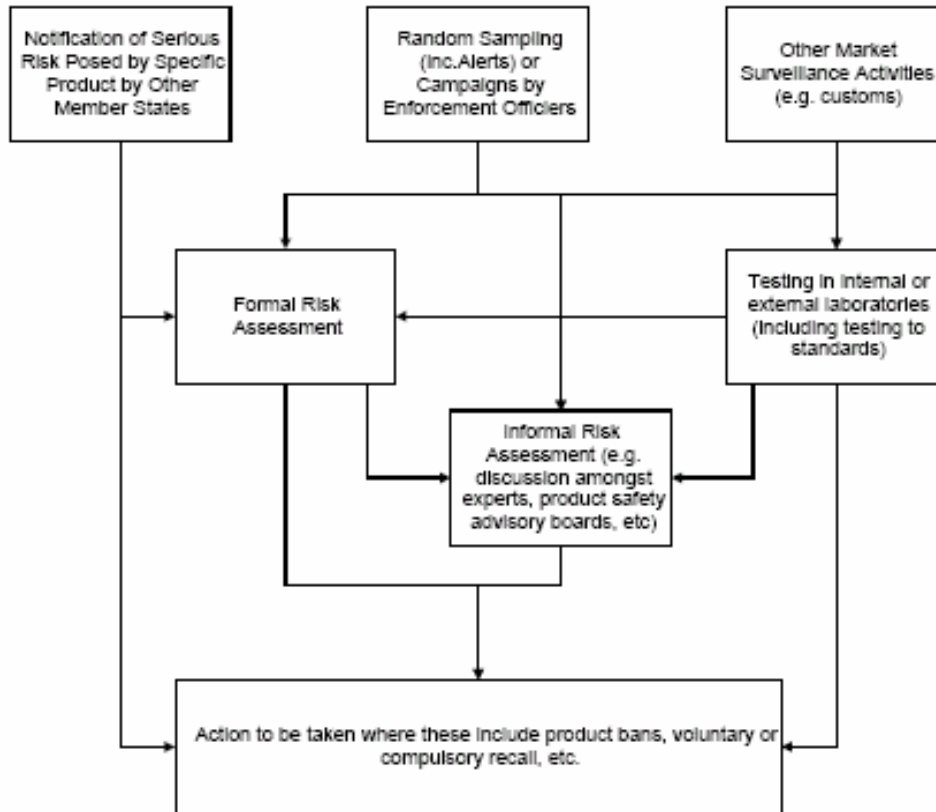
Achieving Consistent Enforcement

A major problem that exists in any jurisdiction where enforcement of legislation is the responsibility of more than one enforcement authority is the necessity to ensure consistency in the interpretation and implementation of the legislation. The potential consequences of inconsistency in application of risk assessment methodologies and enforcement measures taken are considerable. If the risk posed by a product is assessed to be higher than is actually the case, there may be significant economic consequences, in terms of lost sales for producers and distributors and lost access to products for consumers. On the other hand, if the risks are assessed to be lower than they actually are, there could be impacts on consumer safety in the form of continuing injuries or even fatalities. The European Community in trying to achieve consistency in risk assessment and enforcement of the GPSD has taken a number of steps to improve the cooperation and uniformity among the enforcement authorities in member states such as a the exchange of information via a rapid alert system (RAPEX), support of PROSAFE (the Product Safety Enforcement Forum of Europe), and research and development of guidance documents for enforcement officials and suppliers.

¹⁷⁰ EC regulation No. 339/93/EEC (Third Country Regulation)

¹⁷¹ DG SANCO, European Commission, *Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices*, Risk & Policy Analysts Limited, February 2006.

Figure 1: Description of Overall Approach to Ensuring Product Safety in the EU



Exchange of Information Via a Rapid Alert System

The GPSD¹⁷² establishes a system for the rapid exchange of information (RAPEX) between Member States and the Commission on measures and actions related to consumer products that pose a serious risk for the health and safety of consumers. Moreover, the notification procedure in Article 11 of the GPSD is also intended to exchange information on measures and actions in relation to consumer products that do not present a serious risk to the health and safety of consumers. These procedures are part of the provisions of the GPSD aimed at ensuring an effective and consistent enforcement of the applicable safety requirements. In Article 8 of the GPSD, the different types of measures and actions that should be notified under RAPEX are listed. These measures and actions are aimed at:

- Imposing conditions prior to the marketing of a product;
- Requiring that a product be marked with warnings concerning any risks;
- Alerting consumers about a risk related to a product;
- Banning temporarily or definitively the supply, the offer to supply or the display of a product;

¹⁷² Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), Article 13 OL L 011, 15/01/2002 P004-0017

- Organizing the withdrawal or the recall of a product; and
- Ordering producers and distributors to withdraw a product, recall it from consumers, and destroy it.

Other measures and actions that authorities can adopt or take and should notify are:

- Agreements with producers and distributors to take actions necessary to avoid the risks posed by products;
- Agreements with producers and distributors to organize jointly the withdrawal, the recall of products from consumers and their destruction or any other relevant action; and
- Agreements with producers and distributors to coordinate the recall of a product from consumers and its destruction.

Cooperation Among Enforcement Officials

Prosafe (the Product Safety Enforcement Forum of Europe) is an organization that was established entirely by enforcement officers. These officers recognized that it was important to build links in operational understanding and trust between them in enforcing community law. PROSAFE is now supported by the European Commission Health & Consumer Protection Directorate General (DG), Internal Market DG, and the Enterprise and Industry DG

Consistent Risk Assessment

Central to the European consumer product safety system is the identification and assessment of risks associated with consumer products. Guidance on how to draft a risk assessment to meet the provisions of the GPSD is provided by RAPEX Guidelines.¹⁷³ However, even though the basic concepts and methodology are sound, the guidelines on risk assessment have been difficult to apply in practice. As a result, there are key differences and divergences in the approaches and the risk assessment methods used to determine what measures should be applied to deal with unsafe products by enforcement authorities and conformity assessment bodies. Different types of products, and risks lead to different assessments, and consequently an uneven level of consumer protection across the EU. To achieve greater consistency between assessors and improve the guidelines, the EU established the Working Group (WG): Improvement of Risk Assessment Guidelines. This WG is following a practical approach, starting from the already published RAPEX Guidelines and it is anticipated that a revised draft document will be out for information and consultation by the end of 2006.

In addition to the WG the EC commissioned a study to compare and analyze current approaches, methods and practices used by enforcement authorities and

¹⁷³ EC DG Health and Consumer Protection, *Guidelines for the Notification of Dangerous Consumer Products to the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC*. http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidelines_en.htm

conformity assessment bodies.¹⁷⁴ The researchers were also required to identify best practices, further development needs and standardization of risk assessment methods. The study confirmed that consistency in the level of risk that will trigger a notification to the Commission or an enforcement action varies from member state to member state. For example, the significant costs associated with risk assessment and product testing can result in some states not undertaking such analysis. Instead, some relied on enforcing notifications made by other Member States. The study found that some Member States have the resources to focus on only a limited number of products at any particular time. Similarly, other authorities had considerable expertise in risk assessment and had the ability to develop and apply reasonably sophisticated approaches. The variation was even greater where there are no relevant regulations or standards, as there was no common basis against which producers and distributors could assess the safety of a product. In such cases, judgments on safety tended to be either subjective or based on risk assessment criteria developed for other related sectors or products.

The study¹⁷⁵ concluded that that risk assessment best practice would include:

- Providing guidance to ensure that risk assessors actually understand the basis (i.e. the strengths and weaknesses as well as bias), process (i.e. applying the various scales and ratings) and results of any risk assessment methodology applied;
- Creating a clear link between the output of the risk assessment methodologies and the enforcement action to be taken to ensure product safety; and
- Using more than one risk assessment methodology, where possible and ensuring that all risk assessment results are discussed and agreed by an expert panel.

Guidance Documents

The GPSD provides for the “establishment of non-binding guidelines aimed at indicating simple and clear criteria and practical rules, which may change in order to be completed, improved or adapted in the light of the experience and new developments, to facilitate the effective operation of RAPEX by the Commission and the competent authorities of the Member States”. Due to these provisions and the request of Member States and suppliers, a number of guidance documents have been prepared to clarify the relationship between the GPSD and

¹⁷⁴ DG SANCO, European Commission, Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices, Risk & Policy Analysts Limited, February 2006.

¹⁷⁵ DG SANCO, European Commission, Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices, Risk & Policy Analysts Limited, February 2006.

other directives^{176, 177} to facilitate the effective enforcement of the Directive, the consistent application of the notification provisions of the GPSD and the operation of the RAPEX system.¹⁷⁸ In addition, new guidelines were developed to provide businesses with the practical details of how they should notify dangerous consumer products to the competent authorities¹⁷⁹. Prosafe and other organizations were also supported by the EC to develop a guide to corrective actions including recalls.¹⁸⁰

The General Product Safety Directive Committee

The GPSD provides for the establishment of a Committee to assist the Commission with certain tasks related to the implementation of the Directive.¹⁸¹ The committee is made up of representatives from national authorities responsible for product safety at the national level. The Committee develops positions on draft Commission Decisions related to products presenting serious and immediate risks and on amendments to the Annex to the Directive, which sets out the operating procedures for RAPEX. The Commission also consults the committee on referencing of European standards, in the Official Journal, and on other matters relevant to the application of the Directive. For example, when the Commission makes Decisions requiring the Member States to urgently introduce temporary measures restricting the placing on the market or requiring the rapid withdrawal of products posing serious risks, it is assisted by the GPSD Committee. The decisions are valid for up to one year and may be prolonged with the assistance of the Committee.¹⁸²

European Standards and Conformity Assessment

Role of Standards

During revision of the GPSD, provisions were added to ensure that standards play a significant role in implementation of the Directive. As with the “New Approach” Directives, the GPSD now states that compliance with harmonized

¹⁷⁶ EC DG Health and Consumer Protection, *Guidance Document on the Relationship Between the General Product Safety Directorate (GPSD) and Certain Sector Directives with Provisions on Product Safety*, November 2003. http://ec.europa.eu/consumers/cons_safe/keydocs/index_en.htm

¹⁷⁷ EC DG Health and Consumer Protection, *Guidance Document on the Relationship Between the General Product Safety Directorate (GPSD) and Certain Sector Directives with Provisions on Product Safety, Second Chapter, (Directives on Medical Devices, Construction Products, Machinery, Medical Products and Motor Vehicles,)* November 2005.

¹⁷⁸ EC DG Health and Consumer Protection, *Guidelines for the Management of the Community Rapid Information System (RAPEX) and Notifications Presented in Accordance with Article 11 of Directive 2001/95/EC*.

¹⁷⁹ EC DG Health and Consumer Protection, *Guidelines for the Notification of Dangerous Consumer Products to the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC*.

¹⁸⁰ Prosafe et al, *Product Safety in Europe A Guide to Corrective Actions Including Recalls*, June 2004.

¹⁸¹ Commission of the European Communities, *Directive on General Product Safety (2001/95/EC)*, Article 15 O L L 011, 15/01/2002.

¹⁸² http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/emergencies_en.htm

European Standards¹⁸³ referenced in the *Official Journal of the European Communities* provides the product with a presumption of conformity to the Directive. This means, basically, that the manufacturer is in conformity with the law and the product is presumed to be safe, as long as the risk in question is covered by the standard. Since European standards have to be transposed in a uniform way into national standards, the corresponding national standards provide the same presumption of conformity. Moreover, the standards provide enforcement authorities with a common base for evaluating the safety of consumer products.

The European Commission can request the European standards bodies to prepare standards in order to implement the Directive.¹⁸⁴ A contractual relationship is created, with the Commission providing financial support when needed. This standardization is 'mandated' by the Commission, through the Standing Committee of GPSD. The contract (or mandate) stipulates that a standard will be produced that will provide a technical solution, or a technical interpretation, of essential health and safety aspects. Once completed and the conditions of the Commission are met, it is referenced in the *Official Journal of the European Communities*. In practice, this means that standardization has taken on much of the authorities' previous provisional work.

Compliance with harmonized standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements. However, the producer has an obligation to prove his products are safe and in conformity with the essential requirements of the Directive if he uses other means (for example by means of any existing technical specifications). The main advantage of conformity to European harmonized standards is the recognition of the standard all over Europe. It means that the supplier can sell his products throughout Europe without expensive retesting in every country.

Standards do not, however, remove the need for risk assessment. Compliance with a standard does not remove the general obligation under the GPSD to ensure that products are safe. It is possible for a product to comply with the relevant standard(s) and still be unsafe. For example, the standard might not address a risk posed by a new or modified version of a product or the fault may relate to inadequate quality control procedures or lack of warnings. Standards, by definition, relate to past problems and due to the five year target for review can be slow to adapt to modified or new products and the risks associated with them. Concerns have also been raised about the lack of standards for some

¹⁸³ "Harmonized standards" are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties.

¹⁸⁴ Commission of the European Communities, *Directive on General Product Safety* (2001/95/EC), Article 4 O L L 011, 15/01/2002

products and the fact that industry representatives often dominate the standard development process.

In some cases, the European standards bodies have failed to elaborate adequate harmonized standards. As a consequence, consumer products made according to these standards are not in conformity with the requirement of marketing a safe product despite the fact that harmonized standards are used. Under such a circumstance, the authority in a member state can take appropriate measures to withdraw the product from the market even though it complies with a harmonized standard. Moreover, where a member state has evidence that the harmonized standard does not address the risks posed by a product, the issue can be brought before the Standing Committee of GPSD and depending on its opinion, the publication of the reference in the Official Journal can be withdrawn by the Commission. In such cases, the harmonized standard will cease to provide a presumption of conformity.¹⁸⁵ This authority is commonly referred to as the “safe guard” clause, which is a counterweight to the presumption of conformity.

Conformity Assessment

The essential objective of conformity assessment is to provide enforcement authorities with confidence that products placed on the market conform to the requirements in the applicable directives such as the GPSD. Conformity assessment is based on the manufacturers’ internal design and production control activities. A producer may declare after performing the necessary product evaluations (Declaration of Conformity) that the product meets the essential requirements of the Directive. Or he can use a third-party conformity assessment body, which is “notified” on the basis of harmonized criteria. Notified Bodies are independent testing houses, laboratories, or product certifiers authorized by the EU Member States to perform conformity assessment tasks. A Notified Body must have the necessary qualifications to meet the testing and/or certification requirements set forth in a directive and must be able to demonstrate independence, impartiality, and integrity.

In the EU, conformity assessment is subdivided into modules, which relate to the design phase of products and to the production phase. As a general rule, a product should be subject to assessment for both phases before being able to be placed on the market if the results are positive. There are a number of modules that cover the two phases in a variety of ways depending on such factors as the product, the risk involved and the type and importance of production.

The EU established a uniform marking system known as the CE-Marking in association with the conformity assessment system. Affixing the CE marking to a product is a declaration by the manufacturer (or the distributor) that the product in question has been designed and manufactured to meet the essential safety requirements of a directive and creates a presumption that the product is entitled

¹⁸⁵ European Commission, Enterprise and Industry, *Harmonized standards*.
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/index_en.html

to free circulation within the EU/EEA market. As the General Product Safety Directive imposes a general safety requirement for a wide range of consumer products and does not specify any essential safety requirements like the sectoral directives, there are no provisions for CE marking on products falling under the scope of the GPSD.

Conclusions

As the second version of the GPSD is still in the initial stage of implementation, it is not yet possible to assess the extent to which it will be successful at resolving the issues that initiated the revisions to the first version. Much of the success of Directive 2001/95/EC will depend upon the adequacy and consistency of enforcement measures. As the national legislation varies and enforcement is left to individual Member States, it is likely that the conclusions from risk assessments, enforcement measures taken and the penalties applied will not be consistent across the EU. That is why steps are being taken to strengthen cooperation between enforcement authorities, improve the risk assessment process and clarify the criteria for notifications on the part of member states and suppliers. Even though the notification criteria will be clarified, it is anticipated that the fundamental conflicts with constitutional protections against self-incrimination in some Member States will continue to ensure an uneven enforcement of these provisions.

Another potential barrier that will continue to contribute to uneven implementation is the demanding surveillance burden Article 9 places on Member States. As a result of the costs associated with establishing and maintaining such a system, many Member States, especially some of the less economically stable ones, may experience difficulty meeting these obligations.

The apparent dependence on standards as an alternative form of regulation and the issues related to the development of standards will need to be resolved. There is concern, for example, about the lack of balance and the degree of industry influence on the standardization committees. In addition, government may not have the capacity to monitor or participate in the work to develop standards for products.

The Better Regulation initiative¹⁸⁶ of the Commission that is designed to improve the regulatory environment could result in revisions to the GPSD in the future. The range of activities that make up this initiative include the screening of pending legislation to identify those that should be withdrawn, the review of existing acts for the purpose of simplifying the regulatory environment, revised impact assessment guidelines to improve the analysis of economic, social and environmental impacts, measurement of the administrative costs arising from regulation in order to reduce these costs and the appointment of a high level Better Regulation Group to advise the Commission on regulatory issues.

¹⁸⁶ European Commission, Press Release, Spring Summit 2006: Cutting red-tape and over-regulations, MEMO/06/135, Brussels, 21 March 2006

It has been argued that there is a need for a central European Agency for Consumer Product Safety to provide the ability to move rapidly to address emerging product safety problems across the EU, to bring together and make available the expertise to deal with highly complex technical issues, to provide linear consistency and continuity in policy and decision making, to achieve economies of scale and to support the development of standards. Due to problems related to the fact that EC officials are not elected nor are they accountable to elected individuals it is unlikely that Member States would support the establishment of a central agency.¹⁸⁷

7. Policy Considerations and Underlying Principles¹⁸⁸

Introduction

Amongst this report's Principal Findings and Conclusions are two subjects - choosing between regulation or voluntary standards, and the effectiveness of the GSR- that call for explicit consideration of relevant criteria. These criteria or measures of evaluation are applicable to a clustered sequence of policy questions:

- Should government act in response to a particular policy concern? (ie: the desire for enhanced consumer product safety.)
- Which instrument amongst the range of policy tools available to it should government chose? (In this case the choice is between detailed or product-specific regulation and a performance-based standard taking the form of a general safety requirement.)
- What considerations most directly affect the utility and effectiveness of the approach selected? (ie: how can the design and operation of a general safety requirement help to ensure compliance?)
- Whatever decisions are taken in relation to the preceding matters, are there factors of general application relating to norms of modern governance that should be respected as underlying values?

These, or similar questions related to other sectors and objectives, have been repeatedly asked in numerous jurisdictions including Canada, with the result that a certain general orientation can be discerned. Drawing upon that experience, an overview of general policy considerations (to which more extended reference will be made in discussion of particular features of our discussion of the general safety requirement) can be provided.

¹⁸⁷ Hodges C., *European Regulation of Consumer Product Safety*, Oxford University Press, Oxford UK, 2005.

¹⁸⁸ This section is supplemented by reference to the OECD paper, "Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance" and the Dutch Ministry of Justice paper "The Table of Eleven."

This overview addresses core principles of regulatory effectiveness, the evolution and applicability of those core principles in Canada, factors affecting ultimate compliance with regulatory instruments and associated legal principles.

Core Principles of Regulatory Effectiveness

In recent advice to the UK government, the multi-stakeholder Better Regulation Task Force identified five over-arching principles relevant to the effectiveness of regulatory initiatives, with the concept of effectiveness broadly understood to encompass what might otherwise be described as legitimacy and acceptability. These principles - transparency, consistency, targeting, proportionality and accountability - are explained as follows by the task force:¹⁸⁹

- Transparency is achieved by ensuring that: policy objectives and the need for regulation are effectively communicated to all concerned parties, regulations are simple and clear, additional guidance is available in plain English, where necessary, individual obligations under the scheme are widely understood, and the regulated community knows what to expect from enforcing authorities. Consultation and good communication with regulator can enhance transparency.
- Consistency is achieved by ensuring that new regulations are consistent with existing regulations and with related government obligations, for example, under inter-governmental agreements and international treaties. Regulatory authorities with overlapping responsibilities and concurrent regulation-making powers exercise those responsibilities and powers consistently with one another. Relevant authorities evenly enforce the regulatory regime exercising discretionary powers with reasonable predictability, and regulations are administered consistently across regions.
- Effective Targeting is achieved by ensuring that selected regulatory mechanisms are aimed at the problem and not “scatter-gun or universal” in approach. A goals-based approach is adapted to the extent feasible, allowing for future flexibility and leaving those being regulated some freedom concerning the means of achieving those goals. Regulations are

¹⁸⁹ *The Better Regulation Guide*, 1998, prepared by the Regulatory Impact Unit of the Better Regulation Task Force. (UK) The Better Regulation Task Force was appointed in September 1997 to advise the UK Government on regulatory issues. It is independent of Government and supported by the Cabinet Office. The Task Force is chaired by Lord Haskins, with 18 Members drawn from big and small businesses, consumer and citizen groups, the charity and voluntary sector, the trade union movement and enforcement community to ensure a balanced approach.

revisited from time to time to determine if they are still necessary, or if they require modification or elimination.¹⁹⁰

- Proportionality is achieved by ensuring that viable alternatives to regulation (or alternative compliance mechanisms) are carefully considered before deciding to regulate. The least intrusive mechanism required to achieve the regulatory objectives effectively is employed, the regulatory impact on those affected is carefully considered, a good balance between risk and cost is attained, and the sanctions imposed are proportionate and appropriate to the seriousness of the violation.
- Accountability is achieved through effective mechanisms for making regulators accountable to government, citizens and Parliament. There is meaningful consultation with affected parties before regulatory decisions are taken, the regulatory process is fair and perceived as such, well-publicized, accessible, fair and efficient appeals procedures are available under the scheme, and evaluation of regulatory systems and programs are carried out and adjustments made as appropriate.

Arguably, (despite certain differences as to terminology,) the Canadian federal regulatory experience has moved into general alignment with these core principles of regulatory effectiveness. It is therefore appropriate to briefly review that experience.

The Regulatory Reform Process in Canada: 1983-2006

Over the past quarter century, several distinct regulatory reform initiatives have been pursued at the federal level in Canada. These initiatives, outlined below, have combined distinctive key elements with shifts in emphasis intended to highlight particular elements of reform, or to consolidate a more comprehensive framework:

- Decriminalization of Regulatory Offences: Efforts were made between the 1983-86 period to modify the long-established “command and control” approach to regulation and to “convert” criminal offences to regulatory offences where appropriate.¹⁹¹
- Streamline Regulatory Process / Compliance Reform: The first comprehensive approach to federal regulatory policy became evident between 1986 and 1992. This involved measures to streamline the regulatory process, to enhance regulatory effectiveness, to manage the risk of regulatory liability, and to develop compliance strategy and practice.

¹⁹⁰ *Ibid.*, *The Better Regulation Checklist*, available on the Better Regulation Task Force Web Site at <http://www.brtf.gov.uk/> See also OECD’s Web Site *Overview on Regulatory Reform* at http://www.oecd.org/topic/0,2686,en_2649_37421_1_1_1_1_37421,00.html

¹⁹¹

During this period the range of regulatory instruments available to regulators expanded with encouragement to regulate “smarter” (reflecting the growing influence of international trade considerations) ie: to use the “least intrusive” regulatory method available.¹⁹²

- Reinventing Government:¹⁹³ During the 1992-97 period, the regulatory policy focus indicated a shifting emphasis towards deregulation, privatization, alternatives to regulation, and regulatory flexibility. Efforts to rationalize the role of government *vis a vis* the private sector, to downsize and “reinvent” government, and to explore public-private partnerships reflected important concerns surrounding Canadian competitiveness in a global economy and fiscal limitations.¹⁹⁴
- Performance-based / Accountable Government: From 1997-2003 the focus of federal regulatory policy shifted in the direction of business planning intended to enhance operational efficiency and improved governance practices. Efforts were undertaken to implement results-oriented accountability involving the use of objective performance criteria. In order to achieve coherence across a range of policy sectors, attention was devoted to resolving horizontal issues.
- Smart Regulation: The current period, as indicated in the introduction to this report, revolves around the Smart Regulation initiative.

Over the course of the previous quarter century it is possible to discern varying degrees of emphasis within Canadian regulatory policy on factors corresponding to the core principles of regulatory effectiveness as articulated by the UK Better Regulation Task Force. Certainly, attention has been directed towards transparency, and accountability, towards the proper definition or targeting of the policy challenge, and towards consistency whether in the form of explicit policies on enforcement and compliance or in terms of efforts to increase horizontal coherence. While reference to proportionality is less common in Canadian policy discussion than in other jurisdictions (notably the European Union), significant regulatory activity in Canada, whether in the form of RIAS or increasingly selective approaches to instrument choice, or, on occasion in the context of reasonableness analysis within the framework of the *Charter of Rights and Freedoms*, is evidently directed towards similar considerations. The Canadian experience thus broadly mirrors a recent synthesis of regulatory evolution within the OECD community:

¹⁹²Regulatory policy statement, instrument choice literature, Neilson task force, Prichard and Trebilcock on “smarter” regulation

¹⁹³ Regulatory Affairs Committee on C-62; PPP literature; early OECD regulation studies

¹⁹⁴ See, for example, the Government’s 1993 Reply to the Parliamentary Subcommittee Report on “Regulations and Competitiveness” at http://www.pco-bcp.gc.ca/raoics-srdc/docs/publications/responsive_reg_canada_e.pdf

In the 1990s the focus of regulatory reform at OECD has turned from deregulation to regulatory quality management – improving the efficiency, flexibility, simplicity and effectiveness of individual regulations and non-regulatory instruments. Regulatory reform is now entering a third phase – the management of regulation – to improve the total impact of regulatory systems in achieving their social and economic goals.”¹⁹⁵

Regulatory Compliance and Instrument Choice

Within the context of this report’s discussion of a general safety requirement as an instrument capable of contributing to increased consumer product safety in Canada, issues associated with compliance figure prominently alongside more general norms of regulatory effectiveness. This is because any possible advocacy of the general safety requirement must ultimately rest on the capacity of this approach to bring about beneficial changes in the behaviour of those whose conduct and performance affects the level of consumer safety in Canada. The general safety requirement is thus fundamentally oriented around expectations for behaviour, and within the framework of a new legislative initiative the relevant behaviour – and thus the eventual utility of the initiative - is measured in terms of compliance.

Insistence on the importance of behaviour and compliance is now central to regulatory decision-making and the choice of governing instrument. The OECD study quoted above asserts firmly:

The traditional regulatory approach of establishing standards of behaviour and legal enforcement mechanisms is not the sole means for governments to influence the behaviour of citizens and enterprises and may not be the most effective. In order to achieve regulatory objectives, regulatory policymakers need a clear understanding of the nature of different policy instruments, of the habits of the regulated target group, and of the regulatory context, to achieve regulatory objectives.¹⁹⁶

An important and influential analysis for the Dutch Ministry of Justice to which we will refer again in further detail underlines the centrality of behavioural and compliance objectives. It does so, furthermore, with reference to social order and the rule of law:

The government wants to make changes to society by influencing the behaviour of citizens and businesses. One of the policy tools, which the government can use to achieve this, is legislation... Legislation, however, also assumes some level of compliance with it by the target group. Non-compliance decreases the chance of realizing the policy objective. Moreover, legislation is also meant to be

¹⁹⁵ “Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance,” OECD, PUMA (2000) 4, 7

¹⁹⁶ Ibid, 5

complied with: compliance maintains the legal nature of society, and non-compliance affects that nature.¹⁹⁷

As a field of specialized inquiry, regulatory compliance is substantially broader in scope than the more familiar subject of “enforcement.” Many factors influence compliance under regulatory schemes. Compliance rates may be as adversely affected by a confusing legislative mandate as by poor enforcement practices or by any number of socio-psychological, sociological or criminological factors across the entire spectrum of regulatory activity. From preliminary consultations, through draft legislation to program implementation, compliance promotion, monitoring, inspection and eventual enforcement actions, consideration must be given to at least this range of influences on the effectiveness of regulation.

The current view of the pre-conditions and components of a successful regulatory compliance and enforcement program is the product of numerous multi-disciplinary studies, supplemented by general views and practical experience in the field of law enforcement. Despite many different formulations of the accumulated wisdom by modern regulators in western democratic countries, there is a surprising degree of unanimity on the key factors:

These elements include effective techniques for encouraging voluntary compliance, a credible monitoring and inspection scheme, the ability to respond quickly and effectively to specific incidents of non-compliance and a flexible range of civil, administrative and criminal sanctions to be applied in a manner that is proportionate and appropriate to the seriousness of the violation in question.¹⁹⁸

For many years, Canadian regulatory statutes relied virtually exclusively on the deterrent effect of criminal sanctions to promote compliance with regulatory statutes. After an abortive attempt was made in the late 1970’s and early 1980’s to find a bright line distinction between “criminal” and “regulatory offences”, the federal government adopted a more strategic, problem-solving perspective on regulation and compliance.

Recognizing that there are many ways to advance regulatory objectives - legislative and non-legislative - and many factors which affect compliance, government embarked upon a more comprehensive approach. Designing an effective regulatory regime including an effective compliance and enforcement program, necessarily involves several steps, namely to:

- Carefully identify the significant regulatory issue, compliance problem or regulatory objective to be achieved;

¹⁹⁷ The Table of Eleven (November 2004) 4

¹⁹⁸ See *R v. Consolidated Maybrun Mines Ltd.* (1993) 86 C.C.C. (3d) 317, at 338. (Affirmed on other grounds by Ont. C.A. at (1996) 28 O.R. (3d) 161; appeal dismissed by the Supreme Court of Canada at [1998] 1 S.C.R. 706).

- Analyze the underlying reasons for the issue, or problem, including the reasons for real or anticipated non-compliance;
- Consider the policy framework options (including the legal framework options) available for addressing the regulatory issue, compliance problem or objective to be achieved;
- Develop the regulatory instruments and programs under chosen policy option(s) – legislative or non-legislative - which are responsive to the identified issues and objectives; and
- Implement the policy and related programs using good management principles.

The incremental reasoning implicit in these five steps is relevant to analyzing the effectiveness of existing regulatory regimes, to designing new regulatory schemes, or to adapting aspects of foreign regulatory regimes to the Canadian context as is contemplated in connection with current consideration of a general product safety requirement in the consumer product area.

The Dutch Ministry of Justice, in the study noted above, has elaborated upon factors that affect compliance with legislation. Many of these will be more fully discussed in relation to specific aspects of the possible adoption, design and implementation of a general safety requirement in Canada, but it is nevertheless convenient to set out for reference the “Table of Eleven” factors that influence compliance.

The Table of Eleven

1. Knowledge of Rules
 - Familiarity with rules
 - Clarity of rules
2. Cost / Benefits
 - Financial/economic costs and benefits
 - Intangible costs and benefits
3. Extent of Acceptance
 - Acceptance of a policy objective
 - Acceptance of the effects of a policy
4. The target groups’ respect for authority
 - Official authority
 - Competing authority
5. Non-official Control (social control)
 - Social control
 - Horizontal supervision

6. Risk of being reported
7. Risk of Inspection
 - Records inspection
 - Physical inspection
8. Risk of Detection
 - Detection in a records inspection
 - Detection in a physical inspection
9. Selectivity (Targeting)
10. Risk of Sanction
11. Severity of Sanction

Each of these factors is explained in a 2004 publication by the Ministry of Justice in the Netherlands entitled: *The Table of Eleven: A Versatile Tool*.¹⁹⁹ A variation of the Table of Eleven (focusing on factors affecting voluntary compliance, control factors and sanctions) was included as an Annex to a 1999 report by Lyle S. Fairbairn, Q.C. and Margot Priest to the Canadian Human Rights Act Review in 1999. That material, which contains a point form elaboration of many of the factors outlined in the Table of Eleven, is included as Annex 3 to this Paper.

The Proportionality Principle (Europe)

European officials have enormous discretion under ‘New Approach’ regulations, the General Product Safety Directive and Member State regulations transposing the Directive. Even where products ‘presumptively’ conform to a European Standard, officials may act against an individual product that appears to be ‘unsafe.’ The European Court of Justice, however, has developed a ‘Principle of Proportionality’ as a basis for challenging arbitrary legislative, administrative or enforcement action.

In relation to regulations (and, presumably also to ‘standards’ when substituted for regulations under the ‘New Approach’), proportionality requires:²⁰⁰

that a regulation-making authority maintain a proper balance between any adverse effect on the rights, liberties, and interests of citizens and the purpose of

¹⁹⁹ See the Table of Eleven, developed in the Netherlands by the Ministry of Justice, Law Information Expertise Centre, accessed on August 10, 2006, at:

http://www.sam.gov.lv/images/modules/items/PDF/item_618_NL_The_table_of_Eleven.pdf

²⁰⁰ Paul Salembier, *Regulatory Law and Practice in Canada*, Butterworths, 2004, pp. 359-61

the regulation. As described by S.A. de Smith,²⁰¹ the proportionality test, as applied to regulations, has two principle formulations:

1. *The balancing test*, which requires a balance of the ends to be achieved against the means applied to achieve them,²⁰² and,
2. *The necessity test*, which requires that the least harmful of available means be adopted to achieve the regulatory objective.²⁰³

While the European Principle of Proportionality, as a basis for challenging *regulations* appears similar to the Canadian administrative law concept of 'unreasonableness,' Canadian law generally limits a challenge of legislative action on the basis of 'unreasonableness' to questions of *jurisdiction*. Did the public official, department or agency have legal *authority* to take a particular action or decision, or to enact a specific regulation?

It goes without saying that it is not for a court to determine the wisdom of delegated legislation or to assess its validity on the basis of the court's policy preferences. The essential question for the court always is: does the statutory grant of authority permit this particular delegated legislation?.....The regulations must of course be seen as in some way related to the purpose of the Act but this does not mean that a court can review them to see if they are necessary, wise, or effective in practice.²⁰⁴

The reasonability test for attacking general administrative decision-making is broader, but still more qualified and limited in reach than the European 'Proportionality Principle.' The legal use of the term 'unreasonable' has been qualified in Canadian administrative law for many years along the following lines:

But unreasonable in what sense? If, for instance, they were found to be partial and unequal in their operation as between different classes; if they were manifestly unjust; if they disclosed bad faith; if they involved such oppressive or gratuitous interference with rights of those subject to them as could find no justification in the minds of reasonable men, the Court might well say, "Parliament never intended to give authority to make such rules; they are unreasonable and *ultra vires*". But in this sense and in this sense only, as I conceive, that the question of unreasonableness can properly be regarded. A by-law is not unreasonable merely because particular judges may think that it goes further than is prudent or necessary or convenient, or because it is not accompanied by a qualification or an exception, which some judges may think ought to be there.²⁰⁵

²⁰¹ S.A. de Smith, *Judicial Review of Administrative Action*, 5th ed. (London: Sweet & Maxwell, 1995, at pp. 595-96

²⁰² *Bela-Muhle Josef Bergmann v. Grows-Farm*, [1977] E.C.R., 1211 ; *The Case of Lithgow and Others*, E.C.H.R. (My 22, 1984) Series A, No. 102

²⁰³ *Cassis de Dijon*, [1979] E.C.R. 649

²⁰⁴ *Jafari v. Canada (minister of Employment and Immigration)* [1995] 2 F.C. 595 (C.A.)

²⁰⁵ *Kruse v. Johnson* [1898] 2 Q.B. 91 (H.L.), at p. 99-100.

In Europe, the *substantive basis* of a decision may be challenged if an administrative action is disproportionate to the risks involved or is more intrusive than necessary. It therefore provides a broader basis for challenging administrative action than is available under Canadian administrative law. In Canadian administrative law, the concept of 'reasonableness' is not used in its intuitive sense, but rather as a "glaring indicator that the power being exercised (may be) beyond what Parliament intended to confer, and that the hunt should be on for interpretive evidence to substantiate that suspicion."²⁰⁶

Thus, the kind of unreasonableness which invalidates a by-law is not the antonym of 'reasonableness' in the sense of which that expression is used in the common law, but such manifest arbitrariness, injustice or partiality that a court would say 'Parliament never intended to give authority to make such rules; they are unreasonable and *ultra vires*.

Proportionality arguments have had some impact on judicial review proceedings in jurisdictions outside Canada, but have yet to make inroads into Canadian administrative law as a ground of judicial review.²⁰⁷ The general principles of judicial review are:

1. That judicial review is not an appellate procedure;
2. *That the court must not substitute its opinion for that of the decision-maker,*
3. That the court must rule only upon the legality of the decision and not its correctness; and,
4. *That the court will concern itself only with the manner in which a decision is reached and not with the substantive merits of the decision itself.*²⁰⁸

The broad discretion given to administrative officials under the General Product Safety Directive in Europe is, therefore, balanced by the Proportionality Principle, under which the European Court of Justice can challenge the substantive decisions taken by administrative officials. If Canada were to adopt a voluntary standards-based approach to regulating consumer products, it would be important to design appropriate checks and balances on the exercise of that discretion, since the Canadian concept of 'reasonableness' is different and much more limited in its application

The concept of proportionality is not entirely foreign to Canadian law of course. A concept of 'proportionality' is employed in some Canadian *Charter* decisions where the Court must balance competing rights under a constitutional challenge to a legislative provision. Though not legally binding on government, some regulatory *policies* incorporate elements of 'Proportionality.' For example, Canada's regulatory policy once prominently included a '*Citizens' Code of Regulatory Fairness*,' requiring, among other matters, that sanctions under

²⁰⁶ Paul Salembier, *Regulatory Law and Practice in Canada*, Butterworths, 2004

²⁰⁷ *Ibid.*, at p. 359

²⁰⁸ *Ibid.*, at p. 354, citing *Associated Provincial Picture Houses v. Wednesbury Corp.* [1948 1 K.B. 223 (C.A.)

federal statutes be ‘*proportionate and appropriate to the seriousness of the violation.*’ Elements of the *Citizens Code* have been incorporated into subsequent updates of the federal regulatory policy,²⁰⁹ including the following elements of the *Code* which address the issue of proportionality in taking regulatory action:

(1) Canadians are entitled to expect that the Government’s regulation will be characterized by minimum interference with individual freedom consistent with the protection of community interests.

(8) The government will take all possible measures to ensure that businesses of different sizes are not burdened disproportionately by the imposition of regulatory requirements.

(10) The government will not use regulation unless it has clear evidence that:

- A problem exists
- Government intervention is justified; and
- Regulation is the best alternative open to government

(11) The government will ensure that the benefits of regulation exceed the costs and will give particularly careful consideration to all new regulations that could impede economic growth or job creation.²¹⁰

Given the very significant increase in administrative and enforcement discretion under a standards-based GSR regime, is the mere possibility of judicial review of administrative action a sufficient safeguard against misuse of that discretion? Should additional safeguards be included in legislation granting extended powers under a GSR regime? For example, if the power to order a recall of consumer products were to be included were it otherwise constitutionally appropriate?²¹¹ Since a reference to voluntary standards under a standards-based regime is a form of authorized sub-delegation of legislative power, should Courts be given a wider opportunity to review the substance of standards substituting for regulations where they have an unreasonable or highly disproportionate impact on individual rights?

In the early days of Parliamentary democracy, the courts were not reluctant to substitute their own views for those of the legislature. In *Bonham’s case*, a decision rendered in 1610, the court noted: “when an act of Parliament is against common right and reason, or repugnant, or impossible to be performed, the common law will control it, and adjudge such act to be void.”²¹²

²⁰⁹ *The Citizens’ Code of Regulatory Fairness* was a document which helped to explain the guiding principles of Canada’s new regulatory policy, established in 1986.

²¹⁰ *The Citizens’ Code of Regulatory Fairness* (This document formed part of the Federal Government’s Regulatory Policy of 1986. The Code contained the general principles underlying the new policy.) Some federal regulatory *processes* also demand that proportionality issues be addressed as regulations are developed, such as the requirement for a Regulatory Impact Assessment process, a Business Impact Test and Cost-Benefit analysis.

²¹¹ See *infra*, under the heading *Recall: An Instrument of Last Resort*.

²¹² (1610, 8 Co. Rep. 113b, at 118a, 76 E.R. 646, at 652)

*Echoes of this view are discernible to this day in the jurisprudence related to delegated legislation. The question this raises, however, is whether the separation of the legislature and judiciary in our modern conception of a Parliamentary democracy leaves room for the *judicial invalidation of a delegated law* on the ground of the wisdom, or lack thereof, of its substance.²¹³ (Emphasis added)*

While the legal relevance of the Proportionality Principle is still evolving in the European Court of Justice, it is clearly relevant to the issue of 'recall', which is widely regarded as a remedy of last resort. The concept has also been given recent mention in some European Treaties as a broad principle, alongside the principle of 'Subsidiarity,' which preceded it. The essence of the 'Subsidiarity principle' is that the European Parliament cannot legislate 'European' law where unnecessary, that is, where the matter is more appropriately left to the Member States to legislate for themselves. Member States retain the residual, or original, jurisdiction to legislate in Europe. Balancing Community and National Sovereignty is a delicate process in Europe.

The 'Proportionality Principle' is given a similar application. The Principle was originally developed as a brake on administrative action, that is, government officials should not take steps disproportionate to the needs or seriousness of an issue or problem. Given the broad new powers and discretion available to officials under the GSR to challenge products as 'unsafe' (even products presumptively conforming to the General Safety Requirement), an important policy decision for Canada is how far that discretion or those powers should be subject to additional checks or controls other than by normal judicial review by the Court. For example, should something akin to an expanded (or legislated) *Citizens' Code of Regulatory Fairness* or the UK's *Enforcement Concordat* (being considered for legislation) be available as a formal basis for reviewing administrative decisions and/or enforcement measures?²¹⁴

The Precautionary Principle

The 'Proportionality Principle' raises some conflict with another principle incorporated into the revised General Product Safety Directive, namely, the *Precautionary Principle*. The precautionary principle evolved in the environmental area, but was given political impetus in the consumer protection area by the BSE (mad cow) crisis. The Principle was expressly included in the *General Product Safety Directive* at the insistence of the European Parliament. Both the wording of the principle in the GPSD, and the meaning of the principle

²¹³Paul Salembier, *Regulatory Law and Practice in Canada*, Butterworths, 2004 at p. 351

²¹⁴The UK has had a voluntary *Enforcement Concordat* in place as a policy document for about a decade. Consideration is now being given to updating the *Concordat* on risk assessment / risk management principles and to legislating the revised *Concordat* so that it might be enforced against a public authority taking disproportionate action against a defendant.

itself, are far from clear.²¹⁵

The ‘Precautionary Principle’ is mentioned not only in the GPSD, but also in several recent pieces of European legislation. The principle, on its face, is in conflict with the proportionality principle. There is currently no guidance on how the potential conflict will be sorted out. For this reason, the European Commission is proceeding carefully in terms of developing guidelines on recall, so as not to upset the balance between the proportionality, subsidiarity and precautionary principles. (Hodges interview)

In theory the Proportionality and Precautionary principles might be reconciled by an effective risk assessment process focusing on ‘serious’ risk. However, the precautionary principle was really developed to deal with things like climate change where the consequences could be quite catastrophic. Such decisions are never easy.

The European Commission considers that serious decisions addressing issues like applying the precautionary principle to the BSE issue – where entire industries may be destroyed by the exercise of the precautionary measures - should be taken at the *political* level. Under the UK regulation transposing the General Product Safety Directive, however, the decision is given to local trading standards officers. On the one hand, it is difficult to envisage removing operational decisions to the political level; on the other, there is compelling logic for inserting some political involvement in decisions having such serious consequences.

With this uncertain background, the UK Department of Trade and Industry has provided the following guidance to Industry, Businesses and Enforcement Authorities in its *Guidance Note on the UK General Product Safety Regulations of 2005*, transposing the GPSD:

76. Where appropriate, enforcement authorities are to be guided by the Precautionary Principle when taking measures under the Regulations to protect consumers from unsafe products.
77. The Precautionary Principle applies where there are threats of substantial, serious or irreversible harm to consumers but there is clear scientific uncertainty over the extent of the threats posed.

²¹⁵ “Article 8.2 requires that Member States shall act in accordance with the precautionary principle. The Directive does not define ‘the precautionary principle’ but some guidance is given in a Commission paper issued in 2000, which treats the precautionary principle as ‘part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy. The reference to the precautionary principle in article 8.2 was politically motivated and its meaning in practice is uncertain.” (Hodges p. 170)

78. Judgments handed down by the Court of Justice (C-434/02 and C-210/03) presuppose that for the Principle to apply the risk should be plausible and realistic based on the identification of potentially negative effects on health and safety and a comprehensive assessment of the risks based on the most reliable scientific data available (including international research). Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of the scientific study into the risk, but the likelihood of real harm to public health and safety persists should the risk materialize, the Precautionary Principle justifies the adoption of measures under the Regulations.
79. A measure adopted under the Precautionary Principle must recognize that it is not appropriate to seek to reduce the risk to zero. It should also be proportionate to the expected risk and appropriate for attaining a high level of public health in accordance with the definition of a safe product in the Regulations. The enforcement authority taking the measure must keep it under regular review in the light of new scientific evidence.

In taking enforcement measures, officials often take a pragmatic approach to the application of the precautionary principle, that is, they will want to be 'on the safe side of an issue.' If, for example, officials have concerns resulting from reports about metal candleholders exploding for no known reason, they may first raise their concerns with producers and others. If it appears the problem is not so serious as first reported, they might continue their discussions until the risk is identified and some proportionate action taken. If the producer agrees that there is a severe problem, officials view the precautionary principle as largely irrelevant, because they will insist on decisive action. It is treated, in effect, as an aspect of risk assessment and risk management. (Meijer interview)

Officials must recognize, however, that the Precautionary Principle is only a principle and not a rule of law. It provides some policy guidance on the exercise of pre-existing legal authority; it does not provide original legal authority.

Decisions which take the Precautionary Principle into consideration must usually be based on some evidence of risk and likelihood of harm should the risk materialize. In Europe, the 'Proportionality Principle' operates as a check on administrative action, thus a decision which takes the Precautionary Principle into account may be overturned in Europe under the Proportionality Principle if it is not based on appropriate evidence and results in an action being taken which is disproportionate to the risk.

There remains much uncertainty, therefore, about the nature of the 'Precautionary Principle' and the means of applying it, especially in view of the unsettled and potentially conflicting relationship with the "Proportionality Principle".

The Role of Voluntary Standards in Regulating Consumer Products in Europe, Canada and the US

Europe

At the European level, voluntary standards largely displace technical regulations under Europe's New Approach to Regulation, which provides the underlying legal framework for the *General Product Safety Directive*. Voluntary standards (and especially European Community standards where they exist) play a crucial role in establishing conformity with the *GPSD* in Europe.

Canada

There is no current commitment under Canada's regulatory policy to *substitute* voluntary standards for regulation in the manner or on the scale that has occurred in Europe under the New Approach to Regulation.' The 'New Approach' has frequently been described as a form of 'privatization of regulation.'

In the Occupational Health and Safety area in Canada and the UK, the role of voluntary standards is to *supplement* (rather than supplant) and sometimes to *defer* formal regulation where the regulatory objective can be better achieved under voluntary standards on a more flexible basis. This position is more consistent with Canada's position on the use of voluntary standards under its Draft Regulatory Policy. It is also more consistent with the policy position of the United States, its major trading partner, on the use of voluntary standards in rulemaking by the Consumer Product Safety Commission (CPSC).

There is a strong case to be made for encouraging the proliferation of flexible, continuously improving, voluntary standards as a complement to safety regulation in the consumer products area. The *Robens Committee on Safety and Health at Work, 1970-72* discussed in this Paper²¹⁶ made a compelling case for encouraging the use of voluntary standards in the workplace safety area.

The United States

"The interface between the world of voluntary standards and the smaller universe of consumer products, as regulated by the safety responsibilities of the Consumer Product Safety Commission, is unique. The enactment of the *Consumer Product Safety Act* represented an effort to balance the expertise and comprehensiveness of voluntary standards with a high level of concern and government involvement in the safety of products which are used by consumers. The issue of how to effectively utilize the already vast body of voluntary standards in connection with mandatory safety requirements of the CPSA has been evolving at least since 1968."²¹⁷

²¹⁶ See Section entitled *The Occupational Health and Safety Model – Lessons Learned*, and Annex 6, (supporting text) *Lessons Learned from the Robens Committee*.

²¹⁷ Address by Michael R. Lemov to the 13th Annual Meeting and Training Symposium, of the International Consumer Product Health and Safety Association, (ICPHSO), May 11, 2006, at p. 5. Mr. Lemov is a principal author of the Consumer Product Safety Act and the author of the Consumer Product Safety Commission – Regulatory Manual. (Shepard's/ McGraw Hill, 1981)

In 1968, Congress established a National Commission on Product Safety (NCPS) to “conduct a comprehensive study and investigation of the scope and adequacy of measures now employed to protect consumers against unreasonable risks of injuries that may be caused by hazardous household products.”²¹⁸ The Commission was also directed to undertake a study determining “to what extent does self-regulation by industry afford adequate protection against such hazards” which chiefly involved examining the role of voluntary standards.²¹⁹

Admiral Hyman G. Rickover, who testified before the Commission, said for example that ‘industry codes have a built-in weakness, for they are prepared and controlled on a voluntary basis by the very people to whom they are to be applied...’ With this and similar testimony, the commission was clearly troubled about recommending the unconditional use of such standards in the marketplace for the protection of the public. But the NCPS in its final report ultimately concluded that, although the quality of many of the voluntary standards it studied was less than acceptable, the *potential* of voluntary standards to enhance safety in the marketplace was very great. The Commission said:

Industry activities to develop safety standards can provide an important forum for marshalling the technical competence necessary for this work, but their voluntary nature inherently inhibits the development of optimal standards...

However, the Commission concluded that:

...voluntary safety programs with due regard for the public interest need and warrant federal technical and financial assistance and oversight.²²⁰

Initially, in 1972, the CPSA was cautious in its utilization of voluntary standards as rules having the force of law. It required that all such standards, if they were to be utilized by the Commission, be vetted by the CPSC and ultimately be issued by that body. As initially enacted, the CPSA did not contain any reference to voluntary standards.

In 1978, the Commission issued regulations describing the extent and form of Commission involvement in the development of voluntary standards.²²¹ In the Background section, the Commission acknowledged the contribution that voluntary standards had made to reducing hazards associated with consumer products, and stated that it supported an effective voluntary standards program.

²¹⁸ P.L. 90-136, 1968

²¹⁹ The Commission published an extensive evaluation of its findings regarding self-regulation by industry, primarily in the form of the voluntary standards process. See NCPS Final Report, June 30, 1970, Chapter 4, pp.47-62.

²²⁰ Per Michael R. Lemov to the 13th Annual Meeting and Training Symposium, of the International Consumer Product Health and Safety Association, (ICPHSO), May 11, 2006, p. 9

²²¹ 43 FR 19216, 16 CFR part 1032

The Commission also stated its belief that a proper combination of voluntary and mandatory standards can have a higher ‘payoff’ in increased product safety than either mandatory or voluntary standards alone could have.²²²

In 1981, Congress amended the *Consumer Product Safety Act*, the *Federal Hazardous Substances Act*, and the *Flammable Fabrics Act* to require the Commission to give preference to voluntary standards over promulgating mandatory standards *if* it determined that a voluntary standard would eliminate or adequately reduce an injury risk, and that there would be a likelihood of substantial compliance with the standard. The amendments also required the Commission to provide administrative and technical assistance to organizations engaged in voluntary standards development.²²³

Section 7 of the current *Consumer Product Safety Act*²²⁴ enables the CPSC to ‘promulgate safety standards’ in accordance with the provisions of section 9. Section 9 of the *CPSA* governs the procedure to be adopted in Commission rulemaking; it requires, among other matters, that advance notice of a proposed rule be published in the Federal Register in order to elicit public comment and/or participation in the proposed rule making.

Section 9, subsection (2) (B) also provides that, if a voluntary standard meets the ‘successful-risk-elimination’ and ‘likelihood-of-substantial-compliance’ conditions:

... the Commission shall **terminate** any proceeding to promulgate a consumer product safety rule respecting such risk of injury and shall **publish** in the Federal Register a notice which includes the determination of the Commission and which notifies the public that the Commission will **rely** on the voluntary standard to eliminate or reduce the risk of injury, except that the Commission shall terminate any such proceeding and rely on a voluntary standard only if such standard is in existence. (Emphasis added)

The nature of the reliance by the CPSC on voluntary standards deferred to under section 9 is a matter of some controversy in the U.S. There are two schools of interpretation. Some commentators argue that the CPSC is entitled to rely on such standards to the same extent (including for enforcement purposes) as if the standard had been promulgated by the Commission itself, as a mandatory consumer product safety standard.²²⁵ They take this position, partly, because there is a form of equivalency in the conditions to be met between the proposed voluntary standard published by the Commission and one formally promulgated by the Commission.

²²² Federal Register, July 10, 2006, Vol. 71, No. 131, Background section of final rule on Commission Involvement in Voluntary Standards.

²²³ *Ibid.* Background section of final rule on Commission Involvement in Voluntary Standards.

²²⁴ 15 U.S.C. 2056

²²⁵ See prepared addresses by David H. Baker LLC, and Michael R. Lemov to the 13th Annual Meeting and Training Symposium, of the International Consumer Product Health and Safety Association, (ICPHSO), May 11, 2006

Others argue that the statutory intent of the CPSC is much more limited. The historical objective of Section 9, they argue, was to avoid *unnecessary* regulation (as part of a 'de-regulation policy thrust) and cannot be relied upon outside the context of rulemaking or, in the case of a breach of such a standard, as potentially triggering the obligation to report a "substantial product hazard" under section 15.²²⁶ It is argued that to rely on voluntary standards, as if they were promulgated by the Commission as Commission standards, would be to create a form of "back-door rulemaking."²²⁷ This appears to be the prevalent view where voluntary standards are treated, as in Europe, as quasi-mandatory.

The only apparent agreement between the two schools of interpretation is that the matter should ultimately be sorted out in the legislation itself. However, the importance of Commission involvement in the development of voluntary standards as an adjunct the Commission's role in developing mandatory standards is largely unquestioned:

The CPSC has issued less than forty so-called mandatory standards under its five jurisdictional statutes (*the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Poison Prevention Packaging Act, the Flammable Fabrics Act and the Refrigerator Safety Act*) since its formation in 1972.

During the same period, the American Society for Testing and Materials ('ASTM'), the American National Standards Institute ('ANSI'), Underwriters Laboratory ('UL') and other standards organizations in the U.S. have probably issued over twenty thousand standards.²²⁸

Recently the Commission has requested voluntary standards organizations to assist it by developing voluntary standards for consumer products, including a safety standard for children's folding chairs. Commission representatives regularly participate in the standards development activities of voluntary organizations, as do representatives of other government agencies.²²⁹

The participation of Commission officials in the development of voluntary standards has raised a number of concerns for the Commission relating to the possibility of conflicts of interest, confusion about the status of standards in which officials have had a hand in developing, unauthorized use of resources, and issues of prejudice to the Commission's enforcement role through a perceived loss of independence and impartiality.

²²⁶ 15 U.S.C. 2064. per address by Rob Raffety, Legal Counsel to the Chair of the CPSC

²²⁷ (See 653 Fed. Sup. 1079 – a voluntary standard does not pre-empt, nor is it the same as, a voluntary standard – review case.

²²⁸ Address by David H. Baker LLC, to the 13th Annual Meeting and Training Symposium, of (ICPHSO), May 11, 2006, *supra*, at p. 1.

²²⁹ Per Michael r. Lemov, *supra*, address to ICPHSO, May 11, 2006, p. 6.

Given the existence of thousands of voluntary standards, the Commission must act judiciously in selecting the appropriate activities in which to engage. The current regulation does not make reference to the existing agency practice of permitting staff to participate only in those activities specifically identified in the operating plan, performance budget, mid-year review, or other official Commission documents. Where appropriate, Part 1031 should include language to permit staff involvement in only those standards expressly approved by the Commission.²³⁰

On July 10, 2006, the Commission published a final rule on *Commission Involvement in Voluntary Standards*.²³¹ In addition to asserting more control over the activities of Commission Staff in the development of voluntary standards, the Rule provides that the Commission will consider the extent to which specific criteria are met in considering Commission involvement in the development of voluntary safety standards for consumer products.

The listed criteria address numerous issues, including: the overall effectiveness of a voluntary standard, maintaining its currency, avoiding anticompetitive results in the standard-setting process, verification of continuing compliance with the standard, tracking products and injuries, and meaningful participation of all interested parties in the standard-setting process. Before participating in the development of a voluntary standard, the Commission must now consider the following criteria.

- a. The likelihood the voluntary standard will eliminate or adequately reduce the risk of injury addressed and that there will be substantial and timely compliance with the voluntary standard;
- b. The likelihood that the voluntary standard will be developed within a reasonable period of time;
- c. Exclusion, to the maximum extent possible, from the voluntary standard being developed, of requirements which will create anticompetitive effects or promote restraint of trade;
- d. Provisions for periodic and timely review of the standard, including review for anticompetitive effects, and revision or amendment as the need arises;
- e. Performance-oriented and not design-restrictive requirements, to the maximum practical extent, in any standard developed;
- f. Industry arrangements for achieving substantial and timely industry compliance with the voluntary standard once it is issued, and the means of ascertaining such

²³⁰ Federal Register, July 10, 2006, Vol. 71, No. 131, Explanation section, section2 of final rule on Commission Involvement in Voluntary Standards.

²³¹ Federal Register, July 10, 2006, Vol. 71, No. 131

compliance based on overall market share of product production;

- g. Provisions in the standard for marking products conforming to the standard so that future Commission investigation can indicate the involvement of such products in accidents and patterns of injury;
- h. Provisions for insuring that products identified as conforming to such standards will be subjected to a testing and certification (including self-certification) procedure, which will provide assurance that the products comply with the standard; and
- i. The openness to all interested parties, and the establishment of procedures which will provide for meaningful participation in the development of such standards by representatives of producers, suppliers, distributors, retailers, consumers, small business, public interests and other individuals having knowledge or expertise in the areas under consideration, and procedures for affording other due process considerations.²³²

The importance of ensuring meaningful participation of public interest stakeholder participation in the standard-setting process to the effectiveness and legitimacy of any voluntary standard intended to supplement, displace or defer regulation is a recurring theme across jurisdictions. In Europe, it is a concern of the European Association for Coordination of Consumer Representation and Standardization - a concern recently reiterated in a Report dated March 10, 2006, outlining *Proposals for Improving Public Interest Stakeholder Participation in Standardization*.²³³ As one U.S. commentator also noted:

To the extent public, consumer and non-industry representation is increased in the voluntary standards-making process, it is more likely that a risk will be adequately eliminated as required by the CPSA and that there will be substantial compliance in the marketplace. To the extent that standards applying to consumer safety represent something more than 'consensus standards' and come closer, through open and inclusive procedures, to a level of safety reasonably necessary to eliminate hazards to consumers, they are more likely to be accepted by government, recognized by the courts, and complied with in the market place. Compliance would also furnish some evidence of due care by manufacturers in the production of consumer products.²³⁴

While public officials sometimes consider voluntary standards as an inexpensive substitute for regulation, it seems clear that the effective utilization of voluntary standards requires considerable input from public authorities. If it is to be done properly, voluntary standards development will often be resource-intensive and may be as, and occasionally more, time-consuming than developing regulations.

²³² Federal Register, July 10, 2006, Vol. 71, No. 131, Sec. 1031.5

²³³ See ANEC report, March 10, 2006, *Proposals for Improving Public Interest Stakeholder Participation in Standardization*, p. 2.

²³⁴ Per Michael r. Lemov, supra, address to ICPHSO, May 11, 2006, p. 12

Nevertheless, the process may well produce more effective and longer lasting safety outcomes for the reasons indicated.

For the purposes of determining the broad *range* of 'voluntary standards bodies' with which a public authority may become involved as an advisor or funding authority – and in relation to which it should be adequately resourced - it is useful to consider the definition of that term by the CPSC:

...'voluntary standards bodies' are private sector domestic or multinational organizations or groups, or combinations thereof, such as, but not limited to, all non-profit organizations, industry associations, professional and technical societies, institutes, and test laboratories, that are involved in the planning, development, establishment, revision, review or coordination of voluntary standards. Voluntary standards development bodies are voluntary standards bodies, or their sub-groups, that are devoted to developing or establishing voluntary standards.

Policy Criteria for Making a Choice to Regulate or to Rely on Voluntary Standards?

When are voluntary standards likely to be inappropriate as an alternative to regulation? "When to regulate?" is a question that is closely related to the issue of choices about the utilization of voluntary standards in regulating the safety of consumer products.

There is surely no single answer to the question of whether regulatory agencies should use performance-based regulation... performance-based regulation is not a "magic bullet" or "one size fits all" approach applicable in all situations... In determining whether to use a performance standard, and if so, the specific type of standard to adopt (e.g. loosely vs tightly specified), decision makers need to consider the conditions under which the standard will be applied."²³⁵

The UK Consumer Safety Review in the mid 1970's considered when formal regulation was appropriate and developed a series of factors to be taken into account in determining whether to regulate or not, or to adopt some alternative approach to dealing with a consumer safety issue. The criteria developed by the Review as to the proper use of prescriptive regulations are instructive in that they help identify the scope of operation of a general safety requirement.

The factors that the Review Committee suggested be taken into account in considering proposals for regulations were:

- a. Evidence whether the goods in question are being widely sold;

²³⁵ Harvard Workshop on Performance-based regulation, *supra*, under the heading "Conditions for Performance-based Regulation.

- b. The degree of risk which they present and the cost to manufacturers ultimately to consumers, of eliminating or reducing the hazard;
- c. Whether a British Standard, or other suitable specification on which regulations can be based, exists;
- d. Any proposals for harmonization of safety requirements under consideration within the EEC; and
- e. Whether voluntary action the trade itself is prepared to take is likely to be effective in reducing or removing the hazards and the risk of such action being undermined by lack of co-operation from a minority of manufacturers or importers.²³⁶

The 1999 *Report of the Commonwealth Interdepartmental Committee Report on Quasi-Regulation: Grey-Letter Law* sets out the following criteria for choosing prescriptive regulation:²³⁷

- The problem is high risk, of high impact / significance, for example a major public health and safety issue;
- The government requires the certainty provided by legal sanctions;
- Universal application is required (or at least where the coverage of an entire industry sector, or more than one industry sector) is judged as necessary;
- There is a systematic compliance problem with a history of intractable disputes or flagrant breaches of fair trading principles and no possibility of effective sanctions being applied; or
- Existing industry bodies lack adequate coverage of industry participants, are inadequately resourced, or do not have a strong regulatory commitment.

Criteria for Choosing External Standards (Quasi-Regulation)

Quasi-regulation in the Australian Report on Grey Letter Law includes the use of voluntary performance standards promoted by government for regulatory purposes, but not incorporated into regulations. The Australian Commonwealth Interdepartmental Committee on Quasi-regulation recommended that Quasi-regulation be considered where:

- There is a public interest in some government involvement in regulatory arrangements and the issue is unlikely to be addressed by self regulation;
- There is a need for an urgent, interim response to a problem in the short term, while a long term regulatory solution is being developed;
- Government is not convinced of the need to develop or mandate a code for the whole industry;
- There are cost advantages from flexible, tailor made solutions and less formal mechanisms such as access to a speedy, low cost complaints handling and redress mechanism; or

²³⁶ *Ibid.*, para 30

²³⁷ *Grey Letter Law*, Report of the Commonwealth Interdepartmental Committee on Quasi-Regulation (Australia), p. 409 (Web site: <http://www.pc.gov.au/orr/greyletterlaw/>) , (Chapter 3 *Choosing From the Regulatory Spectrum*)

- There are advantages in the Government engaging in a collaborative approach with industry, with industry having substantial ownership in the scheme. For this to be successful, the following conditions need to apply:
 - A specific industry solution is required rather than regulation of general application;
 - There is a cohesive industry, with like-minded participants, motivated to achieve the goals;
 - A viable industry association exists with the necessary resources to develop and / or enforce the scheme;
 - Effective sanctions or incentives can be applied to achieve the required level of compliance, with low scope for benefits being shared by non-participants; and
 - There is effective external pressure from industry itself (survival factors), or threat of consumer or government action.

8. Implementation, Operational Considerations and Compliance Issues

Introduction

Adoption of a GSR, should that decision be made, will require a comprehensive program for implementation involving a series of important operational and resource considerations, and ultimately requiring compliance measures to enhance effectiveness.

In this section of the report, we describe a number of implementation, operational and compliance issues and endeavour to assess some of the relevant options with reference to guiding principles and compliance factors identified in the preceding section. For convenience, the guiding principles are set out below:

- **Transparency/Consultation of Canadians.** Regulatory objectives, policies and assessments of risks should be accessible and transparent to all concerned parties, be easily understood and effectively communicated to those affected. Where facts are uncertain or unknown, government should seek to make clear what gaps exist and what is being done to address them. Citizens and the private sector should have an opportunity to actively participate through consultation in the decision making process. Moreover, supplier obligations under the scheme need to be widely understood so that the regulated community knows what to expect.
- **Consistency** is achieved by ensuring that new regulations are consistent with existing regulations and government obligations such as those prescribed by inter-governmental agreements or international treaties. Government will seek to apply a consistent approach to its assessment of risks. Regulatory authorities with overlapping responsibilities and concurrent regulation-making powers exercise those responsibilities and powers consistently with one another. Relevant authorities enforce the regulatory regime consistently across regions.
- **Evidence.** Government will aim to ensure that all relevant evidence has been considered and, where possible, quantified before it takes decisions on risk. In addition, it will seek impartial and informed advice from a range of perspectives.
- **Effectiveness** is achieved by ensuring that selected regulatory and enforcement initiatives are aimed at the problem so they achieve the intended objectives and national priorities. A goals-based approach is adopted to the extent feasible, allowing for future flexibility and leaving some freedom to those being regulated concerning the means of achieving those goals. Regulations are revisited from time to time to determine if they are still necessary, or require modification or elimination.

- **Proportionality** is achieved by ensuring that government intervention is needed and that viable alternatives to regulation (or alternative compliance mechanisms) are carefully considered before deciding to regulate. The least intrusive mechanism required to achieve the regulatory objectives effectively is employed. The sanctions imposed are proportionate and appropriate to the seriousness of the violation.
- **Accountability.** Regulators must account to government, citizens and Parliament for their performance. There is meaningful consultation with affected parties before regulatory decisions are taken. The regulatory process is fair and perceived as such. Well-publicized, accessible, fair and efficient appeals procedures are available under the scheme. Evaluation of regulatory systems and programs are carried out and adjustments are made as appropriate.

OECD²³⁸ research on compliance factors highlighted three main factors that affect the level of compliance with regulatory requirements:

- Knowledge and understanding of the rule with which compliance is expected, a factor affected by the clarity and certainty with which the rule is articulated;
- Willingness to comply, a factor affected by the cost of compliance, the adequacy of prior consultation, and government's commitment to enforcement; and
- Ability to comply, a factor affected by the skills and capacity of the organization and the information and guidance provided by government.

Issue Identification and Summary

For the purpose of identifying implementation issues calling for closer scrutiny, this report draws upon three valuable sources:

- Europe. Personal interviews with numerous European experts representing the EC, Member States (Belgium, the Netherlands and the UK), standard setting organizations, private law firms involved in applying the GPSD, and academics. They included Dr. Bernardo Delogu and Dr. Erik Hansson who are senior officials at the European Commission and were involved with the writing of the first GPSD in 1992 and the revisions in 2001; Dr. Dirk Meijer from the Netherlands who is the current Chair of PROSAFE, and Dr. Chris Hodges who practiced in the area of consumer product safety with a global law firm for many years before writing a book and becoming a professor at Oxford. All generously gave up time from their busy schedules to help us understand the challenges in developing

²³⁸ OECD, *Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance*, 2000.

and implementing the GPSD. The general thrust of the interviews was guided by the questions we developed (Annex 4). The names and specific affiliations of all of the experts interviewed are listed in Annex 5;

- Canada. Departmental consultations with Canadian stakeholders.
- Canada. Academic commentary on consumer safety protection regimes.

Europe. Implementing the European General Product Safety Directive (GPSD): Highlights and Recurring Themes

It will be recalled that the European Union has already acquired considerable experience with a General Safety Requirement. Indeed, on the basis of an initial period of operational experience, the EU conducted a comprehensive review prior to revising the governing directive.

We analyzed the information obtained from the interviews that was relevant to implementation of the GPSD in light of the three factors identified by the OECD as having an impact on the private sector's ability or willingness to comply with regulatory requirements.²³⁹

We also took into consideration, the core principles of efficient regulation²⁴⁰ as well as the Table of Eleven²⁴¹ which is a Dutch model using eleven dimensions with criteria that enable an assessment of whether draft legislation is enforceable.²⁴² According to the Dutch authorities, rather than looking at cost benefit of a new regulation, they now use the Table of Eleven to look at the likelihood of the regulation being voluntarily enforced and how much effort will have to be put in by government to make the regulation work. Questions include: how much incentive do people have to comply or not comply, how far is the natural inclination to act in the way proposed by the regulation, and does it have a good foundation for eliciting good practices. The details of the interviews are in Annex 6. The salient points from these interviews are summarized below:

- ***Evolution of the General Safety Requirement***

There was a need to harmonize regulations to enable free trade within the European Union. Under the old approach where everything had to be specified within the law, it was impossible to produce enough legislation harmonized amongst the Member States to meet the demand. The Cassis de Dijon decision was the first one where the European Court gave a clear signal that it would assist with the creation of an internal common market without barriers to trade between Member States. About the same time, there was a new directive stating that if a Member State wanted to

²³⁹ OECD, Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance, 2000

²⁴⁰ Lyle S. Fairburn Q.C., *Performance-based Regulations, Current Issues*, January 14, 2002

²⁴¹ The Table of Eleven, A versatile tool, Law Enforcement Expertise Centre, Dutch Ministry of Justice, The Hague, version November 2004.

²⁴² Table of Eleven p.4

enact new technical rules, they would have to give notice to the Commission and every other Member State. This made everyone aware of the serious intent and force of the common market on domestic law making.

These challenges led to the development of The New Approach, which is a tool for technical harmonization, by the European Council in May 1985. This politically changed the rules and allowed the EU to get into the business of developing domestic laws. The New Approach has variously been referred to as a policy, philosophy, strategy, but is generally regarded as a regulatory technique including an “enforcement measure” or a framework for dialogue. The New Approach is a two tier system in which legislative essential requirements, or the broad principles, related to health, safety and the environment are defined in EU Directives, and the details on how these requirements can be fulfilled are found in standards which are not included in the law.

The 1992 EC General Product Safety Directive had a GSR and followed the style of the New Approach Directives in that it contained the essential legislative requirements and some common safety denominators with the details for how to meet those requirements specified in standards. Member States are obliged to transpose the requirements of the GPSD into their country legislation. Since many already had a GSR type of approach in their own consumer legislation, the GPSD did not result in major changes in approach although some of the powers in the GPSD differ. In particular, recall was not in the UK legislation and resulted in the UK not transposing the first Directive.

The GPSD was designed as a “final safety net” to ensure at a minimum that products were “safe” throughout the EU in case harmonization was not fully achieved. The second objective was to provide Member States with the obligations and powers to ensure safe products. The purpose and role of the GPSD may be changing from a safety net to an alternative form of regulation²⁴³. It was not designed for this; it was to be a means of bridging an enforcement gap, to prevent harm while a safety issue is being assessed and sometimes, to bridge the gap to formal regulation of the risk.

- **Scope of the GPSD**

The GPSD applies to non-food consumer products and products that are not subject to specific vertical directives. This covers less than 50 percent

²⁴³ In Canada, there could be pressure to use the GSR excessively as an alternative mechanism to weak or lacking remedies or sanctions in the sectoral legislation if those remedies are not separately reviewed for their sufficiency – a catchall that could, by default, become an alternative approach to regulating.

of the products on the European market. There are GPSD requirements including labelling, tracking and notification that apply to specific vertical regulations. In addition, the powers in the GPSD can be used across the vertical directives. Gaps in the vertical directives should be filled by revision, but the GPSD can be used in emergencies. For example, it was used to ban phthalates in toys. The GPSD can be used for life cycle management, although the view is that a product should be unusable before it becomes unsafe.

- ***Implementation of the GSR***

One of the factors leading to successful implementation is the degree to which the target group knows and understands the rules. The first Directive was adopted in 1992, with quite some reluctance in several Member States. Those affected by the GSR (Target Group) did not appear to know what was intended in the Directive; in fact Germany took the EC to court on the basis that it had exceeded its discretion. After five years, many of the Member States had still not transposed the Directive into their legislation; industry wanted it repealed; and Small and Medium Enterprises (SMEs) believed it would bankrupt them. The situation improved with the discussions prior to the revised Directive. Now business lobbies to ensure there is effective enforcement. An EC (DG Enterprise) study of obstacles to business found the least obstacles to business were created by the GPSD. Industry viewed it as prescribing only what should be common practice. They saw it as a kind of checklist of what they should have in place.

The second factor that can influence implementation of a regulation is the degree to which the target group is willing to comply voluntarily. This will be driven not only by the costs to the target group, but also whether it has been consulted before implementation and whether the government is serious about enforcing the regulation to deter non-compliance.

In the EU, the consultations on the revised directive, the GPSD, helped in securing greater understanding of the intent and functioning of the Directive, although there still seems to be misunderstanding particularly amongst SMEs and foreign suppliers. The GPSD requires that only safe products be produced and leaves it up to industry to determine what that entails. In the EU, the requirements vary according to size, capacity and volume of the supplier, and administrative discretion is applied to the circumstances of the distributor.

The EC has made calculations on costs and determined that the GPSD is more costly than the old system.²⁴⁴ In addition to the burden placed on industry, the switch from a pre- to post-market approach in the GPSD

²⁴⁴ Unfortunately these cost data were not publicly available from the EC at the time of our interviews

places a significant burden on the EC²⁴⁵ and Member States who are responsible for enforcement.²⁴⁶ In some instances, government assumes some of the testing costs as well as the increased costs to enhance enforcement and custom control. Systems have to be put in place to track suspicious goods and collect injury data, which are then shared with the EC and all Member States. Recalls are new to the GPSD and are also expensive for all Member States. Because of the variability in enforcement across the Community, the EC is financing a project, to be carried out by PROSAFE over three years, to develop a common approach to enforcement and to develop guidelines and best practices on surveillance and enforcement²⁴⁷.

Effective market surveillance is an important component of enforcement. Under RAPEX, the Member States are obliged to notify the EC when they adopt measures to prevent, restrict or impose conditions on the marketing or use of a consumer product and when industry takes voluntary measures on products in cases of serious risks. The current level of reporting under RAPEX is extremely variable as is the capacity to identify cases of serious risk from products on the market and to notify other Member States. As a result, the EC is now developing an information technology application where notification can be made by and to all EU Member States and is working to establish greater consistency in risk assessment across the EU.

The third factor influencing implementation of a regulation is the degree to which the target group is able to comply with it. Since standards are developed at the general (product sector) level, not on the basis of individual products, there are additional financial implications. SME's constitute 60 percent of the suppliers in the EU and require considerable help under a standards regime including testing by the government and compliance advice on a case-by-case basis.

Standard setting is complicated in the EU. There is a push to have harmonized or Community standards that would enhance trade amongst Member States. The cost of establishing new standards is mainly paid for by industry. However for harmonized standard setting through CEN (European Committee for Standardization), the EC R&D program puts up 50 percent of the money for development of methods of analysis, and the EC funds the secretariat. National standard setting bodies can set standards, and some of them are used as the basis of harmonized

²⁴⁵ EC is funding Prosafe, CEN (European Standards Body) and upgrade to RAPEX

²⁴⁶ The NL have 120 FTEs and 15 million Euros for enforcement with an additional 1 million Euros for improvements to RAPEX and increased investigations; Belgium has 50 million Euros for GPSD activities and considers it insufficient.

²⁴⁷ Prosafe²⁴⁷ is an informal network that allows discussion (not at an official level) amongst market surveillance officers across the EU on issues arising on products, and sharing of what worked and what did not work

standards at the EU level. Over the years, the EU has evolved from relying on national standards to developing harmonized European standards, and there is some movement towards harmonization between European and ISO standards.²⁴⁸

Once the standards are set, industry needs to have a clear understanding of what it takes to comply with those standards, and they look to government to provide the information on what is required. As a result, the EC puts forth great effort not only to encourage development of harmonized standards, but also to produce guidance documents for industry on what is involved in assessing the safety of their products. In the case of toys and electrical products from China where most problems arise, the EC has an initiative to educate Chinese manufacturers since it appears that many of them are not aware of the GPSD. Another approach taken by many companies to assure compliance is to submit their products to independent testing labs (Notified Bodies) since they believe it helps build a defence in the case of enforcement action²⁴⁹.

Cost-Benefit of a GPSD in Europe

There was strong political interest in reducing technical barriers to trade within the EU. The first step was the introduction, in 1985, of the New Approach, which was a tool for technical harmonization. This approach was extended to consumer products in 1992, and there was a subsequent revision of that Directive in 2004. Although there was evidence that a GSR would be more costly than the existing regulatory systems within each of the Member States, these costs were considered outweighed by the significant economic benefits emanating from enhanced free trade of European manufactured goods within the EU. The costs of implementing a GSR in Canada are likely to be similar to those in Europe, but the benefits may be significantly different.

- ***Compliance and Enforcement***

The inclusion of recall in the revised Directive caused anxiety in some of the Member States, which felt that there were other less draconian ways of removing unsafe products. Relevant to the issue of recall in the EU is the proportionality principle. In the latest European Treaty, proportionality is mentioned as a broad principle where steps should not be taken that are disproportionate to the needs or seriousness of the issue. The inclusion of

²⁴⁸ Canada has some reservations about adopting ISO as a default position. Also, there are other North American standards, which are not ISO standards that Canada must take into account.

²⁴⁹ A Notified Body (NB) is an inspection body or organization (private company) which is competent to perform tasks relating to the conformity assessment mentioned in certain directives. This authority is designated by the Member State on the territory where it is established if it satisfies the criteria with regard to competence and the requirements established in the relevant directive and is notified to the Commission and to the other Member States. It could be called an “approved laboratory”, authorized by the government in the country in which it exists to do testing within the GPSD for approval for the CE marking for example.

the Precautionary Principle in the GPSD appears to be in conflict with the proportionality principle. Another complication in Europe is the principle of subsidiarity, meaning that a matter cannot be legislated on a European law basis where unnecessary, and it should be left to the Member States to legislate for themselves. The Member States have the residual or original jurisdiction. Clearly, there is a balance between Community and National Sovereignty. Given all the issues, the EC is proceeding carefully in terms of developing guidelines on recall so as not to upset the balance between proportionality, subsidiarity and precautionary principles.

The EC considers that recall is a last resort and that less intrusive action (than full recall) should be taken if possible, although there may be some increase in recalls because of the attention paid to it in the revised directive. In the UK, section 11 of the Consumer Protection Act allows the Secretary of State to make regulations in respect of the product. He can do that on an emergency basis without consulting or on a general basis with consultation (the emergency regulation). The action can last for 12 months, and if it needs to be extended there has to be a proper consultation. The recall power does not appear to have been abused. In one case in the European court, not under the GPSD, but some other directive, the court found the action was correct.

- ***Legal Considerations***

Key Legal Issues: Key legal issues that arose or were considered include: (i) the nature of a GSR and how to interpret it in practice (what kind of guidance can be found to design and produce a product; what standards exist and documents are available; what kind of assistance is available); (ii) delegation of legislative responsibility – ministerial responsibility; (iii) due diligence; (iv) liability creep; (v) interface between tort and GSR (two aspects are the government liability ie: for responding effectively to complaints, and the industry side ie: the possibility of liability creep); (vi) safeguards in recall; and (vii) the European principle of proportionality and how it is applied.

Case Law: There is very little case law experience in the courts because so few cases go to prosecution. There seems to be a sense that most products are safe and a light touch is justified; nevertheless a big stick is necessary to wield for the few that need it. The legal profession is interested in the GPSD, in particular the new obligation on business to notify authorities when they have placed non-compliant products on the market because of the potential for self-incrimination. There is not much case law yet to answer this.

Due Diligence: The very limited case law on the GPSD makes it difficult to assess the impact of new and improving standards on the standard of care required to be shown to establish a due diligence defence. There seems

to be a presumption that the natural result of new and improving standards will inevitably raise the bar on a due diligence defence, but the same might have been true no matter the reason standards were improved. The UK is probably the only country in the EU to insist upon the due diligence defence which sits uncomfortably alongside the absolute liability posture of the Directive.

- **Stakeholders' Position on the GSPD**

The GPSD which some feel “privatizes the regulatory process” still causes some problems, especially with consumer interest groups which feel that their modest influence is overwhelmed by industry interests and that the standards, once published can be difficult to amend or place under review.

Canadian Stakeholder Concerns Regarding GSR Implementation

During the course of consultations on a GSR carried out by Health Canada officials, stakeholders identified a number of concerns or policy issues relating to implementation and compliance with the proposed regime.

One of the central considerations affecting regulatory effectiveness is the need for the regulated community to understand what is required to comply with any regulations and to know what is expected from enforcing authorities. However, in departmental consultations, suppliers²⁵⁰ raised a number of concerns that are related to this very principle, including the lack of guidance and clarity around many of the provisions that would normally be included in a GSR. The concerns underline the degree to which suppliers remain unsure about what will be expected from them. Basically, they are asking for clear policy direction from Health Canada with respect to a series of questions: what would be acceptable to demonstrate compliance i.e. that the product in question did not present an undue health risk; how much safety is ‘reasonable’ or ‘adequate’ for purposes of compliance; what decision-making process should be followed in product development; what criteria should ground the decisions that suppliers must make in the course of product development and distribution?

Outlined in more detail below are the concerns that were raised during the consultations:²⁵¹

- **Acceptable Standards, Regulations, Risk Assessment Process.** Suppliers have asked for clarification with respect to which standards, regulations, conformity assessment systems or risk assessment processes will be acceptable to demonstrate compliance with a GSR, and how these will be identified by Health Canada.

²⁵⁰ National Consultations on the Renewal of the Federal Health Protection Legislation, Minister of Public Works and Government Services Canada 1999, ISBN: 0-662-27596-9

²⁵¹ National Consultations on the Renewal of the Federal Health Protection Legislation, Minister of Public Works and Government Services Canada 1999, ISBN: 0-662-27596-9

- **Absence of an Acceptable Standard or Regulation.** Where, as is often the case, particularly regarding products that are new to the market or products for which no problem has previously been identified, suppliers would like to know how they will be able to demonstrate compliance with the GSR. Will it be necessary to develop a new standard? Will a detailed risk assessment be required, and, if so, according to which methodology?
- **Meaning of the Term “unsafe”.** The definition of the expected level of safety appears to be one of the key issues among those supplying consumer products to the Canadian market, for the meaning of the term “unsafe” is critical to understanding how to comply with a GSR.
- **Criteria for Reporting an Adverse Incident.** Suppliers have called for clarification with regard to their obligations to report adverse incidents. Will all incidents, however low their risks, be subject to reporting obligations, or will HC develop criteria and guidelines in this area, possibly along lines formulated in the United States and Europe.
- **Meaning of Exercising “Reasonable Care.”** Both manufacturing and retail sectors identified the concept of “reasonable care” as problematic. If steps are taken to choose an appropriate existing standard or regulation and to ensure that the product complies with the standard/regulation, suppliers believe that they will have exercised “reasonable care” to place a safe product on the market. However, they are concerned about their criminal liability if, after taking these steps, the product is associated, for any reason, with an adverse incident.
- **Overlap With Provincial/Territorial Legislation.** In certain product areas such as household electrical products and some foods, overlap will exist between provincial/territorial legal instruments and a GSR²⁵². As a result, it will most likely be necessary to develop a consensus among a number of government agencies and levels of government on such questions as the following:
 - How will the provinces/territories work with the federal agencies to implement a GSR?
 - Will the provinces/territories be able to draw on the provisions of the GSR and enforcement authorities provided under federal legislation to deal with importation, reporting and recalls?
 - To whom will reports of adverse incidents be made?
- **Absence of Injury Data and Research.** Suppliers point to the sheer volume of products available on the market and the lack of national injury data on product-related injury and death as factors that make the assessment of risks very difficult. Compounding the difficulty is the limited

²⁵² Case Studies 2 and 3, Annex 1

nature of product safety research. As a result, it will be difficult for both suppliers and government to determine the actual cause of the problem and the interventions that will be necessary to address it.

- **Accessibility of the Standards Making Process.** Concerns have also been raised about the standards making process including: the resourcing of the process; about the ability of all stakeholders, particularly small enterprises and consumer representatives, to participate; and about the possible domination of the process by large industry organizations.

Promoting Consumer Product Safety: Academic Perspectives

Academic interest in issues surrounding consumer product safety has grown significantly in recent years, in part as a consequence of trade-related considerations, and stimulating attempts to formulate a framework for comparative analysis.²⁵³ While the global marketplace presents substantial challenges on the basis of its complexity alone, it is still useful to consider the most basic elements of a generic product safety system.

In *European Regulation of Consumer Product Safety*, Christopher Hodges identifies five general techniques for controlling product safety.²⁵⁴

- Control of the design process;
- Pre-marketing assessment requirements;
- Control of the manufacturing environment and process;
- Post-marketing requirements on producers, distributors and the authorities; and
- Requirements of users.

As previously explained in this report, the GSR is a form of performance-based regulation relying heavily on industry self-regulation at the pre-marketing phase (i.e. the first three control techniques).²⁵⁵ Accordingly, government faces distinctive implementation challenges under a GSR regime in developing effective *post-marketing* compliance and enforcement measures. In several respects, of course, government's post-marketing responsibilities coincide with the ongoing responsibilities of manufacturers and distributors, but government responsibilities are extensive nevertheless. Hodges²⁵⁶ sets out a suggested framework for the post-marketing activities of authorities, namely:

²⁵³ Mathias Reimann, "Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?" (2003) 51 Am. J. Comp. L. 751; Geraint G. Howells, "The Relationship Between Product Liability and Product Safety – Understanding a Necessary Element in European Product Liability through a Comparison with the U.S. Position" (2000) 39 Washburn L.J. 305

²⁵⁴ Christopher Hodges, *European Regulation of Consumer Product Safety*, (Oxford University Press, 2005)85

²⁵⁵ For an analysis that heavily features the contribution of the design stage to consumer and environmental protection, see Professor Ashford's paper accompanying this report.

²⁵⁶ Hodges, *European Regulation of Consumer Product Safety*

- *Verification*: checking that economic operators have correctly and adequately carried out their functions and obligations, both pre-marketing and post-marketing;
- *Market surveillance*: identifying those products that have been placed on the market and are in use that are unsafe, so that steps can be taken to avoid or minimize any injury that they may cause;
- *Taking action*; ensuring that appropriate action is taken when safety issues are identified, so that the safety of users is subsequently maximized;
- *Collaboration*; sharing information with other regulatory authorities, economic operators, and consumers/users;
- *Enforcement*; imposing sanctions, or proposing to courts the imposition of sanctions on economic operators for non-compliance with legal obligations, and
- *Providing public information* such as through vigilance, information databases, answering questions from stakeholders about reporting thresholds, and possibly providing rulings on whether particular products meet the general safety requirement.

It is evident from the foregoing that a legislatively-mandated General Safety Requirement applicable to designated participants in the private sector network of product developers, manufacturers and distributors is not a self-administering regime. A substantial role remains for government to exercise responsibilities that are central, rather than merely residual to the success of the overall framework. Indeed, it is apparent that enhanced consumer safety will be the result of the cumulative effect and inter-action of efforts by both suppliers and regulators.

Not only are the responsibilities of government under a GSR vital to its effective operation, they will require the allocation of significant resources. Accordingly, before turning to the series of issues that are likely to arise in connection with the implementation of a GSR, we review in general terms the administrative tasks and resources that the GSR entails.

Administrative Tasks and Resource Implications

One illustration, drawing upon Hodges' discussion of government's responsibilities for verification, will serve to suggest the scope and nature of the implementation commitment that may arise.

To perform the verification activities required under a post-marketing GSR regime, public authorities must be equipped to assess risks (or to assess the suppliers' assessment of those risks) associated with potentially "dangerous products" on a case-by-case basis as they emerge. This will involve an ability to

address at least the following questions associated with the prior conduct of the producer or supplier.

- Has the producer assembled the technical documentation on the product's design, manufacture and accompanying documentation (labeling, assembly and operating instructions). Does this include a risk assessment, and has this material been kept up to date and available?
- Did the producer collect, record and collate safety information from users, retailers, distributors, regulators, or any other source, including scientific and technical literature, on how safe the product is in practice and whether it continues to conform to the standards of safety as these evolve in the light of new scientific and technical information?
- Where appropriate, did the producer adequately investigate negative (harmful) incident information?
- Did the producer undertake an adequate assessment of the information thus garnered? Did the producer make appropriate use of external technical, regulatory, medical, or legal advice? Has the product's assessment been suitably updated where warranted?
- Was information required in law to be reported to a regulatory authority adequately reported and on a timely basis?
- Did the producer respond appropriately to the results an original or updated product assessment? In particular did the producer (i) make changes in the design, manufacture, labeling, or packaging in relation to products not yet placed on the market, or (ii) take action such as informing users, distributors, regulators, or others of changes in potential risks with the product, or instituting a recall of products already on the market?²⁵⁷

In addition to a post-marketing verification role, generally conducted on the basis of audits or inspections, government authorities may be expected to perform a significant testing and advisory function and to develop extensive guidance material, especially for small business, to address multiple layers of uncertainty under the GSR. These uncertainties, and other matters to be resolved, include:

- What conditions of a product's use are 'normal' or 'reasonably foreseeable'?
- Which is the correct risk assessment methodology?
- According to designated thresholds or categorization framework, is a particular risk 'minimal', 'acceptable' or 'serious'? Should it be reported?

²⁵⁷ Hodges, 132

- What are the appropriate measures to be taken in recalling a product, or in rendering it 'safe?'

We make no attempt here to provide a comprehensive assessment of personnel, financial or systems resource requirements associated with verification, testing, advisory support or other governmental responsibilities under a GSR. It is possible, however, to summarize the tasks that must be addressed by Health Canada.

To ensure that the transition from the existing legislation to new legislation or regulations is smooth and seamless and that the Department will be able to deal with the new provisions and products that will be covered, it will be necessary for Health Canada to identify, develop and/or implement:

- Changes and/or additions to its management processes and knowledge management systems to meet new and changed provisions and authorities in new GSR legislation such as the adverse event reporting system. The impact will be significant for those parts of the organization or other organizations responsible for unregulated consumer products or foods where systems or processes for reporting of adverse events or dealing with mandatory recalls have not been established.
- Tools, information and training for employees who will need to administer and enforce new provisions applicable to many products not previously dealt with;
- Training, information and guidance documents (including web-based access) to provide previously unregulated suppliers with an understanding of how to comply with any new provisions;
- Functions of staff and the skills, expertise that staff will require to administer the new provisions in areas previously unregulated and to evaluate the various instruments that suppliers could use;
- Financial resources to develop and implement new systems for reporting, tools or training within Health Canada and other responsible government agencies e.g. Canadian Food Inspection Agency or Provinces/Territories and to hire expert analytical staff^{258, 259};
- A dispute resolution system;
- Personal information privacy protection arrangements; and
- Processes to ensure consistency in administration and enforcement for many new products across federal or provincial/territorial organizations that share responsibility.

²⁵⁸ The initial cost of establishing the Marketed Health Products Directorate in the Health Products and Food Branch for post market surveillance of drugs, biologics and natural health Products was \$10 million and 50 staff members. Health Canada press release 02-105156-410, April 2, 2002.

²⁵⁹ Annual cost for post market surveillance by PMRA of the 7-8 thousand registered pest control products is approximately \$7 million dollars and 83 staff members. PMRA Progress Report, 2003 at <http://www.hc-sc.gc.ca/pmra-arla/>

In addition, Health Canada will be required to provide Cabinet with accurate, complete and up-to-date information on the results of:

- An analysis of the proposal and the alternative solutions considered;
- Consultations with those who have an interest in the matter, including other departments that may be affected by the proposed solution;
- An analysis of the impact of the proposed solution on the operating environment and costs to small, medium and large suppliers; and
- An analysis of the resources that the proposed solution would require, including those needed to implement or enforce it.²⁶⁰

Specific Implementation Issues

The scope of potential resource requirements is further illuminated by a review of the principal implementation challenges, operational considerations and compliance issues that may be expected to arise. We turn now to the following aspects of the GSR:

Standard-setting

The Nature of Standards

In its most basic form, a standard is a “document, established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at achievement of the optimum degree of order in a given context.”^{261, 262} There are four main types of standards which include: product standards which define safety requirements, performance criteria, design criteria and tests to follow for specific products; process standards outlining production processes; management standards which set out requirements for organizational quality management practices; and conformity assessment standards which describe how to monitor and verify compliance with the requirements of a standard.

The Role of Standards

Standards, in one form or another, are critical to protecting the health and safety of Canadians, providing consumers with greater certainty about the quality and safety of products, and ensuring the efficient operation of national and international trade. Standards provide benefits such as defining accurate and necessary measurements, improving product safety and performance and addressing market failures such as risks to health, imperfect information and environmental degradation.

²⁶⁰ Justice Canada, *Cabinet Directive on Lawmaking*, 2003-07-08. Privy Council Office, *Regulatory Policy*, June 2000.

²⁶¹ ISO/IEC Guide 2:2004, Standardization and related activities, General vocabulary, definition 3.2.1.1

²⁶² Professor Ashford’s paper accompanying this report (Annex 12) contains further discussion of more varied meanings of standards in different jurisdictions, and including standards understood to be voluntary in nature.

The general public and voluntary organizations are concerned that the GSR might weaken regulations and that dependence on standards and voluntary codes could place the public at risk. Suppliers, on the other hand, would like to know what standards or voluntary codes would be considered acceptable to demonstrate compliance with a GSR. For example, they would like to know: whether voluntary codes or quality management systems adopted by industry or a retailer fall under the definition of a generally accepted standard; what criteria Health Canada will use to determine whether or not a standard is acceptable; and, whether or not Health Canada will identify the standards or instruments that are generally acceptable or provide a list of the standards that would confer an absolute defence of compliance similar to Europe.

The Standard-setting Process

A standard can be produced through the formal national and/or international standards system or through a more informal process by industry or organizations outside the formal standard-setting system. In the latter case, the document may or may not be subject to full public enquiry or established acceptance criteria that are required by the formal standards system. Although private and public interests may coincide in standard-setting, often they diverge where, for example, there are spillover costs such as health, safety or environmental impacts. Under such circumstances greater government involvement to ensure standards are written in the public interest may be required.

Other questions also arise: whether it is necessary for standards that are used to fulfill the policy requirements of a GSR to meet certain principles or criteria as outlined in the following table;²⁶³ would standards be lowered if harmonization was pursued; and would Health Canada be abandoning its responsibility to protect Canadians from hazards to their health.²⁶⁴

Checklist for assessing the acceptability of a standard/or instrument

Standards or instruments that conform to legislative and best design requirements must comply with the following criteria to ensure that:

- The standard, voluntary code or other instrument applies to the product or to similar products;
- The standard or instrument was meant to address all the risks and/or categories of risk associated with the product including the particular risk or hazard of concern;
- The standard or instrument does not contravene or conflict with requirements established in federal or provincial/territorial legislation or regulations;
- The standard or instrument is recognized as the norm by a significant number of suppliers in this segment of the industry;
- The standard or instrument setting process follows established recognized approaches and offers sufficient guarantees of integrity, objectivity, thoroughness, and sensitivity to consumer interests, to ensure that health and safety issues are adequately addressed;
- The provisions of the standard or instrument ensures a level of safety that is acceptable to the consumer;
- The standard is performance and outcomes based;
- The results of complying with the standard are measurable;
- The standard is based on available current technology and is reviewed regularly to

Another common problem regarding the use of standards to meet policy objectives is the cost and ease of accessing them. This both increases the costs to business of complying with legal requirements and limits the capacity of consumers to keep track of their legal entitlements.

Harmonization of standards and the adoption of international standards are not always considered to be suitable in Canada or acceptable to the public. For example, international standards may be inappropriate due to the Canadian climate and/or infrastructure, or they may be out of date, or not widely implemented around the world. Any decision to align with an international

Harmonization of Standards

During consultations, participants articulated a number of criteria for Health Canada to follow should it pursue harmonization of standards. These included ensuring that:

- The standards in the other countries are based on sound science;
- The mutually recognized standards are at least as high as our own;
- The agreements do not limit Health Canada's capacity to regulate products within Canada;
- The agreements do not limit Health Canada's capacity to conduct its own risk assessment and risk management; and
- The legislation should favor our official partners in international accords such as NAFTA, when global harmonization is not yet achieved.

It was also suggested that while Health Canada explores opportunities to pursue its mandate for health and safety through suitable international accords, the department might also work to ensure a comparable harmonization of standards across Canada.²⁶⁵

The reliance on standards will require substantial participation by government officials at the national and international levels to ensure that the standards developed address the health and safety concerns of Canadians. Moreover, the fact that many standards reference other standards increases the workload. Nevertheless, Health Canada's experience in other sectors (pharmaceuticals, medical devices and pesticides) has demonstrated that the criteria listed above can be met when the parties are prepared to work together to achieve them.

Assessment: Standard-setting in the Context of Core Principles of Regulation and Compliance Factors

The many and varied ways in which standard-setting might be undertaken to produce standards in any one of several forms clearly engage many of the core principles of regulation and the compliance factors previously identified. Given such variations it is impossible to do than to underline basic relationships such as:

²⁶⁵ National Consultations on the Renewal of the Federal Health Protection Legislation, Minister of Public Works and Government Services Canada 1999, ISBN: 0-662-27596-9

- The principle of transparency requires appropriate opportunities for participation in a process leading to understandable and accessible standards;
- The principle of consistency calls for a significant degree of similarity between and among standards for products presenting comparable or equivalent risks, however that equivalency is determined;
- The principle of evidence requires that standards be formulated with reference to available scientific and technical information, and, indeed, that efforts be made to enhance the availability of such evidence; and
- The principle of accountability suggests the importance of ensuring that mechanisms are in place to monitor the effectiveness of such standards as are set to provide for adjustments and refinements where the need is identified.

The manner in which standard-setting takes place has various implications, from the perspective of compliance, that affect the resulting levels of understanding. Opportunities for participation, or their absence, are among factors influencing the legitimacy or acceptability of standards, and hence the willingness of those subject to them to comply.

Industry Self-Regulation and Voluntary Codes

Introduction to Voluntary Codes

As previously noted, the GSR model encourages those responsible for products²⁶⁶ within the defined scope of the instrument to contribute to health protection in the course of business operations. While it is by definition a “requirement” and thus an instrument entailing the possibility of sanctions for non-compliance, its objective of promoting a “culture of safety” results in elements of its actual operation falling within the general realm of self-regulation.

Many factors in contemporary society encourage self-regulation. A sense of moral obligation may combine with the desire to preserve one’s reputation in the community or in the company of one’s peers. Appropriate self-regulation also constitutes what might be described as a form of insurance. For example, where an injury has occurred, a suitable program of self-regulation may offer some assurance against liability in tort. Or, where conduct amounting to a breach of certain statutory requirements has occurred, self-regulatory measures may provide a defense in criminal proceedings. In the context of these examples, a standard for self-regulation must be met. In the former circumstance, the degree of self-regulation must exceed the degree of care associated with negligence, while in the latter, the degree of self-regulation must meet or exceed a level of performance otherwise known as due diligence. In either situation, (and we

²⁶⁶ This includes primary suppliers/producers and secondary suppliers/distributors as described in Fig 1 Annex 1

consider them to be roughly equivalent,) therefore, so-called self-regulation is subject to assessment against some independent legal standard.²⁶⁷

Responsible parties seeking to conduct their operations in a manner that will avoid liability or conviction reasonably inquire about the standard or benchmark of performance they should seek to achieve. On the assumption that they have met that standard, they then expect to avoid liability or conviction if an injury or statutory violation should arise despite the care they have taken.

The precise nature of voluntary codes remains the subject of academic debate. It is useful for introductory purposes here to include one formulation, simply to benchmark the concept under consideration:

Voluntary codes are one example of a private regulatory instrument – a system involving a set of non-legislatively required commitments agreed to by one or more private firms that are designed to influence firm behaviour, and are to be applied in a consistent manner by all signatories.²⁶⁸

In discussion of voluntary measures as a source of standards, it has been observed that:

Voluntary standards can be particularly effective benchmarks, because they are specifically intended to establish a level of ‘good practice.’ The more widely such standards are used, within and across industries, the greater their weight in the courts.²⁶⁹

It was noted, however, that there are variations in the legitimacy or credibility of such standards. Credibility is enhanced, “if they are developed through an inclusive, open and transparent process, with input from all relevant stakeholders, including government, industry and non-governmental organizations.”²⁷⁰

Oversight and Procedure for Self-Regulation and Voluntary Standards
On the subject of voluntary standards, the Canadian government has regarded such codes as appropriate as internal standards for industry, but remained concerned about its own ongoing obligations to monitor and report to Canadians about what is going on. There are potential liabilities - legal and political - associated with voluntary codes.²⁷¹

²⁶⁷ Voluntary Codes: A Guide for Their Development and Use (Industry Canada, March 1998). For a discussion of the equivalence of the due diligence and negligence standards, see Diane Saxe, ISO 14001 and Compliance in Canada, (CSA Special Publication, PLUS 1162, July 2001) 2-3

²⁶⁸ David Cohen, “The Role of the State in a Privatized Regulatory Environment” in Kernaghan Webb ed. Voluntary Codes: Private Governance, the Public Interest and Innovation (Carleton Research Unit for Innovation, Science and Environment, Carleton University, 2004) 35

²⁶⁹
²⁷⁰ Saxe, 7. See also, Voluntary Codes: A Guide for Their Development and Use (Industry Canada, March 1998)

²⁷¹ Voluntary Codes: A Guide for their Development and Use (Industry Canada, March 1998)

Canadians, when consulted on a GSR, were divided on the question of allowing industry to regulate itself.²⁷² The view was expressed that industry has a responsibility, as a good corporate citizen, to regulate itself and that self-regulation is in industry's interest, since harming the consumer is never good business. On the other hand, industry self-regulation, without appropriate checks and balances, was not felt to provide an acceptable level of proof that the requirements were followed, particularly for products that can impact significantly on the health of the public. It was concluded that Health Canada needed to be involved and not surrender its responsibilities or its decision-making authority.

Voluntary codes, a type of industry self-regulation, provide an example where government oversight can be incorporated. Voluntary codes or codes of conduct, if well designed and properly implemented, can be very effective tools in demonstrating compliance with the GSR. The advantage of a voluntary code is that it can include elements that are not always possible for inclusion in a regulation such as purchasing and process controls, or qualifications of staff that can be audited by an independent third party.²⁷³ The safety requirements can also significantly exceed those specified in a regulation or a national standard. In considering a voluntary code to demonstrate conformity with the GSR, preference should be given to those that are certified or audited by independent third parties or that are joint government/industry initiatives monitored by the government. These types of voluntary codes that are monitored or audited could provide the public with proof that the code was in fact followed.

The challenge for government officials and suppliers is to know when a voluntary code or code of conduct will be successful and which elements will contribute to its success. The same criteria as outlined above for choosing an appropriate standard will apply and, in addition, the following general requirements for an effective voluntary code or initiative should be considered:

- The leaders of the organization promote the use of the codes;
- The employees of the organization understand the code, its objectives and their role;
- The aims, roles and responsibilities are clearly articulated;
- The objectives and results are measurable and are verified;
- The development and implementation is open and transparent with the participation of stakeholders;
- Regular monitoring and public feedback on how the code is working, are obtained;

²⁷² Health Canada Working Document, *National Consultations 2004, Renewal of Federal Health Protection Legislation*.

²⁷³ ISO standards, for example, provide for external certification and may involve regular verification and review procedures. It is also possible for insurance arrangements to call for disclosure and verification in ways that amount to independent external monitoring. See for purposes of illustration, Larry Reynolds, "New Directions for Environmental Impairment Liability Insurance in Canada," (1996) 6 J.E.L.P. 89.

- An effective and transparent dispute resolution system is in place;
- A mature industry or an industry association is able to ensure compliance of its members to the code; and
- There are meaningful inducements to participate or businesses have self-interest in changing their behavior with negative repercussions for failure to join or comply.²⁷⁴

Research into best practices for the Corporate Executive Board provides discussion of a range of corporate experience for managing product safety and quality.²⁷⁵

Criteria for Choice: Regulation or Voluntary Standards?

Bearing in mind the potential attractions of voluntary measures when properly formulated and effectively put into operation, it is still necessary to determine when reliance on voluntary measures is or is not a suitable alternative to regulation. We must therefore ask when voluntary standards are likely to be inappropriate as an alternative to regulation. Or, to reverse the perspective, “When to regulate?” is a question that is closely related to the issue of choices about the utilization of voluntary standards in promoting the safety of consumer products.

The UK Consumer Safety Review in the mid 1970’s considered when formal regulation was appropriate and developed a series of factors to be taken into account in determining whether to regulate or not, or to adopt some alternative approach to dealing with a consumer safety issue. The criteria developed by the Review as to the proper use of prescriptive regulations are instructive in that they help identify the scope of operation of a general safety requirement.

The factors that the Review Committee suggested be taken into account in considering proposals for UK regulations were:

- Evidence whether the goods in question are being widely sold; the degree of risk which they present and the cost to manufacturers ultimately to consumers, of eliminating or reducing the hazard;
- Whether a British Standard, or other suitable specification on which regulations can be based, exists;
- Any proposals for harmonization of safety requirements under consideration within the EEC; and
- Whether voluntary action the trade itself is prepared to take is likely to be effective in reducing or removing the hazards and the risk of such action being undermined by lack of co-operation from a minority of manufacturers or importers.[Para 30]

²⁷⁴ Industry Canada and Treasury Board Secretariat, *Voluntary Codes: A Guide for their Development and Use*, March 1998

²⁷⁵ Corporate Executive Board

Assessment: Voluntary Standards in the Context of Core Principles of Regulation and Compliance Factors

Somewhat ironically, voluntary standards may be considered in the context of core principles of regulation as well as in relation to compliance factors. Some of the issues to arise from this include:

- To ensure transparency, voluntary standard-making procedures should provide for some form of public or third party involvement;
- Consistency may be promoted within the context of voluntary standards by adopting procedures and incentives that encourage comprehensive participation across the relevant industry sector or product category;
- The involvement of external reviewers or expert public interest participants alongside verifiable assessment procedures may increase the extent to which evidence-based decision-making is achieved; and
- Challenges surrounding accountability may be addressed even in voluntary schemes through community involvement, the use of performance targets, and public reporting.

In principle, compliance may be facilitated through the use of voluntary standards on the basis that they ought to be understandable by those subject to them; and that their willingness to comply should be largely assumed on the basis of their adoption by consent, which is most likely to rest upon a self-assessed ability to perform according to expectations. Yet all of this must be cautiously approached with reference to the appropriateness of the regulator's independent determination about whether to regulate or not.

Risk-based Decision Making

One of the core elements in the implementation of a GSR or similar regulatory instruments in the context of consumer product safety is the formulation of effective frameworks to identify and address risk, including risk assessment, risk management, and risk communication procedures.²⁷⁶ While these arrangements will vary somewhat in relation to the particular product and context for manufacture, distribution and use, it is possible to identify general characteristics in the overall framework that are expected to be found.

On the basis of a detailed and comparative review of twelve major risk frameworks currently utilized in the areas of human health, ecological and occupational health risk, a recent publication provides an overall guide to what might be considered key elements and a checklist of best practices. The key elements include:

- Problem formulation stage;
- Stakeholder involvement;
- Communication;
- Quantitative risk assessment components;

²⁷⁶ Cindy G. Jardine et al, "Risk Management Frameworks for Human Health and Environmental Risks," (2003) *Journal of Toxicology and Environmental Health* 569. William Leiss, *In the Chamber of Risks*

- Iteration and evaluation;
- Informed decision-making; and
- Flexibility.

A proposed checklist, possibly characterized as a best practices approach would involve the following:

- Make sure you are solving the right problem;
- Consider the problem and the risk within the full context of the situation, using a broad perspective;
- Acknowledge, incorporate, and balance the multiple dimensions of risk;
- Ensure the highest degree of reliability for all components of the risk management process;
- Involve interested and affected parties from the outset of the process;
- Commit to honest and open communication between all parties;
- Employ continuous evaluation throughout the process (formative, process, and outcome evaluation), and be prepared to change the decision if new information becomes available.²⁷⁷

Information is an essential ingredient of any risk framework. It is, in effect, the foundation of an evidence-based approach that provides the basis for the selection of appropriate instruments to reduce risks, the determination of an unsafe product, the identification of effective interventions and the reporting of adverse health effects. The type of information needed to identify any hazards and assess the risk includes the following:

- Any accident, incident or malfunction data related to the product or similar products;
- Design drawings or other means of establishing the nature of the product;
- Limits of the product such as durability, life span of parts or deterioration due to weather;
- Identification of all intended or possible users and anyone who may come into contact with the product;
- Vulnerability of the users - the age and physical and psychological characteristics of the users such as strength, motor skills, experience, anthropometrical characteristics; and
- Information on the environment in which the product will be used, exposure of other persons and impact on non-users.

These information elements can have a more important role to play when no regulations, standards or codes exist to address the problems identified.

The knowledge obtained about the hazards and risks associated with a product make it possible for the supplier to establish measures such as design changes, manufacturing or distribution controls, or improved consumer information that will

²⁷⁷ Jardine et al

reduce the risk. In this way, one can imagine progress towards a “culture of safety,” while suppliers will be in a better position to demonstrate that all “reasonable care” has been taken to market a safe product and thus to support a successful due diligence defence should the need arise to do so.

Indeed, potential proposals outlined within the framework of Health Canada’s Legislative Renewal Paper specifically cited “guiding principles on risk decision-making” for their relevance to “reasonable care.” As summarized in the Renewal Paper:

the assessment of risk should be based solely on science and objective observation; potential positive and negative effects for the people must be weighed; the concept of precaution will be applied; the desire of individual Canadians to make informed decisions concerning their own health will be recognized; consideration will be given to the fact that the same measure may impact differentially on various people; and the connection between human health and the environment must be acknowledged.

In many cases, however, there are gaps in the evidence needed to carry out a risk assessment, making it difficult for those responsible to comply with new provisions. In the case of new products, in particular, significant information gaps must be explored through testing and experimentation, on the basis of comparisons with related, if not identical experience, and so on. Yet many companies, even large ones, do not have the expertise or capacity to assess risks in products. For example, manufacturers in other countries do not always make information about product design, component materials or manufacturing processes available to importers, and there is a lack of product related injury data within Canada. Not only does this make it difficult for a supplier to determine whether a product is safe, but it also makes it difficult to identify the inventions that will correct any problems. The need for increasing the data available and the knowledge of suppliers about hazard identification and risk assessment is central to the successful implementation of the GSR or similar regulatory provisions. Data limitations will continue to limit the ability of independent risk assessment specialists to provide professional services in this area that will be of particular relevance to small and medium-sized ventures that will less-readily be able to provide in-house capacity in this area.

Assessment: Risk-based Decision-making in the Context of Core Principles of Regulation and Compliance Factors

The acknowledgement of risk and of the need for effective management responses in regulatory settings has become sufficiently widespread that a significant literature has emerged.²⁷⁸ For present purposes, it is sufficient to

²⁷⁸ Archibald, Judd and Roach *Regulatory and Corporate Liability: From Due Diligence to Risk Management*; W. Leiss, *In the Chamber of Risks: Understanding Risk Controversies* (McGill-Queen’s University Press, 2001); J. Steele, *Risks and Legal Theory*; C. Hood ed. *The Government of Risk*; E. Fisher, *Risk Regulation and Administrative Constitutionalism*; J. Fraiberg and M.J. Trebilcock, “Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform,” (1998) 43 McGill L.J. 835

remark that risk-based decision-making may be assessed with reference to the core principle of regulation previously identified:

- Even the forms of stakeholder participation encouraged as elements of best practices will not, in and of themselves, contribute in any significant degree to transparency and consultation as those concepts are understood as core principles of regulation;
- For risk-based decision making carried out in the pre-market stage by manufacturers and suppliers to operate in a consistent manner, certain important external influences will be required; these might include a clear statement of expectations from regulators, firmly understood professional standards within the ranks of risk management advisors and consultants, and effective insistence of the reasonable care standard through civil or regulatory enforcement;
- Risk-based decision-making offers important opportunities to incorporate and take account of all available evidence, thereby attaching the procedure firmly within the realm of evidence-based approaches;
- Elements of best practices for risk management, notably appropriate problem identification, information-based decision-making, and flexibility in response to changing assessments would contribute to effectiveness; and
- Accountability for pre-market risk management procedures undertaken by manufacturers and suppliers is unlikely to arise apart from civil or regulatory proceedings in the aftermath of injuries, at which point compliance with the standard of reasonable care or due diligence may be formally tested.

Information Management: Reporting, Monitoring, and Surveillance

In contrast with pre-market assessment and approval schemes where government regulators have advance opportunities to assess the risks associated with the proposed introduction of a product or substance, the GSR - from a government perspective - is largely a post-marketing regime. Accordingly, the availability of ongoing information and the capacity to respond appropriately to emerging risks revealed by that flow of information are essential components of the GSR approach to enhancing consumer product safety. The effective implementation of a GSR calls for integration of supplier and regulatory operations.

Reporting Obligations of Suppliers

Legislative commentary prepared by the department anticipates that suppliers²⁷⁹ (any person who manufactures, imports, distributes, promotes or markets a product or an activity) would be responsible for “reporting adverse health incidents, as prescribed by regulation”. (B3.2.3) In addressing offences or prohibitions, the legislation is expected to establish that “no person shall fail to report adverse health incidents, as prescribed by regulation.”(B2.7)

²⁷⁹ A more complete definition is found in Fig 1, Annex 1

An initial observation with regard to the reporting requirement is that it serves, even within the context of a general safety requirement, as a residual safety net. It exists to provide a systematic basis to identify and where appropriate to respond to situations in which an unsafe consumer product may have entered the market-place either because pre-market assessment failed to identify or effectively assess some form of risk, under-estimated the likelihood or severity of a risk, or because such assessment was not, in fact, ever undertaken.

No regulations, standards or codes exist that specify how a report should be made, the criteria or the level of safety that would initiate a report of an adverse health incident, the content of the notification or to whom the report should be made. In order to establish the mechanisms necessary to collect and report these data, guidance in terms of establishing criteria for reporting and reporting procedures is required.

In general, we can identify several components of the reporting obligation:

- The threshold or trigger: What degree of severity is required to constitute an adverse incident of a reportable nature?
- Form of reporting: What information is required in a report? In what manner is it to be presented? To whom is it to be provided?
- Timeliness: Within what period of time from the moment a supplier has knowledge of an adverse incident should the report be provided?

There is clearly room for variation in relation to each of these elements. If the threshold is set too low, there is a risk that minor or trivial incidents might overwhelm the capacity of officials to perform review functions effectively. The information provided needs to be responsive to the nature of the hazard while respecting victim privacy and other elements of the legal process. With regard to the latter, it may be worth highlighting that suppliers are required to report adverse incidents; they are not required to report that they have or may have committed an offence relating to an unsafe product or products. As noted and explained in the Case Study Report, it must also be determined whether reports would be submitted to Health Canada in Ottawa, to regional offices, or to provincial or territorial officials.²⁸⁰

Reports should be provided in a timely manner, but requirements must permit some reasonable compliance period, bearing in mind the varied capacities of those subject to the reporting requirement and the existence of a penalty for failure to comply. In connection with timing, for example, several options would appear to be available. Reports might be required on a uniformly fixed delivery schedule, either at fixed intervals, or within a fixed number of days of a reportable incident. Or, reporting requirements might vary depending upon the severity of the incident, with injury reporting allowing for a longer delay than in

²⁸⁰ Annex 1

circumstances involving death. Generic or notional requirements are also possible, taking the form of “forthwith,” “immediately,” or “without delay.”

While each of these matters remains to be determined, we can nonetheless look to experience in other settings for some guidance as to what might be involved. Sources of such guidance include the European and American contexts where similar issues have already been addressed and other Canadian legislation where adverse incident reporting requirements presently exist. This information is consolidated in Annex 8.

Monitoring and Surveillance Measures

In addition to the administrative requirements associated with providing guidance to suppliers in connection with the reporting obligations that form a vital part of the GSR model, public authorities will be expected to implement a significant number of additional measures. These include:

- Verification measures of the kind noted above to confirm information provided by suppliers;²⁸¹
- Monitoring and surveillance activities that may be undertaken independently by departmental officials in connection with a compliance program, e.g. inspection, testing, data gathering from other sources (inter-governmental exchange; consumer groups; medical and hospital reports); and
- Follow-up measures that may be undertaken in response to adverse incident reports or the results of monitoring and surveillance activity: e.g. if one retailer reports an adverse incident or incidents, does this trigger interest on the part of HC to make more active inquiries with other retailers for confirmation or otherwise of the unsafe product risk?

Reporting, monitoring and surveillance measures in a post-marketing context such as that presented by the GSR will often become the initial point of interaction between suppliers and regulators. This is in contrast, for example, with other models of regulatory supervision in which pre-market product approvals are required (pharmaceuticals, medical devices, food additives, pesticides, and so on,) or where market entry itself is subject to prior authorization (broadcasting, commercial fishing, and so on.)

How regulatory officials will manage this initial interface in relation to post-marketing reporting and surveillance therefore remains to be determined. We note only that the manner in which this is done will be extremely important from the perspective of compliance and enforcement, and thus to the effectiveness of the GSR. The OECD has, on occasion, addressed some of the associated challenges. Given limited regulatory resources, how should they best be deployed to promote regulatory goals? One approach involves so-called tiering:

²⁸¹ See above, for Professor Hodges’ description of verification tasks.

A significant development is to use risk analysis to identify targets of possible low compliance. Enforcement agencies are beginning to decide when and where to do inspections by analysis of data on where risks of non-compliance are likely to be highest. Tiering is an important tool for this task since not all regulated entities can be monitored or inspected all the time. It is very important to have a rational system for deciding which to target.

Those regulated can be tiered according to size – ranked according to the number of employees, operating revenues, assets or market share. This may be useful because larger enterprises may be judged to present a greater risk because of the pure quantity of breaches they can produce, for example, the quantity of pollution or employee injuries or customer dissatisfaction. ... Other risk analysis-based factors for targeting inspections include geographic location (e.g. whether a manufacturing plant is close to where people live or to environmentally sensitive areas), previous violations (whether those with a history of recidivism should be targeted), and the age of the facility (older plants may be judged more risky than newer ones).

Another useful way for regulators to target enforcement efforts in such a way that resources are used most efficiently is to tailor inspections according to the risk represented by individual firms determined by their own ability to comply, including their own attempts to meet those risks. For example, if an enterprise has conducted its own risk analysis and put in place its own compliance system, then it may warrant lower priority for inspection, than one that has not. When that enterprise is inspected, then the inspector may only check the functions and outcomes of the enterprise's own compliance system, rather than conduct various inspections to determine whether specific rules have been violated.²⁸²

Assessment: Reporting, Monitoring and Surveillance in the Context of Core Principles of Regulation and Compliance Factors

Although initial reporting is largely a responsibility of private sector suppliers, the manner in which government responds to adverse incidents and the manner in which it proceeds with arrangements for inspection and surveillance may be considered with reference to core principles of regulation and compliance factors:

- Transparency is clearly relevant to the criteria government might establish in terms of reporting obligations;
- Consistency in the manner in which inspections and surveillance and follow-up measures are implemented in relation to comparable degrees of risk will also be an objective; and
- Opportunities to increase the effectiveness of GSR monitoring arrangements may arise from the regulator's ability to learn from experience with the regime and to adapt it in a flexible manner where improvements can be identified.

²⁸² “Reducing the Risks of Policy Failure: Challenges for Regulatory Compliance,” 35

Reporting is one dimension of the GSR regime where the level of compliance will be very closely associated with both clarity of understanding around what is to be reported, when and to whom, as well as with the ability to regulators to encourage high levels of performance through their own investment in inspection procedures and follow-up monitoring.

Current Situation

It is appropriate to appreciate the nature of existing arrangements, for as the Case Studies on Implementation accompanying this report indicate, forms of recall are presently available under other pieces of legislation along with authority to issue interim orders which may perform similar or analogous functions. Illustrations of their use are also provided in the Case Studies paper. For present purposes, one example will serve.

The Canadian Food Inspection Agency Act, based upon concurrent federal regulatory authority over Agriculture, authorizes recall under conditions set out below:²⁸³

Recall order

19. (1) Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister.

Contravention of recall order

(2) Any person who contravenes a recall order referred to in subsection (1) is guilty of an offence and liable on summary conviction to a fine not exceeding \$50,000 or to a term of imprisonment not exceeding six months or to both.

Notification of order

(3) For greater certainty, a recall order is not a statutory instrument for the purposes of the *Statutory Instruments Act*, but no person shall be convicted of an offence under subsection (2) unless the person was notified of the order.

Recalls pursuant to section 19 which involve a ministerial recall order are “mandatory” in nature and are announced formally under the heading “Health Hazard Alert – Minister Orders Mandatory Recall.” More commonly, however, it is understood that the CFIA encourages “voluntary” recalls, which are then announced simply as “Health Hazard Alert.”

Ministerial recall orders under section 19 are rare. Among these, the Aylmer Meat Packers case (Fall 2003) is comparatively well-known. The Konjac Mini

²⁸³ Canadian Food Inspection Agency Act, S.C. 1997, c. 6, s. 19.

Cup Jelly Products experience of November 2001²⁸⁴ has been described in the Case Studies accompanying this report. Other examples of where mandatory recalls were ordered:

- Labonté brand Natural Honey from Blueberry Blossoms (April 2004);²⁸⁵
- Janes brand Battered Mozzarella Sticks (March 2002);²⁸⁶
- Rajah brand Tandoori Masala (October 2003);²⁸⁷ and
- kid3.com Capsules (June 2003);²⁸⁸

Although there was litigation in relation to Aylmer,²⁸⁹ the most relevant judicial discussion of the recall power for present purposes arose in the aftermath of *Labonté* where the impugned party sought judicial review of the order.²⁹⁰ In *Labonté* the manufacturer sought three declarations to quash the order, to review the grounds on which it had been issued and to affirm that its entitlement to procedural fairness had not been satisfied:

D'annuler l'ordonnance du Ministre;

De déclarer que l'ACIA et le Ministre n'avaient aucun motif raisonnable de croire que le miel naturel liquide de fleurs de bleuet portant le code de production 033196 ("le miel de la demanderesse") représentait un risque pour la santé publique;

De déclarer que l'ACIA et le Ministre ont violé leur devoir d'équité en ne permettant pas à la demanderesse de connaître au préalable les raisons invoquées par l'ACIA, les données scientifiques dont elle disposait et la méthode d'analyse qu'elle appliquait, et de présenter ses contre-expertises.²⁹¹

The application for judicial review was rejected.

In issuing his very thorough reasons Justice Noël, noted that the recall power could be asserted on the basis of reasonable grounds for believing that a product presented a risk to public health:

À mon avis, il ne faut pas voir cette question comme une question de compétence. La LACIA dit que le rappel peut être ordonné *s'il y a des motifs raisonnables de croire qu'un produit présente un risque pour la santé publique.*²⁹²

²⁸⁴ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2001/20011121e.shtml>

²⁸⁵ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2004/20040403be.shtml>

²⁸⁶ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2002/20020302ce.shtml>

²⁸⁷ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2003/20031031e.shtml>

²⁸⁸ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2003/20030604be.shtml>

²⁸⁹ *Aylmer Meat Packers Inc. v. Ontario*, [2006] O.J. No. 2296 (Ont. S.C.J.)

²⁹⁰ *Miel Labonté Inc. c. Canada (Procureur général)*, [2006] A.C.F. no 247 (F.C. (T.D.))

²⁹¹ *Labonté*, *supra* note 2906 at para. 2.

²⁹² *Ibid.*, at para. 16. [Emphasis added.]

Thus, the only criterion is the reasonable belief of CFIA that the product represents a public health risk. In delivering his reasons Justice Noël points to research on which CFIA was entitled to, and obviously eventually did, rely concerning the health effects of nitrofurans, which in turn CFIA could reasonably believe were contained in the manufacturer's honey.²⁹³

In carrying out the “pragmatic and functional analysis” to determine the standard of judicial review, Noël noted that the decisions of the Minister (or Agents thereof) are discretionary, and therefore subject to a heightened degree of judicial deference.²⁹⁴ After completing the entire analysis, His Honour decided that section 19 decisions were reviewable by a court solely on the “patently unreasonable” standard.²⁹⁵

In deciding whether or not the manufacturer had received the “procedural fairness” to which it was entitled in the context of the recall order, Justice Noël concluded that where public health was involved, procedural entitlements would be limited:

De toutes ces considérations, je conclus que *l'obligation d'équité procédurale est très limitée* en l'espèce, et que la démarche suivie par l'ACIA est correcte. *Dans un contexte où la santé publique est en jeu*, on devrait donner à la personne intéressée l'occasion de collaborer, l'informer de la nature de la décision envisagée et lui transmettre le résultat des analyses et des raisons justifiant cette décision.²⁹⁶

In concluding that the recall order was legal, Noel J. noted the reasonable risk that CFIA was attempting to avoid. That risk, coupled with the fact that the product was widely available to consumers on store shelves justified the use of the recall power. On these grounds, the recall order was upheld, and the application for declarations quashing the order, was rejected.

It is also important to appreciate the circumstances in which “voluntary” recalls may be encouraged. These voluntary actions in fact take place against the backdrop of a “government-imposed” recall. The so-called ‘gorilla in the closet’ in the form of the section 19 authority serves as an effective inducement for voluntary product withdrawals. An example of the mandatory recall power being reserved is the following:

²⁹³ See *ibid.*, at para 44: L'expression "motifs raisonnables" signifie à mon avis, comme le dit le juge Mackay dans l'affaire Friends of Point Pleasant Park, précitée, au para. 49, qu'"*une certaine preuve [...] doit exister à l'appui de [la] décision*". En l'espèce, le Ministre disposait d'une preuve abondante de nature à le convaincre qu'il existait un risque pour la santé publique. [Emphasis added.]

²⁹⁴ See *ibid.*, at para. 31.

²⁹⁵ See *ibid.*, at para. 37. “L'analyse pragmatique et fonctionnelle me mène donc à la conclusion que la norme de contrôle applicable à une décision rendue par le Ministre en vertu du paragraphe 19(1) de la LACIA est celle de la décision manifestement déraisonnable.”

²⁹⁶ *Ibid.*, at para. 68. [Emphasis added.]

OTTAWA, February 1, 2005 - The Canadian Food Inspection Agency and Natrel are warning the public not to consume Sealtest brand 1 % Chocolate Milk described below. This product may be contaminated with a chemical sanitizer.

The affected product, Sealtest brand 1 % Chocolate Milk, is sold in a 1 L carton bearing UPC 0 64420 00170 2. The affected code FE 07 appears on the carton near the spout. No other codes are affected.

*The manufacturer, Natrel, Don Mills, Ontario, is voluntarily recalling the affected product from the marketplace. The product has been distributed in Ontario.*²⁹⁷

It is assumed by observers that had Natrel *not* “voluntarily” recalled the product, CFIA would have proceeded with section 19 authority.

Countervailing Considerations

Notwithstanding an outcome favourable to the exercise of the recall power in *Labonté*, the case alerts us to important underlying considerations. The recall power is a forceful tool in the enforcement arsenal for consumer protection. Its utilization entails the exercise of administrative discretion, which must not only be defensible in substantive terms, but must also accord with the requirements of procedural fairness. As well, precipitous or unreasonable use of a recall power in Canada might result in a *Charter* challenge on the basis that it is an unreasonable seizure, or to a claim for civil damages associated with allegations of negligent *over-enforcement*.

Safeguards

When the UK expanded the powers of administrative officials to halt the sale of goods suspected to be dangerous under the *Consumer Protection Act, 1987*, the Government also took care to balance the new powers with additional safeguards, including providing compensation for errors of preliminary judgment about the safety of goods.

Bearing in mind that potential damage to life and limb can be permanent, there is a strong case for authorities to have wider powers to halt the sale of consumer goods where there are grounds for believing them to be dangerous. In the event that the initial suspicions cannot subsequently be confirmed it would be fair that the trader concerned should receive compensation for the loss from the authorities. Wider discretion to authorities to protect the general public should not, therefore, involve penalizing accidentally suppliers whose goods are safe.²⁹⁸

The GSR, however, broadens administrative discretion exponentially because uncertainty in defining which products are ‘safe’ or ‘unsafe’ leaves administrative officials with an ultimate discretion to act against goods they consider to be

²⁹⁷ <http://www.inspection.gc.ca/english/corpaffr/recarapp/2005/20050201e.shtml>. [Emphasis added.]

²⁹⁸ *The Safety of Goods*, A Report presented to the UK Parliament by the Secretary of State for Trade and Industry, July 1984, Cmnd. 9302, para. 24

unsafe even where they conform, presumptively, to an approved or published standard. Some commentators in the U.S. regard such reliance on voluntary standards as a form of ‘back-door Regulation by administrative officials. This also helps to explain the evolution of the European principle of ‘proportionality’ as a check on administrative action.²⁹⁹

The limitations placed on the recall power in Europe well illustrate the application of the proportionality principle to the recall power. An *administrative* recall order (one made by administrative officials intended to have immediate effect, based on findings of fact made by enforcement officials) is a highly intrusive and extraordinary measure to be used where no other suitable remedy is available, and only in the face of serious risks to public health or safety. It is an injunctive remedy not to be used as a colorable means of circumventing the judicial process for obtaining mandatory injunctions, or as a simple alternative to prosecution. Its purpose is to achieve the (safety) objective where there are no reasonable alternative remedies.

The preamble of the revised GPSD recites the need for additional obligations to be placed on producers including, “*as a last resort*” the duty “to recall (dangerous products) when necessary, which may involve (depending on the provisions applicable in Member States) an appropriate form of compensation, for example exchange or reimbursement.”³⁰⁰ The Preamble of the GPSD goes on to provide that, where producers fail to act, Member States are to be provided with the power

To order or organize, immediately and efficiently, the withdrawal of dangerous products already placed on the market and *as a last resort to order, coordinate or organize the recall from consumers of dangerous products* already supplied to them. Those powers should be applied when producers and distributors fail to prevent risks to consumers in accordance with their obligations. Where necessary, the appropriate powers and procedures should be available to the authorities to decide and apply any necessary measures rapidly.³⁰¹

The operative provisions of the GPSD provide for producers to undertake ‘voluntary’ recalls at the request of a competent authority. Article 5 1(b), provides that:

Recall shall take place *as a last resort where other measures would not suffice to prevent the risks involved*, in instances where the producers consider it

²⁹⁹ The ‘Proportionality Principle’ enables the European Court of Justice to review not only the procedural fairness of administrative decisions (the main focus of Canadian administrative law), but also to review the substantive policy or enforcement decisions (including decisions of a legislative nature) where the actions taken by an authority are ‘disproportionate’ to the risk being addressed. Under a GSR regime, uncertainties surrounding the definition of ‘safe product’ and the residual discretion left to officials in this regard, blur the distinction between legislative and administrative decisions.

³⁰⁰ 2001/95/EC, Preamble, para (19)

³⁰¹ *Ibid.*, para 23

necessary or where they are obliged to do so further to a measure taken by a competent authority. It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.

Under Article 8 (f), Member States are empowered, in relation to any dangerous product still on the market:

(ii) to order or coordinate or, if appropriate, to organize together with producers and distributors its recall from consumers and its destruction in suitable conditions.

In undertaking powers of direct action, competent authorities are expressly bound by Article 8 (2) to adhere to the 'Proportionality Principle':

When the competent authorities of the Member States take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f), they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, *in such a way as to implement the measures in a manner proportional to the seriousness of the risk and taking due account of the precautionary principle.*

In this context, they shall encourage and promote *voluntary* action by producers and distributors, in accordance with the obligations incumbent on them under this directive, and in particular Chapter III thereof, including where applicable by the development of codes of good practice.

If necessary, they shall organize or order the measures provided for in paragraph 1 (f) if the action under taken by the producers and distributors in fulfillment of their obligations is unsatisfactory or insufficient. *Recall shall take place as a last resort.* It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.

The United Kingdom strenuously resisted the recall power in the consumer products area for many years, fearing excessive and disproportionate use by officials. When Europe finally mandated the recall power under Europe's 'revised' GPSD, the UK delayed transposing the revised Directive until appropriate safeguards were developed as a check on administrative discretion in using this draconian power. The recall power was the most controversial element of the transposition process.³⁰²

In the Regulatory Impact Statement accompanying the UK regulation transposing the revised GPSD, four options were considered to allay the concerns of the business community about the introduction of the recall power, namely:

- Option 1 – Make no special provisions; let the Trading Standards Officers administer the new power;

³⁰² *Final Regulatory Impact Assessment on the Implementation of Directive 2001/95/ EC, General Product Safety*, July, 2005, para. 7.2

- Option 2 - Create a National Decision-Making Body to make consistent and binding decisions and to address Business concerns about over use of the new power;
- Option 3 – Establish an Advisory Process which would provide non-binding advice on recalls; and
- Option 4 – Make recall subject to an application to a Court for an order.³⁰³

Option 1 was rejected as being unresponsive to business concerns. Option 2 was viewed as too costly, given the limited use likely to be made of such a body since most recalls are undertaken on a voluntary basis. Option 4 was rejected owing to the delays anticipated in the Court process (six or more months) and the likelihood of inconsistent decisions by different courts.

Option 3 – creating an advice-based mechanism – became the preferred option because:

Discussions with the Chartered Institute of Arbitrators (CI Arb) developed a strong case for developing a bespoke form of Early Neutral Evaluation. (ENE) that would deliver a reasoned opinion by a former member of the Judiciary on a recall case based on the evidence presented by the parties. The benefits included an independent if non-binding review of the facts, relative speed and simplicity (requiring no more than two to four weeks per case) and the scheme's adaptability to ad hoc and infrequent use.³⁰⁴

The UK transposed the revised General Product Safety Directive in the *General Product Safety Regulations, 2005*³⁰⁵. The recall provisions, including provision for referring factual issues on a recall to an evaluator appointed by the Chartered Institute of Arbitrators, are contained in section 15 of the *Regulation*. The advisory scheme for Product Recall under the General Product Safety Regulations, 2005 is described in detail in Annex B to Guidance Notes prepared by the Department of Trade and Industry styled *Guidance for businesses, consumers and enforcement authorities*.³⁰⁶

Assessment: Remedies in the Context of Core Principles of Regulation and Compliance Factors

Experience elsewhere suggests the need for a range of remedial responses, including, typically as a last resort, the use of the power to recall consumer products that are considered to be unsafe. This approach may be assessed with reference to several principles of regulation and from the perspective of compliance.

- A significant theme in the discussion of remedies is the importance of proportionality to ensure that measures suitable to a variable range of

³⁰³ *Ibid.*, para. 7.

³⁰⁴ *Ibid.*, para. 7.19

³⁰⁵ Statutory Instrument 2005, No. 1803

³⁰⁶ Accessed on July 13, 2006 at <http://www.dti.gov.uk/files/file22713.pdf>

- concerns around different degrees of product safety and supplier behaviour are available to enforcement officials; and
- Although the Labonté decision suggests that, at least in the context of a potentially harmful food product already in circulation, the procedural obligations of decision-makers contemplating a recall may be modest; nevertheless procedural obligations reinforce the principle of transparency.

It is equally worthwhile noting that effective remedial measures to promote compliance are central elements of the GSR approach. Notwithstanding that this approach is intended to promote or strengthen a culture of safety within the ranks of suppliers, it will be necessary to have an enforcement capacity in place.

9. Product Liability Legislation, Negligence and Statutory Due Diligence

Expectations for a GSR and their Relationship to Existing Law

The suggestion is made in Health Canada's issue paper on GSR that "(r)esponsible makers of products are already exercising due diligence and addressing the health or safety risks in their products, thus conforming with the General Safety Requirement." As quoted elsewhere in this report, in the context of introducing a GSR requirement to the consumer setting, the UK DTI expressed one of its objectives as follows: "The Government's intention is to encourage more efficient use of existing resources by facilitating better identification of unsafe goods before they are distributed and streamlining the procedures for halting their supply."

By implication, the Health Canada comment suggests that those who currently meet the standard of due diligence are essentially in conformity with the GSR as proposed, while the DTI observation focuses on improvements to be made in the "better identification of unsafe goods before they are distributed." Whether these two government perceptions are inconsistent, and, if so, whether they can be reconciled is of some importance.

If some significant element of Canadian businesses potentially subject to the GSR are essentially in conformity already, it might be assumed that behaviour changes and adjustment costs on their part will be modest, but so, presumably, will any overall improvement in the safety of consumer goods for which they are responsible; that is, the job is already (largely) being done. The DTI objective, on the other hand, does appear to focus quite explicitly on a problem – unsafe goods – with the intention of identifying them in advance and curtailing their distribution, a task that is to be accomplished on the basis of using existing resources more efficiently. Taken together, admittedly in isolation from their own broader contexts, the two departmental observations do highlight the importance of conclusions articulated by the OECD in connection with considerations that

can reduce the risk of policy failure. In particular, government objectives (other than more regulation) must be precisely defined; the targets of regulation need to be clearly identified (everyone, some sectors only, particular problem areas); expectations should be communicated in a fully understandable way and measures of success/failure determined. [OECD]

Existing Legal Requirements to Exercise Care Regarding Consumer Product Safety

Because this report is particularly concerned with some of the implications – for industry and government - of introducing a GSR, it is worthwhile to consider briefly the status quo. An understanding of how the current legal framework encourages or supports actions to ensure consumer product safety is a pre-condition for understanding how a GSR might alter that framework, and in so doing, alter the behaviour of those who would be subject to its obligations in such a way as to produce better outcomes.

Apart from several specific areas where regulations applicable to consumer products have already been introduced, (for example, in relation to children's safety,) two general fields of law have the potential to promote consumer safety. The first of these is the statutory law of product liability. The second is tort liability, notably the law of negligence, (*les delits*) and corresponding dimensions of Quebec's civil law regime. Each is briefly considered here in turn.

Product Liability Legislation

Consumer protection legislation is widely understood to address issues associated with financing and credit transactions or the quality of items purchased from a sale of goods perspective. However, certain provincial jurisdictions have introduced provisions dealing with issues around product liability.

In New Brunswick, section 27(1) of the *Consumer Product Warranty and Liability Act* states:

A supplier of a consumer product that is unreasonably dangerous to person or property because of a defect in design, materials or workmanship is liable to any person who suffers a consumer in the loss because of the defect, if the loss was reasonably foreseeable at the time of his supply as liable to result from the defect.

It is of further interest in connection with this report to observe that section 27(1)(c) refers explicitly to the significance of federal standards. Thus, liability under the provincial statute might arise where:

...the defect arose in whole or in part because of (the supplier's) failure to comply with any mandatory federal standards in relation to health or safety, or the defect caused the consumer product to fail to comply with any such standards.

Suppliers are understood to be strictly liable under the legislation on the basis of section 27 (4), which indicates that “the liability of a person under this section does not depend on any contract or negligence.”

The Consumer Protection Act of Quebec as expressed in the *Civil Code* is also relevant to the existence of liability for failing to meet product safety requirements. Articles 1468 and 1469 state:

1468. The manufacturer of a movable property is liable to reparation for injury caused to a third person by reason of a safety defect in the thing, even if it is incorporated with or placed in an immovable for the service or operation of the immovable.

1469. A thing has a safety defect where, having regard to all the circumstances, it does not afford the safety which a person is normally entitled to expect, particularly by reason of a defect in the design or manufacture of the thing, poor preservation or presentation of the thing, or the lack of sufficient indications as to the risks and dangers it involves or as to safety precautions.

Other related provisions refer to circumstances in which a manufacturer or supplier is exempt from liability. In addition to the influence of “superior force,” or the victim’s knowledge of the defect, according to Article 1473:

... Nor is (the manufacturer, distributor or supplier) liable to reparation if he proves that, according to the state of knowledge at the time that he manufactured, distributed or supplied the property, the existence of the defect could not have been known, and that he was not neglectful of his duty to provide information when he became aware of the defect.

Should the decision be taken to proceed with the introduction of a GSR at the federal level, attention will need to be directed to inter-action between federal and existing standards and requirements in a legal and operational sense. Some indication of the necessary co-ordination is illustrated in the Case Studies accompanying this report. For present purposes, product liability provisions of the kind noted here are simply set out to indicate that, along with general principles of negligence law, they constitute elements of the existing legal framework that is intended in some respects to encourage the safety of consumer products in Canada.

Negligence: Liability for Unsafe Consumer Products

In turning to negligence law, we may note as a point of departure the foundational decision of *Donoghue v Stevenson* where Lord Atkin observed:

A manufacturer of products, which he sells in such form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up

of the products will result in an injury to the consumer's life or property owes a duty to the consumer to take reasonable care.³⁰⁷

From this basis Canadian negligence law in relation to consumer protection has evolved to the point that a recent doctrinal summary expresses the situation this way:

The duty of care may now be restated as a duty to take all reasonable steps necessary in the design, manufacture, distribution, advertising and sale of products to protect the public from unreasonable risk of harm, including the duty to provide adequate warnings and to recall products subsequently found to have any defect in their design, manufacture or warnings.³⁰⁸

In addition to manufacturers, parties now subject to a duty of care in relation to consumers also include those responsible for product assembly and repair, as well as persons involved in the distribution of products. The rationale for this extension was addressed in *Phillips v Ford Motor Co. of Canada*, where the court explained that a distributor places itself in a relationship – for profit – with the consumer and is accordingly responsible to that consumer for defects that ought to have been discovered by a distributor exercising reasonable care.³⁰⁹ In the words of Dean F. Edgell, distributors owe a duty to “use reasonable care in selecting, inspecting, testing, packaging and handling products.”³¹⁰

As previously suggested, the scope of potentially-harmful activity for which a defendant might be held responsible in the event of injury is broad. It encompasses three general categories: design defects, manufacturing defects or failures to provide adequate or appropriate warnings. Each of these may be briefly described.

The existence of a design defect, as explained by Lewis Klar, is generally determined with reference to a series of factors considered relevant in establishing whether a product creates an unreasonable risk:

- The utility of the product to the public as a whole and to the consumer;
- The likelihood of harm;
- The availability of a safer design;
- The costs, both in terms of functionality and the price of the safe design;
- The ability of the consumer to avoid harm by careful use of the product;
- The ability of the consumer to become aware of the risks; and
- The manufacturer's ability to spread the costs related to improving the safety of the design.

³⁰⁷ [1932] A.C. 562 (H.L.) at 599

³⁰⁸ L.G. Theall et al., *Product Liability: Canadian Law and Practice* (Aurora: Canada Law Book, 2005 at L1-7)

³⁰⁹ [1970] 2 O.R. 714

³¹⁰ Edgell, *Product Liability Law in Canada* (Toronto: Butterworths, 2000) 62

A detailed examination of case law and commentary would be necessary to demonstrate in a more comprehensive and nuanced way the manner in which these considerations figure into the judicial assessment of alleged design defects. Some basic elements of analysis must suffice. Firstly, inherently dangerous products may nevertheless be valuable to consumers.³¹¹ Although the consumer's unintended use of a product might still result in liability for injuries from a design defect where the use was foreseeable, this is not considered likely where the consumer used a product "in flagrant disregard of the manufacturer's express instructions or recommendations."³¹² Failure to adopt a safer design may well be determinative, however, unless the less satisfactory design creates some benefit that outweighs the risk.³¹³ Courts may also refer to industry standards to determine whether a defect exists, bearing in mind the conduct of competitors and the risks associated with other products of similar kind.³¹⁴ In connection with an underlying objective of the GSR to promote a culture of safety, it is also worthwhile to observe that manufacturers may be found negligent for failing to test adequately for potential defects.³¹⁵

In addition to potential liability for defects in design, situations may arise in which the alleged negligence is associated with the manufacturing process. In the case of a manufacturing defect, potential liability arises where a discrete unit of the product in question fails to meet the specifications called for in relation to products of that kind. As explained by Denis Boivin, the defect is attributable to poor production or manufacture rather than to poor design. In other words, even when the design, blueprint or conceptualization of a product is not defective, specific or discrete units may nevertheless be defective as a consequence of manufacturing deficiencies, even while other units do not exhibit similar deficiencies.

Boivin further observes that a manufacturing defect, by comparison with a defect in design, is relatively easy to establish where a plaintiff can point to the difference between the impeached unit and other examples of the same product, and indicate how the difference renders the defective product dangerous or unsafe.

Other elements of a negligence action in relation to manufacturing defects remain to be established. Did the manufacturer's performance fall below the standard of care required in the circumstances? Factors relevant to this determination (that is, whether a manufacturer exercised reasonable care in the course of production) will be considered again shortly in relation to due diligence, but include:

³¹¹ Edgell, 56

³¹² Theall, L2-5

³¹³ *Nicholson v John Deere Ltd.* (1986), 58 O.R. (2d) 53 at 56

³¹⁴ Theall, L2-9, L 2-10

³¹⁵ Edgell, 55

- The manufacturer’s knowledge of the deviation, or its foreseeability;
- The probability of the deviation occurring; and
- The costs of prevention.

As a matter of practice, however, Klar indicates that where a plaintiff can establish that a particular product contained a manufacturing defect when it left the plant, and that defect was the cause of his damages or injuries, “the inference of negligence is practically irresistible.”

Manufacturers’ liability may arise in a third respect, that is, in relation to the duty to warn consumers of known dangers in the foreseeable use of the product. The rationale for this obligation was discussed by the Supreme Court of Canada in *Hollis v. Dow Corning Corp.* where it was stated that “[t]he duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed choices concerning the safe use of the product.”

When ‘failure to warn’ cases arise, courts are called upon to assess the adequacy of any warning provided by the manufacturer. They do so in relation to the level of risk associated with normal product use. Again, as stated in *Hollis*:

The nature and scope of the manufacturer’s duty to warn varies with the level of danger entailed by the ordinary use of the product. Where significant dangers are entailed by the ordinary use of the product, it will rarely be sufficient for manufacturers to give general warnings concerning these dangers; the warnings must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from use of the product.

Not only must the warnings address “specific dangers” associated with the product, but the duty to warn is a continuous one which does not cease at the point the product has left the manufacturer’s premises. A manufacturer who learns after a product is on the market of a risk associated with that product has a continuing duty to communicate to consumers about that risk. Particularly high standards in respect of warnings apply to inherently dangerous goods and in relation to drugs and medical products. When these cases come forward, the burden rests with plaintiffs to demonstrate that the manufacturer’s warning was not effective, and that, had they been warned effectively, the injury would not have occurred.

In respect of each of these areas – design, manufacture, and warnings – the existence of potential liability in negligence is understood to provide incentive or encouragement for reasonable care to be taken to ensure consumer safety. In so far as this is equally a stated objective of the GSR proposal, it is worthwhile to observe that considerations of foreseeability, of product testing, of effective communication about risks, including “new” risks are already part of the law of negligence relating to consumer products.

What Does the GSR Change?

Returning to the previous discussion of remarks by Health Canada and the British DTI concerning expectations for a GSR, it is important to consider particular objectives in light of present circumstances. The rationale for adding a GSR to the incentives for safety found in existing product liability statutes or tort law, may take one or more of several forms. A GSR will certainly be intended to alter the framework in some manner. Perhaps the existing set of incentives does not operate entirely effectively,³¹⁶ or perhaps there are distinct gaps in its applicability. Thus, for whatever reason, it is understood that some manufacturers of consumer products are insufficiently motivated by the current tort regime.

In the minds of some observers, it might be thought that even if the compensatory goal of tort law is realized through the existing negligence regime, a firmer preventive thrust is called for than tort alone can deliver. From this perspective, it might be assumed that the GSR can provide a more effective stimulus to take care because as a statutory principle its existence may be more readily communicated to industry, or that because the GSR establishes a framework for responsibility anchored (in the Canadian context) in the criminal law power, obstacles to tort law enforcement such as the rules on legal fees, or access to class actions will not apply. For the moment we defer discussion of this latter possibility, apart from noting that the effective operation of a GSR scheme will require resources to support compliance and to pursue enforcement.

Reasonable Care and Due Diligence

We turn next to a matter still closely linked to the form of behaviour encouraged by negligence law where it is presumed to operate effectively. To avoid liability in tort, a defendant manufacturer must be found to have performed at a level that is non-negligent. In other words, the manufacturer will not be liable where its behaviour satisfies the standard of reasonable care. It is therefore appropriate to recall essential features of reasonable care in the tort context as further background to a consideration of how a GSR might affect the conduct or level of performance and consequently of safety in relevant industry.

In determining whether the standard of care has been met, courts will inquire into, (in addition to the range of factors mentioned above in discussion of different aspects of product liability negligence): "... the risk of potential harm... and where that potential harm is great, the reasonable manufacturer acting prudently will be expected to consider (foresee) even a small risk of that harm occurring and to take reasonable steps to avoid it."³¹⁷

³¹⁶ Dewees and Trebilcock, 1992

³¹⁷ Edgell, 18

In order to consider whether a GSR regime would call for a greater or different level of care, some transitional remarks are in order. Firstly, we may note that in the context of GSR, in particular in the context of possible conviction for an offence, the defendant will have available a defence of 'due diligence.' It is therefore of interest to inquire (speculate?) as matters of law and as matters of practice affecting the substantive level of safety that might be expected in consumer products in Canada how reasonable care and due diligence compare one with the other.

Proving Reasonable Care and Due Diligence

A brief procedural point can be noted. In negligence litigation, the burden rests on the plaintiff to establish according to the civil standard of proof (balance of probabilities) and in addition to all other elements of the tort, that the defendant has not acted with reasonable care. Should the defendant wish to introduce evidence on its behalf it will do so for the purpose of casting doubt on the plaintiff's case, but the defendant in negligence does not have to establish affirmatively that it did, indeed exercise reasonable care in the circumstances. On the other hand, where an offence under the GSR regime is alleged and reaches trial where "unsafeness" is proven according to the criminal standard (beyond a reasonable doubt), the accused will have the opportunity to establish a defence of due diligence, an evidentiary burden that rests upon it and must be met according to the civil standard of proof. We do not, at this point, consider it necessary to elaborate upon this procedural issue for the reason that we assume actual prosecutions will be rare events and the GSR regime is fundamentally oriented towards the challenge of encouraging a culture of safety more generally for preventive purposes.

Are Negligence and Due Diligence Equivalent?

A conceptual matter also arises: whether negligence and due diligence are equivalent. Some indication of current thinking is provided by Archibald, Judd and Roach in their new loose-leaf service on *Regulatory and Corporate Liability: From Due Diligence to Risk Management*. In addition to stating that the negligence standard is "central to due diligence," they observe:

A violation of a regulatory statute by itself may be some evidence of negligence, but is not determinative of the issue. In the same way, a violation of the actus reus of a regulatory statute may be proven by the prosecution, but is not determinative without the consideration of due diligence.³¹⁸

Another way of explaining the relationship between the concepts is to observe that:

The reasonable person is negligent if his or her conduct creates an unreasonable risk of harm. Due diligence turns this concept on its

³¹⁸ Ibid. at 4-16.

head by requiring the defendant to show that he or she was not negligent, and that he or she took appropriate steps to avoid an unreasonable risk of harm.³¹⁹

In the recent regulatory decision in *R. v Petro-Canada*, Justice Smith of the BC Court of Appeal further explains due diligence by remarking that:

in principle the defence is that all reasonable care was taken. In other circumstances, the issue will be whether the accused's behaviour was negligent in bringing about the forbidden even when he knew the relevant facts.³²⁰

For present purposes, we conclude that the conduct that might be encouraged on the part of potential tortfeasors in order to avoid liability for negligence is substantially equivalent to the level of care that might be undertaken by the same parties in order to ensure themselves of the availability of a due diligence defence under a GSR.

It is still worthwhile to describe further some of the factors that would be relevant to judicial determination of due diligence, should the need for such a determination arise in connection with the GSR. Although particular variations in the statutory language might raise issues around how due diligence would actually apply under the GSR, we can usefully report a range of observations on what is expected by those who may be called upon to present a due diligence defence, for this is – in general terms - the standard of behaviour one would ordinarily expect responsible manufacturers, distributors and suppliers of consumer products to strive for in regular operations. Professional and judicial commentary helps to highlight the role of industry standards, variations between large operations and the situations of SMEs, reliance on third parties (including expert consultants) and so on, in meeting a due diligence test.

“Due diligence” was introduced to Canadian law by the Supreme Court of Canada in *R. v Sault Ste. Marie*³²¹ where Dickson J explained that, in order to invoke the defence, a defendant must prove that it took all reasonable care to avoid committing the regulatory offence. This it was explained:

involves consideration of what a reasonable [person] would have done in the circumstances. The defence will be available if the accused reasonably believed in a mistaken set of facts which, if true, would render the act or omission innocent, or if he took all reasonable steps to avoid the particular event.³²²

Stranz, writing in 1992, credits the *Sault Ste. Marie* decision with changing the legal landscape by “changing the legal and business considerations necessary

³¹⁹ 4-17.

³²⁰ From *R v. Petro-Canada*, reproduced at page 4-3 of Archibald.

³²¹ ...and expanded upon in *Wholesale Travel*.

³²² *R v. Sault Ste. Marie (City)*, [1978] 2 SCR 1299.

for proper risk analysis.”³²³ This two-part analysis exercise consisting of the assessment and management of risks is very closely related to expectations for a culture of safety that might be engendered by a GSR. Risk assessment refers to identifying potential harm or risk while risk management is associated with responses to those risks, once identified. Due diligence, certainly in the context of consumer products would appear to entail both phases or stages, that is, both the identification of risks and responses to them.³²⁴

Due diligence is factually contingent or context sensitive. Courts will look at the “facts of each case, and the particular industry or activity involved”.³²⁵ Archibald, Judd and Roach remark that:

The assessment of due diligence by way of a defence...incorporates industry standards, technological standards, and choices about the management of risks. The analysis may be one of risk analysis in reverse since a prohibited event has occurred. The exercise may be one of looking backwards to estimate whether the mishap could have been prevented with appropriate risk management.

How then might one, looking backwards, go about demonstrating that due diligence was exercised. Otherwise put, what might courts take into account in evaluating a due diligence defence? As one court has emphasized: “it is the employer’s specific reasonable care or non-negligence in relation to the statutorily-defined actus reus of the particular offence that is determinative and not a general state of reasonable care or non-negligence.”³²⁶

Archibald *et al*, offer the following list of factors that might be taken into account. No ranking has emerged in the jurisprudence, and in some instances, the factors defeat each other.³²⁷

- **The nature and gravity of the adverse effect**

The nature and gravity of the adverse effect is understood to refer to “the scope of the defendant’s preventative efforts [is] in proportion to the potential gravity of the adverse effects that may occur”.³²⁸

*R v. Ontario (MOE)*³²⁹ stands for the proposition that a corporate defendant might rank the source of harm or injury as a lesser priority than other concerns and still avail itself of the due diligence defence. In that case, the defendant allowed a damaging substance to seep into a waterway from a leaky pipe. The leaky pipe was a low priority relative to

³²³ Stranz, *supra*.

³²⁴ See e.g. Archibald, 4-2, 4-15, 4-31.

³²⁵ Stranz, *supra*.

³²⁶ *R v. Cancoil Thermal* (1988), 1 COHSC 169 (Ont Prov Ct), cited in *Modern Niagara, infra*, at para 134.

³²⁷ 4-53

³²⁸ 4-27.

³²⁹ Unreported: June 27, 2001, Ont. Court of Justice

the mining company's other concerns, such as dangerous mine shafts. The court accepted as valid the argument that the pipe was a lower priority than life threatening conditions in the mine. Yet Archibald et al point out that the leaky pipe could not be set aside indefinitely. Rather, in looking at due diligence, "[t]he relative priority and timing of the remediation of the seep is the issue."³³⁰

- **The foreseeability of the effect, including abnormal sensitivities**
The "foreseeability of the effect," is a consideration that can be traced to the 1988 *Rio Algom* case, which explained, "the issue is whether a reasonable person would have foreseen the danger of the event occurring, and not merely whether this defendant in fact foresaw it."³³¹ The more recent case of *R v. MacMillan Bloedel Ltd.*³³² affirmed that the "foresight required will vary with the level of expertise generally acceptable in a given industry, and a link can be made to the factor of industry standards."
- **The alternative solutions available**
The due diligence assessment may also entail asking whether any alternative solutions were available to the defendant other than those it chose to employ. As explained by Archibald *et al*, "[c]ourts have found that reasonableness of care is often best measured by comparing what was done against what could have been done." The defendant must establish on the civil standard that no feasible alternatives existed that might have avoided this harm.³³³
- **Legislative or regulatory compliance**
Legislative or regulatory compliance is the fourth factor listed by Archibald *et al*.³³⁴ "The focus of the due diligence test is the conduct which was or was not exercised in relation to the 'particular event' giving rise to the charge, and not a more general standard of care."
- **Industry standards**
In relation to the role of industry standards in due diligence, Stranz notes that the standard of due diligence may change with time: the defence evolves with our scientific and technological knowledge.³³⁵ Archibald *et al* urge caution with regard to industry standards, for these:

May serve to perpetuate old practices that are not necessarily the best practices. A related concern is that industry may well

³³⁰ 4-27, 28.

³³¹ *R v Rio Algom*, (1988) 3 CELR (NS) 171 OCA

³³² 2002) 220 DLR (4th) 173 (OCA)

³³³ 4-29. Referring to *R v Gonder* (1981), 62 CCC (2d) 326 (Yukon Territorial Ct.)

³³⁴ 4-31: *R v Imperial Oil Ltd.* (2000), 148 CCC (3d) 367 (BCCA)

³³⁵ Having reproduced this quote, I realize that Stranz wrote in 1992. I have supplemented her writing with more current cases and doctrine and have only cited her assertions that are not outdated. She does, however, provide a useful framework in which to analyze the defence.

set standards that are lower than the regulatory scheme contemplated and, through the operation of due diligence, the ultimate standards would be lowered.³³⁶

In discussing *R v. Modern Niagara Toronto Inc*, Mary Beth Currie³³⁷ explains that

“the courts rejected the defence that compliance with industry standards automatically provides a due diligence defence in a regulatory prosecution. In fact, the prevailing view was that industry standards are irrelevant if they do not meet the minimum statutory requirements.”

Under the rubric of industry standards, here are some specific measures courts have viewed favourably in the context of the due diligence defence:

- The hiring of a chemist to offer a peer review of technological solutions; and
- Reliance on comparative data if the information in Canadian industry is not wide enough to develop proper standards.³³⁸

- **The character of the neighborhood**

Courts will also look at the efforts made by a defendant to address the problem. Pointing to *Amoco Fabrics*, the authors note two bases of liability leading to a possible due diligence defence: the initial spill and an inadequate response to the incident.³³⁹ The authors note that actions of the accused after the charge period should not be relevant to the due diligence defence unless they fall within a narrow rule of evidence.³⁴⁰

- **What efforts have been made to address the problem**

The next factor to assess under due diligence is the period of time in which the event occurred and the promptness of the defendant’s response. The authors explain that the essence of the defence requires the accused to lead evidence regarding pre-charge steps they took to avoid the incident.³⁴¹ In environmental cases where the damage is ongoing, (possibly analogous to continuing consumer exposure to unsafe products that have entered the marketplace,) the authors explain that, “a defendant will be liable for the continuing discharge up until the time when the defendant intervenes in a reasonable manner.”³⁴²

³³⁶ 4-32.

³³⁷ “Due Diligence more than standard” <http://www.ohscanada.com/LawFile/dueDil.asp> (Accessed: May 2, 2006).

³³⁸ In *R v. Amoco Fabrics and Fibres Ltd.*, (1992), 73 CCC (3d) 558 (Ont Prov Div.) cited at 4-33, the court approvingly considered the sequential steps taken by the defendant to remediate a contaminated site in the context of standard American practice..

³³⁹ Ibid.

³⁴⁰ 4-36.

³⁴¹ 4-37.

³⁴² 4-38.

- Over what period of time, and promptness of the response**
 Courts will also consider “matters beyond the control of the accused.” This factor considers what possible solutions the defendant can carry out given “technological limits.” Archibald explains that this consideration speaks to technology during the charge period.³⁴³
- Matters beyond the control of the accused, including technological limitations**
 A further factor on the list is the “skill level expected of the defendant.” It is understood that higher standards of conduct are required of “sophisticated” defendants, although the inexperience of a less developed firm will generally not constitute a defence. That both of these principles seem to work against the defendant, speaks to a concern that reliance on the skill of the defendant will undercut regulatory standards or lower standards.^{344 345}
- Skill level expected of the accused**
 Reliance on consultants is also singled out as a common issue in due diligence. The authors explain: “[t]he extent to which courts will permit a due diligence defence based on reliance on consultants is directly proportional to the degree of experience of such consultants.”³⁴⁶ In this context, courts will assess whether a particular consultant was appropriately qualified.³⁴⁷
- The complexities involved**
 The “complexities involved” are also taken into account. If a defendant, in good faith, takes a great deal of time to deal with a matter in order to find the best solution, courts might take this into account in considering due diligence. This must be distinguished from instances where a defendant is “dawdling” to avoid spending money to rectify the problem.³⁴⁸
- Preventative systems**
 Courts may also have regard to preventative systems put in place by the defendant. More specifically, courts consider “whether a given violation is an anomaly within a legitimate prevention program, or whether it is symptomatic of a larger failure in the organization.”³⁴⁹

³⁴³ Archibald points to *R v. Hen-Sieg Holdings Ltd.* (1996) 21 CELR (NS) 57 (Ont. CJ), where the defendant remediated a contaminated site to the best of anyone’s efforts or knowledge in the field.

³⁴⁴ 4-42, 43.

³⁴⁵ 4-42. In *R v. Imperial Oil*, (2000), 148 CCC (3d) 367 (BCCA) the “sophisticated” defendant was not allowed to rely on testing of a harmful substance done by a third party which did not deem it toxic; given its stature, Imperial Oil ought to have carried out its own tests. Imperial Oil ought to have been familiar with the substances used in its operations..

³⁴⁶ 4-44.

³⁴⁷ Ibid.

³⁴⁸ Ibid.

³⁴⁹ 4-46.

- **Economic considerations**
“Economic considerations” speak to economic factors that courts will weigh in assessing whether a defendant behaved reasonably; these are one group of factors that the court will examine.³⁵⁰ While courts are mindful of the reality of economic circumstances, they are also reluctant to allow defendants to use lack of resources as a justification for environmental or occupational offences.³⁵¹
- **Actions of officials.**
The final item on the due diligence inventory is “Actions of government officials”: “the advice, actions or lack thereof, and opinions of government officials are factors in considering the defendant’s knowledge of the problem and solutions.” The authors suggest that this is a difficult factor to establish, as the defendant will still be expected to act diligently, advice notwithstanding.

Regulatory Liability of Public Authorities

In general, lawsuits against governments are on the rise, especially in areas of environmental and health regulation. The reasons for this include:

- Changing societal demographics calling for greater demands on the health care system;
- Progress in medical science making a wider variety of more expensive pharmaceuticals and technologies available;
- The desire of aggrieved plaintiffs to seek redress from responsible parties with adequate resources to pay damages, and, when such defendants are not available, to avail themselves of the perceived “deep pockets” of government;
- The desire of aggrieved plaintiffs to prod government officials into taking a particular course of administrative action;
- The desire of aggrieved plaintiffs to make a ‘political statement’;
- The availability of class actions; and
- The fact that Canada has become a more litigious society generally, in which there are higher public expectations of a duty of care on government.³⁵²

³⁵⁰ 4-46, 47.

³⁵¹ 4-48, citing *R v. International Graphite* (unreported, Feb 28, 2003 ON Ct. (Prov. Div.)) Archibald et al also include a subsection on “Economic Considerations and Government Defendants”, explaining how economic considerations affect public bodies, such as Crown Corporations. See pp. 4-49 ff.

³⁵² Jack Coop, *Public Law Liabilities and Litigation: The Latest and Most Significant Issues*, February 3, 2005, Ontario Bar Association Institute of Continuing Legal Education, p. 2

The enactment of a general safety requirement as part of a new Canada Health Protection Act (CHPA) raises a number of regulatory liability issues for Health Canada. These include:

- ***The Government's private law duty of care under the proposed CHPA***
Will the new Canada Health Protection Act (in particular, the GSR provision) be construed by the Courts as a statute envisaging that decisions made by officials will be of the type that raise a private law duty of care³⁵³ to individuals or particular segments of the public, on the one hand, or only to the public-at-large, on the other?
- ***Immediate increase in scope of regulatory responsibility under the GSR***
How can Health Canada manage its policy and operational decisions effectively to minimize the Government's increased exposure to regulatory liability resulting from an immediate, exponential increase in its regulatory authority for all currently unregulated products and unforeseen product risks following the enactment of a GSR?
- ***Greatly expanded advisory functions under the GSR / Negligent Misrepresentation***
How far will Health Canada's extensive advisory functions under the GSR lead to increased exposure to claims against government based on negligent misrepresentation, as officials try to help industry deal with the multiple uncertainties associated with administering a GSR regime? (Which standards apply? What constitutes compliance? Etc.)
- ***Implementing risk-based strategies – Reporting Requirements / Enhanced Risk Assessment / Duty to Warn or to Act***
Will Health Canada be under an enhanced duty to warn consumers of products risk, or to act more expeditiously against non-compliers based on better information about dangerous products under more effective reporting requirements and complaints programs instituted under a new GSR regime, that is, where producers fail to discharge their primary duty to warn under the GSR? Having better identified specific product risks through enhanced risk assessment strategies and better injury data collection, will Health Canada have the capacity (resources and skills) to deal with those risks under its compliance and enforcement policies where industry has failed to act responsibly?
- ***Proper use of significantly increased official discretion under GSR – 'Over-enforcement'***

³⁵³ For example, to effectively supervise the self-regulatory responsibilities of industry; to warn the public when industry fails to meet their responsibilities and place members of the public in danger, or to act to mitigate or remediate the danger when industry fails to do so.

How will Health Canada manage the greatly increased enforcement discretion Health Canada's officials have to proceed with 'general safety violations' under a GSR to minimize damage claims based on negligence resulting from over-enforcement?

It is well established in Canada that a public authority's private law duty of care toward individuals is determined in accordance with the two-step analysis first enunciated by the House of Lords in *Anns v. Merton London Borough Council*:

First one has to ask whether, as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity or neighborhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause damage to the latter — in which case a prima facie duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negate, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise.³⁵⁴

Much of the recent case law under this test has focused on the requirement that there be the "requisite proximity of relationship" between government and individuals adversely affected by government action to found a private law duty of care. "Proximity" is established by three methods: a) by establishing that the case falls within categories of proximity already recognized by the courts;³⁵⁵ b) by showing an actual proximate relationship on the facts of the particular case, or c) by showing that the governing statute establishes the proximity necessary upon which to found an actionable private law duty of care.³⁵⁶

Private Law Duty Emanating from the Governing Statute(s)

In the case of *Mitchell Estate v. Ontario*³⁵⁷, the plaintiff alleged that the Ontario Government had been negligent in its under funding and restructuring of the of the health care system resulting in delayed emergency room treatment and the consequent death of an infant. While the court might have dismissed this case on the basis that it involved an attack on a traditional '*policy*' decision concerning the allocation of funds to health care and health care institutions, instead, the Court closely examined the duties implied under the legislative scheme to determine whether it contemplated the creation of a private law duty of care toward individuals. The Court concluded it did not.

³⁵⁴ [1978] A.C. 728, at pp. 751-52:

³⁵⁵ For example, an act foreseeably causing physical harm, negligent misstatements, where a duty to warn has been recognized, misfeasance in public office, road maintenance cases, and municipal inspection cases.

³⁵⁶ *Cooper v Hobart* (2001) S.C.C. 79, at para's. 36 and 41-43

³⁵⁷ [2004] 242 D.L.R. (4th) 560 (Div. Ct.)

These provisions show that the Minister has a public duty to 'promote and assist in the development of adequate health resources, both human and material, in Ontario'. Nothing in the Act gives the Premier of the Minister of health or any Ministry official authority to supervise the day-to-day operations of a hospital or medical and nursing staff.

Thus, the governing statutes make it clear that the Minister has a wide discretion to make policy decisions with respect to the funding of hospitals. The legislative framework gives the Minister the power to act in the public interest, and in exercising her powers, she must *balance a myriad of competing interests*. The terms of the legislation make it clear that *her duty is to the public as a whole not to a particular individual*.³⁵⁸ (Emphasis added)

In the case of Health Canada under a GSR regime, however, the department is likely to have day-to-day responsibility for overseeing the effectiveness of self-regulatory activities of producers, suppliers and importers of consumer products. One of the effects of increased litigation against government is the "continuing pressure by plaintiffs to strain the boundaries of conventional tort law in their quest for a ruling in favour of regulatory liability."³⁵⁹ The law in this area is in flux, and merits close monitoring by Health Canada."

One line of recent cases in which negligence has been alleged in the federal and provincial governments handling of the SARS crises and the West Nile Virus disease merits special monitoring by the Department.³⁶⁰ Most of these decisions arose before trial in the context of a 'motion to strike,' that is an argument by the defendant that the plaintiff had failed to establish that the Government owed a *prima facie* duty of care to the plaintiff and that there was, therefore, no cause of action. Since Courts are careful not to end disputes prematurely on such motions, the defendant must usually establish that it is 'plain and obvious' that there is no chance of success at trial from the outset.

In *Williams v. Canada (Attorney General)*,³⁶¹ the plaintiff alleged that the Ontario Minister of Health acted prematurely in announcing that the SARS outbreak was under control and in relaxing hospital safety measures *in order to have a travel advisory against the City of Toronto lifted by the World Health Organization*. The announcements by the provincial officials were said to be premature because a second wave of SARS commenced at North York General Hospital. As a result of the position taken by the defendants and pressure they exerted to have the hospital deny that further cases had been discovered, a number of SARS patients were mis-diagnosed and transferred the disease to other patients

³⁵⁸ *Ibid.*

³⁵⁹ Jack Coop, *Public Law Liabilities and Litigation: The Latest and Most Significant Issues*, February 3, 2005, Ontario Bar Association Institute of Continuing Legal Education, p. 2

³⁶⁰ See, in particular, *Williams v. Canada (Attorney General)*, 2005 CanLII 29502 (ON S.C.); *Eliopoulos v. Ontario (Minister of Health and Long Term Care)*, 2004 CanLII 4030 (ON S.C.) and *amal v. Scarborough Hospital*, 2005 CanLII 29500 (ON S.C.)

³⁶¹ 2005 CanLII 29502 (ON S.C.);

and staff of the hospital. Subsequently, the government officials announced that, contrary to their previous statements, the outbreak had not been contained.

In *Williams*, the Court considered whether the defendant government's duties under the relevant Health Statutes placed them in a position that was sufficiently 'proximate' to the injured plaintiffs as to support a private duty of care in favour of the plaintiffs to avoid the foreseeable harm that occurred to them. In searching for a relationship of proximity outside the standard categories of negligence, the Court stated that the following factors were to be taken into account.

(a) Does the legislation expressly, or by implication, disclose a legislative intention to confer- or to exclude - private law rights of compensation on individuals who suffered damages caused by the breach? In many cases, the search for an implication either way in the guise of an exercise in statutory interpretation will involve "looking for what is not there"³⁶²;

(b) Were the duties imposed in the interests of the public or in those of discrete classes, or groups, of individuals that include the plaintiff? In this connection, it will be relevant to ask whether decisions to perform such duties – or to perform them in some manner or to some extent - "require the exercise of legislatively delegated discretion and involve pursuing a myriad of objectives consistent with public rather than private law duties":³⁶³ If the existence of a private law duty would potentially conflict with overarching duties owed to the public, this will tend to preclude a finding of a private law duty;

(c) Did the alleged breach of duty consist of a failure to exercise the statutory duties, or of a purported exercise of them, that specifically affected a discrete class, or group, of individuals that included the plaintiff?³⁶⁴

(d) How close is the causal connection between the alleged breach of duty and the damages allegedly suffered?

(e) What, if any, representations were made by the defendant and did the plaintiff reasonably rely on them or otherwise on the performance of powers and duties conferred, or imposed, for the protection of the public?³⁶⁵

(f) What, if any, were the plaintiff's other reasonable expectations? and

(g) Were the relevant statutory duties imposed on officials to whom political sanctions will be potentially applicable? (emphasis added)

³⁶² *Saskatchewan Wheat Pool*, at page 226, but inferences may be drawn from the purpose and overall scheme of the legislation –*Cooper*, at para 49

³⁶³ *Edwards*, at page 572; *Cooper* at page 559.

³⁶⁴ see *Air India*, at pages 138-9; *Jane Doe v. Toronto (Metropolitan) Commissioners of Police*, [1989] O.J. No. 471 (G.D.), (1990), 74 O.R. (2d) 225 (Div. Ct.), at pages 230-1

³⁶⁵ *Cooper*, at page 552

In *Williams*, the allegations pleaded against Health Canada, that it had failed in its duty under section 4 of the *Department of Health Act*,³⁶⁶ were disallowed by the Court because the duties under that Act were clearly owed to the “People of Canada” *collectively*, and not individually. Accordingly, no relationship of proximity was established with individual defendants such as would support any private cause of action.

The relationship between the government and the governed is not one of individual proximity. Any, perhaps most, government actions are likely to cause harm to some members of the public. That is why government is not an easy matter. Of course, the government owes a duty to the public but it is a duty owed to the public collectively and not individually. The remedy for those who think that duty has not been fulfilled is at the polls and not before the Courts.³⁶⁷

Despite finding that the federal *Department of Health Act* provided inadequate support for the existence of a private law duty of care owed to the plaintiffs in the class action, the Court stated that it was still possible that, having decided to perform its statutory duties in a particular manner, proximity may be established by the *conduct* of a Minister, or employees of a Ministry, *vis a vis* particular individuals or classes of individuals in the course of such performance. The allegations against the *Provincial* government, went beyond references to statutory duties. The Plaintiffs alleged that the Provincial Minister breached duties or abused discretionary powers provided for in the legislation *directed specifically at health care precautions to be taken to prevent the transmission of SARS at public hospitals in, or near, the City of Toronto*. These included:

- A directive by the Minister that hospitals were to offer only essential services;
- A series of directives to hospitals regulating the admission of patients and visitors, and the use of protective clothing and equipment;
- The premature lifting of the emergency, dismantling of the SARS operations centre, public statements that the outbreak had been contained

³⁶⁶ Section 4 of the *Department of Health Act*, S.C. 1996 c. 8, provides: that.

4. (1) the powers, duties and functions of the Minister extend to and include all matters over which Parliament *has jurisdiction relating to the promotion and preservation of the health of the people of Canada* not by law assigned to any other department, board or agency of the Government of Canada. (2) Without restricting the generality of subsection (1), the Minister's powers, duties and functions relating to health include the following matters: ... (b) the protection of the people of Canada against risks to health and the spreading of diseases; (c) investigation and research into public health, including the monitoring of diseases; ... (h) subject to the Statistics Act, the collection, analysis, interpretation, publication and distribution of information relating to public health; and (i) cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

³⁶⁷ Per Hugessen J. in *A.O. Farms Inc v. Canada*, [2000] F.C.J. No. 1771 (F.C.T.D.), at para 11:

- notwithstanding information that further cases continued to be diagnosed; and
- Advising hospitals to ease their infection control procedures.

In the face of these allegations, and the allegations of the motivation behind the decisions that led to (c) and (d) above, it was not ‘plain and obvious’ to the Court that the plaintiff would be unable to establish proximity between the Provincial Crown and class members and the issues were left to the trial judge. The allegations were allowed to proceed to trial.

In *Eliopoulos v. Ontario (Minister of Health and Long Term Care)*,³⁶⁸ a group of approximately 40 actions were launched against the government of Ontario by plaintiffs who were infected by West Nile Virus (“WNV”) in 2002. The plaintiffs alleged that they were infected with or affected by WNV as a result of the defendant’s negligence resulting from its failure to meet a private law duty of care emanating under Ontario’s *Health Protection and Promotion Act*.³⁶⁹

The duties in Ontario’s *Health Protection and Promotion Act* (HPPA) resemble more closely those likely contemplated by Health Canada under the proposed Canada Health Protection Act. In *Eliopoulos*, the Court found that the HPPA conferred wide powers on the government and local boards to make policy decisions and to make and implement operational decisions, sufficient to find a private law duty of care if the *Anns* test were met and if it could be held that the alleged negligent acts and omissions of the government arose as a result of the government *implementing policy at the operational level*.³⁷⁰

³⁶⁸ 2004 CanLII 4030 (ON S.C.)

³⁶⁹ , [R.S.O. 1990, c. H.7](#)

³⁷⁰ Section 86(1) of Ontario’s Health Protection and Promotion Act, [R.S.O. 1990, c. H.7](#) states:

86(1) if the Minister is of the opinion that a situation exists anywhere in Ontario that constitutes or may constitute a risk to the health of any person, he or she may investigate the situation and take such action as he considers appropriate to prevent, eliminate or decrease the risk

Section 6(2) of the Ministry of Health and Long Term Care Act, [R.S.O. 1990, c. M 26](#) states

6(2) the Minister in exercising his or her powers in carrying out his or her duties under this Act (b) shall promote and assist in the development of adequate health resources both human and material in Ontario.

Section 2 of the Health Protection and Promotion Act (“HPPA”) reads.

2. The purpose of this Act is to provide for the organization and delivery of public health programs and services, the prevention of the spread of disease and the promotion and protection of the health of the people of Ontario.

Part VII of the HPPA contains many of the Minister’s powers. Under sections 78 and 80, the Minister has the power to conduct investigations and to appoint inspectors to carry out the Act. Under sections 81 and 82, the Minister is required to appoint a Chief Medical Officer of Health and assessors.

The Court also found that there was a sufficient 'proximity' of relationship with the plaintiffs to satisfy the first branch of the *Anns* test.

The plaintiffs allege that, in our case, a duty was owed to a special group in a special area. They argue that they need not show, as the defendant suggested, that the defendant could have predicted which mosquito was going to bite which person. The plaintiffs allege that the defendant's acts and omissions closely and directly affected the persons infected with WNV. They allege that the government's surveillance of birds indicated that the government *knew where the WNV "hotspots" would be*. Most cases of WNV were centered in Toronto and Mississauga. I find that if the facts alleged by the plaintiffs are true, the plaintiffs were in sufficient proximity to satisfy the first branch of the *Anns* test.³⁷¹ (emphasis added)

The Court then canvassed whether the decisions of Ontario officials complained of in this case were policy or operational decisions. A private law duty of care may only arise when a government is carrying out its policy decisions at the operational level. As with many principles of law, however, it is easier to state the principle than to actually draw the line between policy and operations, especially where the alleged negligence is based on an *omission* to do something that perhaps ought to have been done. In this case, the Court found that many of the decisions taken under Ontario's Health Protection and Promotion Act could be construed as operational decisions and thus were remitted to the trial judge for consideration.

(Note: On November 3, 2006, after the completion of this Report, the Ontario Court of Appeal allowed the Ontario Government's appeal in the *Eliopoulos* (West Nile Virus) case.³⁷² The court found that the generalized risk presented by West Nile Virus was not the type of risk whose management raised a private law duty of care under Ontario's *Health Protection and Promotion Act*. The Court concluded that the powers and duties the Act prescribes did not create a relationship of proximity between Ontario and Eliopoulos sufficient to ground a private law duty of care.

In my view, these important and extensive statutory provisions create discretionary powers that are not capable of creating a private law duty. The discretionary powers created by the *HPPA* are to be exercised, if the Minister chooses to exercise them, in the general public interest. They are not aimed at or geared to the protection of the private interests of specific individuals. From the statement of purpose in s. 2 and by implication from the overall scheme of

The *HPPA* gives considerable power and responsibility to local boards of health and medical officers of health. The defendant submits that this indicates that it is the local boards, if anyone, who would be subject to duties under the Act. However, I find that it is apparent from the statutory scheme that the Minister retains control over the enforcement of the *HPPA*, either personally or through his delegates.

³⁷¹ *Eliopoulos* decision, *supra*, para. 28.

³⁷² *Eliopoulos v. Ontario (Minister of Health and Long Term Care*, decision rendered November 3, 2006, Docket C44577, accessed on November 7, 2006 at <http://www.ontariocourts.on.ca/decisions/2006/november/C44577.htm>

the *HPPA*, no doubt there is a general public law duty that requires the Minister to endeavour to promote, safeguard, and protect the health of Ontario residents and prevent the spread of infectious diseases. However, a general public law duty of that nature does not give rise to a private law duty sufficient to ground an action in negligence. I fail to see how it could be possible to convert any of the Minister's public law discretionary powers, to be exercised in the general public interest, into private law duties owed to specific individuals. Although *Mitchell (Litigation Administrator of) v. Ontario* (2004), 71 O.R. (3d) 571 (Div. Ct.), was concerned with a different statute, I agree with and adopt Swinton J.'s analysis at paras. 28 and 30 as applicable to the present case.³⁷³

The respondents also submitted that the even if the *HPPA* by itself imposed no private law duty, by issuing the Plan, Ontario made a policy decision to act and therefore triggered a private law duty to use due care *to implement the Plan at the operational level*: The Court of Appeal rejected this argument on the view that the Ministry undertook to do very little under the surveillance plan, if anything at all, beyond providing information and encouraging coordination. The implementation of specific measures was essentially left to the discretion of members of the public, local authorities, and local boards of health.

To summarize, the Plan provided information about WNV and encouraged members of the public and local authorities, in cooperation with various governmental and non-governmental agencies, to undertake surveillance and preventative measures. The Ministry did not undertake to collect infected birds, conduct inspections, or take measures to reduce or eliminate the mosquito population, nor did it mandate such measures. The Ministry merely provided others with information and recommendations. In my view, the Plan falls well short of the sort of policy decision to do something about a particular risk that triggers a private law duty of care to implement such policy at the operational level in a non-negligent manner.³⁷⁴

As of the date of this addendum to our Report, no decision had been taken about a further appeal to the Supreme Court of Canada. Health Canada should, therefore, carefully monitor developments in this case, and in the SARS cases, since they may have important implications for Health Canada's exposure to regulatory liability under a GSR regime in the consumer product safety area. The most recent decision of the Ontario Court of Appeal, however, suggests great hesitation on the part of the judiciary to find a private law duty of care on the part of governments attempting to prevent injury to the public at large from generalized risks.)

Importance of Ensuring that Operational Plans are Adequately Resourced

Health Canada's compliance and enforcement resources may be severely strained under the sweeping, and somewhat indeterminate, scope of regulatory responsibility brought in with the enactment of a general safety requirement.

³⁷³ Ibid., para. 17

³⁷⁴ Ibid., para 25.

Health Canada will have to be particularly careful to ensure that its operational plans for implementing the GSR are sufficiently resourced before they are finalized; otherwise the Department will be unreasonably exposed to claims in negligence based on the failure to act in accordance with their own policy.

Normally, the Courts consider the allocation of funds in compliance and enforcement programs to involve pure policy decisions, but this does not mean a Court will not review any decision involving money, or accept the fact that an approved enforcement plan is under-resourced as a defence to evade liability.

The defendant argued that courts have held that one of the hallmarks of a policy decision is that it considers economic factors. It is partly on this basis that the defendant has argued that the government's action or inaction in response to West Nile Virus was a matter of policy. The defendant is correct that policy decisions are political decisions largely based on allocation of funds and that it is not the role of the courts to dictate how public funds should be spent. The appropriate check on governmental spending policies is the ballot box.

This does not mean, however, that the courts may not review any decision involving money. In our case, the government at the policy level decided to address WNV. The defendant cannot suggest that the government would create a detailed operational manual for dealing with WNV without having made the necessary budgetary decisions for the implementation of the Plan. Indeed, the defendant stated in its factum that the decisions outlined in the Plan clearly take into account economic, social, and political factors. *If the government has committed to and planned for the taking of certain steps, it cannot sidestep liability by claiming that implementation involves money.*

Cory J. in *Just* made it clear that the courts may scrutinize expenditures, or the lack of them, when looking at the operational aspects of government action or decisions. *Part of the consideration of whether actions and decisions were reasonable may entail an examination of the budgetary circumstances that were set out in the policy decisions that mandated the operational aspect of the impugned conduct. This acknowledges that the broad budgetary issues and allotment of funds took place at the policy level. The reasonableness of operational actions may be judged in light of how that money was used and if it was used in a way consistent with the underlying policy and statutory obligations.* At this early stage, we do not have all the facts about what role, if any, money played in the impugned decisions of the government. These are details that may only come to light at trial. (Emphasis added)³⁷⁵

To summarize, therefore:

What each of the cases underscore is the importance of a careful analysis of the statutory scheme under the second stage of the *Anns* test, when dealing with an action for regulatory negligence. When members of the public seek to hold particular public officials accountable in negligence for making a decision in their

³⁷⁵ *Eliopoulos* decision, supra, para's 51-52

official capacity, the issue quickly devolves into one of whether the statute creates proximity and a private duty of care to the individual plaintiff. The courts consider such factors as whether the decision requires the exercise of a broad statutory discretion, is a policy decision, is made in the public interest and for the benefit of the public generally (as opposed to for the plaintiff personally), requires the balancing of competing interests, creates a proximate relationship to the particular plaintiff, or is otherwise protected by a statutory immunity provision.”³⁷⁶

Negligent Misrepresentation - Health Canada’s Advisory Function under the GSR

Given the multiple layers of uncertainty associated with the GSR in the definition of “safe” or “unsafe” consumer products, inconsistency in the results produced by risk assessment methodologies and uncertainty in the methods of establishing conformity with the GSR, it is to be expected that industry will rely heavily on Health Canada for advice to clarify the requirements under the law for general ‘comfort’, possibly on a product-by-product basis. The Government’s advisory function will take many forms, including: oral advice from officials, published policies and guidelines, rulings, warnings, exemptions, compliance orders, operational manuals or sharing research conducted within the Department upon which producers might be expected to rely (for example, in relation to the availability of standards raising a presumption of conformity with the GSR).

The potential for negligent misrepresentation by officials therefore looms large under the GSR. Tort liability will attach to the government’s advisory function where officials provide false or misleading information on which producers or others in the supply chain may be expected to rely and, in consequence of that advice suffer damage, usually in the form of financial loss.

....if in a sphere in which a person is so placed that others could reasonably rely upon his judgment or his skill or upon his ability to make careful inquiry, a person takes it upon himself to give information or advice to, or allows his information or advice to be passed on to, another person who, as he knows or should know, will place reliance on it, then a duty of care will arise.³⁷⁷

Federal officials will likely be asked frequently for ‘interpretations’ of elements of the GSR given the vagueness of some of its terms, and doubts surrounding the Government’s conformity assessment requirements. In *H.L. & M. Shoppers Ltd. V. Town of Berwick*³⁷⁸ a municipal employee failed to correctly interpret a

³⁷⁶ Jack Coop, *Public Law Liabilities and Litigation: The Latest and Most Significant Issues*, February 3, 2005, Ontario Bar Association Institute of Continuing Legal Education, p. 15

³⁷⁷ *Hedley Byrne & Co. v. Heller & Partners Ltd.*, [1964] A.C. 465, per dictum of Lord Morris of Borth-y-Gest

³⁷⁸ (1977), 82 D.L.R. (3d) 23 (N.S.S.C.)

building bylaw that had already been definitively interpreted by the Courts in another decision. The Municipality was found vicariously liable for damages caused to the plaintiff for issuing a building permit in error and then having to revoke it. Financial loss awards are of particular concern to governments because of their potential enormity. It is not difficult to foresee the potential for large awards in the consumer product area if producers were to make costly, but unnecessary, changes in their production process on the basis of false or misleading information supplied by government officials about safety requirements.

In addition, the law may impose a duty to provide *complete* information on officials of government who are represented as subject experts or professionals for the purpose of providing clarifying advice to industry on the operation of the GSR. Providing less than complete advice has been found to constitute negligent representation where it is given by “experts”, or professionals.³⁷⁹

In *Fletcher v. Manitoba Public Insurance Corporation*,³⁸⁰ the plaintiff, a purchaser of car insurance from the public automobile insurer, was not told of the various types of insurance policies that were available and chose the least expensive package, one that failed to cover all of his expenses arising from an out-of-province accident. The court found a duty of care relating to provide *complete* information about the various options based upon the fact that such information was in the nature of *professional advice*.

*Spinks v. Canada*³⁸¹ also demonstrates how *foreseeable reliance* on advice may create a special relationship between the advisor and the recipient of the advice such as to create a private law duty of care. In *Spinks*, the plaintiff was an employee of Atomic Energy Canada Ltd. At his ‘signing on interview with personnel officers of AECL, he was not informed of his right under the applicable regulations to buy back his prior pensionable service with the government of Australia for the purpose of augmenting his subsequent pensionable service with AECL. After 13 years with AECL, he became aware of the buy back option, at which time the cost of the buy back was \$210,000. If he had been advised of the option on hiring, the cost would have been \$68, 000. He claimed the difference as damages arising from the alleged misrepresentation on the part of AECL’s personnel employee on the ground that he had failed to advise him fully and correctly of his buy-back options.

While the Trial Judge dismissed the claim on the view that the staffing officer did not owe the employee any duty of care, the Federal Court of Appeal reversed the

³⁷⁹ In *R v. Inco Ltd.*, (2006) 80 O.R. (3d) 594 the Court held that an employee of the Investigations and Enforcement Branch of the Ontario Ministry of the Environment was an “expert” witness in the circumstances of this case notwithstanding that his independence might appear to be impaired by the fact of his employment by one of the parties.

³⁸⁰ [1990] 3 S.C.R. 191

³⁸¹ [1996] 2 F.C. 563 (C.A.).

finding. The Appellate Court held that a special relationship between representor and representee is usually created where reliance on the representations is clearly foreseeable. The Court required no proof that the plaintiff actually relied on the misrepresentation. In this case, AECL had also created a *manual*, which explicitly required staffing officers to advise new employees of pension rights and found that AECL had breached the standard of care that could reasonably be expected of employers when advising new employees in such circumstances.

Duty to Warn – Reporting Requirements / Complaints / Injury Data Collection

The law recognizes that a duty of care may take the form of a ‘duty to warn’ particular individuals or classes of persons of potential harm. In some factual circumstances, therefore, the failure to notify or warn will constitute actionable negligence where harm occurs that might otherwise have been avoided or mitigated had the warning been given. In the *Eliopoulos* decision mentioned above (The West Nile Virus case) for example, the plaintiffs alleged that, “the government’s surveillance of birds indicated that the government *knew where the WNV “hotspots” would be*. Most cases of WNV were centered in Toronto and Mississauga.” Such circumstances might raise a duty to warn individuals visiting or working in Toronto hospitals (or a residents of Toronto generally) of special vulnerability to contracting the disease based on local data about infections.

In *Teachers Investment and Housing v. Jennings*³⁸² the court refused to strike out a statement of claim in a negligence action brought against provincial regulatory authorities for failing to warn a regulated investment cooperative that its investment activities were imprudent or possibly unauthorized by governing legislation. The court found that the statutory powers and duties of the official in question, the Superintendent, included protection of a cooperative association.

If reporting responsibilities under a GSR produce much more complete information about risk of injury from unregulated dangerous products and about the population vulnerable to such risks, the government’s exposure to liability flowing from the failure to meet a duty to warn, or to act in accordance with its compliance policies, where the producer (who has the primary duty to warn of defective products) fails to do so, could increase significantly. The government’s exposure to liability will be influenced greatly by whether or not government might be fixed with a secondary duty of care (i.e.: arising on the producers failing to warn) under the proposed CHPA, or establishes an enforcement policy calling for warning the public and then negligently fails to carry it out.

³⁸² (1990), 44 B.C.L.R. (2d) 203 (S.C.), affid, 56 B.C.L.R. (2d) 145 (C.A.),

10. Other Legal Considerations

Legal Framework Issues / Recall Orders

In Europe, most of the Member States have direct *regulatory* authority for consumer product safety legislation. As a consequence, Member States are able to employ a full range of administrative, civil and criminal remedies in furtherance of the product safety schemes.

Under Canada's Constitution³⁸³, "health" is not assigned as an exclusive head of power to either the provincial or federal governments.³⁸⁴ Apart from exceptional use of the Peace, Order and Good Government power³⁸⁵, the federal government's authority to legislate in the area of health is based on its authority, under section 91(27) of the *Constitution Act* to punish conduct that is dangerous to health.³⁸⁶ In terms of designing a GSR for the proposed *Canada Health Protection Act*, two important consequences flow from this basis of authority, namely:

- A more limited range of remedies (perhaps not including administrative recall) is available under the scheme; and
- While there is a broad scope for the federal government to "regulate" for criminal law purposes (e.g. to protect public health), there is no bright line between regulating for criminal law purposes and federal regulation that may interfere unduly with provincial responsibility for "property and civil rights." Accordingly, additional care must be taken in designing a GSR to ensure that the regulatory aspect of the scheme is closely linked to the

³⁸³ *The Constitution Act, 1867*

³⁸⁴ See *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1995] 3 S.C.R. 199, at para. 32: "As Estey J. observed in *Schneider v. The Queen*, [1982] 2 S.C.R. 112, at p. 142 "health" is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending in the circumstances of each case on the nature or scope of the health problem in question.

Given the "amorphous" nature of health as a constitutional matter, and the resulting fact that Parliament and the provincial legislatures may both validly legislate in this area, it is important to emphasize once again the plenary nature of the criminal law power. In the *Margarine Reference*, supra, at pp. 49-50, Rand J. made it clear that the protection of "health" is one of the "ordinary ends" served by the criminal law, and that the criminal law power may validly be used to safeguard the public from any "injurious or undesirable effect". The scope of the federal power to create criminal legislation with respect to health matters is broad, and is circumscribed only by the requirements that the legislation must contain a prohibition accompanied by a penal sanction and must be directed at a legitimate public health evil. If a given piece of federal legislation contains these features, and if that legislation is not otherwise a "colourable" intrusion upon provincial jurisdiction, then it is valid as criminal law.."

³⁸⁵ The POGG power may be invoked to deal with problems that have attained a "national dimension", or to deal with national health emergencies.

³⁸⁶ Peter W. Hogg, *Constitutional Law of Canada*, Student Edition, 2005, at p. 484

protection of health and not, “*in pith and substance*”, for some other purpose – for example, to promote the international harmonization of product regulations to enhance international trade.³⁸⁷

The ordinary, though not exclusive purposes served by the criminal law are public peace, order, security, *health* and morality.³⁸⁸ Sections 91(27) and 92(14) of the *Constitution Act, 1867* spell out the precise distribution of powers between the federal and provincial governments. The Federal Parliament has power under section 91(27) to make laws in relation to: “the criminal law, except the constitution of the courts of criminal liability, but including the procedure in criminal matters.”

Provincial legislatures have power to make laws in relation to: “the administration of justice in the provinces, including the constitution, maintenance and organization of provincial courts, both of civil and criminal jurisdiction, and including procedure in civil matters in those courts.”

If Health Canada considers that a recall power is essential for the effectiveness of a general safety requirement, the Department should require an early legal opinion to confirm that this remedy is constitutionally available under the proposed GSR scheme. There are reasons to believe that it might not be.

A recall order is civil remedy in the nature of a mandatory injunction.³⁸⁹ In 1986 the Competition Tribunal was established with adjudicative authority to make a variety of orders including the cessation of certain anti-competitive trade practices, the prohibition of mergers or their approval subject to conditions, *the divestiture of assets or shares*, the dissolution of amalgamations and consent orders. While many of these powers were subsequently upheld under federal authority over “Trade and Commerce,” Professor Peter Hogg, in his text on *Constitutional Law of Canada*, in commenting on these powers, noted:³⁹⁰

These powers cannot be upheld as criminal law, because the Tribunal is not a court of criminal jurisdiction, and the orders can be made without any prior conviction for a criminal offence.

³⁸⁷ See *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1995] 3 S.C.R. 199 and the cases cited thereunder. See also Hogg, *Constitutional Law in Canada, supra*, pp. 499-503 under the heading *The Criminal Law and Regulatory Authority*.

³⁸⁸ Hogg, *supra* at p. 477, citing the *Margarine Reference*, [1949] S.C.R. 1, per Rand J. at p. 50.

³⁸⁹ Sharpe, Mr. Justice Robert I. J., *Injunctions and Specific Performance*, loose-leaf ed. (Aurora, Ont: Canada Law Book, 1998), at paras. 1.10, 1.60; See also *R. v. Mills* [1986] 1 S.C.R. 863, at para. 43, per Lamer J. and *Pinet v. Administrator, Mental Health Centre, Penetanguishene et al.* (2006) (80) O.R. (3d) 139 at 159.

³⁹⁰ At p. 489. See also pages 495-503, under the headings *the federal power to create civil remedies; the Criminal law power to create remedies and Criminal law and regulatory authority*. See also

Currently, only three federal statutes provide for product recalls, all of which are constitutionally supported under heads of federal authority other than the criminal law power. The federal statutes with recall powers include:

- The Canadian Food Inspection Agency Act, S.C. 1997 c. 6, s. 19³⁹¹;
- The Pest Control Products Act, 2002, c. 28, s. 21 (5)³⁹²; and
- *The Transportation of Dangerous Goods Act*, S.C. 1992, c. 34, s. 9 (2).³⁹³

The *Canadian Food Inspection Agency Act* and the *Pest Control Products Act* are constitutionally based, at least in part, on the Federal Government's authority to enact laws in relation to "Agriculture." Under section 95 of the *Constitution Act, 1867* both levels of government may make laws in relation to 'agriculture.'

In each Province the Legislature may make Laws in relation to Agriculture in the Province, and to Immigration into the Province; and it is hereby declared that the Parliament of Canada may from Time to Time make Laws in relation to Agriculture in all or any of the Provinces, and to Immigration into all or any of the Provinces; and any Law of the Legislature of a Province relative to Agriculture or to Immigration shall have effect in and for the Province as long and as far only as it is not repugnant to any Act of the Parliament of Canada.

³⁹¹ The *Canadian Food Inspection Agency Act* provides:

19. (1) Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, *order that the product be recalled* or sent to a place designated by the Minister.

(2) Any person who contravenes a recall order referred to in subsection (1) is guilty of an offence and liable on summary conviction to a fine not exceeding \$50,000 or to a term of imprisonment not exceeding six months or to both.

(3) For greater certainty, a recall order is not a statutory instrument for the purposes of the Statutory Instruments Act, but no person shall be convicted of an offence under subsection (2) unless the person was notified of the order.

³⁹² The *Pest Control Products Act*, 2002, c. 28 provides, in section 21. (5) that:

When cancelling the registration of a pest control product under this section or any other provision of this Act, the Minister may

(a) allow the continued possession, handling, storage, distribution and use of stocks of the product in Canada at the time of cancellation, subject to any conditions, including disposal procedures, that the Minister considers necessary for carrying out the purposes of this Act;(b) *require the registrant to recall and dispose of the product* in a manner specified by the Minister; or (c) seize and dispose of the product.

³⁹³ The *Transportation of Dangerous Goods Act* provides, in section 9 (2) that .."Where the Minister or a person designated for the purposes of this section believes on reasonable grounds that any standardized means of containment are unsafe for handling or transporting dangerous goods, the Minister or the designated person *may direct the manufacturer or importer who supplied them to issue notices of defective construction or recall* to the persons to whom they were supplied.

The Transportation of Dangerous Goods Act is founded not only upon federal legislative authority in relation to criminal law (i.e. protection of public health and safety) but also rests upon federal constitutional authority over inter-provincial or international transport.³⁹⁴

Delegation of Legislative Authority – Back-Door Rulemaking?

The principle of the rule of regulatory law known as the rule against sub-delegation provides that, *in the absence of express authority*, a delegate of legislative powers may not further delegate those powers to another.

The rule against sub-delegation is rooted in the rule of law – the set of overriding principles on which the operation of all legislative regimes is premised. These principles operate as a constraint on the exercise of governmental power and serve as a guide to fair and effective law-making. One objective of the rule of law is to ensure that laws are produced in a manner that permits a citizen to be effectively governed by them. This requires, among other things, that governance must be effected by rules:

1. That are made in advance of when they are to be applied;
2. That operate prospectively; and,
3. That have been publicized or otherwise made available to those whom they are to govern.

Subdelegation undermines each of these objectives.³⁹⁵

In the unique circumstances of the European Community, sub-delegation of legislative authority is a rather more common practice than in North America, where it is more likely to be viewed as a form of ‘back-door’ rulemaking.

It is a primary function of Parliament to determine the guidelines of legislative policy. Parliament should not, therefore, delegate to Ministers power to make regulations on matters of general principle unless it lays down in the enabling Act standards delimiting the boundaries of the delegate’s discretion. Skeleton legislation is justifiable only in order to deal with a state of dire emergency (such as the Northern Ireland situation since 1972) *or a quite exceptional situation, such as has been created by Britain’s accession to the European Communities.* (emphasis added)³⁹⁶

Quite apart from Community regulations which are directly applicable of their own force, further regulations have been and will have to be made in this country under powers delegated by the (*European Communities*) Act, 1972, (s. 2(2)) to give effect to Community directives and decisions and also to implement in fuller

³⁹⁴ Hogg, *Constitutional Law in Canada*, supra at p. 554, et seq.

³⁹⁵ Paul Salembier, *Regulatory Law and Practice in Canada*, Butterworths, 2004, at p. 248

³⁹⁶ de Smith, *Constitutional and Administrative Law*, Pelican Books, 5th ed. at p. 351

detail some Community regulations. Orders in Council and departmental regulations made under these delegated powers *have the effect of Acts of Parliament* and can include any provision that might be made in an Act of Parliament, except that they are not to impose or increase taxation or have retroactive effect or sub-delegate legislative powers (other than the power to make procedural rules for the courts and tribunals) or create a new criminal offence punishable with more than two year's imprisonment or a fine more than 2000 pounds. *This is probably the most sweeping grant of delegated legislative powers to the Executive in modern times except under emergency conditions.*³⁹⁷

The General Product Safety Directive in Europe, and the New Approach to Regulation of which it is an integral part, establishes a *form* of, 'authorized' delegation of legislative authority. Essential product safety requirements are set out in the governing legislation (or Directive), which provides that voluntary technical standards developed by third-party 'experts' are to be substituted for regulations for the purpose of determining presumptive conformity with the governing legislation.

An important question, therefore, is whether the GSR approach to regulation effectively ensures the 'rule of law' in regulating product safety. Or are the uncertainties involved in defining what is 'safe', or the risk assessment processes for determining what is 'unsafe', so imprecise and inconsistent that issues of 'safety' are, in practice, being determined on a more subjective, case by case, basis by individuals or committees of 'experts'?

"A more insidious form of sub-delegation can occur when vague terminology is employed in drafting regulatory rules. Consider the example:

No person operating a truck shall carry a load in an unsafe manner.

If we assume that no consensus exists, either within the regulated industry or the public at large, as to the meaning of 'unsafe', then the breadth of possible meanings that can be given to that term gives an enforcement officer the discretion not as to whether a stated fact situation exists, but rather what the rule actually is. While an enforcement official could interpret this rule as a simple prohibition against carrying an insecurely fastened load, he or she might also consider it to confer the right to decide (by choosing to ticket or not) what the maximum speed should be for transporting a given load, what type of safety equipment a given truck must carry for a given load, or even on what highways particular loads can or cannot be carried. *The vagueness inherent in this type of drafting gives the enforcement officer the ability not simply to enforce the rule, but in effect to decide what the substance of the rule is.* (final emphasis added)³⁹⁸

Possible vagueness in the definition of the term 'safe product', and uncertainty about which standards suitably raise a presumption of conformity with the 'General Safety Requirement' are potentially vexatious issues for the GSR. The

³⁹⁷ *Ibid.*, pp. 352-53

³⁹⁸ *Ibid.*, at p. 267

General Safety Requirement was designed as a form of regulatory safety net for dealing with *unregulated* dangerous products and *emerging* (possibly unforeseen) risks, so there may well be *no* domestic standards available for determining whether a particular product conforms, presumptively, to the essential safety requirement. In Europe, very few standards have been established specifically to facilitate the operation of the GPSD.³⁹⁹ The fact that foreign standards may be employed to establish (a presumption of) conformity with the GSR is neither conclusive; nor is it necessarily conducive to consistent interpretive results.

Nevertheless, there are circumstances that import ‘a certain amount of inherent uncertainty’, where courts have recognized that a high degree of precision is simply not attainable and rules which are ‘acceptably vague’ may stand.

Rules with some inherent uncertainty can be used without crossing over into sub-delegation where the expression used to delimit the key criterion:

1. Have a core meaning generally accepted by the public at large; or
2. Have a meaning generally accepted within the regulated industry.⁴⁰⁰

For example, Courts have found the term ‘beverage’ clearly included ‘water’ within its scope within the custom of beverage manufacturers. “Generally accepted accounting principles,” while unclear in its meaning to the general public, has a clear meaning in accounting practice. Similarly, a Quebec Court held that there was no uncertainty as to the meaning of “current information in medical science” used in a statutory prohibition against medical practitioners undertaking action contrary to such information, on the grounds that practitioners are obliged to stay abreast of such information as a requirement of professional competence.⁴⁰¹

Whether a rule is so imprecise as to sub-delegate a discretion to the official enforcing it will in each case be a question to be determined by reference to context and, where applicable, industry practice.⁴⁰²

Uncertainty

The law of sub-delegation is closely related to challenges of regulations based on the fact that they are *uncertain* to the point of being unintelligible and therefore offend the principles of fundamental justice under the *Canadian charter of Rights and Freedoms*.

³⁹⁹ (Insert reference to material forwarded by Elizabeth in this regard.)

⁴⁰⁰ Paul Salembier, *Regulatory Law and Practice in Canada*, Butterworths, 2004, at p. 268, and cases cited under footnotes 83 and 84.

⁴⁰¹ *Ibid.* See *Windish-Laroche .v. Biron*, [1992] R.J.Q. 1343 (C.S.), affd J.E. 97-323 (C.A.).

⁴⁰² Paul Salembier, *Regulatory Law and Practice in Canada*, *supra*, at p. 269.

A law must not be so devoid of precision in its content that a conviction will automatically flow from the decision to prosecute... *When the power to decide whether a charge will lead to conviction or acquittal, normally the preserve of the judiciary, becomes fused with the power to prosecute* because of the wording of the law, then a law will be unconstitutionally vague.⁴⁰³ (Emphasis added)

In short, the vagueness must be so serious that a judge would conclude that a reasonably intelligent man sufficiently well informed would be unable to determine the meaning of the law and govern his actions accordingly.⁴⁰⁴ Health Canada's consultations with stakeholders disclosed widespread concern about what precisely would be required of them to comply with the proposed new law. Addressing these concerns will undoubtedly be a major preoccupation of Health Canada as it moves forward with the policy proposal.

In Canada, the sole basis for invalidating a statute for vagueness is a failure to accord with the principles of section 7 of the *Canadian Charter of Rights and Freedoms* – that is, if “it so lacks precision as not to give sufficient guidance for legal debate.”⁴⁰⁵ The Supreme Court of Canada summed up the doctrine of vagueness (uncertainty) in the leading case of *R. v. Nova Scotia Pharmaceutical Society*,⁴⁰⁶ as follows:

The doctrine of vagueness can be summed up in one proposition: a law will be found unconstitutionally vague *if it so lacks in precision as not to give sufficient guidance for legal debate* -- that is, for reaching a conclusion as to its meaning by reasoned analysis applying legal criteria. The term "legal debate" is not used to express a new standard, or one departing from that previously outlined by this Court. It is rather intended to reflect and encompass the same standard and criteria of fair notice and limitation of enforcement discretion viewed in the fuller context of an analysis of the quality and limits of human knowledge and understanding in the operation of the law. *The criterion of absence of legal debate relates well to the rule of law principles* that form the backbone of our polity. Legal provisions by stating certain propositions outline permissible and impermissible areas, and they also provide some guidance to ascertain the boundaries of these areas. They provide a framework, a guide as to how one may behave, but certainty is only reached in instant cases, where law is actualized by a competent authority. By setting out the boundaries of permissible and non-permissible conduct, these norms give rise to legal debate. They bear substance, and they allow for a discussion as to their actualization. They therefore limit enforcement discretion by introducing boundaries, and they also sufficiently delineate an area of risk to allow for substantive notice to citizens. No higher requirement as to certainty can be imposed on law in our modern State. *The modern State intervenes today in fields where some generality in the enactments is inevitable. The substance of these enactments must remain*

⁴⁰³ *R v. Nova Scotia Pharmaceutical Society*, [1992] 2 S.C.R. 606, at p. 636. Regulations and bylaws that fail to meet this standard will also be unconstitutionally vague. See Salembier, *Regulatory Law and Practice in Canada*, *supra*, at p. 341, including the cases cited in footnote 163.

⁴⁰⁴ *City of Montreal v. Arcade Amusements Inc.*, (1985) 18 D.L.R. (4th) 161 (S.C.C.)

⁴⁰⁵ *R v. Nova Scotia Pharmaceutical Society*, [1992] 2 S.C.R. 606, at pp. 638-39

⁴⁰⁶ [1992] 2 S.C.R. 606, 1992 CanLII 72 (S.C.C.)

nonetheless intelligible. The standard of "absence of legal debate" applies to all enactments, irrespective of whether they are civil, criminal, administrative or other. (Emphasis added)

Prior to the *Nova Scotia Pharmaceutical Society* decision, numerous bylaws and regulations were held invalid by reason of uncertainty. The following cases illustrate some of the circumstances where by-laws or regulations have been held void for uncertainty:

- A closing by-law purporting to exclude shops that specialized in the sale of "small articles of small value"⁴⁰⁷ (How small is small? Or, in the case of consumer products: How safe is safe?);
- A by-law requiring all persons attending dance halls to be "attired in a costume usual and seemly for such occasions;"⁴⁰⁸
- A by-law that purported to regulate stores selling "erotic magazines," that is, those "appealing to or designed to appeal to erotic or sexual appetites or inclinations;"⁴⁰⁹ and
- Charges were dismissed against a nursing home for contravening a provision stating that "every nursing home shall be free from anything that might be hazardous to the health or safety of the residents"

The use of the term "reasonably foreseeable conditions of use" in the definition of a 'safe product' under the GPSD may also raise vagueness concerns with a Court. In *Weir v. R.*, the court held a City of Toronto anti-smoking bylaw to be invalid on the ground that it imposed an uncertain duty and a vague obligation upon proprietors of retail shops to make "reasonable efforts" to prevent smoking in violation of the by-law.

The key word to take note of here is "reasonable," which is almost always the hallmark of vagueness in delegated legislation. It is virtually always capable of at least two, and usually three, different meanings:

1. Reasonable in the opinion of the enforcement officer;
2. Reasonable in the opinion of the regulated person; and
3. Reasonable in the opinion of the court.⁴¹⁰ (emphasis added)

The UK refused to make failure to meet many of the duties prescribed under the original *General Product Safety Directive* (92/59/EEC) a criminal offence on the grounds of imprecision and uncertainty.⁴¹¹ In the revised *GPSD*, (2001/95/EC)

⁴⁰⁷ *Bunce v. Cobourg (Town)* [1963] 2 O.R. 343

⁴⁰⁸ *Clarke v. Wawkwon (Rural Municipality)*, (1930), 1 W.W.R. 319 (Sask. C.A.)

⁴⁰⁹ (1983), 143 D.L.R. (3d) 498 (Ont. C.A.).

⁴¹⁰ Salembier, *Regulatory Law and Practice in Canada, supra*, at p. 344.

⁴¹¹ See Christopher Hodges, *European Regulation of Consumer Product Safety*, Oxford University Press, 2005, at p. 180, footnote 121. "As an example of the variations in enforcement sanctions that can occur, contravention of the producers' duties 2, 3, or 4 (provide consumers with relevant information, adopt remedial 'measures', inform authorities about dangerous products) or distributors' duty 3 (act with 'due care' to ensure compliance) under the UK General Product

additional criteria were added to help a court determine when a product was 'deemed' to be safe. In cases where there were no specific rules of national law from which to infer conformity with the GPSD, Member States (and Courts) may now assess conformity of a product by taking into account the following elements in particular, where they exist:

- Voluntary national standards transposing relevant European standards....
- The standards drawn up in the Member State in which the product is marketed;
- Commission recommendations setting guidelines on product safety assessment;
- Product safety codes of good practice in force in the sector concerned;
- The state of the art and technology; and
- Reasonable consumer expectations concerning safety.⁴¹²

Additional precision was also added to the producers' duty to "adopt measures" commensurate with the characteristics of the products which they supply to remain informed of product risks and to take "appropriate" action to remediate or eliminate the risks. The measures referred to include, for example:

- An indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified; and
- In all cases where appropriate, the carrying out of sample testing of marketed products, investigating and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring.⁴¹³

Failure to meet any of the above-mentioned duties now constitutes the specific offence under the UK legislation transposing the revised *GPSD*, along with the additional criteria set out in 2001/95/EC in relation to the performance of those duties.⁴¹⁴ The revised *GPSD* is very recent (in force, January 2004) but there do not appear to be any cases on record yet challenging the revised provisions on

Safety Regulations, 1994, Regulation 12, was not an offence. This is a surprising omission. The UK Government took the position that the nature of these obligations was not sufficiently prescriptive or clearly defined to be made subject to criminal penalties and that the goals of product safety and consumer protection could be adequately achieved by use of the product-directed (as opposed to person-directed) powers contained in Part II of the Consumer Protection Act, 1987, such as suspension notices, forfeiture orders, prohibition notices, and notices to warn. This is a curious state of affairs but has not been the subject of objection by the Commission. It is true that the definition of these duties is general and imprecise, but no more so than the only other relevant method of quasi-enforcement by means of civil liability for negligence, which is defined in similarly wide terms as breach of a reasonable standard of conduct. The failure to provide for what might be regarded as the normal enforcement sanction by one Member State, when such a sanction exists in others, is not satisfactory."

⁴¹² 2001/95/EC, Article 3 (3)

⁴¹³ *Ibid.*, article 5 (b)

⁴¹⁴ *The General Product Safety Regulations, UK, 2005*, S.I. 2005, No. 1803, s. 20

the grounds of vagueness. Nevertheless, there remains considerable disquiet amongst some businesses (particularly small business) about what, precisely, is required for compliance with the GSR.

While the Courts, since the *Nova Scotia Pharmaceutical Society* decision, have shown increased deference to regulators on issues of uncertainty – and a tendency to treat regulations more like statutes for the purpose of assessing uncertainty - there is no ‘bright line’ between what is certain and what is vague.⁴¹⁵

Vagueness concerns will also often arise where administrative officials have a very broad discretion to levy charges under a regulatory scheme, as is the case under the GSR. European officials may charge a defendant with the breach of a GSR even where the defendant’s product presumptively conforms to a community standard where a particular product presents dangers to the public in the enforcement official’s opinion.

The "doctrine of vagueness" is founded on the rule of law, particularly on the principles of fair notice to citizens *and limitation of enforcement discretion*. Fair notice to the citizen comprises a formal aspect -- an acquaintance with the actual text of a statute -- and a substantive aspect -- an understanding that certain conduct is the subject of legal restrictions. *The crux of the concern for limitation of enforcement discretion is that a law must not be so devoid of precision in its content that a conviction will automatically flow from the decision to prosecute*. The threshold for finding a law vague is relatively high. The factors to be considered include (a) the need for flexibility and the interpretative role of the courts; (b) the impossibility of achieving absolute certainty, a standard of intelligibility being more appropriate, and (c) the possibility that many varying judicial interpretations of a given disposition may exist and perhaps coexist. (emphasis added)

Even where a regulation is sustained under the more forgiving criteria outlined in the *Nova Scotia Pharmaceutical Society* decision, a Court (and particularly a Criminal Court) may be reluctant to *enforce* a law lacking in precision. Greater precision is likely to be required by a Criminal Court where the object is penalization.

It may be a poor or meaningless order. *It may well be so lacking in clarity that it is incapable of enforcement. Presumably, if a Provincial Judge so finds, he will acquit*. Nonetheless, there is nothing to suggest that the determination made by the Commission in pronouncing para. (3) was in excess of its jurisdiction. This Court cannot quash that paragraph of the order. (Emphasis added)⁴¹⁶

⁴¹⁵ ⁴¹⁵ Paul Salembier, *Regulatory Law and Practice in Canada*, *supra*, at pp. 346-47 and 349.

⁴¹⁶ *Ibid.*, p. 349, citing *Mid-west By-Products co. v. Manitoba (Clean Environment Commission)*, (1979) 102 D.L.R. (3d) 208 (Man. Q.B.)

The multiple layers of uncertainty referred to throughout this Paper in defining and administering the GSR, therefore, will have an important impact on the public authority's ability to successfully prosecute GSR cases. If prosecutors have not yet been consulted as part of the policy development process, Health Canada might wish to do so before finalizing its policy proposals.

Protection Against Self-Incrimination: Mandatory Reporting Requirements

Some care will be required in drafting and administering the mandatory reporting requirements under any GSR regime given the legal protection against compelling self-incriminatory evidence in penal proceedings.⁴¹⁷ The principle against self-incrimination is “a general organizing principle of criminal law” that an accused is not required to respond to an allegation of wrongdoing made by the state until the state has succeeded in making out a *prima facie* case against him or her. It is a basic tenet of criminal justice that the Crown must establish a “case to meet” before there can be any expectation that the accused should respond.⁴¹⁸

Officials in the United Kingdom and the Netherlands, both of which employ penal sanctions in their consumer protection legislation, were concerned that the mandatory GPSD requirement that producers' and distributors' report to competent authorities about potentially dangerous products which they had placed on the market might infringe the legal protection against self-incrimination. The Netherlands initially resisted implementing the reporting obligations under the GPSD on this ground.

The wording of the duty to report under Article 5 (3) of the GPSD⁴¹⁹ is not framed in terms of requiring a report on “dangerous products placed on the market”. Those facts would amount to an admission of the general duty violation. Rather, producers are required to report when “a product they have placed on the market poses risks to the consumer *that are incompatible with the general safety requirement...*”⁴²⁰

⁴¹⁷ This could occur, for example, by committing a breach of fundamental justice under sections 7, 8, 11(c) or 13 of the Canadian Charter of Rights and Freedoms.

⁴¹⁸ *R. v. White*, [1999] 2 S.C.R. 417, at para. 41.

⁴¹⁹ 2001/95/E.C.

⁴²⁰ The UK transposed the GPSD reporting obligation of producers and distributors into section 9 (1) of its General Product Safety Regulations, 2005, ⁴²⁰ in the following terms:

9. —(1) Subject to paragraph (2), where a producer or a distributor knows that a product he has placed on the market or supplied poses risks to the consumer that are incompatible with the general safety requirement, he shall forthwith notify an enforcement authority in writing of that information and— (a) the action taken to prevent risk to the consumer; and (b) where the product is being or has been marketed or otherwise supplied to consumers outside the United Kingdom, of the identity of each Member State in which, to the best of his knowledge, it is being or has been so marketed or supplied.

The wording of the mandatory reporting requirement under the GSR, and the manner in which it is to be employed, are significant because the legal protection against self-incrimination in Canada depends greatly on the context and circumstances of each case.⁴²¹ A Court will be more, or less, inclined to extend legal immunity against the use of such a report in subsequent penal proceedings depending upon whether or not the report was made for strictly regulatory purposes, or as a known condition of licensing activities in which the accused could choose to participate in or not;⁴²² upon the extent of any adversarial or inquisitorial relationship between the State and the individual at the time the report is made,⁴²³ and whether or not the public authority was acting for auditing or investigative purposes at the time the information in the report was compelled.⁴²⁴

For example, the Supreme Court of Canada in *R. v. Fitzpatrick*⁴²⁵ admitted mandatory fishing logs and hail reports (which indicate the estimated poundage of the catch by species, and the date, time and location of catch during each trip) as evidence of the accused person's guilt in a regulatory prosecution for exceeding fish quotas. In *Fitzpatrick*, the Court concluded that the report was made for the strictly regulatory purpose of managing the offshore fishery. At the time the report was made, there was no "adversarial or even inquisitorial" relationship between the accused and the State.⁴²⁶

The essential purpose of this requirement is not to accumulate information that can later be used against the fishers who supply it. It is not compiled during the course of any investigation into wrongdoing. Instead, the purpose of the self-reporting

(3) In the event of a serious risk the notification under paragraph (1) shall include the following—information enabling a precise identification of the product or batch of products in question,(b) a full description of the risks that the product presents,(c) all available information relevant for racing the product, and(d) a description of the action undertaken to prevent risks to the consumer.

⁴²¹ See, for example, *R. v. White*, *supra*, at para.45. "The residual protections provided by the principle against self-incrimination as contained in s. 7 are specific, and contextually-sensitive. This point was made in *Jones*, *supra*, at p. 257, per Lamer C.J., and in *S. (R.J.)*, *supra*, at paras. 96-100, per Iacobucci J., where it was explained that the parameters of the right to liberty can be affected by the context in which the right is asserted. The principle against self-incrimination demands different things at different times, with the task in every case being to determine exactly what the principle demands, if anything, within the particular context at issue. See also *R. v. Lyons*, [1987] 2 S.C.R. 309, at p. 361, per La Forest J.

⁴²² *R. v. Fitzpatrick*, [1995] 4 S.C.R. 154 (mandatory reporting of fish logs and hail reports- fishing quotas)

⁴²³ *R. v. White*, *supra*.(mandatory statement to police following an accident, required under the B.C. Motor Vehicles Act.)

⁴²⁴ *R. v. Jarvis*, [2002] 3 S.C.R. 757, 2002 SCC 73

⁴²⁵ [1995] 4 S.C.R. 154

⁴²⁶ *Ibid.*, at para 34: "First, the information provided in this case was not provided "in a proceeding in which the individual and the state are adversaries". Instead, it was provided in response to a reasonable regulatory requirement relating to fishery management. Second, the "coercion" imposed on the appellant is at best indirect, for it arose only after he had made a conscious choice to participate in a regulated area, with its attendant obligations."

obligation is to provide fisheries officials with up-to-date information necessary for the effective regulation of the fishery. The establishment of quotas depends on accurate information about the size of catches, as well as about their particular location, and the fishers themselves are in the best position to provide this information. Enforcement of the quotas, in turn, is of benefit to commercial fishers as a group, for it ensures the continuing survival of the fishery and the fair distribution of its profits, which provide commercial fishers with their employment and income.⁴²⁷

The *Fitzpatrick* decision also illustrates the *balancing process* between public and private interests that the Court undertook to determine whether to apply the principle against self-incrimination to a fisher making mandatory reports in a licensed industry. .

At issue in this case is the ability of the government to enforce important regulatory objectives relating to the conservation and management of the groundfish fishery. To suggest that s. 7 of the *Charter* protects individuals who voluntarily participate in this fishery from being "conscripted" against themselves, by having information used against them that they were *knowingly required to provide as a condition of obtaining their fishing licences*, would in my view be to overshoot the purposes of the *Charter*. The right against self-incrimination has never yet been extended that far; nor should it be. The *Charter* was not meant to tie the hands of the regulatory state. (emphasis added)

The General Safety Requirement, however, is rarely applied to regulatory regimes involving pre-licensing approvals or pre-marketing certification. It was developed primarily as a post-marketing regulatory technique for unregulated hazardous products with mandatory reporting of dangerous products that have slipped through to market as a form of market surveillance. Such a report is likely to raise at least an "inquisitorial" relationship with Health Canada. Moreover, Health Canada officials may, simultaneously, begin to "investigate" a producer or distributor known to have a poor compliance history, or press for more particulars in a producer's report. Clearly, a Court could view this in a somewhat different context than did the Court in the *Fitzpatrick* case.

In *R. v. White*, for example, the issue was whether a statement that a declarant was required to make to a police officer preparing an accident report under section 61 of the B.C. Motor Vehicles Act could be used as evidence of the declarant's guilt in a subsequent prosecution under the Criminal Code.⁴²⁸ In

⁴²⁷ Ibid., para. 35.

⁴²⁸ Section 61 provided as follows:

(1) Where a vehicle driven or operated on a highway, either directly or indirectly, causes death or injury to a person or damage to property causing aggregate damage apparently exceeding the amount set out in subsection (1.1), the person driving or in charge of the vehicle shall report the accident to a police officer or to a person designated by the superintendent to receive those reports, and shall furnish the information respecting the accident required by the police officer or designated person.

White, the Supreme Court concluded that a driver who provides an accident report under s. 61 is *not* in the same situation as the commercial fisher who radios in or documents the quantity of the day's catch.

The provincial decision to vest the responsibility for taking accident reports in the police has the effect of transforming what might otherwise be a partnership relationship (aimed at securing safe roads for the benefit of all citizens) into one that is potentially adversarial. Very often, the police officer who is receiving the accident report is *simultaneously investigating a possible crime, in relation to which the driver is a suspect*. At the same time that the officer is required by s. 61(4) of the Motor Vehicle Act to obtain information about the accident from the driver, the officer may equally be required or inclined to inform the driver of possible criminal charges and of the driver's legal rights under the Charter, including the right to remain silent. The result is seemingly contradictory instructions from police. Importantly, also, the driver is generally in the officer's immediate physical presence. The result is, quite unlike the situation in *Fitzpatrick*, a context of pronounced psychological and emotional pressure.⁴²⁹

R. v. Jarvis,⁴³⁰ illustrates how the *purpose for which the information is collected* affects the context in which the protection against self-incrimination may arise. The *Jarvis* case involved a prosecution for income tax evasion premised largely on information that the defendant was statutorily required to surrender to auditors. The protection against self-incrimination in that case turned on the distinction between "audit" and "investigation."

In our view, where the predominant purpose of a particular inquiry is the determination of penal liability, CCRA officials must relinquish the authority to use the inspection and requirement powers under ss. 231.1(1) and 231.2(1). In essence, officials "cross the Rubicon" when the inquiry in question engages the adversarial relationship between the taxpayer and the state. There is no clear formula that can answer whether or not this is the case. Rather, to determine whether the predominant purpose of the inquiry in question is the determination of penal liability, one must look to all factors that bear upon the nature of that inquiry.⁴³¹

(4) The person receiving a report under this section shall secure from the person making it, or by other inquiries where necessary, the particulars of the accident, the persons involved, the extent of the personal injury or property damage and other information necessary to complete a written report of the accident, and shall forward the written report to the superintendent within 10 days after being advised of the accident.

⁴²⁹ *R. v. White*, [1999] 2 S.C.R. 417, at para. 58. The admissibility of statements given under compulsion pursuant to provincial motor vehicle accident legislation is governed by the same principles as those laid down in *California v. Byers*, (1971) 402 U.S. 424. If a statute has a non-criminal purpose, is not directed at an inherently suspect group, and is essential to the fulfilment of a valid regulatory purpose, such statutory compulsion does not violate constitutional protections: *Sydholm v. The Queen*, (B.C. Ct., February 2, 1983); leave to appeal refused (B.C.C.A., May 9, 1983). Section 13 of the Canadian Charter of Rights and Freedoms only applies to a "witness in any proceedings", not to a person who is interviewed by the police in the course of an investigation: *Prousky v. Law Society of Upper Canada* (1987), 41 D.L.R. (4th) 565 (Ont. S.C.); leave to appeal refused (1987), 62 O.R. (2d) 224 (Ont. C.A.).

⁴³⁰ [2002] 3 S.C.R. 757, 2002 SCC 73

⁴³¹ *Ibid.*, para 88

An inspection or administrative inquiry becomes an “investigation” at the point where officials begin to collect evidence of intent (or negligence) in the commission of an offence.

The other pole of the continuum is no more attractive. It would be a fiction to say that the adversarial relationship only comes into being when charges are laid. Logically, this will only happen once the investigators believe that they have obtained evidence that indicates wrongdoing. Because the s. 239 offences contain an element of mental culpability, the state will, one must presume, usually have some evidence that the accused satisfied the mens rea requirements before laying an information or preferring an indictment. *The active collection of such evidence indicates that the adversarial relationship has been engaged*, since it is irrelevant to the determination of tax liability. Moreover, although there are judicial controls on the unauthorized exercise of power (Roncarelli v. Duplessis, [1959] S.C.R. 121; Babcock v. Canada (Attorney General), [2002] 3 S.C.R. 3, 2002 SCC 57, at para. 25), we believe that allowing CCRA officials to employ ss. 231.1(1) and 231.2(1) until the point where charges are laid, might promote bad faith on the part of the prosecutors. Quite conceivably, situations may arise in which charges are delayed in order to compel the taxpayer to provide evidence against himself or herself for the purposes of a s. 239 prosecution. Although the respondent argued that such situations could be remedied by the courts, we view it as preferable that such situations be avoided rather than remedied. It is for this reason that the test is as set out above.⁴³²

Whether or not the self-incrimination issue is raised as a *legal* concern in relation to the GSR reporting requirement, it will be a practical concern to producers and distributors and could adversely affect the reporting scheme as an effective preventive measure. If the purpose is to be primarily regulatory and preventive, the Department may wish to consider introducing a use immunity provision along the lines of section 61(7) of the British Columbia *Motor Vehicles Act*.⁴³³ Section 61(7) of that Act supplements the reporting scheme by creating use immunity for a declarant in relation to the information provided pursuant to s. 61(1). The declarant is protected against self-incrimination by a statutory guarantee that, with two exceptions, neither the report nor any information contained in it is admissible in a trial or proceeding arising out of the accident:

(7) The fact a report has been made under this section is admissible in evidence solely to prove compliance with this section, and the report is admissible in evidence on the prosecution of any person for the offence of making a false statement therein, but neither the report nor any statement contained in it is admissible in evidence for any other purpose in a trial or proceeding arising out of the accident referred to in the report.

⁴³² Ibid., para. 91 See also, Peter W Hogg, *Constitutional Law in Canada*, 2005, Student edition, at pages 1069-1073 (*Right to Silence*)

⁴³³ RSBC [1996] Chapter 318

Alternatively, the Department could ‘remain silent’ on the issue of use immunity for mandatory dangerous product reports, perhaps on the European view that the *quid pro quo* to be exacted from industry in return for self-regulation is precisely this form of accountability. If so, the Department might wish to have its Legal Services Unit provide an opinion on whether, or to what an extent, Canadian courts would support that view on the line of cases mentioned above.

Case Law Related to the General Product Safety Directive

There is little reported case law dealing with General Product Safety Provisions. In the UK, there is also little experience in the Criminal Courts with the GPSD because so few cases go to prosecution; those that do are often heard in Magistrate’s Court and unreported. Miles Alexander, of Simmons and Simmons, identified a number of *disincentives* to prosecution in the UK, namely:

- *Expense* - It is very costly to prosecute cases in the UK. The costs usually run into the thousands of pounds when opportunity costs, including salaries, are taken into account;⁴³⁴
- *Exposure to product liability* – A successful prosecution can have product liability consequences far greater than any fine imposed;
- *Orientation of the regulations* – The regulations under the General Product Safety Directive are drafted in a way to facilitate discussion and settlement and to discourage confrontation, which can be injurious to trade; and
- *Enforcement posture* – The United Kingdom’s Regulatory Policy and *Enforcement Concordat*⁴³⁵ encourage a “light touch” approach to enforcement, with formal enforcement in the background if the company is disinclined to comply. “Voluntary” compliance may, however, be a bit of a euphemism given the tension present in settlement or remediation discussions.

Notwithstanding a paucity of case law related to the GSPD, there are a few noteworthy decisions concerning:

- The jurisdictional underpinnings of the GPSD in Europe;⁴³⁶

⁴³⁴ The BBC News reported on one private prosecution against a cell phone manufacturer under the General Product Safety Provision alleging that the phones produced cancer producing waves. This action was reported as costing the complainant over 20,000 pounds to prosecute. In dismissing the prosecution, the Court reportedly tendered the view that the subject matter was better left to science than the courts to resolve.

⁴³⁵ See UK Cabinet Office, *The Enforcement Concordat*, PDF accessed on October 27, 2006, at:

<http://www.cabinetoffice.gov.uk/REGULATION/documents/pst/pdf/concord.pdf>

⁴³⁶ *Federal Republic of Germany v Council of the European Union*, Case C-359/92.

European Court reports 1994 Page I-03681; accessed on September, 17, 2006, at: <http://www.bailii.org/cgi-bin/markup.cgi?doc=eu/cases/EUECJ/1994/C35992.html&query=%22general%20product%20safety%20%22>

- The scope of the European Commission's 'direct' authority to act against specific products and hazards;⁴³⁷
- The jurisdictional constraints against enacting directives for the sole, or primary, purpose of protecting public health and safety (Challenge to EU's Tobacco Directive);⁴³⁸
- The interface between the GPSD and Member State legislation dealing with similar products or hazards (Second-hand car);⁴³⁹
- The exercise of the public authority's power to warn the public of dangerous products (Baby Walkers);⁴⁴⁰
- The extent to which the element of 'causation' in tort law is relevant, if at all, under a general product safety provision in assigning responsibility for successive failures to meet obligations imposed by the GPSD throughout the supply chain (for example, as an excuse for retailers seeking to escape their obligations under the GPSD where producers and distributors failed earlier to meet their own product testing obligations). (Claw hammers imported from China);⁴⁴¹
- The application of the defence of due diligence in a UK Criminal Court (toy caps for cap pistols);⁴⁴²
- An approach to dealing with an alleged regulatory gap in the context of an application to amend pleadings (Felt Pen caps – children's' choking hazard);⁴⁴³
- The importance of leading evidence as to the degree of hazard presented by a product in a prosecution under GPSD regulations, (Shaggy Dog soft toy);⁴⁴⁴ and
- The application of different and competing limitation periods for bringing actions under general product safety provisions (Laser Pointer).⁴⁴⁵

⁴³⁷ *Ibid.*, see also ECJ, Case C-376-98 dealing with directive 98/43/EC, banning tobacco advertising and sponsorship of tobacco products., European Court reports 1994 Page I-03681

⁴³⁸ *Ibid.*

⁴³⁹ *Caerphilly County Borough v. Stripp* [2000] E.W.J. No. 1779.

⁴⁴⁰ *Baby Products Assn. V. Liverpool City Council*, [1999] E.W.J. No. 6012; Case No: CO/3733/99, Also reported at: [2000] L.G.R. 171

⁴⁴¹ See, *Padgett Brothers (A-Z) Limited vs The Coventry City Council*, CO/3892/97, H.C.J. (Queen's Bench, Divisional Court); accessed on September, 17, 2006 at <http://www.bailii.org/cgi-bin/markup.cgi?doc=ew/cases/EWHC/Admin/1998/20.html&query=%22general%20product%20safety%20%22>

⁴⁴² *Powys County Council v. David Halsall International Limited*, CO/9162/2005 [2006] EWHC 613 (Admin), High Court of Justice Queen's Bench Division Divisional Court

⁴⁴³ *R. v. Newcastleupon Tyne Magistrate's Court (Ex parte Poundstretcher Limited)*, [1998] EWHC Admin 251 (3rd March, 1998), accessed on September, 17, 2006, at <http://www.bailii.org/cgi-bin/markup.cgi?doc=ew/cases/EWHC/Admin/1998/251.html&query=%22general%20product%20safety%20%22>

⁴⁴⁴ *The Queen v. The West Midlands Magistrates, Ex Parte PMS International Group PLC*, [1993] E.W.J. No. 3485, CO 1446/92

⁴⁴⁵ *R. v. Thames Magistrates Court (Ex Parte Academy International PLC)*, H.C.J. C.O. C.).-293-99, [1999] EWHC Admin 548 (June 14, 1999)

These decisions are summarized in Annex 7. Of particular note, is the recent UK decision *Powys County Council v. David Halsall International Limited*,⁴⁴⁶ dealing with the defence of due diligence under a GPSD regime.

The very limited case law under the GPSD makes it difficult to assess the impact of evolving UK standards on the standard of care required to be shown to establish a due diligence defence. There is a presumption that the natural result of new and improving standards will raise the bar on a due diligence defence, but the same might have been true no matter the reason standards were improved.

Section 29(1) of the UK regulation transposing the revised General Product Safety Directive provides for a 'due diligence defence' in the following terms:

29. —(1) Subject to the following provisions of this regulation, in proceedings against a person for an offence under these Regulations it shall be a defence for that person to show that he *took all reasonable steps* and exercised all due diligence to avoid committing the offence. (emphasis added)

Mr. Mark Dewar (of Simmons and Simmons, London, UK)⁴⁴⁷ stated that the words “took all the necessary steps” which precede the words “exercised all due diligence to avoid committing the offence” makes the due diligence defence very difficult to advance, especially in view of the absolute liability thrust of the Directive. The “all reasonable steps” terminology may be used to refer to improving standards of risk assessment and advanced process requirements in relation to new products. The UK is thought to be the only country in the EU to insist upon the due diligence defence – which fits uncomfortably with the absolute liability posture of Europe’s GPSD..

Mr Alexander (also of Simmons and Simmons) considered that the main use of the due diligence defence, likely, was to illustrate to clients what they may/must do to position themselves well to avoid a successful prosecution. (ie: by demonstrating that risk assessment has taken place, compliance plans have been drawn up, etc.) To that extent, the defence has some *preventive* value where clients may be expected to consult lawyers.

Christopher Hodges (Oxford University)⁴⁴⁸ noted that similar wording has prevailed for some time in the UK *Health and Safety at Work Act* and in the *Consumer Protection Act, Part II*. It was carried over into the *General Product Safety Directives* of 1995 and 2004. He agreed that it was very difficult for that defence to succeed:

You’ve got to show not just that you were reasonably competent; you have to show that you have taken “all the necessary steps”, and the courts have said that

⁴⁴⁶ CO/9162/2005

[2006] EWHC 613 (Admin), High Court of Justice Queen’s Bench Division Divisional Court

⁴⁴⁷ Interviewed, December, 2005

⁴⁴⁸ Interviewed December, 2005

'all' means 'pretty high'. So if you are unlucky enough to be prosecuted, or deserve to be prosecuted, you are not going to 'wriggle off' the hook. That is entirely consistent with having a generally low-key regulatory approach. The perception is, that U.S. regulatory authorities are much more aggressive, in which case you might want a different balance, for constitutional reasons, that is, a broader defence.

In accountability terms, therefore, some opinion leaders argue that the *quid pro quo* for the high degree of self-regulation allowed industry under the GPSD should be higher penalties and a higher burden on the defence.⁴⁴⁹

While the value of the Powys decision (see Annex 7 - Case Law) on due diligence suffers from some procedural defects, it does provide an excellent, albeit isolated, example of just how difficult it is for a defendant to establish a defence of due diligence in the U.K under the General Product Safety regime. Notwithstanding the elaborate efforts made by the Company in that case through its in-house testing program, and the absence of any independent testing laboratories in the UK to undertake the relevant testing in that case, the Company's successful due diligence defence has to be qualified as a 'close call.' Had a question been posed on the sufficiency of the evidence establishing the comparability of the Company's in-house tests with those of the relevant British standard for such tests, the decision might easily have gone the other way.

11. Canadian Case Study Issues and Summary

Three Case Studies

The Case Studies were developed on the basis that a GSR could be implemented in Canada. That is a decision to be taken by the Government, and it may be informed by the information presented in this report. If implemented, a GSR that basically prohibits unsafe products from being placed on the Canadian market will impose many new responsibilities on suppliers and government. There will be operational and financial implications for the suppliers who must comply with it and for government agencies responsible for implementing and enforcing it.

The three case studies included in this report in Annex 1 provide details of the impact of a GSR. The first case study examines the impact on suppliers of products that are not currently regulated and for which there are no national standards. The second case looks at products that that are inadequately

⁴⁴⁹ Some firmly believe that the penalties should be higher under the GPS regulation. In the UK, there is an ongoing debate as to whether they should have a "corporate manslaughter" offence, that is, whether the Directors should also be prosecuted along with the company. That has been a fiercely fought issue for a very long time and the Government is said to have only made a few tentative steps into that direction for the moment.

regulated, and the third case at products that are subject to Federal and Provincial/Territorial regulation. The potential to establish regulations under existing legislation as an alternative approach is also examined.

These case studies are based on the following assumptions:

- The GSR would complement any regulations by acting as a 'safety net' in the absence of a regulation that addresses the health risk or hazard in question.
- A GSR would make it illegal for a supplier to manufacture, promote or market a product that may pose a risk to the health or safety of consumers when used under intended or reasonably foreseeable conditions.
- In trying to demonstrate conformity to a GSR in response to the occurrence of non compliance, a supplier would be required to demonstrate that all reasonable care was taken to comply with the provisions of a GSR including identifying any associated product hazards, assessing the related risks and managing these risks.
- Like the obligations on business in Europe and the US, the GSR would require suppliers to monitor the safety of their products and notify a government regulator of any unsafe or potentially unsafe products that have been placed on the market. Government on receiving a notification would be obligated to take relevant certain action based on its legal obligations and the seriousness of the problem. and
- Unlike the US system, the GSR would not contain a provision that the government must consider the development of voluntary standards before considering the development of regulations. Nor like the European system would Canadian standards be developed that would confer a presumption of conformity with the GSR. Conformity with voluntary standards developed through a recognized system could, however, be used to demonstrate conformity where no regulations exist or where the standard addresses a risk not covered by an existing regulation.

Regulatory requirements for the provision of safety information prior to marketing and for mandatory reporting of adverse incidents to Health Canada already exist for drugs, natural health products, biologics and medical devices under the *Food and Drugs Act* (F&DA). Similar requirements do not exist for all foods regulated under the F&DA or for consumer products under the *Hazardous Products Act* (HPA) or *Radiation Emitting Devices Act* (REDA). As a result, the impact on suppliers of these products and those responsible in Health Canada will be greater than in the areas where these provisions have existed for a number of years.

The impact on suppliers could also vary depending on their role in the supply chain. The supply chain for consumer products is presented in Figure 1 in the Case Studies. Producers are primary suppliers who have the ability to influence the safety of consumer products or first to place a product on the Canadian

market. Distributors are secondary suppliers who have limited ability to influence the safety of consumer products.

Case Study 1, using the example of bicycles, the situation where no Canadian standards or regulations exist is examined. Here, the supplier would be required to identify the product hazards and their source, assess the risks from the perspective of both intended and reasonable foreseeable use, implement procedures or processes to mitigate the risks, monitor them and report any adverse health effects to the responsible government agency. Unfortunately, many importers and importer/retailers do not have the same level of knowledge about a bicycle as a manufacturer and might have significant difficulty in responding in a similar manner. The situation is further complicated because some foreign manufacturers are not always willing to provide the information required to identify and assess potential risks associated with their bicycles.

Case Study 2, using the example of Konjac Jelly Mini-cups, the situation is examined where the existing regulatory framework does not provide the authority to address: all hazards related to the regulated product; changes in the product due to technical advancements; or usage of the product in a manner that was not contemplated when the regulation was developed.

The safety of food is more complex than many other product areas since it involves more than 30 different government departments, agencies (federal, provincial/territorial and/or municipal) depending on the product or problem. At the Federal level, Health Canada is responsible for developing the food safety regulations under the F&DA and the Canadian Food Inspection Agency (CFIA) is responsible for enforcing these regulations. The provinces/territories also develop and enforce statutes to minimize food safety risks in various commodities produced and sold within the province/territory. Municipal public health officials, who are often the first to be notified of food safety problems, also play an integral role in the food safety system. They can set food safety standards and policies for food premises and have the power to condemn food. The challenge is for governments at all levels to work cooperatively to reduce the risks and to streamline and enhance the system.

Konjac Jelly Mini-cup products are food products covered by the *Food and Drugs Act and Regulations* (FDA&R). Unfortunately, the Act does not prohibit food that due to its physical or mechanical properties adversely affects the health or safety of a consumer. As a result, it was not possible for CFIA to use the F&DA to address the problem of the Konjac Jelly Mini cups. The *Hazardous Products Act*, which provides Health Canada with the authority to deal with mechanical choking hazards in consumer products, could not be used either since food is specifically exempted from this Act. Ultimately, a mandatory recall was issued under the *Canadian Food Inspection Agency Act* (CFIA Act).

If a GSR were considered to address situations such as this, steps similar to those discussed in Case Study 1 would be involved for both suppliers and government. There would be significant challenges due to the lack of data and research on adverse events caused by the mechanical properties of food making it difficult for a producer to assess the risk associated with the Konjac Jelly Mini-cups. In addition, it will have to be determined whether the HACCP-based Quality Management System adopted by CFIA as well as internationally as a code of practice in the food trade will be accepted as a way to demonstrate compliance with a GSR.

Case Study 3, using the example of household electrical products, examines the situation where two levels of government have the authority to deal with the same product and the requirements may or may not be consistent across the country. Although Health Canada has the authority to regulate these products under the *Hazardous Products Act*⁴⁵⁰ (HPA) no regulations for these products have been developed. All the provinces and territories have enacted legislation and regulations to deal with the installation and safety of electrical equipment connected to the electrical system including equipment used in and around the home. These regulations mandate the *Canadian Electrical Code* (CEC) and require that all household electrical products are approved by provincial/territorial authorities or are certified to the product standards referenced in the CEC. However, no level of government has the authority to order a mandatory recall of a dangerous household electrical product or to require suppliers to monitor their products and report adverse incidents.

Normally, the provisions included in a GSR or similar regulatory initiatives require a producer to assess and manage all risks associated with a product, monitor the product in the marketplace and report any adverse incidents. As a result, a producer could comply with all the standards under the CEC mandated by provincial/territorial regulations and still be at risk of Health Canada taking action against him/her under the criminal code if a hazard not addressed by the standards was identified.

Summary of the Key Findings in the Case Studies

Using three different case studies, the implications for suppliers and government of implementing such provisions under a GSR or through regulatory amendments under existing legislation were investigated and a number of key findings were identified and are described below:

- The costs for suppliers in complying and government agencies in administering and enforcing the reporting provisions will vary significantly depending on what systems and reporting mechanisms are already in place and on the criteria that will be used to trigger a report. In the case of consumer products like bicycles and household electrical products,

⁴⁵⁰ Justice Canada, *Hazardous Products Act*, Paragraphs 6.1 (a) and (b), March 3, 2006

harmonization with the systems in Europe and the United States could help maximize the usefulness of the data collected and minimize the costs.

- There are a number of policy issues that will need to be resolved in order to successfully implement a GSR or similar regulatory provisions. Many of the issues are common to all three case studies included in this report and are related to the need for guidance and clarity around new requirements. For example, suppliers and government staff who provide advice need to know:
 - What standards, regulations, conformity assessment systems or risk assessment process will be acceptable to demonstrate conformity with a GSR;
 - What level of safety will be required to demonstrate compliance with a GSR;
 - What type of adverse incident or level of injury will trigger a report of a problem product or a recall; and
 - To whom and what system will be used to report adverse incidents.
- One of the core elements in the implementation of a GSR or similar regulatory amendments is hazard identification and risk assessment. Such an approach based on evidence provides the basis for the selection of appropriate instruments to reduce risks, the determination of an unsafe product, the identification of effective interventions and the reporting of adverse health effects. In many cases, there are gaps in the information that suppliers need to carry out a risk assessment making it difficult for them to comply with new provisions. Moreover, many suppliers, even large companies, do not have the expertise or capacity to assess risks in products. For example, manufacturers in other countries do not always make information about product design, component materials or manufacturing processes available and there is a lack of product related injury data within Canada. The need for increasing the data available and the knowledge of suppliers about hazard identification and risk assessment is core to the successful implementation of the GSR or similar regulatory provisions.
- To ensure that the transition from the existing legislation to new legislation or regulations is smooth and seamless and that the Department will be able to deal with the new provisions and products that will be covered, it will be necessary for Health Canada to identify, develop and/or implement:
 - Changes and/or additions to its management processes and knowledge management systems to meet new and changed provisions and authorities in new legislation such as the adverse event reporting system. The impact will be greatest for those parts

of the organization or other organizations responsible for unregulated consumer products or foods where systems or processes for reporting of adverse events or dealing with mandatory recalls have not been established;

- Tools, information and training that the employees will need to administer and enforce the new provisions that will apply to many products not previously dealt with;
 - Training, information and guidance documents to provide previously unregulated suppliers with an understanding of how to comply with any new provisions;
 - Functions of staff and the skills, expertise that staff will require to administer the new provisions in areas previously unregulated and to evaluate the various instruments that suppliers could use;
 - Financial resources to develop and implement new systems, to hire expert analytical staff, tools or training within Health Canada and other responsible government agencies e.g. Canadian Food Inspection Agency or Provinces/Territories;
 - A dispute resolution system;
 - Protection of personal information; and
 - Processes to ensure consistency in administration and enforcement for many new products across federal or provincial/territorial organizations that share responsibility.
- In certain product areas such as household electrical products and some foods, overlap will exist between provincial/territorial legal instruments and a GSR. As a result, it will most likely be necessary to develop a consensus among a number of government agencies and levels of government on the following questions:
- How the provinces/territories will work with the federal agencies to implement a GSR or new regulatory provisions?
 - Will the provinces/territories be able to draw on the provisions of the GSR and enforcement authorities under federal legislation to deal with importation, reporting and recalls?
 - What level of safety will be considered unacceptable and will trigger enforcement action or reporting of an adverse incident?
 - To whom will reports of adverse incidents be made?
 - What type of information manuals and/or training will need to be developed to assist suppliers and government officials in understanding the new requirements?

The policies and the form of any working arrangements developed with the provinces and territories will have a significant impact on whether or not any overlap that exists between them has a negative or positive benefit.

- The reliance on standards will require substantial participation by government officials to ensure that the standards developed address the health and safety concerns of Canadians. Moreover, the fact that many standards reference other standards increases the workload.
- In order for cabinet to make a decision on new legislation or regulatory changes, it will be necessary for Health Canada to obtain accurate, complete and up to date information based on the results of:
 - An analysis of any proposed changes and the alternative solutions considered;
 - The consultation with those who have an interest in the matter, including other departments that may be affected by the proposed solution;
 - An analysis of the impact of the proposed solution on the operating environment and costs to small, medium and large suppliers; and
 - An analysis of the resources that the proposed solution would require, including those needed to implement or enforce it.
- The legal implications of a government agency being informed of a safety hazard in a product needs to be addressed, particularly, if it means that all reports cannot be investigated.

12. ‘Outcome Oriented’ Legislation

Introduction

One of Health Canada’s objectives under the Legislative Renewal Initiative is to foster an ‘outcome oriented’ (or performance-based) product safety regime that facilitates both technical innovation and continuously improving safety standards in the public interest.

The GSR, as mentioned earlier in this Paper, is a form of performance-based regulation, albeit a somewhat extreme form given that voluntary standards effectively substitute for technical regulations. From a policy development perspective, the GSR’s advantages and limitations closely parallel those of a performance-based regime. As in the case of performance-based regulation, Europe’s ‘General Safety Requirement’ is given operational effect through a series of directives in the nature of framework legislation, essential requirements expressed as performance standards, supplementary legislated duties and obligations, voluntary specification standards, guidelines, codes of practice and related guidance documents, ever increasing in their operational detail.

In a globalized economy, the role of government *vis a vis* the regulated community has been reconsidered over the last twenty years. Where

government must regulate to protect public health and safety and the environment, or to regulate the economy, it now seeks to use the least intrusive measure that is effective. Using voluntary standards or codes in lieu of regulation, or in conjunction with goal-oriented regulation, are methods of limiting government's intrusiveness. Performance and instrument choice are priority issues with most Western governments today.

Canada's budgeting process is performance-based. Parliament requires goal-based reporting as the new measure of public accountability, linking government action and expenditures to previously announced regulatory objectives. Government is committed to "business plans," to results-oriented accountability, to demonstrating "operational" efficiency and to reporting the "bottom line" to Parliament.

In most western democratic countries, including Canada, there is a growing convergence between industry and business practices, management theory and approaches to public administration. Management by objectives, performance-based expenditures, risk assessment, risk management, quality assurance, knowledge management, information systems and performance measurement -- are mutual preoccupations of the public and private sectors.

Outcome oriented (performance-based) regulation - though largely untested by time and the courts - is viewed by both sectors as a promising vehicle for better meeting regulatory objectives and advancing the growing convergence between business and regulatory practices. Yet the benefits and limitations of performance-based regulation, in which law, business, industry and the stakeholders relying on regulatory protection, interface, remain the subject of continuing debate and some controversy.

Uncertainty, Information Needs, Risk Assessment, Performance Measurement

In May 2001, the Kennedy School of Government at Harvard University (The Regulatory Policy Program) sponsored a workshop entitled *Performance-based Regulation: Prospects and Limitations*. The title of this Workshop, considering its venue and recentness, underscores the persistent controversy about this regulatory technique.

Harvard professor Cary Coglianese and a team of researchers were investigating "how to implement performance-based approaches to improve the efficiency and effectiveness of health and safety regulation across a variety of regulatory domains."⁴⁵¹ The conundrum to be addressed by this work was that the

⁴⁵¹ The Federal Railroad Administration of the United States Transportation Department sponsored this project.

theoretical benefits of performance-based regulation had been long recognized, but more prescriptive approaches to regulation still tend to dominate many fields of regulation. The purpose of the initiative was to learn when and how to implement performance-based regulation, in order to exploit its theoretical advantages.

Participants at the Harvard Workshop on Performance-based Regulation noted that uncertainty, access to reliable information and performance assessment are persistent problems under GSR regimes.

Performance-based regulation raises a number of issues relating to uncertainty, information, and the role of experts in regulatory decision-making. Perhaps the biggest uncertainty of all is the *performance* of performance-based standards. Participants noted a general absence of empirical studies evaluating the effectiveness of performance-based standards, let alone systematic work showing when, where, and how well performance-based standards work in various regulatory settings.

In Europe, uncertainty, monitoring, surveillance, enforcement and securing reliable information under the *GSPD* regime clearly remain issues of concern despite a decade of experience with the initiative.

The Harvard Workshop considered a number of the elements of performance-based regulation previously touched on by Canada's Office of the Auditor General. In 1997, the Auditor General summarized the essential components of an effective performance-based regime from an auditing perspective. Auditing for effectiveness is an important perspective on performance-based regulation, given the critical importance of relevant and reliable data in determining whether performance goals are in fact met. The Auditor General looks for the following essential elements in a PBR regime when assessing its effectiveness:

1. Clear and comprehensive performance objectives or goals for each of the areas subject to regulation;
2. Formal risk analysis leading to the identification of the key performance goals for which data are to be gathered to monitor performance;
3. The specifications of the measurement procedures and data to be used to monitor performance;
4. Procedures to ensure timely and unimpeded access to all necessary data; and
5. Assessment of the data quality, and procedures to carry out independent verification of the data.⁴⁵²

⁴⁵² Paragraph 19.109, Annual Report of the Auditor General, 1997. These essential components of a PBR regime are very close to those identified by Transport Canada (Safety Review Committee) which included:

- identification of regulatory goals;
- general reliance on standards of quality and performance measurement;
- determination of the most effective means of mitigating and monitoring air navigation system-related risks; and

The Harvard Workshop proceedings, the material developed by the Auditor General in 1997 in its audit of a Transport Canada program and related studies of performance-based regulation in other countries illustrate some of the limitations of performance-based regulation:

- Non-quantified performance objectives do not always meet the "clear and comprehensive performance objectives" requirement of the federal Auditor General;
- Risk analysis, while a useful management tool, is an evolving discipline.⁴⁵³ It is particularly problematic under the *GPSD* regime in Europe, where one hypothetical test of the risk formula for establishing whether a product was safe or unsafe involving several Member States led to a split decision on the result. As indicated earlier in this Paper, Europe has a major reassessment of risk assessment methodology under way in an effort to achieve greater consistency;
- Predictive risk analysis models often contain many hidden value judgments and, despite their scientific cloak, can be quite unreliable. This is especially so with computer-generated models, as the unreliability of the Weatherman's five-day predictions often confirm;
- Performance-based approaches rely heavily on "experts" in risk analysis, risk management and performance measurement. As participants at the Harvard Workshop noted, "many people lack the training to understand these models. *As a result, the number of people who can knowledgeably participate in regulatory decision making declines as the complexity of the analysis increases;*"
- The Commission of European Communities, in a White Paper on European Governance (2001) commented on the use of experts in the legislative and regulatory process. The Commission intends to "publish guidelines on collection and use of expert advice, so that it is clear what advice is given, where it is coming from, how it is used and what alternative views are available;⁴⁵⁴

development of extensive feedback mechanisms to sample, analyze, and evaluate the effectiveness of the risk mitigation.

⁴⁵³ Some approaches to risk analysis, however, are in common use and quite effective. (E.g. HACCP Hazard Analysis and Critical Control Points methodology, commonly adopted in food safety regulations.

⁴⁵⁴ See A White Paper on European Governance, Commission of The European Communities, Brussels, 25.7.2001. The full excerpt, from which the quote was drawn is:

"When legislating, the Union needs to find ways of speeding up the legislative process. It must find the right mix between imposing a uniform approach when and where it is needed and allowing greater flexibility in the way that rules are implemented on the ground. It must boost confidence in the way expert advice influences policy decisions.

The Commission will:

- Promote greater use of different policy tools (regulations, "framework directives", co-regulatory mechanisms).
- Simplify further existing EU law and encourage Member States to simplify the national rules which give effect to EU provisions.

- The development of performance measures and performance evaluation are complex undertakings, and providing the information required can be extremely burdensome on industry and business. Participants at the Harvard Workshop on PBR noted the irony that government policies favour performance-based regulation, on the one hand, and the reduction of red tape (paper burden), on the other; and
- Performance indicators should reflect a *preventive* regulatory strategy to the extent practicable, that is *performance indicators should be embedded well below the level of the ultimate objective to give regulators enough time to prevent bad performance.*" Performance measures based only on accident, or incident reporting, for example, are inappropriate to regulated sectors where the adverse events are rare, but serious or catastrophic when they occur. (E.g. nuclear reactors, airline safety).

Risk assessment of product hazards is a critical feature of Europe's General Product Safety regime. In Europe, there are two initiatives underway to improve risk assessment methodology and guidelines. One group was established by the European Union to assist enforcement authorities who need a better risk assessment tool in their daily work. This group is entitled the EU Working Group Improvement of Risk Assessment Guidelines (IRAG). It was formed to review and improve the risk assessment guidelines that are used with the RAPEX system.

The Working Group started by following a practical approach, starting from the already published RAPEX Guidelines. The aim is to amend the method in order to achieve more consistency and less variation between assessors. Several proposals have been made to improve the scales of severity and probability used in the method. For example, four levels of severity have been proposed and eight levels of probability (the lowest being 'less than 1 in 1.000.000' and from there increasing by factors of 10). The Working Group anticipates that all factors, like exposure and vulnerability, will ultimately be included in the probability of harm.

A second group, the Eurosafe Working Group on Risk Assessment, was established around the same time to determine a good scientific basis for risk assessment, listing all essential steps and relevant factors. Theoretically, its product should form the basis of the revisions carried out by the EU IRAG to improve the RAPEX model and the EU IRAG has agreed to consider this approach. At this stage, however, no decision has been made with respect to which model will eventually be recommended to the EC.⁴⁵⁵

Publish guidelines on collection and use of expert advice, so that it is clear what advice is given, where it is coming from, how it is used and what alternative views are available."

⁴⁵⁵ Information provided by Elizabeth Nielsen. Euro-Safe is a new initiative of the European Consumer Safety Association. (ECOSA), and has been established as a working group that operates under the legal and financial responsibility of ECOSA. Its objective is to facilitate partnering for joint proposals for research and action, involving dedicated research and safety promotion institutes around Europe.

Given the importance of effective risk assessment to the functioning of a general safety requirement and the controversy still surrounding the question of acceptable risk assessment methodologies, an important policy question facing Health Canada, is whether the GSR is likely to be an acceptable instrument of choice for Health Protection legislation, especially when that legislation would necessarily be based on a criminal law (penal) model demanding a high degree of certainty for dispute resolution purposes.

Australian Experience with Grey-Letter Law” – Standards, Guidelines, Codes of Practice

Australia has had many years of experience with the innovative use of standards in regulation and in the use of performance-based regulation generally. In Australia, as in other Western democratic countries, the search for regulatory flexibility has shifted to the search for less intrusive methods than prescriptive regulation for accomplishing regulatory objectives. In 1997, a Report of the Commonwealth Interdepartmental Committee on *Quasi-Regulation* in Australia entitled *Grey-Letter Law* canvassed the use of standards and other non-prescriptive methods for achieving regulatory goals:

Regulation can usefully be considered as a spectrum ranging from self-regulation where there is no government involvement, through various regulatory arrangements with increasing degrees of government influence and involvement, to explicit government regulation (often referred to as "black-letter law").

In this report, the term "quasi-regulation refers to the range of rules, instruments and standards where government influences businesses to comply, but which does not form part of explicit government regulations. Quasi-regulation can take many forms such as codes of practice, advisory notes, guidelines, and rules of conduct issued by either non-government or government bodies. In the context of a regulatory spectrum, quasi-regulation might be considered as "grey-letter law" (p. ix)

The boundaries between self-regulation, quasi-regulation and prescriptive regulation are frequently indistinct. Parliament may, for example, require that industry codes be made mandatory, resulting in prescriptive regulation. Or government may indirectly influence business practices through official endorsement, representation on monitoring committees, provision of guidelines, or voluntary agreements with industry. Government involvement in quasi-regulation, however, is often perceived by industry as *requiring* compliance with the particular code, standard or arrangement and therefore may have considerable impact on industry.⁴⁵⁶

The Advantages of Alternatives to Prescriptive Regulation

⁴⁵⁶ *Grey Letter Law*, Report of the Commonwealth Interdepartmental Committee on Quasi-Regulation (Australia), p. 409

Alternatives to regulation (Quasi-regulation) have advantages and disadvantages. The advantages were summarized in the Australian Report, *Grey Letter Law*:

*Compared to black-letter law, quasi-regulation, as with self regulation, can offer the advantages of flexibility, responsiveness, less cost to government and greater collaboration with industry, particularly with industry initiated schemes. Greater compliance is possible if the rules are clear and designed in collaboration with industry experts. Quasi-regulation can also make use of innovative compliance mechanisms and quicker, cheaper, dispute resolution schemes and, due to greater involvement and ownership, industry may also be willing to contribute resources to developing, implementing and enforcing this type of regulation.*⁴⁵⁷

The Disadvantages - A Hidden Regulatory Burden?

The disadvantages associated with the use of standards, codes of practice and other alternatives (or, instruments of quasi-regulation) set out in the Australian Report included:

- Increased regulatory burden due to administrative costs shifting to business;
- Information on particular codes and rules is often less accessible than for laws;
- Private standards and codes may overlap with other codes and standards or with regulatory standards; and
- Compliance obligations are often unclear under quasi-regulation

Quasi-regulation can result in a form of "regulatory creep." It is not subject to the same vetting process as regulations. It can be introduced without formal assessment of its net benefit, compliance costs, economy wide impacts, or its impact on small business, or international competitiveness.. *The concern, essentially, is "backdoor regulation" without formal justification or risk assessment - leading to inappropriate quasi-regulation with which industry feels obliged to comply.*⁴⁵⁸

In a Paper released by the OECD entitled *Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance*,⁴⁵⁹ the concept of 'regulatory inflation' is discussed. In this Paper, the term regulatory inflation is used to describe the cumulative impact of multiple regulations that individually serve logical purposes, but combine to produce an overwhelming incomprehensible whole.

⁴⁵⁷ *Ibid.*, P. 40

⁴⁵⁸ One of the principle reasons for the *Grey-Letter Law* study (supra) in Australia, was concern raised in the 1996 National Small Business Summit and in the report of the Small Business Deregulation Task Force that can affect the behaviour of businesses and impose a burden similar to explicit government regulation without any assessment of net public benefit.

⁴⁵⁹ PUMA (2000) 4, distributed on March 24, 2000 for the 21st Session of the Public Management Committee held in Paris, April 6 and 7, 2000.

Unfortunately, performance-based regimes, over time, suffer from a similar shortcoming. Earlier in this Paper we noted the striking similarities between the (“New”) performance-based approach to regulation adopted by Europe under the GPSD and similar reforms in the UK in the occupational health and safety sector in the early 1970’s. The OECD paper makes clear that both prescriptive and performance-based regimes may face identical problems of regulatory ‘inflation’ as they mature.

Even where an effort is made to reform regulation to make it simpler, easy to understand, and to include the private sector in drafting rules, a “regulatory ratchet” takes effect. This means that, without vigilance, *the overall regulatory structure tends to become more technical and unworkable as details are added and loopholes are closed.* For example, reforms to occupational health and safety regulation initiated in England and modelled in many other countries were intended to replace many technical rules with a few easy to understand, flexible, general rules. *The aim was to facilitate employer self-regulation of occupational health and safety on an individualized site-by –site basis.* However, over time many technical and detailed ‘codes of practice’ have developed under the general provisions of the occupational safety and health regulation to address specific hazards and make the law more certain for employers. *The proliferation of these codes of practice which have the effect of law means that now many businesses in Britain find them too complex and voluminous to be easily comprehensible.*⁴⁶⁰ (Emphasis added)

Making Choices: Prescriptive Regulation? Or Non-Prescriptive Alternatives?

The Australian Commonwealth Interdepartmental Committee Report developed a template that may be helpful to Health Canada in determining whether prescriptive regulation or voluntary or other non-prescriptive regulatory approaches are appropriate for dealing with health protection issues under its Legislative Renewal Initiative.

Criteria Suggested for Choosing Prescriptive Regulation

The Report of the 1999 Commonwealth Interdepartmental Committee Report on Quasi-Regulation sets out the following criteria for choosing prescriptive regulation:⁴⁶¹

- The problem is high risk, of high impact / significance, for example a major public health and safety issue;

⁴⁶⁰ *Ibid.* p. 12 under the heading *Non-compliance related to lack of regulatory knowledge or comprehension by the target group.*

⁴⁶¹ Chapter 3 *Choosing From the Regulatory Spectrum*

- The government requires the certainty provided by legal sanctions;
- Universal application is required (or at least where the coverage of an entire industry sector, or more than one industry sector) is judged as necessary;
- There is a systematic compliance problem with a history of intractable disputes or flagrant breaches of fair trading principles and no possibility of effective sanctions being applied; and
- Existing industry bodies lack adequate coverage of industry participants, are inadequately resourced, or do not have a strong regulatory commitment.

Criteria for Choosing External Standards (Quasi-Regulation)

Quasi-regulation in the Australian Report on *Grey Letter Law* includes the use of voluntary performance standards promoted by government for regulatory purposes, but not incorporated into regulations, similar to Europe's *GPSD* regime. The Australian Commonwealth Interdepartmental Committee on Quasi-regulation recommends that Quasi-regulation be considered where:

- There is a public interest in some government involvement in regulatory arrangements and the issue is unlikely to be addressed by self regulation;
- There is a need for an urgent, interim response to a problem in the short term, while a long term regulatory solution is being developed;
- Government is not convinced of the need to develop or mandate a code for the whole industry;
- There are cost advantages from flexible, tailor made solutions and less formal mechanisms such as access to a speedy, low cost complaints handling and redress mechanism; and
- There are advantages in the Government engaging in a collaborative approach with industry, with industry having substantial ownership in the scheme. For this to be successful, the following conditions need to apply:
 - A specific industry solution is required rather than regulation of general application;
 - There is a cohesive industry, with like-minded participants, motivated to achieve the goals;
 - A viable industry association exists with the necessary resources to develop and/or enforce the scheme;
 - Effective sanctions or incentives can be applied to achieve the required level of compliance, with low scope for benefits being shared by non-participants; and
 - There is effective external pressure from industry itself (survival factors), or threat of consumer or government action.⁴⁶²

⁴⁶² See The Report of the 1999 Commonwealth Interdepartmental Committee Report on Quasi-Regulation: Grey-Letter Law (Chapter 3 Choosing From the Regulatory Spectrum),

A Canadian Example

In Canada, the Offshore Oil and Gas sector is a leading proponent of performance-based regulation. (PBR) In October 2000, the Canadian Oil and Gas Administrative Advisory Council held an international workshop on *Performance-based versus Prescriptive Regulation*. The themes were similar to those discussed in the Harvard Workshop and also motivated by an apparent disconnect between government policies on the use of PBR and legislative practice. While the conference attendees were largely drawn from government and industry, a number of generic 'lessons-learned' emerged from those proceedings, including:

- Performance-based regulations form part of a spectrum of approaches to regulation between pure goal setting and prescription. These forms of regulation *complement* one another and are often employed in the same regulation; they should not be conceptually polarized;
- The Canadian Offshore Oil and Gas Regime, like many other regulatory regimes, is a "mixed" regime and, while essentially prescriptive, has many performance-based features, including frequent reference to standards;
- The criteria for determining an appropriate "mix" between prescriptive and performance-based approaches are unclear;
- Not all stakeholders agree on the merits of the "flexibility" provided by the performance-based approach to regulation;
- There is a significant disconnect between regulatory policy and legislative practices regarding the use of performance-based approaches to regulation;
- Broad agreement is needed amongst affected stakeholders on the objectives, principles and overall vision for a major overhaul of a regulatory regime; and
- Regulators, and some stakeholders, harbour significant doubts about the enforceability of performance standards.

A number of the Workshop participants rightfully challenged the premise that performance-based and prescriptive approaches to regulation were polarized concepts. One participant - echoing the lessons learned from the Australian Grey-Letter Law study - questioned whether there was any practical distinction between the two concepts – at least from an industry perspective.

This whole discussion of performance versus prescriptive regulation may be a bit of a red herring. At the end of the day you have prescription.

Under (the performance-based approach, the regulator) asks the duty holder how they will address a particular health and safety issue. The regulator has a responsibility to review it and (if satisfactory) to authorize it. Then, at that point, the operator has to follow the prescriptive operation or procedure, or what have

you, they have outlined. It is a responsibility for the regulator to monitor audits and have inspections to see that it is being followed.

Under the prescriptive approach, the regulator either makes reference to standards, or sets them, and proceeds in that fashion. Perhaps we end up at the same point (prescription) at the end of the day. One could argue that this (debate about performance versus prescriptive regulation) is simply about the best way to get there.⁴⁶³

During the Workshop, breakout sessions were held. All of the breakout groups experienced difficulty analyzing the Offshore Oil and Gas regime issues on the narrow basis of prescriptive *versus* performance-based regulation. Some abandoned the debate, turning their attention to a broader, more practical, question - "What do we want the regulatory regime to look like?"

The breakout sessions concluded with a number of essential elements being advanced as important attributes in a regulatory regime with a balanced mix of regulatory instruments. Many of the essential elements developed in this Workshop would clearly be desirable attributes of any regulatory regime that relies heavily on industry self-regulation, including a GSR regime, namely:

- Clear identification of the responsible duty holders;
- An operating philosophy of continuous improvement, rather than a strict compliance attitude;
- Regulatory processes which minimize adversarial relations between government and stakeholders;
- Goals that translate into a definitive plan, but a plan that is flexible in circumstances where flexibility is required;
- Due attention is given by the regulator to the circumstances of the operator;
- Avoiding undue reliance on exemption provisions as a mechanism for achieving flexibility;
- Adequate training of the work force on safety issues throughout the industry;
- A single window approach to dealing with the industry;
- Better delineated responsibilities of multiple regulators;
- Provision for evaluating the *regulators'* performance in relation to goal-setting and continuous improvement on the same basis as industry;
- Clear regulatory policy objectives, clearer linkages between policies and regulations;
- Regulations which effectively balance the need for a good fit with local social, cultural, political and geographic requirements, yet which are harmonized optimally with national or international standards;
- Effective benchmarks and measures to ensure that performance objectives are being met;

⁴⁶³ Proceedings of international Workshop on *Performance-based versus Prescriptive Regulation*, October, 2000, sponsored by the Canadian Oil and Gas Administrative Council

- Rational, effective compliance and enforcement measures by the regulator; and
- Adequate resources consistent with the needs of a goal-based regime, including the resources needed for new skill sets required under such a regime (i.e. including, auditing, performance measurement, risk management expertise).

In this Paper, we have commented on the enormous discretion left to enforcement officials under Europe's GSR regime – a discretion greatly amplified by uncertainty about conformity requirements and even risk assessment methodologies. This has led many commentators to conclude that the exercise of such a broad discretion by enforcement officials constitutes “back door rulemaking.”

Canadian experience with the failed "*Regulatory Efficiency Act*", tabled as Bill C 62 in Parliament in 1994, also demonstrated the pitfalls involved with alternatives to regulation, which are not sufficiently accountable to Parliament or to the needs of the intended beneficiaries of the regulatory regime. In reviewing similar legislation proposed in Australia, the Law Reform Committee of the Parliament of Victoria commented on the failure of the proposed Canadian legislation following the "fairly scathing report by the (Canadian) Standing Joint Committee for the Scrutiny of Regulations." The concerns raised by the Joint Committee to the proposed *Regulatory Efficiency Act* resonate with the “back-door rulemaking” criticisms of the GSR. (See Annex 9)

Since the GSR uses voluntary standards as quasi –regulatory instruments to replace regulations, Health Canada officials should, in advancing any GSR proposals, be prepared to address considerations of the type usually addressed by legislative drafters and/or the Standing Joint Committee, including whether the proposal constitutes:

- A law or structure of a law that will promote disrespect for the law or the legal system;
- A law that is not capable of being fairly applied in accordance with the principles of natural justice;
- Laws that circumvent or render inapplicable procedures that are normally applicable to the examination, registration and publication of regulations;
- Laws in which substantive legal matters are absent from the law and are left to be determined by regulations or in some other way;
- Policy statement provisions that have no meaning in law;
- Provisions that allow a substantive law to be amended outside the parliamentary process;
- Provisions that provide uncircumscribed power to make exemptions from the law;
- Provisions saying that treaties, conventions or agreements, etc. have the force of law;

- The need to make the language of the law as clear as possible; and
- Other policy issues, as for example, whether a new law is needed (can the policy objective be accomplished without another Act or regulation?)

Instrument Choice

There is surely no single answer to the question of whether regulatory agencies should use performance-based regulation... performance-based regulation is not a "magic bullet" or "one size fits all" approach applicable in all situations... In determining whether to use a performance standard, and if so, the specific type of standard to adopt (e.g. loosely vs tightly specified), decision makers need to consider the conditions under which the standard will be applied.⁴⁶⁴

Under its Legislative Renewal Initiative, Health Canada proposes to include a GSR provision that would apply to all constituent Acts to be included in the proposed new *Canada Health Protection Act*. However, the constituent Acts and Regulations under the proposed CHPA are not all on the same footing. For example, a general safety requirement may be superfluous for product lines that are already closely controlled at the *pre-marketing* stage under licensing or certification schemes, such as drugs, medical devices and natural products. The GSR in Europe was developed as a *post-marketing* mechanism implemented to provide a common safety 'floor' for hazardous products that were not yet integrated into Community harmonized standards or, if regulated, involved emerging, unforeseen risks.

Moreover, some of the regulations enacted under the *Food and Drugs Act* dealing with medical devices and natural products have established virtual GSR regimes as conditions of licencing.⁴⁶⁵

While there is no "formula" for deciding when to choose performance-based regulation, it is possible to identify specific factors influencing the choice of this instrument on a program-by-program basis. Many of the jurisdictions considering performance-based regulation have adopted a "cautious and incremental" strategy for introducing this regulatory technique. The key factors to be considered in whether or not to adopt a performance-based approach to regulation include:

- The choice of any regulatory instrument *depends upon on a variety of local circumstances*, including the nature of the matter being regulated, the number and type of stakeholders affected by the regime, legal and constitutional requirements, the sophistication of the regulated community,

⁴⁶⁴ Harvard Workshop on Performance-based regulation, *supra*, under the heading "Conditions for Performance-based Regulation.

⁴⁶⁵ See, for example, *Medical Devices Regulations*, SOR / 98- 282, sections 10 to 20 and the *Natural Health Products Regulations* SOR/ 2003 –196

- and their willingness to provide data required to support a PBR approach, among other factors;
- Performance-based regulation increases the discretion given to the regulator and the regulated industry or business, sometimes significantly. The *degree of stakeholder trust* in the regulator(s) and industries in question is therefore a key factor in deciding whether a proposed performance-based regulation has any chance of becoming law;
 - *Historical experience in the community with self-regulation techniques*, or internal responsibility systems, can have a major impact on when it is feasible or timely to propose a performance-based regulation. For example, a notorious regulatory failure, such as the Westray mining disaster or the series of securities frauds in Canada and the United States, may have a significant impact on the timeliness and feasibility of extending the performance-based approaches in the occupational health and safety or securities areas. Such failures can result in pressure to retrench toward more prescription and more severe sanctions;
 - Where public health and safety is concerned, there is usually strong resistance in the public to relaxing the precision of prescriptive regulations. This is the case even where the risk of an adverse event is low, if serious or catastrophic consequences may follow. The Australian Radiation and Nuclear Protection Safety Agency recently rejected a proposed significant shift performance-based regulation on these grounds;⁴⁶⁶
 - The Australian Radiation and Nuclear Protection Safety Agency recommended a cautionary, incremental, approach to introducing performance-based approaches into an essentially prescriptive regime where public health and safety is a major concern. It also emphasized the key role industry would have to play in educating the industry on risk analysis and management in making such a shift.

The performance-based approach is also inappropriate to regulate activities that require a high level of safety and for which the risk of a breach would have very serious consequences. As such, activities of even large firms or corporations which can afford to conduct their own risk assessment and management, may need to be regulated through the prescriptive approach if their activities of high level of safety and may cause externalities that can adversely affect public health or safety....

There is still a general reluctance in Australia to accept performance-based approaches in the area of radiation protection. This was well illustrated in the submissions to the Issues Paper. The general view was that leaving it to the industry to demonstrate compliance would not work as private firms are profit motivated and would invariably select low cost control systems and compromise on safety standards.

⁴⁶⁶ See Australian Radiation and Nuclear Protection Safety Agency, Draft Final Report on *National Competition Policy Review of Radiation Protection Legislation*, February 2001: accessed on September 25, 2006, at (http://www.arpansa.gov.au/pubs/dft_fnl_rpt.pdf)

*The Council of Australian Governments calls on regulators to move away from overly prescriptive standards towards performance-based standards. However, COAG also cautions regulators that prescriptive requirements may be needed to ensure public safety. In particular, COAG makes several references in its guidelines to the fact that a prescriptive approach may be unavoidable in regulations that deal with public health and safety.*⁴⁶⁷

- The U.S. Mines and Minerals Service representative at the Offshore Oil and Gas Workshop in 2001 supported the cautious, incremental approach to performance-based regulation:

We will add more performance-based rules to the mix when it makes good sense. We will look for opportunities to align our domestic requirements with international standards so long as it protects the integrity of our regulatory program and improves efficiency for government or industry. Finally, we will continue to promote and support non-regulatory initiatives like SEMP and EMS, whenever they will enhance safe and clean offshore operations without creating regulatory conflicts.

- The Australian Radiation and Nuclear Protection Safety Agency recommended two techniques for introducing a performance-based approach progressively into a regulatory regime, that is, either through use of the "safe harbour" approach, or through the innovative use of exemption provisions in the governing statute.

Agencies can introduce a performance-based approach to radiation protection legislation gradually without immediately exposing the regulatory regime to the risks that could arise from a performance-based approach. The transition to a performance-based approach could be aided by using a "dual track" method with either "safe harbour" or "waiver / variance" provisions in regulations.

⁴⁶⁷ Ibid., (p29) *"Even if a performance-based approach is to be adopted for particular activities in radiation safety administration, this has to be gradual and only after a thorough risk analysis to determine which activities may be regulated by an outcome based approach. The Review Team acknowledges that a shift to performance-based regulations to achieve radiation protection objectives has to be approached very cautiously mainly because of the assessment above that although the likelihood of a radiation risk causing event may be low, the consequences of such an event could be serious to catastrophic.*

Even if a performance-based approach is to be adopted for particular activities in radiation safety administration, this has to be gradual and only after a thorough risk analysis to determine which activities may be regulated through an outcome-based approach.

Where performance-based approaches are to be adopted, the implementation has to be accompanied by substantial industry efforts to educate the industry on risk analysis and management. Experience in some jurisdictions (such as marine safety) demonstrate that a well-designed transition plan is required to overcome the resistance to performance-based approaches."

Safe harbour provisions in performance-based regulations enable firms that do not have the resources to comply with the outcomes-based approach to elect certain prescribed rules or specified standards. This enables firms that prefer to comply with prescribed rules to have the option to do so while others use the performance-based approach.

Alternatively, regulations may continue to be prescriptive but may contain provisions that empower agencies to grant waivers or variances on a case-by-case basis to firms that demonstrate compliance through alternative means.

Since the Community Standards under Europe's New Approach to Regulation are treated as 'voluntary' standards, they could be viewed as a form of 'safe harbour' quasi-legislation. However, the Community standards only offer a *presumption* of conformity and thus enforcement authorities may, in their discretion, act against specific consumer products they consider to present 'unacceptable' risks. Alternatively, enforcement authorities may fail to act against an industry that has developed its own standards, even though consumer interests contest the adequacy of such standards. The result, frequently, may be uncertainty about what the 'law' is.

13. Summary of Advantages and Limitations of a GSR

As noted earlier in this Report, the General Safety Requirement constitutes a form of performance-based regulation. From a policy development perspective, its advantages and limitations closely parallel those of any performance-based regulatory regime. The perceived advantages and limitations of the GSR are summarized below. The 'advantages' are expressed as *perceived* advantages because they are sometimes illusory and sometimes offset by key disadvantages.

The Perceived Advantages

The perceived advantages of a General Safety Requirement include:

- ***Immediate extension of Health Canada's regulatory reach*** to include all new unregulated dangerous products, and to emerging, unforeseen risks in regulated products;
- ***More timely, preventive inspection and enforcement action*** against such products and risks;
- ***Earlier detection of product risks*** due to enhanced reporting and data requirements under a GSR;

- ***An enhanced culture of safety within industry*** by reason of improved self-regulatory practices, more effective risk assessment by industry and improved management practices in developing and marketing products;
- ***A perceived reduction in the need for government intervention to achieve regulatory goals*** resulting in **possible resource savings** from less Government involvement in pre-marketing approvals, formal inspections, seizure of products, etc. under a command and control regulatory model;
- ***Better use of compliance and enforcement resources*** due to the shift in emphasis from routine formal inspections to auditing for problems in industry quality management systems, self-regulatory processes and conformity assessment practices;
- ***Increased product safety innovation*** by reason of the increased flexibility Industry is given in achieving regulatory goals under a voluntary, standards-based GSR regime;
- ***Minimal market distortion*** compared with prescriptive regulation because the GSR is so closely integrated with industry and business practices;
- ***Potential for reduced compliance costs for industry***, again because of the greater flexibility afforded to industry in choosing less costly methods for achieving compliance with the General Safety Requirement;
- ***Enhanced global competitiveness*** when performance standards are more closely harmonized with domestic and international standards than regulations developed on a 'top down' basis;
- ***More targeted enforcement measures*** made possible under a GSR regime once effective reporting requirements and injury data systems are in place;
- ***Due diligence defences in regulatory prosecutions are more easily established*** by producers and suppliers that have effective risk assessment and quality management and production processes in place that meet GSR expectations;
- ***Reduced regulatory burden on industry*** through the use of voluntary performance standards designed to coincide more closely with industry practices, in contrast with 'top down' regulation;
- ***Enhanced voluntary compliance*** through the use of 'consensus standards' developed by all key stakeholders resulting enhanced

stakeholder 'buy-in' promoted during effective consensus-based processes;

- **Enhanced international harmonization of product standards** flowing from the participation of formal standard setting bodies in developing approved consensus standards under the GSR;⁴⁶⁸
- **'Approved' voluntary standards provide an operational basis for third-party quality assurance certification programs;**
- **Quicker, cheaper and less formal dispute resolution mechanisms** may be developed under a standards-based approach to regulation than is normally the possible under the Criminal Justice system; and
- **Industry may contribute resources** to developing, implementing and enforcing voluntary standards.

The Limitations of a GSR

- **Multiple layers of uncertainty** are evident under the General Safety Requirement making implementation difficult. (Uncertainty concerning the definition of a 'safe' product, the meaning of 'serious' risks that trigger reporting responsibilities, the inconsistent results of various risk-assessment methodologies, and the means of establishing conformity with 'essential requirements', among other uncertainties);
- **Tendency to undermine the 'rule of law' and legal certainty** when voluntary standards are treated as quasi-mandatory rules. (See note above);
- **Heavy implementation burden on officials to 'fill in the blanks'** to provide a higher degree of certainty and comfort for industry about compliance on a product- by- product basis, through Government advisory services, policies, guidelines, rulings, etc;
- **Increased exposure to Court challenges and judicial review** as officials, attempting to deal with the regime's uncertainties, are 'second-guessed' by the Courts under various causes of action such as regulatory negligence, negligent misrepresentation, official misdirection, lack of authority to impose conditions or recall orders, the nature of 'due diligence', unreasonable exercise of enforcement discretion fettering official discretion through overly-detailed guidelines, or Court challenges to

⁴⁶⁸ For example, 27% of Europe's CEN standards correspond with international standards and 65% of standards produced by the national Australian standard-setting agency are harmonized with ISO or IEC international standards for those subjects where an international standard exists.

the legislative scheme itself based on vagueness, or the imprecise formulation of quasi-criminal offences;

- **Poor Political Optics** resulting from substituting voluntary standards for regulations in the public health and safety area. This practice tends to be viewed by the beneficiaries of the regulatory scheme as *de-regulation* or *capture* by industry. In Europe, the New Approach is often described as the ‘privatization of regulation;’
- **Anticipated savings for Government may be illusory** given the need for new auditing skills, to settle risk assessment methodologies, heightened monitoring and surveillance to verify that the self-regulatory activities of industry are effective; government contributions to the standard-setting process to ensure relevant standards are developed on a timely basis, the enhanced duty to take enforcement action against a much broader array of potentially dangerous products reported more frequently under the GSR, the need to develop guidelines, codes of practice, sanctions policy and other collateral documentation to make the scheme operationally effective. The potential cost of court challenges and judgments for civil damages flowing from increased exposure to regulatory negligence is difficult to estimate before the legislation (the CHPA) is settled, but could be significant;
- **Potential, adverse impact on industry competitiveness** - A GSR adversely affects the ‘level playing field’ for industry competition if it is inadequately or unevenly enforced.⁴⁶⁹ There is extensive pressure from industry in Europe for more effective government surveillance and enforcement of New Approach regulations and the GSR for this reason;
- **Adverse impact on small business and industry** - Some medium-sized industries and most small businesses prefer to be told what to do; often they do not consider the regulatory flexibility afforded under the GSR an advantage. While alternative approaches to meeting an ‘approved’ standard may be advantageous to large firms with in-house research and development capabilities, small businesses have little choice but to follow the standard since they would be vulnerable to civil damages if they did not. If product standards are developed under the predominant influence of big industry, an indeterminate number of small businesses may be driven out of business. (There was some anecdotal evidence in the interviews that this occurred in Europe);
- **Government challenge function weakened** – Over-reliance on industry self-regulation can lead to Government neglecting or disabling its

⁴⁶⁹ In Europe, the pressure on Governments to enforce the GSR more effectively is coming mainly from big business and industry concerned about the anti-competitive effects of uneven enforcement against smaller enterprises and importers.

challenge function, or to undermining its capacity to undertake enforcement responsibilities. This occurs where the Authority has misconceptions about the extent of potential resource savings for Government under a self-regulatory regime and, sometimes, because the expert-reliant GSR regime has led to industry hiring most of the available 'experts' concerned with risk or conformity assessment, product testing, safety auditing, etc. thus weakening the Government's capability to mount an effective challenge to industry 'experts;'

- ***Inconsistent Results under different risk assessment methodologies*** - Risk assessment techniques, while appearing to be 'scientific', are often laden with value judgments and thus may lead to dramatically different conclusions on the same facts;⁴⁷⁰
- ***Inconsistent quality of standards*** - Standards-development processes by private agencies or industries may not be as consistent or as effective as the formal processes adopted by national standard development agencies. Under a voluntary standards-based regulatory regime, private standards and codes may overlap with national codes and standards, or with standards incorporated into regulations, making it important for government to develop a scheme for 'approving' standards for conformity assessment purposes. This can be a resource-intensive activity for Government, especially under the GSR where standards are least likely to be available, given the focus of the GSR on *unregulated* products and risks. Neither does Canada have a standard-setting infrastructure as extensive as that which has evolved in Europe over the past 30 years;
- ***Standards development can be as time consuming as enacting regulations*** when done properly by involving all interested stake holders;
- ***Potential for industry 'capture' of the standards-development process.*** There is a tendency for the standards-development process to be captured by vested interests seeking competitive advantage, or otherwise seeking to minimize production costs. Unintentional capture may occur simply due to the unequal resources available to industry and consumers wishing to participate in the standard-setting process. Subsidizing consumer participation in standards development proceedings is a potentially significant area of indirect cost to Government;
- ***Regulatory offences under a GSR are difficult to prosecute and likely to lead to inconsistent results,*** given the difficulty in defining 'safety', the "flexibility" afforded to the defendant under a voluntary standards regime to advance alternative standards of safety, the uncertain scope of the due

⁴⁷⁰ As, in fact, was the case in Europe under a trial assessment as to whether a hypothetical product was 'safe' or not. The results of the trial, involving a number of Member States, led to a virtually polarized split on whether the product was 'safe' or 'unsafe'.

diligence defence under a GSR regime and the relative lack of regulatory expertise in the Criminal Courts. Prosecutors will have difficulty establishing that products are 'unsafe' beyond a reasonable doubt under the general duty violation;

- **Standards developed on a "best practices" basis tend to result in "liability creep"** especially if such standards are relied upon by courts to fix the legal standard of care in private negligence actions or where they have the effect of raising the standard of proof required to make a due diligence defence in regulatory prosecutions;⁴⁷¹
- **Accountability to the public and to Parliament is weakened** under a GSR regime based mainly on voluntary standards because it is a form of 'back-door rule-making' analogous to a sub-delegation of legislative power outside the regulatory process overseen by Parliament. Even the concept of incorporation by reference of standards '*as amended from time to time*' remains somewhat controversial in Canada and is still somewhat unevenly applied. Reliance on voluntary standards as a form of 'quasi-law' developed and amended outside the regulatory process is therefore an approach likely to be vigorously challenged if Canada's experience under the *Regulatory Efficiency Act* initiative is any indication;⁴⁷²
- **Performance measurement can be particularly difficult under a performance-based approach to regulation..** Performance auditing is a relatively new venture; few auditors have the experience required to assess performance-based schemes and performance measurement is still often viewed as an iterative process. The *Harvard Workshop on the Advantages and Limitations of Performance-based Regulation* observed that 'performance' evaluation (the key to accountability) remains a complex and unsettled component of performance-based regulation;
- **Data requirements can be onerous for industry (and Government) under performance-based regimes** such as under the General Safety Requirement. Timely receipt of reliable information about industry performance, production and supply processes, product defects, recalls, complaints, etc is the *quid pro quo* for permitting a higher degree of industry self-regulation and for reducing 'routine' inspections to undertake more targeted, evidence-based, compliance and enforcement initiatives. Government can expect to receive a vast amount of information from industry requiring careful sifting and analysis - another important element of Government cost; and
- **The Exponential growth of 'Grey-Letter law'** - Industry, particularly small industry, tends to regard approved standards, codes of practice,

⁴⁷¹ Regulations are usually based on minimum acceptable standards

⁴⁷² See Annex 9

policies, guidelines as ‘law’, or at least to be unclear about their compliance obligations in relation to such documents. The result, often, is a complex overlay of documentation (or ‘Grey-letter law’) to address operational uncertainties under a GSR regime without the essential checks and balances found in the regulatory process. This leads some industry players to conclude that the end result under performance-based and prescriptive regulation is the same, that is, prescription. Under performance-based regulation, there is a conflict between policies increasing regulatory ‘flexibility’ for industry, on the one hand, and policies purporting to reduce industry’s ‘paper burden’, on the other.

14. Broad Options for Health Canada

The purpose of this Paper was to consider the suitability of the GSR as a regulatory instrument for achieving Health Canada’s objectives under the Legislative Renewal Initiative. Our research has led us to question the suitability of employing a GSR under the proposed *Canada Health Protection Act*. While reaching that conclusion might have been sufficient for the purposes of our mandate under this Project, we are outlining five broad options for Health Canada to consider for addressing its regulatory goals and objectives.

Revisiting the Case for Reform

There are a number of reasons mentioned throughout this Report indicating why Health Canada may wish to reconsider including a general safety requirement as a major element of the proposed new *Canada Health Protection Act*. The GSR is difficult to implement under a criminal law model and some of the remedies, such as administrative recall orders, may not be available to the Department. The need for a ‘safety net’ is not the same under the CPHA’s constituent Acts and Regulations; the Department has much closer control over emerging risks under the pre-marketing licensing and certification regimes in the *Food and Drugs Act* than it does under the *Hazardous Products Act*.

While the ‘New Approach’ to regulation (which provides the regulatory backdrop for the *General Product Safety Directive*) may have been inevitable in the European context, the multiple layers of uncertainty under the New Approach and GPSD regimes have made for complex and difficult implementation of the concept. This uncertainty would make it even more difficult to implement in Canada under a Criminal law model. Moreover, the introduction of standards into Europe’s revised GPSD as a method of conformity assessment is relatively recent; it was implemented only as of January 2004. Both the “New Approach to Regulation and the General Product Safety regime are clearly still ‘works-in-progress’; both are undergoing continuous review and modification.

In Canada and the United States, voluntary standards form part of a spectrum of regulatory mechanisms ranging from simple goal setting to outright prescription. They complement formal regulation by encouraging performance to a best practices level, that is, beyond minimum legal requirements. When incorporated by reference into regulations, voluntary standards also help to define the law. Voluntary standards can help prevent excessive regulation where they effectively remove the *need* for regulation when they serve to meet the same regulatory objective. Outside of formal incorporation by reference into a regulation, however, voluntary standards developed outside of the democratic regulatory process rarely serve as a form of 'law' in Canada or in the United States.

The United States has resisted using voluntary standards as quasi-law on the grounds that this practice constitutes 'backdoor rulemaking' by non-elected third parties outside of the democratic process. U.S. consumer product legislation does vigorously promote the development and promulgation of voluntary product safety standards, even as a *preferred* approach to regulation where such standards demonstrably meet the Government's regulatory goals, but it does so to eliminate the *need* for mandatory rules. In the United States, though, voluntary standards do not operate as 'quasi-law' as they do in Europe under the GSR and New Approach to Regulation.'

In Europe, voluntary standards adopted as Community (harmonization) standards substitute for technical regulation of product requirements. Though expressed to be voluntary, they operate as a quasi-mandatory requirement. Large industry may treat the standards as truly voluntary by developing alternative, equivalent standards, but most have little practical choice but to treat the approved standards as 'law'. This is especially true for small manufacturing enterprises that do not normally have the necessary in-house expertise to develop alternative standards, or the funds to engage third parties to do so on their behalf.

Europe's use of quasi-mandatory 'voluntary' standards was a practical response to the regulatory gridlock that occurred in Europe in the 1980's due to the inability of diverse Member States to agree on the technical details of European laws, and sometimes even on 'essential product requirements'. This situation presented a dangerous obstacle to the establishment of The European Common Market, which required the harmonization of Community standards and, as such, threatened the welfare of the European Community at large.

The cost/benefit considerations of Europe's 'New Approach' to regulation were, therefore, unique. While the regulatory costs to government and industry inherent under the European GPSD regime are significant, the potential financial benefits associated with achieving an effective European Common Market are enormous. The precise contribution of a *General Product Safety Directive* to ensuring *safe* products in Europe, however, is far from established. Much of the effectiveness of the European regime seems attributable to the formidable market sanctions that may be imposed on producers, suppliers and exporters within the Common Market, and the producers' absolute liability for defective

products under the European Product Liability Directive. The resource savings that Health Canada might have been anticipated receiving from simply reinforcing the producers' common law obligation to avoid producing unsafe products by enacting a GSR may also be largely illusory.

While Canada's regulatory policy encourages the use of voluntary standards to achieve regulatory goals, it does not go so far as to encourage the sub-delegation of quasi-regulation-making power to domestic or international standard-setting bodies operating outside of the domestic regulatory process. In Canada, even the concept of incorporating standards by reference *into* regulations remains somewhat unsettled.

The GSR is difficult to contain in the role of a 'safety net'; it tends to evolve into a horizontal form of regulation for unregulated products and 'orphaned' risks and is characterized by multiple layers of uncertainty. Health Canada officials would be placed in the day-to-day position of clarifying these uncertainties for industry on a 'product-by-product basis. In some cases, officials would be placed in the position of explaining what, in effect, the law *is* where no product standards exist for new products. The Department's potential exposure to regulatory liability, particularly from negligent misrepresentations made under the extensive advisory program likely required to make the scheme work, could also increase significantly.

Finally, standards-based regimes are not a panacea. As they mature, they begin to face criticisms similar to those of the prescriptive regime they purported to replace. In Europe, the New Approach to Regulation marked its Twentieth Anniversary at a conference in Brussels in November of 2005. In addition to familiar concerns about delays in 'time to market' resulting from delays in the development of new product standards, concerns persist about inconsistencies in the interpretation and application of New Approach directives (including under the *General Product Safety Directive*); about effectiveness and performance measurement, the reliability of risk assessment methodologies, about the general complexity and growing number of guidance documents, the competence of some accreditation agencies, the impartiality of notifying bodies, and about the relative lack of influence which consumers have in the standards development process.

Summary of Policy Options

Five broad options are available to Health Canada, four of which are alternatives to the GSR, namely:

1. ***The European Model*** – Attempt to adapt the European model of the GSR to the Canadian legal context for inclusion in the proposed *Canada Health Protection Act*. (This was the principle subject of this Report)

2. **Incremental Reform** – Import only needed elements from the GSR into the constituent Acts originally intended for consolidation under the CHPA should the Department decide not to proceed with a consolidation. (i.e. reporting requirements, data-based detection system, missing enforcement powers, etc.) This is the approach adopted by Australia following an extensive review of its consumer protection legislation completed in 2005.
3. **Modified American Approach (HPA Only)** – Under the *Hazardous Products Act*, Health Canada would enact a general prohibition against advertising, selling, importing etc. consumer products which *present an unreasonable risk of injury*. “Risk of injury” would be defined on a basis consistent with the U.S. *Consumer Product Safety Act*, to mean “a risk of death, personal injury, or serious or frequent illness”. ‘Risk of injury’ is an issue that can be determined with much greater certainty, including by criminal courts, than the question as to whether particular products are “safe” or “unsafe”. This Option would be designed to promote closer harmonization of *North American* consumer product standards, injury data collection and enforcement practice.

This Option would apply only to the *Hazardous Products Act* on the assumption that there is no real need for a general prohibition of this kind under the *Food and Drugs Act* and related regulations where closely controlled licensing and certification schemes with *pre*-marketing and adverse incident reporting requirements are already in place. The GSR is a *post*-marketing mechanism that assumes little to no government oversight at the pre-marketing stages of product design, development and production. Moreover, an incremental reform approach is already evident under the *Medical Devices* and *Natural Products Regulations*, which now include a virtual GSR regime linked to conditions of licensing.

4. **Modified American Approach (All Constituent Acts)** – If Health Canada wishes to extend the general prohibition outlined beyond the *Hazardous Products Act*, the scope of the HPA (which is already a form of generic ‘catch-all’, legislation) could be extended to apply to dangerous unregulated products and serious unforeseen risks in product areas covered by the other Acts administered by Health Canada. While the general duty violation and related powers might be situated in the HPA, the authority would be accessible to enforcement officials administering the other enumerated Acts, as needed, likely without requiring significant changes to the Department’s internal organization.

While the HPA is mentioned as a possible ‘home’ for the general prohibition based on American ‘risk of injury’ terminology, it might be located in some other generic statute administered by the Department

such as the *Department of Health Act*,⁴⁷³ or the proposed CHPA if the Department proceeds with the consolidation of constituent Acts under the Legislative Renewal Initiative.

5. **Status Quo with Administrative Reform** - Under this Option, the Department would rely on the existing provisions for Ministerial Interim Orders in the *Hazardous Products Act* or the *Department of Health Act* as the main safety net for dealing with unregulated dangerous products, and unforeseen, emerging and serious risks in regulated products.

In this case, however, the focus would be on making the Minister's existing remedy more efficient by developing internal policies for triggering the use of this power together with a fast-track process for exercising it - all in collaboration with the Minister's Office and relevant Central Agencies of Government. The policy and fast-track process would then become a routine element of briefing for new Ministers of Health so they would be familiar with the emergency measure in advance of the need for urgent intervention against a particularly hazardous product.

Options two to five (i.e. the 'alternative' options) might be accompanied by a Health Canada program to encourage the development and use of effective voluntary product standards with a view to achieving levels of product safety that routinely exceed minimum legal requirements. For example, on July 10, 2006, the U.S. Consumer Product Safety Commission published a final rule on *Commission Involvement in voluntary Standards* indicating how the Commission intends to promote improved voluntary product standards in collaboration with the private sector without compromising the public authority's institutional independence or oversight role.⁴⁷⁴

Option 1. The European (GPSD) Model – Revisiting the Case for Reform

This Option is the principle subject of this Paper. Under this option, Health Canada would attempt to adapt the European General Product Safety to a Canadian model of health protection based on the federal government's constitutional authority for the substantive criminal law. Under this approach a GSR would be legislated as an enforceable, legal obligation in the form of a general prohibition against supplying 'unsafe' consumer products.

The Case Studies included with this Report illustrate how, in practice, the European model of the GSR might operate in Canada and identify the major administrative and resource requirements to implement a GSR effectively.

⁴⁷³ S.C. 1996, c. 8

⁴⁷⁴ Federal Register, July 10, 2006, Vol. 71, No. 131

The European approach to regulation is clearly performance-based, but involves a form of authorized sub-delegation of quasi-legislative authority over technical product requirements to private standard setting bodies. Canadian regulatory policy, while quite supportive of voluntary standards, has not evolved to the point of approving the substitution of voluntary technical standards to masquerade as 'law' in the place of regulations. As noted earlier in this Report, the case for Europe's 'New Approach' to regulation was unique, compelling and linked almost exclusively to Common Market trade considerations.

The European general product safety regime is ill-suited to administration under Canadian criminal law and procedure. The Europeans continue to address a number of important problems with the GSR, including a significant lack of transparency and consistency in its application. The extensive flexibility available to defendants in choosing standards that raise a presumption of conformity with the GSR, coupled with built-in uncertainty in the definition of 'safe' products under the GSR, would make it very difficult to enforce under Canadian criminal and regulatory (penal) law.

The costs associated with adapting a European model of the GSR to the Canadian context may well outstrip the benefits to be expected from importing this regulatory technique and force Health Canada to take an earnest look at alternatives. The GSR cost elements are detailed throughout this Report. The mere enactment of a GSR has little effect on industry behaviour without aggressive complementary programming along the lines of safety campaigns in the occupational health and safety area. The GSR is difficult to explain to regulation-centric industries and there is generally a low awareness of the GSR in small and medium sized enterprises.

Notwithstanding these observations, the more mature consumer product safety programs in Europe are quite effective - to the point where product safety is not regarded as a significant problem in several jurisdictions. Many of these schemes have a full range of civil, administrative and criminal sanctions. But Europe's Product Liability laws, coupled with the potential enormity of the loss of market share following a Rapex Report on a dangerous product, and the fear of damage to corporate reputations remain the main compliance incentives for industry. The contribution of the General duty violation to enhanced product safety remains unclear. There is little case law and Europe has had only minimal experience with the GSR in its present form (The revised GPSD came into force only in January of 2004).

The regulatory authority of the EU Member states and the U.S. Consumer Product Safety Commission differ from that of the federal Government in Canada in that they have direct *regulatory* authority for consumer product safety. This enables these jurisdictions to employ civil and administrative remedies, such as administrative monetary penalties and administrative recall orders that are not available to Health Canada under statutes based exclusively on the federal constitutional authority for substantive criminal law and procedure.

There is little evidence that the mere enactment of a GSR has any significant effect on altering risk assessment practices or contributing toward a 'culture of safety'. There appears to be little awareness of the general safety requirement in Europe outside of big business and industry. It is a difficult concept to explain to 'regulation-centric' industries and has thus proven to be a challenging communications exercise in the European experience. Policy and program measures adopted under existing authorities to encourage a 'culture of safety' in industry should prove to be equally effective with, or without, a GSR regime. Lessons learned by officials in the Occupational Health and Safety area in promoting safe practices in the workplace over the past several decades have, despite the different legal framework, important significance for officials concerned with promoting a 'culture' of consumer product safety.

For these and other reasons detailed throughout the Report, we have concluded that Health Canada may wish to reconsider adapting the European model of the GSR to its health protection regime.

Option 2 - Incremental Reform

Under an 'Incremental Reform Option', Health Canada would import only 'needed elements' of the General Safety Requirement, or powers associated with it, into its constituent Acts and regulations. In fact, this process of incremental reform has already begun under the *Medical Devices* and *Natural Health Products Regulations*, both of which have incorporated key elements of the GSR as conditions of licensing or certification.⁴⁷⁵

⁴⁷⁵ The Medical Devices Regulations under the Food and Drugs Act provide for a closely controlled licensing regime, including a reasonably complete general product safety regime developed as a condition of licensing under sections 10 to 20 of the regulations dealing with Safety and Effectiveness Requirements. Sections 9, 10 and 11 set out the general safety requirement as follows:

9. (1) A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements; (2) A manufacturer shall keep objective evidence to establish that the medical device meets those requirements.

10. A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to

- (a) identify the risks inherent in the device; (b) if the risks can be eliminated, eliminate them; (c) if the risks cannot be eliminated, (i) reduce the risks to the extent possible (ii) provide for protection appropriate to those risks, including the provision of alarms, and (iii) provide, with the device, information relative to the risks that remain; and (d) minimize the hazard from potential failures during the projected useful life of the device

11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.⁴⁷⁵ (emphasis added)

Many of the constituent acts and regulations to be integrated into a proposed *Canada Health Protection Act* already contain general prohibitions that implicitly constitute general safety requirements for the specific product lines (e.g. drugs, medical devices, food). Because the existing prohibitions target specific product lines, they provide a narrower context for legal interpretation of generic terms and may be worded with a degree of precision that more readily satisfies the exigencies of the criminal justice process.

The following prohibitions under the *Food and Drugs Act* already constitute implicit general safety duties for drugs, medical devices and food.

Drugs:

No person shall sell any drug that

- (a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
- (b) is adulterated.⁴⁷⁶

Devices

No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.⁴⁷⁷

Food:

No person shall sell an article of food that

- (a) has in or on it any poisonous or harmful substance;
- (b) is unfit for human consumption;
- (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- (d) is adulterated; or
- (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions⁴⁷⁸

A similar approach is adopted under the more recently enacted *Natural Health Products Regulations*,⁴⁷⁹ which includes many GSR elements under Part 3 on “Good Manufacturing Practices” (sections 43-62) along with reporting

The elements of a virtually self-contained GSR regime (excepting the recall power) are found in the Medical Devices Regulations under the following sections: 12. (device to perform as intended), 13. (safety during the entire useful life of the device), 14..(safety throughout storage and shipping), 15. (obligation to take reasonable measures to ensure compatibility with other materials into which it may come in contact)16. (packaging in such a manner as to minimize enumerated risks)17. (validation of sterilization methods)18. (ensure compatibility with any other components or parts of a ‘system’19. (compliance with measuring tolerances)20. (validation of software performance)21 (Labelling requirements)52-56 (Product tracing information)59-62 (Mandatory Problem Reporting Responsibilities)

⁴⁷⁶ R.S., c. F-27, s. 8.

⁴⁷⁷ R.S., c. F-27, s. 19.

⁴⁷⁸ R.S., c. F-27, s. 4.

⁴⁷⁹ S.O.R./ 2003-196

requirements that include, in section 25, mandatory reporting on product recalls.⁴⁸⁰

Accordingly, the various Acts and Regulations administered by Health Canada are not all on the same footing. An overarching general safety requirement is largely superfluous for product lines already closely controlled at the *pre*-marketing stage under licensing or certification schemes, such as drugs, medical devices and natural products. The GSR in Europe is a *post*-marketing mechanism originally designed to provide a common safety ‘floor’ for a broad range of non-specific hazardous products and risks not otherwise covered by National or Community standards, or regulations.

Criteria Conducive to a ‘Licensing’ Approach

The licensing and certification schemes under the *Food and Drugs Act* provide close control by the public authority, even over emerging risks. This is appropriate for ingested products, which, if unsafe, could lead to serious injury or death. The *Robens Inquiry* set out the policy considerations that demonstrate not only why licensing-type schemes are appropriate for products like drugs, medical devices and radiation emitting devices, on the one hand, but also why they are not appropriate for generic consumer products under a statute like Canada’s *Hazardous Products Act*.⁴⁸¹

Licensing systems provide enforcing authorities with a powerful sanction. Conditions of licence can be imposed, with various penalties for non-observance. These can include withdrawal or non-renewal of the licence.

Many of those submitting evidence to us suggested a considerable extension of licensing to a wide variety of premises, processes and individuals. For example, some urged that all works managers should be licensed to ensure that they possess minimum qualifications of knowledge and expertise in occupational safety and health. *We do not regard this as a practical proposition. In the first place there is seldom much practical value in general licensing criteria applicable to a wide variety of circumstances. If they are to have real significance, licensing criteria must be related to needs and circumstances which can be closely defined. Secondly, the administration of licensing systems is expensive in manpower, and can easily become excessively bureaucratic when applied to large numbers of undertakings or individuals. Finally, too much reliance on licensing might tend to encourage the notion that the primary responsibility for exercising control lies with the licensing authorities rather than with those who created the risks.*

Our view, then, is that whilst licensing provides a tight means of control and a powerful sanction against abuse, *licensing systems should be used very selectively*. We have in mind that the licensing approach should be adopted mainly for the control of high-hazard installations such as bulk storages of

⁴⁸⁰ Section 25 provides that: “ Every licensee who commences a recall of a natural health product shall provide the Minister with the information referred to in section 62 within three days after the day on which the recall is commenced. “

⁴⁸¹ *Robens Inquiry, supra* at paras. 280-82

intrinsically dangerous chemicals; or for particularly hazardous activities such as demolition work. (Emphases added)

The Incremental Reform Option, therefore, would require Health Canada to examine the regulatory gaps in the authorities and powers of each of the constituent Acts and consider importing targeted elements of the GSR to deal with those gaps, such as appropriate reporting, tracking, labelling or warning requirements and, perhaps, upgraded sanctions and sentencing criteria to prevent fines from being treated as the ‘cost of doing business.’

We understand that the process of examining regulatory gaps in the constituent statutes underpinning the proposed *Canada Health Protection Act* is already under way within Health Canada. That process might well continue, but with an Incremental Reform focus.

Option 3 - Modified American Approach (HPA only)

Under this Option, the Department would add to the *Hazardous Products Act* a general prohibition against advertising, selling, importing, etc. of a product which presents an ‘unreasonable risk of injury’. Under a criminal law model, the GSR general duty of care must be worded in the form of a prohibition. The phrase ‘unreasonable risk of injury’ is significant in that it describes the principle mischief addressed by the United States Consumer Product Safety Act. (CPSA) ⁴⁸²

The U.S. CPSA defines a ‘risk of injury’ to mean ‘a risk of death, personal injury, or serious or frequent illness.’⁴⁸³ That degree of gravity seems sufficient to warrant engaging federal criminal law authority in the interest of protecting public health and safety.⁴⁸⁴ Health Canada might have to bring greater precision to the

⁴⁸² In the Congressional findings and declaration of purpose for the U.S. *Consumer Product Safety Act*, first purpose is stated as being: “to protect the public against unreasonable risks of injury associated with consumer products.”, U.S. Code, Title 15, c. 47, s. 2051.

⁴⁸³ See U.S. Code, Title 15, c. 47, s. 2052 (a) (1) (I) (3). ‘Risk of injury’ is defined under the U.S. Consumer Product Safety Act to mean “a risk of death, personal injury, or serious or frequent illness”. See U.S. Code, Title 15, c. 47, s. 2052 (a) (1) (I) (3). Unreasonable ‘risk of injury, imminent product hazard and substantial product hazard’ are all separately defined for different purposes under the *CPSA*.

⁴⁸⁴ *Ibid.*, section 2064 Under the U.S. *Consumer Product Safety Act*, ‘unreasonable risk of injury’, ‘imminent product hazard’ and ‘substantial product hazard’ are terms separately employed for different purposes under the *Act*.

- An ‘unreasonable risk of injury’ constitutes grounds for banning a product⁴⁸⁴
- An “imminently hazardous consumer product” constitutes grounds for “product condemnation and seizure” (quasi-criminal remedies)⁴⁸⁴
- A ‘substantial product hazard’ triggers the manufacturers’ responsibility to report the hazard to the Commission and, in turn, the Consumer Product Safety Commission’s authority to order public notification of the hazard, repair or replacement of the product, a refund of the purchase price, the development of a proposed action plan for dealing with the hazard, and/or a prohibition order against sale and distribution.

Under the U.S. Consumer Product Safety Act, a ‘substantial product hazard means:

- (1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or

meaning of 'risk of injury' for administrative purposes but U.S practices and American case law would likely be of assistance in this regard.

The intent of this approach would be to:

- Lend greater certainty to the general prohibition provision, that is, the general duty violation;
- Access American case law on similar definitions where Canadian courts have to address any residual uncertainty; and
- Promote greater harmonization of North American product safety standards, as well as administrative and enforcement practices.

Under the federal *Hazardous Products Act* (HPA), it is currently an offence to advertise, sell or import a 'prohibited product' or a 'restricted product,' except as authorized under the HPA regulations. 'Prohibited', 'restricted' and 'controlled' products are defined as individual classes of products under section 2 of the Act with precise reference to individual products, materials or substances explicitly scheduled under the *HPA* that have been determined to fall within each class. The HPA applies to goods and substances not specifically regulated under other federal statutes. A new *general* prohibition would apply to all unregulated products not covered by the HPA and *could be extended* to include serious, unforeseen risks emerging from otherwise regulated health products currently outside the scope of the HPA. (Option B, below)

However, no policy decision to adopt a modified American approach should be taken without carefully reconsidering the viability of Health Canada's existing 'safety net' remedy for dealing with emerging product hazards, that is, the Ministerial Interim Order. In particular, the Department should consider whether a new general prohibition is required in light of that provision and whether it could be rendered more effective with administrative reform. (Option 5). Would a general prohibition provision render the Ministerial interim order redundant, or should be retained for some complementary purpose? The utility of this type of order, which also exists in the UK *Consumer Protection Act, 1987* should not be underestimated. Option 5 proposes a closer look at ways of enhancing the efficiency of this regulatory mechanism.

A general prohibition under the HPA against products presenting a risk of injury would, like the GSR, provide a trigger for immediate enforcement action. However, a legal framework for timely settlement or remedial discussions within the context of a criminal process would have to be crafted for the remedy to be effective. Like the GSR, a general prohibition under the HPA would extend the reach of Health Canada's enforcement authority to all products not otherwise regulated that present a serious risk of injury. Health Canada would have to separately consider the administrative and resource requirements necessary to make the general prohibition effective in terms of its day-to-day operations. In

(2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

this regard, it would face some of the same challenges outlined in relation to the GSR.

In particular, Health Canada would have to develop a legal and practical framework within the criminal justice process for resolving disputes about the degree of risk, the requirements of due diligence and the proportionality of remedial actions and sanctions. In this regard, Health Canada might consider adopting the approach under the *Canadian Environmental Protection Act, 1999* (CEPA) to replicate - within a criminal justice process - many of the civil and administrative remedies and dispute resolution techniques employed by the U.S. Environmental Protection Agency, for example:

- ***Environmental Protection Compliance Orders*** under which an enforcement officer may issue under section 235 of *CEPA* (before prosecution) “directing any person described...to take any of the measures ... that are reasonable in the circumstances and consistent with the protection of the environment and public safety, in order to cease or refrain from committing the alleged contravention;”
- ***Environmental Protection Alternative Measures*** under section 296 of *CEPA* which provides a legal framework for discussing compliance problems and undertaking corrective measures (after a prosecution has commenced) in return for a stay of prosecution and which, if successfully completed, result in eventual dismissal of the charges in question;
- ***Strategic Sentencing Criteria*** under section 287 of *CEPA* which include reference to many elements of regulatory due diligence as mitigating factors in sentencing; and
- ***Orders of the Court*** that may be made under section 291 of *CEPA*, which include an extensive array of corrective and preventive measures.

Option 4 - Modified American Approach (All Constituent Acts)

Option 4 is a variation of the Modified American Approach described in the preceding section. It differs only in its scope of application. Instead of applying the general prohibition against advertising, marketing, importing, etc of products that present an “unreasonable risk of injury” *only* to the *Hazardous Products Act*, it would be extended to all of the constituent acts Health Canada had identified for incorporation into the *Canada Health Protection Act*.

As noted above, while the HPA is mentioned as a possible ‘home’ for a general prohibition based on American ‘risk of injury’ terminology, it might equally be located in some other generic statute administered by the Department such as the *Department of Health Act*⁴⁸⁵, or the proposed CHPA if the Department

⁴⁸⁵ S.C. 1996, c. 8

proceeds with the consolidation of constituent Acts under the Legislative Renewal Initiative.

Extending the scope of the general prohibition to health protection statutes that closely control *pre*-marketing activities, however, would involve a different and broader range of implementation issues for the Department to consider. The case for extending a general prohibition to statutes already containing general prohibitions specific to enumerated product lines is, at best, unclear.

Option 5 – ‘Status Quo’ with Administrative Reform

Under the ‘Status Quo’ Option, Health Canada would rely on existing statutory authorities for dealing with unregulated dangerous products or orphaned risks in regulated products and focus on *administrative reforms* to make the exercise of existing powers more timely and effective. To the extent feasible, policy and program measures available under the existing legislation would be enhanced to encourage a general culture of product safety and the promulgation of high quality voluntary standards as a complement to regulation.

Health Canada has current authority to temporarily regulate products falling outside the HPA through Ministerial Interim Orders where “*immediate action is required to deal with a significant risk, direct or indirect, to health or safety.*” The Interim Order provision under the HPA is the principle ‘safety net’ mechanism for dealing with unregulated hazardous products or emerging risks requiring immediate action by the public authority. It provides that:

5.1 (1) The Minister may make an *interim order that contains any provision that may be contained in a regulation* made under this Part if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health or safety.

(2) The Minister may make an interim order in which any power referred to in section 6 is deemed to be exercised, if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health or safety.⁴⁸⁶

An interim order is effective for fourteen days, unless it is repealed or approved by the Governor in Council within that time. However, the interim order may be enforced as if it were a regulation.⁴⁸⁷

In the case of the pre-market control licensing regimes (drugs, medical devices, radiation emitting devices), Health Canada would revisit (under this option) its methods for employing license conditions, sanctions or certifications to achieve

⁴⁸⁶ S.C. 2004, c. 15, s. 67 The interim order is, of course, temporary and subject to a number of important safeguards. The entire ‘interim order provision’ is set out in Annex 9.

⁴⁸⁷ Section 5(6) “ For the purpose of any provision of this Part other than this section, any reference to regulations made under this Act is deemed to include interim orders, and any reference to a regulation made under a specified provision of this Act is deemed to include a reference to the portion of an interim order containing any provision that may be contained in a regulation made under the specified provision.”

timely responses to emerging product risks, more effective risk assessment, an enhanced culture of safety, increased use of high quality voluntary standards and the expedited detection, remediation and removal of unsafe products. As the *Robens* Inquiry noted, licensing authorities have the most powerful remedies for altering undesirable behaviour, including the power to require license conditions, the suspension or cancellation of licenses, and varying administrative requirements with performance results. Some, perhaps much, of the reform needed under Health Canada's licensing-type regimes might, therefore, be met by administrative changes.

Under the *Hazardous Products* regime (which has a *post*-marketing focus), Health Canada would continue to rely on Ministerial interim orders as the principle means of addressing unregulated products or risks. In this case, however, the focus would be on making the Minister's interim order remedy more efficient by developing internal policies for triggering the use of this power, together with a fast-track process for exercising it - all in collaboration with the Minister's Office and relevant Central Agencies of Government. The policy and fast-track process would become a routine element of briefing for new Ministers of Health so they could be familiar with this emergency measure in advance of the need for urgent intervention against a hazardous product. Any policies developed with the Ministers Office or Central Agencies to this end, however, should be careful not to unduly 'fetter' the Minister's discretion.

In both its pre and post-marketing regimes, Health Canada officials are better placed than the authors of this paper to identify potential areas for administrative reform of existing practices. The purpose of outlining this option is simply to indicate that administrative reform of existing practices could be a productive line of inquiry.

Annex 1 – The Case Studies Report

Executive Summary/Key Findings

The network of legislation, regulations and standards at the federal and provincial/territorial levels of government addressing the safety of consumer products has served Canadians well over the years. However, many new products are entering the market and many of these are manufactured in other countries. Responsible government agencies are finding it difficult to deal with this influx. In addition, many products used by consumers are not regulated, are regulated inadequately or the responsible government does not have the authority or the tools to protect the public. In response to the limitations of existing legislation and regulation, Health Canada is considering modernizing its legislative framework. Many new responsibilities for suppliers have been proposed including provisions for a General Safety Requirement (GSR) that basically prohibits a supplier from placing unsafe products on the Canadian Market. Using three different case studies the implications for suppliers and government of implementing such provisions either in legislation or through regulatory amendments were investigated and a number of key findings were identified and are described below.

The costs for suppliers in complying and government agencies in administering and enforcing the reporting provisions will vary significantly depending on what systems and reporting mechanisms are already in place and on the criteria that will be used to trigger a report. In the case of consumer products like bicycles and household electrical products, harmonization with the systems in Europe and the United States could help maximize the usefulness of the data collected and minimize the costs.

There are a number of policy issues that will need to be resolved in order to successfully implement a GSR or similar regulatory provisions. Many of the issues are common to all three case studies included in this report and are related to the need for guidance and clarity around new requirements. For example, suppliers and government staff who provide advice to them need to know:

- What standards, regulations, conformity assessment systems or risk assessment process will be acceptable to demonstrate conformity with a GSR;
- What level of safety will be required to demonstrate compliance with a GSR;
- What type of adverse incident or level of injury will trigger a report of a problem product or a recall; and
- To whom and what system will be used to report adverse incidents.

One of the core elements in the implementation of a GSR or similar regulatory amendments is hazard identification and risk assessment. Such an approach based on evidence provides the basis for the selection of appropriate instruments to reduce risks, the determination of an unsafe product, the identification of effective interventions and the reporting of adverse health effects. In many cases, there are gaps in the information needed to carry out a risk assessment making it difficult for responsible to comply with new provisions. Moreover, many companies even large ones, do not have the expertise or capacity to assess risks in products. For example, manufacturers in other countries do not always make information about product design, component materials or manufacturing processes available to importers and there is a lack of product related injury data within Canada. The need for increasing the data available and the knowledge of suppliers about hazard identification and risk assessment is core to the successful implementation of the GSR or similar regulatory provisions.

To ensure that the transition from the existing legislation to new legislation or regulations is smooth and seamless and that the Department will be able to deal with the new provisions and products that will be covered, it will be necessary for Health Canada to identify, develop and/or implement:

- Changes and/or additions to its management processes and knowledge management systems to meet new and changed provisions and authorities in new legislation such as the adverse event reporting system. The impact will be greatest for those parts of the organization or other organizations responsible for unregulated consumer products or foods where systems or processes for reporting of adverse events or dealing with mandatory recalls have not been established;
- Tools, information and training that the employees will need to administer and enforce the new provisions that will apply to many products not previously dealt with;
- Training, information and guidance documents to provide previously unregulated suppliers with an understanding of how to comply with any new provisions;
- Functions of staff and the skills, expertise that staff will require to administer the new provisions in areas previously unregulated and to evaluate the various instruments that suppliers could use;
- Financial resources to develop and implement new systems, to hire expert analytical staff, tools or training within Health Canada and other responsible government agencies e.g. Canadian Food Inspection Agency or Provinces/Territories;
- A dispute resolution system;
- Protection of personal information; and
- Processes to ensure consistency in administration and enforcement for many new products across federal or provincial/territorial organizations that share responsibility.

In certain product areas such as household electrical products and some foods, overlap will exist between provincial/territorial legal instruments and a GSR. As a

result, it will most likely be necessary to develop a consensus among a number of government agencies and levels of government on the following questions:

- How the provinces/territories will work with the federal agencies to implement a GSR or new regulatory provisions?
- Will the provinces/territories be able to draw on the provisions of the GSR and enforcement authorities provided under federal legislation to deal with importation, reporting and recalls?
- What level of safety will be considered unacceptable and will trigger enforcement action or reporting of an adverse incident?
- To whom will reports of adverse incidents be made?
- What type of information manuals and/or training will need to be developed to assist suppliers and government officials in understanding the new requirements?

The policies and the form of any working arrangements developed with the provinces and territories will have a significant impact on whether or not any overlap that exists between them has a negative or positive benefit.

The reliance on standards will require substantial participation by government officials to ensure that the standards developed address the health and safety concerns of Canadians. Moreover, the fact that many standards reference other standards increases the workload.

In order for cabinet to make a decision on new legislation or regulatory changes, it will be necessary for Health Canada to obtain accurate, complete and up to date information based on the results of

- An analysis of any proposed changes and the alternative solutions considered;
- Consultation of those who have an interest in the matter, including other departments that may be affected by the proposed solution;
- An analysis of the impact of the proposed solution on the operating environment and costs to small, medium and large suppliers; and
- An analysis of the resources that the proposed solution would require, including those needed to implement or enforce it.

The legal implications of a government agency being informed of a safety hazard in a product needs to be addressed, particularly, if it means that all reports cannot be investigated.

Background

The purpose of the three case studies included in this report is to examine the implications for suppliers and government officials of implementing a General Safety Requirement (GSR) in Canada. In applying a GSR to the real world of the Canadian marketplace and global trade, there will be operational and financial implications both for the suppliers who must comply with it and the government agencies responsible for implementing and enforcing it.

It is assumed that, if a GSR were implemented, it would complement existing regulations by acting as a “safety net” to address any unregulated product or an identified risk that is not covered by the existing regulation. On the other hand, it may be possible to provide the authority to address any unanticipated risks through regulatory amendments.

The implications presented in the case studies of this report are based on a number of assumptions about the provisions that would be included in a GSR if it were to be implemented in Canada. These assumptions are derived primarily from:

- The provisions outlined in Health Canada’s Legislative Proposal;⁴⁸⁸
- The General Safety Provisions of Europe’s General Product Safety Directive;⁴⁸⁹ and
- Elements similar to a GSR that are included in the US Consumer Product Safety Act.⁴⁹⁰

The assumptions about the requirements normally included in a GSR are as follows:

- Health Canada would continue to establish in regulations health and safety requirements and specifications for specific products or groups of products when required. The GSR would complement any regulations by acting as a 'safety net' in the absence of a regulation or a regulation that does not address the health risk or hazard in question;
- A GSR would make it illegal for a supplier to manufacture, promote or market a product that may pose a risk to the health or safety of consumers when used under-intended or reasonably foreseeable conditions;
- In trying to demonstrate conformity to a GSR in response to the occurrence of non compliance, a supplier will be required to show that all reasonable care was taken to comply with the provisions of a GSR that are applicable including identifying any associated product hazards, assessing the related risks and managing these risks;
- Like the obligations on business in Europe and the US, the GSR would require suppliers to monitor the safety of their products and notify a government regulator of any unsafe or potentially unsafe products that have been placed on the market. Government on receiving a notification would be obligated to take relevant action based on its legal obligations and the seriousness of the problem;
- Unlike the US system, the GSR would not contain a provision that the government must consider the development of voluntary standards before considering the development of regulations. Nor like the European system would Canadian standards be developed that would confer a presumption

⁴⁸⁸ Health Canada, *Health Protection Legislative Renewal Proposal*, 2003.

⁴⁸⁹ European Commission, *General Product Safety Directive*, (2001./95/EC), Dec 3, 2001.

⁴⁹⁰ United States, *Consumer Product Safety Act*, [Public Law 92-573; Oct. 27, 1972, as amended], www.cpsc.gov/BUSINFO/cpsa.pdf

of conformity with the GSR. Conformity with voluntary standards developed through a recognized system could, however, be used to demonstrate conformity where no regulations exist or where the standard addresses a risk not covered by an existing regulation.

The impact on Health Canada and suppliers of a GSR will vary considerably depending on the obligations under existing regulations. For example, regulatory requirements for the provision of safety information prior to marketing and for mandatory reporting of adverse incidents to Health Canada already exists for drugs, natural health products, biologics and medical devices under the *Food and Drugs Act (F&DA)*. Similar requirements do not exist for all foods or for consumer products under the *Hazardous Products Act (HPA)* or *Radiation Emitting Devices Act (REDA)*. As a result, the impact on suppliers of these products and those responsible in Health Canada will be greater than in the areas where these provisions have existed for a number of years.

The impact on a supplier could also vary depending on their role in the supply chain and their legal obligations established under a GSR or regulatory amendment. In Europe, for example, suppliers are divided into producers and distributors depending on their ability to influence the safety of a product⁴⁹¹. In other countries such as the United States⁴⁹² and Australia⁴⁹³, no differentiation has been made between the various members of the supply chain.

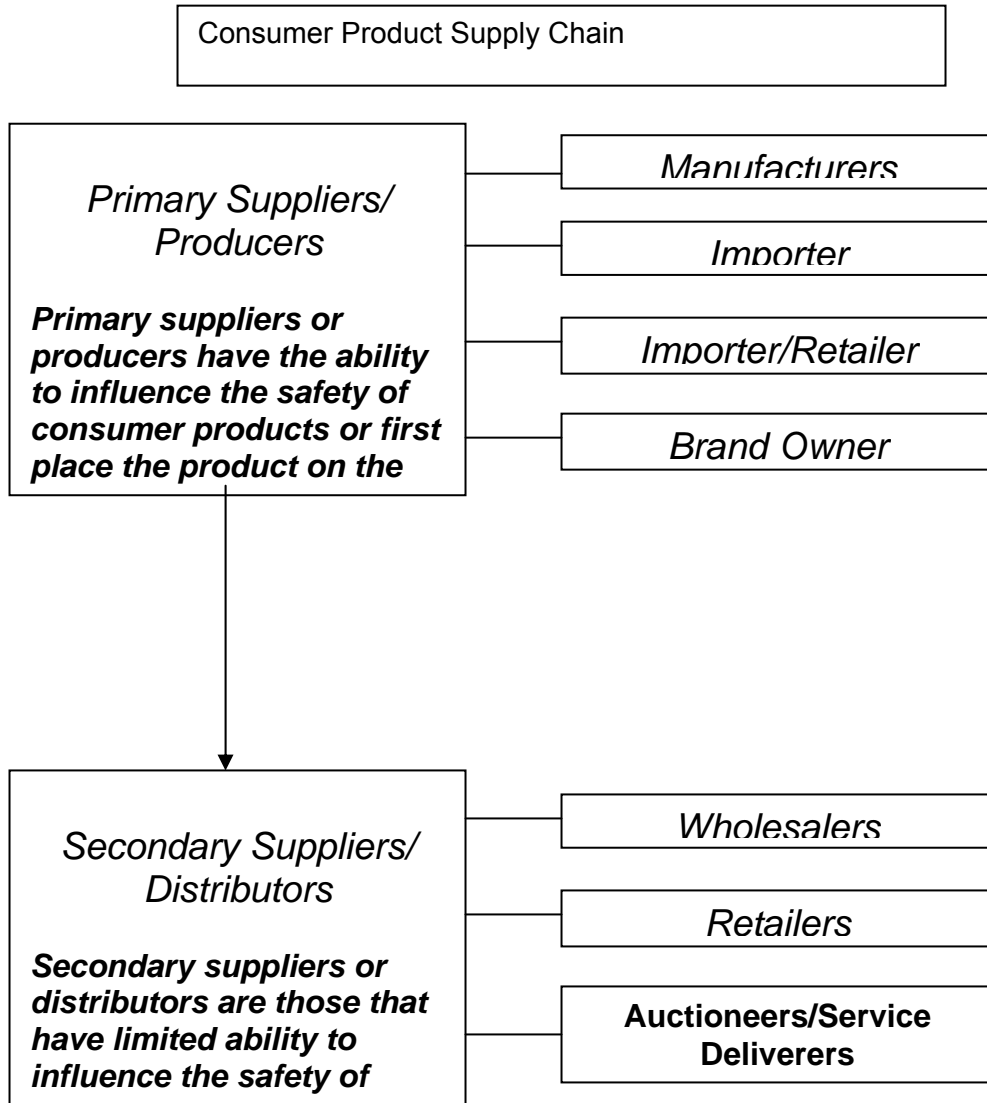
For the purpose of the case studies in this report, it is assumed that the obligations of those supplying consumer products would differ depending on their ability to influence the safety of the product. It is, therefore, assumed that two types of obligations would exist one for primary suppliers known as producers and another for secondary suppliers known commonly as distributors. Producers are those who either first place the product on the Canadian market or whose activities may affect the safety of the product. Distributors, in contrast, are those in the supply chain whose activities do not affect the safety of a product or who have limited influence. Figure 1 illustrates the supply chain for consumer products and those who are included in the two groups of suppliers.

⁴⁹¹ European Commission, *General Product Safety Directive*, (2001/95/EC), Dec 3, 2001.

⁴⁹² Consumer Product Safety Commission, *Consumer Product Safety Act*, Section 19.

⁴⁹³ Australian Government, *Trade Practices Act 1974*.

Figure 1: Consumer Product Supply Chain.



Case Study 1 Bicycles – Unregulated Products and No National Standards

The purpose of this case study is to identify the implications for suppliers and Health Canada of complying with or administering a GSR when a product is not regulated and for which no national standard exists. There are many consumer products on the Canadian market that fall into this category. Everything from assistive devices such as grab bars and bath seats that are not considered to be medical devices and are not regulated under the *HPA* to consumer products such as bunk beds or battery operated tools for which regulations do not exist.

Examples are provided in Appendix 2. Among the many consumer products on the market that are not regulated for safety, bicycles have been chosen to illustrate what suppliers and Health Canada will have to do where no Canadian regulation or national standard exists.

Practically, the obligations that are normally included in a GSR would mean that the producer would be required to identify any hazards associated with the bicycle, assess the related risks, determine how the risks can be addressed and select an instrument from another jurisdiction that addresses the risk either directly or indirectly. If no such instrument exists, the producer would have to develop his own standard and institute a compliance program to ensure that any risks are systematically and continuously addressed. This would have to be done before the product is marketed to demonstrate that all reasonable care was taken to market a product that is safe. In addition, both producers and distributors would be required to establish a monitoring and recall system so that any problems that occur after the product enters the market are identified, reported to Health Canada and corrective actions or recalls are taken and monitored.

An alternative to the implementation of a GSR is the adoption of similar provisions to those that would be included in a GSR in regulations under the HPA. The general safety provisions could be added to individual product-specific regulations using the authority of paragraph 5(a)⁴⁹⁴ of the HPA or as hazard based regulations using the authority provided by paragraph 6(3)⁴⁹⁵. Under paragraph 5 (a), it would appear to be possible to include in either regulatory approach requirements for suppliers to monitor the market, report any adverse incidents and correct any problems. The Medical Device Regulations under the *Food and Drug Act* provide an example of what could be done. Although it would be a difficult and lengthy process to develop a similar regulatory framework for general consumer products like bicycles, it may be worth considering. The implications would be very similar to those described here for a GSR.

Current Situation

Internationally

Many countries such as Australia, the European Union, New Zealand, the United Kingdom, and the United States have enacted mandatory requirements and/or standards for pedal bicycles in response to the number of associated injuries. In fact, over 200 national and international standards exist world wide covering the general safety of bicycles or their components. A list of the regulations and

⁴⁹⁴ “authorizes the advertising, sale or importation of any restricted product and prescribing the circumstances and conditions under which and the persons by whom the restricted product may be advertised, sold or imported”.

⁴⁹⁵ “may describe a product, material or substance or by reference to any other criteria and any product, material or substance that has those properties or characteristics or meets those criteria shall, for the purposes of this Act, be deemed to have been added by the order of Part I or , as the case may be of Schedule I.”

standards that would be of particular interest to Canadian policy makers is provided in Appendix 4.

In Australia, a revised mandatory safety standard for pedal bicycles became effective November 1999 and requires that all suppliers of pedal bicycles — including manufacturers, importers, wholesalers and retailers — must ensure their bicycles comply with Australian/New Zealand Standard AS/NZS 1927:1998 *Pedal bicycles — Safety requirements*. The standard covers everything from design requirements such as sharp edges and braking systems to performance requirements such as steering stability and strength of seat pillars to instructions for use and assembly.⁴⁹⁶ The New Zealand Government also revised its Product Safety Standards (Pedal Bicycles) Regulations in 1999 by referring to the same standard.⁴⁹⁷

The European Union requires conformity to the European standards for bicycles listed in Appendix 4. Conformity to these voluntary standards can assist suppliers of bicycles to comply with the GSR included in Europe's General Product Safety Directive. This Directive also contains a requirement for producers and distributors to notify the competent authorities in the Member States when a product available on the market reveals itself to be dangerous.⁴⁹⁸

The United Kingdom established regulations under the *Consumer Safety Act* in 1984 and these were revised in 2002⁴⁹⁹. The regulations refer to British Standard BS6102 and to the corresponding ISO standard.

In the United States, the U.S. CPSC under the *Consumer Product Safety Act* (CPSA) developed requirements for Bicycles⁵⁰⁰ in 1976 in response to the number of injuries that were taking place. The regulation covers all types of pedal bicycles and establishes, among other things, requirements for assembly, braking, structural integrity and reflectors. The CPSC also requires suppliers to monitor the market and to report products that do not comply with a rule issued under the CPSA, or contain a defect, which could create a substantial risk of injury to the public.

In Canada

Bicycle riding is one of the most popular activities in Canada for both recreational purposes and transportation. In fact, over 52 percent of Canadian households own at least one bicycle, and 42 percent of Canadians participate in biking as an activity. Although biking is somewhat seasonal, over 1.3 million units are sold

⁴⁹⁶ Australian Competition and Consumer Commission, *Product Information A mandatory standard guide: Pedal Bicycles*, January 2000, <http://www.accc.gov.au>

⁴⁹⁷ Ministry of Consumer Affairs, New Zealand Government, *The Product Safety Standards (Pedal Bicycles) Regulations 2000*. www.consumeraffairs.govt.nz/productsafety/standards/st-pedalbicycles.html

⁴⁹⁸ General Product Safety Directive (2001/95/EC)

⁴⁹⁹ Department for Transport, *The Pedal Bicycles (Safety) Regulations 2003 – Regulatory Impact Assessment*. April 2003.

⁵⁰⁰ Code of Federal Regulations Title 16, *Part 1512 – Requirements for Bicycles*, www.cpsc.gov

every year. Imports accounted for 75 percent of the market in 2000⁵⁰¹. Those producing bicycles can be broadly categorized into three groups: Canadian manufacturers, importer-retailers who import directly for sale at retail and importer/distributors who import and re-sell bicycles to retailers. If as assumed importers would have the same status as Canadian manufacturers, they would be held responsible for anything within their control that could affect the safety of a product and for monitoring and addressing any adverse health effects identified.

In Canada, no regulations or standards exist that deal with the safety of bicycles, the reporting of associated adverse incidents or the corrective actions to be followed. Some provinces/territories under Traffic or Highway legislation specify certain use conditions for bicycles as vehicles on roadways such as requiring the use of bicycle helmets, lights between sunset and sunrise and bells or warning devices. These requirements vary from province to province and do not set specifications for the actual safety of the bicycle itself. As a result, there are no rules or protocols for manufacturers or importers to follow in order to demonstrate that the bicycles they sell are safe, to monitor the market or to guide them if corrective action is required.

Like many consumer products, there is no nationwide data on bicycle related injuries and deaths. However, research projects and policy analysis^{502, 503, 504} that have been carried out for specific purposes show that, there are many causal factors affecting injury patterns including mechanical failure and malfunction of bicycle parts. These mechanical failures have the potential of causing significant injuries. The situation is exacerbated by the fact that the consumer is generally unable to assess the safety and roadworthiness of a bicycle at the time of purchase given the technical nature of bicycle design and construction. Examples of reported mechanical problems or failures that can affect the safety of a bicycle and have resulted in recalls include:

- Inaccurate assembly instructions leading to incorrect assembly of brake wheels;
- Breakage or deformation of the forks, steering column or frame;⁵⁰⁵
- Looseness or breakage of handlebar assemblies;⁵⁰⁶
- Wheels or chains coming off; or breaking;⁵⁰⁷
- Brakes locking, failing to stop bicycle or defective brake cable;⁵⁰⁸

⁵⁰¹ U.S. & FOREIGN COMMERCIAL SERVICE AND U.S. DEPARTMENT OF STATE, 2002
⁵⁰² Consumer Affairs Division, Australian Government, Regulation Impact Statement on Pedal Bicycles: Safety Requirements, July 1999.

⁵⁰³ Public Health Agency, Bicycle Injuries – analysis of 1998 hospital admissions with a focus on injury hazard associated with handlebars, CHIRRP News, June 2000

⁵⁰⁴ CPSC, Bicycle Study, Part V. Role of Mechanical Design and Performance in Selected Bicycling Incidents, 1992, p. 95-103

⁵⁰⁵ Recall by Quality Bicycle Products, March 11, 2004, CPSC, VisionTech USA, Inc. Announce Recall of Bicycle Aero Bars, Ban of child bicycle Domino by Czech Republic, May 2005.

- Failure of welds⁵⁰⁹ or pedals;
- Lack of reflectors;
- Clothing caught in the bicycle; and
- Substandard materials in components.⁵¹⁰

Potential Options to Resolve the Issue

Under these circumstances, a producer would be faced with the prospect of either developing a standard and assessing the risks internally or purchasing the scientific, engineering and/or risk assessment expertise required.

Assessment and Management of Risk

In the Canadian situation, where no standards or regulations exist, it is assumed that a GSR or similar regulatory provisions would require that a risk assessment be carried out and that appropriate action be taken to mitigate any risks identified before the product is marketed. It is also assumed that a GSR or regulatory provisions would require suppliers to monitor their products and report any adverse health effects to the responsible government agency. An example of what a producer would need to do is the action that was undertaken a number of years ago by a major Canadian importer/retailer in response to a safety problem that resulted in the expensive recall of thousands of bicycles.

Identification of the Problem and its Cause

The first challenge the company faced was to define the problem and its cause so that appropriate action could be taken to correct it and to reduce the likelihood of a similar recall from occurring in the future. Since neither injury data nor relevant data from the manufacturer existed, the company was forced to evaluate and test the product and its components. The laboratory analysis indicated that the hazard was caused by the weakness of the welds and the sub-standard grade of steel used in the steering column and bicycle forks. This analysis, particularly the metallurgical part, required specialized engineering knowledge and laboratory equipment.

Choice of a Standard or Regulation

Since no standard or regulation existed in Canada for bicycles, the company decided to identify a standard or regulation that it and its manufacturers could follow to address the general safety of bicycles and the specific risks identified. The company reviewed bicycle regulations and standards from other jurisdictions to determine whether or not any of them were suitable. After extensive investigation and analysis, it was found that no existing standard or regulation dealt with the particular metallurgical defects identified. The company concluded that, in order to protect the safety of its customers and prevent expensive recalls

⁵⁰⁶ CPSC, Quality Bicycle Products Announce Recall of Bicycle Handlebar Stems, May 2005; CPSC, Huffy Bicycle Company Announce Recall of “Cranbrook” Bicycles Sold at Wal-Mart, June 2004
⁵⁰⁷ CPSC and Rocky Mountain Bicycles Recall, May 9, 2002, CPSC, Torelli Imports Announce Recall of Bicycle Tires, Aug 17, 2005.
⁵⁰⁸ Recall of BMX bicycle ordered by Norway, Rapex system Nov 2005.
⁵⁰⁹ CPSC, World Wide Cycle Supply Inc Recall, Sept 2, 2004
⁵¹⁰ Product Recalls Australia, Dec 12, 2004,

that damaged its reputation, it would have to develop its own standard. Therefore, the company decided to use the U.S. rule as a base, since it more closely resembled the Canadian situation, and to add requirements to deal with the associated metallurgical safety issues not addressed in the rule.

Development of a Standard and Compliance System

After deciding on the specifications to be included in its standard, the company then had to take steps to ensure that the bicycles they purchased and sold complied with the new standard. Since no testing and certification program existed in Canada for bicycles, the company established its own quality system for bicycles. The establishment of this program and the implementation of the new standard involved the development and establishment of the following:

- Detailed product specifications;
- Information for manufacturers who had to comply with the standard;
- Test protocols, certification type program to approve overseas test laboratories to evaluate bicycles against the standard; and
- A program to monitor compliance and potential adverse effects after marketing.

Analysis of Complaints and Returns

To systematically monitor the effectiveness of the program over the long term, the company now collects and analyses customer complaints, any available injury data and the reasons for product returns. This information is then used to improve the test and certification program, amend the standard or identify production, material or component problems to be corrected.

The actions undertaken by this Canadian importer/retailer illustrates what a Canadian producer will have to do in order to comply with a GSR or risk based regulation. Like the company in question, a producer would be required to identify the product hazards and their source, assess the risks from the perspective of both intended and reasonable foreseeable use and implement procedures or processes to mitigate the risks and to monitor them. Unfortunately, many importers and importer/retailers do not have the same level of knowledge about a bicycle as a manufacturer and might have significant difficulty in responding in a similar manner. Adding to the challenge is

- The lack of national bicycle related injury data and research on interventions to reduce risks;
- The fact that foreign manufacturers are not always willing to provide the information required to identify and assess potential risks associated with their bicycles; and
- The fact that most importers do not have the scientific or engineering expertise or the facilities to carry out a detailed evaluation of a bicycle

Standards

Having identified a hazard that may arise from either intended or reasonably foreseeable use, the producer will need to determine what, if anything, he must do to protect users and third parties against injury from the identified hazard. In the case of reasonably foreseeable use like riding a mountain bicycle over very

rough trails, the answer is clear. The forks and steering mechanism must be made from higher quality steel that has greater load bearing properties and can withstand repeated severe impacts. In addition, instructions for the correct maintenance of the bicycle could reduce the risk of failures due to loose bolts, chains or brake cables. These measures would reduce the risk of exposure to mechanical failures.

For any category of bicycle producer, applying the provisions of an existing standard or regulation that addresses all the potential hazards would be the easiest way to demonstrate compliance with the GSR. Since no such Canadian regulations or standards exist, it would be necessary for them to identify an appropriate standard/regulation from another jurisdiction. This can be a time consuming and expensive process as there can be hundreds of standards/regulations establishing technical specifications that may be appropriate. To review these instruments successfully, scientific and engineering expertise in a number of disciplines would be required. In the case of bicycles, for example, there are over 200 standards or regulations that exist for bicycles and/or their components. The cost of purchasing the standards ranges from \$100 to \$300 each. For those who do not have the technical or financial resources, it is possible to access services from the Standards Council of Canada (SCC). The Council houses full text collections for standards and standards-related documents from key international organizations and jurisdictions and the collections are open to the public by appointment. The Council is also tasked with providing the business sector, government and other stakeholders with technical information on standards and can assist in identifying applicable standards for products on a cost recovery basis⁵¹¹.

Testing and Certification

Needless to say, the establishment of an elaborate testing, auditing and certification program as illustrated in the example would be beyond the capabilities and financial resources of most small to medium sized businesses. To do this a company would be required to have engineering and risk assessment expertise either internally or have the financial capacity to access the necessary expertise externally.

At the present time, a number of internationally recognized standard and certification bodies such as the Canadian Standards Association's On SpeX⁵¹² initiative, Intertek⁵¹³ and TUV Rheinland Group⁵¹⁴ have developed or are starting to offer comprehensive services to assist importers and retailers in assessing and controlling risks, monitoring at all stages in the life cycle of the product from design to production to post market and designing recall initiatives. As an example, the services offered by On SpeX⁵¹⁵ are listed in Box 1 below.

⁵¹¹ The Standards Council of Canada provides the first hour of research free of charge and then charges \$100/hour for research time after that.

⁵¹² www.onspex.com/services/index.htm

⁵¹³ www.intertek-etlsemko.com

⁵¹⁴ www.de.tuv.com/en/products_and_services/product_safety_and_quality/

⁵¹⁵ On SpeX charges \$1000-1200 per day plus travel. Eli Szamosi On Spex.

The cost of the services offered could be paid for either by the importer or retailer or be a contract requirement that the manufacturer must carry out and pay for in order to sell his product.

Box 1: Services offered by On SpeX to its Clients

- Consumer product test protocol development
- Product design reviews and analyses
- Performance and Reliability
- Package Testing
- Factory evaluation and inspection
- Data collection and analysis
- Product return/recall support
- Safety analyses
- Pre-certification assessment
- Social accountability audits
- Review of requirements for certification and compliance with standards

Implications of a GSR for Suppliers

Compliance

The consequences of failing to comply with a GSR or new regulatory requirements could result not only injury to consumers but also financial penalties, product recalls, damage to brand reputation even in some cases reduction in share prices on the stock market.

An example of a mechanism that a company could use to identify and reduce the risks of breaching the provisions of a GSR or similar provisions in regulations, is the compliance program developed by the Australian Competition and Consumer Commission⁵¹⁶. An effective compliance program would contain:

- An up to date list of legislative or regulatory requirements;
- Identification and reassessment of its compliance risks at regular intervals and before supplying new products;
- Management of the risks at critical control points which may be very different for manufacturers and importers;
- Training of staff so that they understand the legal requirements and have the skill and knowledge about compliance management;
- Complaints handling to provide feedback on its products and an early warning mechanism;
- Documentation of compliance efforts, steps to measure compliance and auditing of the program; and

⁵¹⁶ Quinane Mark and Justin Lucas, Australian Competition and Consumer Commission, *The ACCC's approach to trade practices compliance programs*, Presentation to the Australasian Compliance Institute, November 2005.

- Mechanisms for review and continuous improvement; and reporting system of results that is transparent to regulators and interested parties.

According to Australian researchers and government officials, the courts have recognized that a substantial and successfully implemented compliance program to be a mitigating factor when assessing penalties in the event of non compliance.^{517, 518} Such a program could be audited by a third party or government.

Needless to say, there will be operational and financial consequences of establishing new processes and procedures that any new provisions will require. It will be necessary for a supplier to identify the gaps that exist in the skill set of staff, management processes and IT systems and attempt to fill the gaps either internally or externally.

Monitoring and Reporting

To comply with any reporting requirements normally incorporated in a GSR or which could be incorporated into regulations, all types of suppliers must have in place a process to monitor the market, collect and analyze complaints and provide reports as required. Unlike suppliers of health products or veterinary drugs where reporting of adverse incidents is mandatory,^{519 520 521} suppliers of bicycles have not had to report adverse events in Canada and, therefore, have not established the processes and systems to monitor the market, collect data on adverse events and report them to Health Canada. If a company also supplies the US or European markets which have mandatory reporting, it will have in place a system to report adverse incidents and the new requirement will have a lower impact.

When setting up any system to collect data, suppliers will have to comply with the provisions of the *Personal Information Protection and Electronics Documents Act*,⁵²² which governs the manner in which personal information is managed by the private sector. It sets out ground rules for how a private sector organization may collect, use or disclose personal information in the course of commercial activities. The law gives individuals the right to access and request correction of the personal information these organizations may have collected about them. The provision in this case would be obtaining the consent from people to collect, use and disclose personal information.

⁵¹⁷ Australian Competition and Consumer Commission, *Corporate Trade Practices Compliance Programs*, November 2005.

⁵¹⁸ Parker Christine, Law Faculty, University of Melbourne, *Is there a Reliable Way to Evaluate Organisational Compliance Programs*, Australian Institute of Criminology and Reg Net Conference, Melbourne, September 2-3, 2002.

⁵¹⁹ Justice Canada, *Food and Drugs Act, Medical Device Regulations, Section 59, 1998*.

⁵²⁰ Justice Canada, *Food and Drug Regulations, Section C 01.016*.

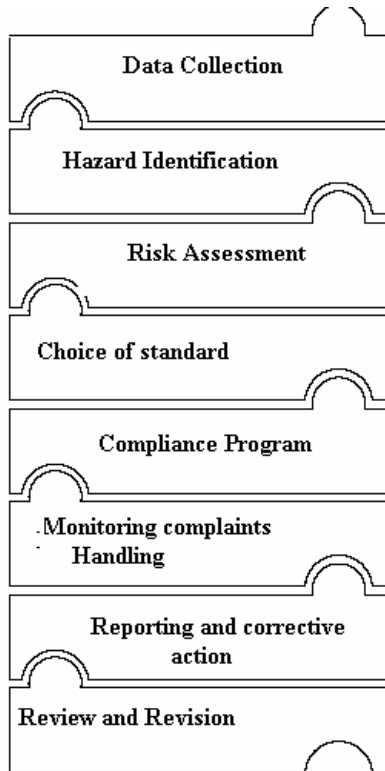
⁵²¹ Justice Canada, *Food and Drugs Act, Natural Health Products Regulations, 2004*.

⁵²² Office of the Privacy Commissioner, www.privcom.gc.ca

Summary

In summary, a supplier who is attempting to sell a product for which no regulations or national standards would be required to put in place the processes and procedures presented in Figure 2.

Figure 2. Risk Assessment and Mitigation Process



Implications of a GSR for Health Canada

With a product like bicycles where no national regulations or standards exist, it is critical that there is transparency and consistency in terms of what suppliers are expected to do to demonstrate compliance with a GSR and how it will be enforced the same applies if regulatory amendments similar to a GSR were made. Transparency and consistency are core principles of efficient regulation that have been articulated by the OECD,⁵²³ the External Committee on Smart Regulations⁵²⁴ and the draft Government Directive on Regulations.⁵²⁵ Therefore, bicycle suppliers will need clarification from Health Canada in terms of:

- Which standards or other similar instruments would be considered acceptable as a defence since no Canadian regulations or standards exist;
- What criteria would be used to determine the benchmark level of safety for this product to demonstrate compliance or to trigger a report of an adverse health incident; and

⁵²³ OECD, *OECD Guiding Principles for Regulatory Quality and Performance*, Adopted, April 2005.

⁵²⁴ External Advisory Committee on Smart Regulations, *Smart Regulation: A Regulatory Strategy for Canada*, Report to the Government of Canada, September 2004.

⁵²⁵ Government of Canada, *Draft Government Directive on Regulating*, November 2005.

- What enforcement actions will be taken and will they be consistent across the country.

The need for clarification is an indication that the provisions proposed under a GSR are not well understood by suppliers. The OECD⁵²⁶ in its research into regulatory reform and compliance concluded that one of the main factors that affects the private sector's ability to comply with regulatory requirements is the degree to which it knows the rules and is capable of complying with them. To achieve a high level of compliance, it will be important for suppliers not only to receive the guidance and information necessary to understand what is being proposed but to be consulted on the policies, regulations or documents that are developed.

Policies to be Developed or Implemented

Acceptable Level of Safety

The basic element included in any GSR is the requirement that a supplier not manufacture, import or market unsafe products. The meaning of the term "unsafe" is not clear and appears to be one of the key issues that needs to be resolved for those producing bicycles for the Canadian market. This is particularly the case where no regulations or standards exist and the producer must determine whether or not a product is safe. The first step would be to define the term and identify a process that a producer can follow when making decisions on safety.

There are some good examples of decisions that have been made related to safety levels and guidelines that have been published for suppliers. The HPFB's Inspectorate's⁵²⁷ guidance document on problem reporting for medical devices defines for producers the meaning of "serious deterioration of health" which triggers a problem report and explains how to make a report. In Europe, guidance in the form of a procedure to assist companies when deciding whether a specific problem caused by a consumer product is serious enough to warrant corrective action or notification to the authorities has been developed and published.⁵²⁸ The estimation of risk and the grading of the risk are illustrated below in Figure 3.

⁵²⁶ OECD, *Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance*, 2000.

⁵²⁷ Health Product and Food Branch's Inspectorate, *Guidance Document on Mandatory and Voluntary Problem Reporting for Medical Devices*, July 6, 2001.

⁵²⁸ European Commission, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with the Article 5(3) of Directive 2001/95/EC*.

Table A - Risk Estimation

		Severity of Health/Safety Damage			Overall Gravity of Outcome
		Slight	Serious	Very Serious	
Probability of Health/Safety Damage	Very High		Very High	High	Very High
	High	Very High	High	Medium	High
	Medium	High	Medium	Low	Moderate
	Low	Medium	Low	Very Low	Low
		Low	Very Low		Very low

Table B – Grading of Risk

Overall Gravity of Outcome	Vulnerable people		Non-vulnerable adults				Adequate warnings and safeguards? Obvious hazard?
	Very vulnerable	Vulnerable	No	Yes	No	Yes	
			No	No	Yes	Yes	
Very High	SERIOUS RISK - Notification required						
High	Moderate risk - Notification required						
Moderate	Low risk Notification, unlikely						
Low							
Very low							

Figure 3. European Risk Estimation and Grading of Risk

Table A is used to determine the gravity of the outcome of a hazard depending on the severity of health/safety damage and the probability of the possible health damage/ safety occurring.

Once the gravity of the outcome has been determined, then Table B is used to determine the rating of the gravity of risk depending on the type of user, whether the product has adequate warnings and safeguards, and whether the hazard is sufficiently obvious. Then it is decided whether a serious risk situation exists and rapid action is required. The following is an example as to how this table may be used. The user of a chain saw suffered a severe cut to his hand because the guard on the blade did not prevent his hand from sliding forward into the blade. Using Table A, the enforcement officer determined that probability of the injury is high because the hazard is present all of these chain saws. The severity of the health/safety assessment is serious. Therefore the overall gravity outcome is high. Now using Table B, the chain saw is for use by normal adults and it has an obvious hazard but inadequate guards. Thus, the

risk rating is moderate. Using the chart, it is determined that there is a serious risk and rapid action is required.⁵²⁹

Compliance

In order for a bicycle producer to assess the safety of a bicycle and choose an appropriate instrument to demonstrate that reasonable care was taken, they will need to know which instruments are acceptable. For example, it will be important for them to know whether or not voluntary codes or compliance programs would be considered to be acceptable; what criteria Health Canada will use to determine this; and whether or not Health Canada will identify the standards or instruments that are acceptable and would confer a presumption of conformity similar to what is being done in Europe.

Normally, a GSR includes provisions that any regulation, standard or code selected must address all identified risks and be developed through a recognized process that has balanced representation, expertise, objectivity and public review. As a result, evaluation of the suitability of an instrument to demonstrate conformity has to be made on a case-by-case basis. Unfortunately, this only increases the confusion and uncertainty for many producers, particularly small and medium sized enterprises, which do not have the knowledge and expertise to carry out a risk assessment.

With respect to some unregulated products particularly those new to the market, there may be no regulations or standards for the product in other jurisdictions like there are for bicycles. Like the situation in Europe, it is anticipated that producers will raise concerns about how they will be able to demonstrate compliance with the GSR or similar regulatory amendments under such a situation. Will it be necessary for them to develop a new standard? Will they have to carry out a detailed risk assessment similar to the European process illustrated in Figure 3?⁵³⁰ Will the establishment of a quality system or compliance program, similar to Good Manufacturing Practices or the ISO 9000 series, be sufficient?

Prior to a proposal for a GSR going forward it will be important for Health Canada to develop policies on standards and provide technical assistance for producers in the area of hazard identification, risk assessment and risk management. This may be in the form of fact sheets, training, manuals or guidelines. A number of examples that could form the basis of guidance on what has to be considered when identifying hazards, assessing risks and managing risks have been developed. These models are referenced in Appendix 3, which illustrates a typical process that could be used by suppliers of bicycles or any other unregulated product.

If compliance with standards is identified in any GSR as a way to demonstrate that all reasonable was taken to market a safe product, Health Canada may need

⁵²⁹ Delogu, B. Best Practice Risk Assessment in Consumer Safety, ECOSA European Conference, Edinburgh, 21-22 April 2005

⁵³⁰ The European Risk Assessment process is currently under review.

to adapt to the changing standards environment and revise its approach. This could include increasing its participation in the development of national and international standards and encouraging Canadian stakeholders to do so as well. It may also be necessary to influence the Standard Developers to ensure that standards for certain products are developed. This may have financial implications, as Standard Developers will not undertake the expense of developing a standard unless the finances to carry out the process are made available. The average range of cost for developing a standard is \$100,000 to \$150,000 according to CSA.⁵³¹

Reporting of Adverse Health Incidents.

As with the European GSR and similar US legislation, it is assumed that a GSR would require suppliers to report any adverse health incidents to Health Canada. Such provisions could also be included in regulations. No regulation or information exists that explains what would be required, what criteria would be used to trigger a report or what reporting procedures would be established. Bicycle suppliers will need to know whether they should report everything that happens or will government want the incidents to be prioritized so that only the most severe ones are reported. Health Canada will be required to establish these elements and provide guidance to suppliers similar to those developed by Health Canada's Therapeutic Products Directorate,⁵³² the US Consumer Product Safety Commission,⁵³³ and the European Commission.⁵³⁴ Moreover, it will be necessary for Health Canada to establish the capacity and expertise to analyze the data for consumer products and radiation emitting devices; to determine what type and level of response is required; and to take appropriate action. This could be similar to what the Marketing Health Products Directorate has done for mandatory reports on adverse health incidents related to drugs, biologics, and natural health products or the US CPSC requires for consumer products.

The costs for suppliers in complying and Health Canada in administering and enforcing the reporting provisions could be significant and will vary depending on the provisions that are specified in a GSR or regulatory amendment. For example, the US CPSC, over a twelve-month period, received 3000 reports of incidents involving consumer products from Wal-Mart alone.⁵³⁵ The CPSC's Office of Compliance, which reviews the reports, developed criteria to ensure that only essential reports and information were provided in order to reduce the number of reports to a manageable level. It is anticipated that, since many Canadian retail outlets are owned by American retailers and carry the same

⁵³¹ Personal communication with Jeanne Bank, Manager of Member Program at CSA, June 2006.
⁵³² Health Canada's Therapeutic Products Directorate, *Guidelines for the Canadian Pharmaceutical Industry on Reporting Adverse Reactions to Market Drugs (Vaccines Excluded)*, Revised July 2001.
⁵³³ US Consumer Product Safety Commission, *Regulated Products Handbook*, 3rd Edition, January 2005, Washington, DC
⁵³⁴ European Commission, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC*, December 2004.
⁵³⁵ Mullan John Gibson, Director of Compliance CPSC, *A Working Model for Retailer Reporting under Section 15*, ICPSO Annual Meeting, Orlando, February 23, 2005.

products, the number of reports made in Canada could be very similar. Harmonization with existing reporting systems in the United States could help in the sharing of information, the eventual integration of the systems, maximize the usefulness of the data collected and minimize the costs for industry and government.

The principle of proportionality needs to be applied with respect to reporting requirements for products that exhibit different levels of adverse health effects. In particular, policy decisions could be made with respect to adopting a threshold level of safety below which no notification would be required. This would help to ensure that limited resources are focused on addressing the most serious problems and that the government is not overwhelmed by problem reports. Legal questions with respect to Health Canada's responsibilities to take action when a problem product is reported will also have to be considered.

Essential to an effective monitoring program is being aware of products coming into the market and their performance. Knowledge regarding products can come from pre-market submissions where they are required; but for bicycles, where no pre-market evaluation is carried out, Health Canada will be required to depend on other sources of information. This could include reporting from injury data, coroners, medical and other professionals and reports of incidents from other jurisdictions.

Recall

The Consumer Product Safety Bureau of Health Canada has provided general guidance to suppliers about when and how to carry out a recall. However, it does not provide advice on what it considers to be the safety level or type of defect that would trigger a recall. The US CPSC, on the other hand, has attempted to define in detail what it considers to be a "substantial product hazard" that would trigger a report or a product recall.⁵³⁶ CPSC's grading of risk is very similar to the European model presented previously in Figure 2.

If Health Canada was to use a risk rating system that was compatible with the US and Europe, it could be possible to share information on defective bicycles, and reduce the cost to suppliers who sell products and possibly recall them in many different countries. The revision of the guidance document and the development of manuals and/or training for suppliers and staff will ensure that they understand what is required to comply with any GSR provisions. Moreover, Health Canada officials will be able to provide advice and enforce the new provisions consistently across the country. Transparency and consistency, which are essential to efficient regulation, will also be enhanced, if Health Canada consults suppliers and interested parties on its policy decisions and the tools being developed to provide guidance to suppliers.

⁵³⁶ US. Consumer Product Safety Commission, *Recall Handbook*, May 1999.

Impact Assessment

In the area of unregulated products where it has never been required to carry out a risk assessment, monitor the market or report adverse health incidents, the costs of developing new processes and obtaining the necessary expertise could be considerable. A cost benefit analysis to obtain the information that is required by Cabinet to make a decision on any new legislative or regulatory initiative would have to be carried out. This analysis is must be carried out in order to comply with Justice Canada's Directive on Lawmaking⁵³⁷ and the Government's Regulatory Policy.⁵³⁸ In fact, depending on the number of suppliers that will be affected, it may be necessary to carry out a Business Impact Test.

Privacy Impact Assessment

The establishment of any new data collection system such as the collection of information on adverse health incidents must respect the *Privacy Act*⁵³⁹. According to Treasury Board policy a Privacy Impact Assessment will need to be carried out.⁵⁴⁰

Operational Changes

On the one hand, moving towards a GSR or a regulatory equivalent will place significant pressure on the financial, technological and human resources of that part of the organization that primarily will be dealing with unregulated products while providing modern tools to increase transparency and efficiency. These new tools may translate into a significant shift in the choice of instruments that are used to achieve policy objectives. It could include the use of foreign bicycle regulations or standards instead of Canadian regulations or standards and change the role the Department plays. Instead of enforcing regulations, it may find that a more effective role in dealing with the multitude of unregulated products is to provide advice on risk assessment, the development of compliance programs and auditing suppliers programs. Such changes would require greater staff knowledge of risk assessment, standards, and standards setting processes and auditing procedures and could affect both human and financial resource requirements.

In order to determine the changes to be made, it will necessary to identify the gap between the processes imposed by the current legislation and what will be imposed if a new Act is passed. This type of analysis will also assist in meeting the requirements included in the proposed Government Directive on Regulation⁵⁴¹ for Compliance and Implementation Plans which identify the human and financial resources that are needed to administer any new initiatives including resources for compliance and enforcement and to ensure that those responsible have the necessary skills and abilities

⁵³⁷ Justice Canada, *Directive on Lawmaking*, 2003-07-08

⁵³⁸ Privy Council Office, *Regulatory Policy*, June 2000.

⁵³⁹ Justice Canada, *Privacy Act*, 1985.

⁵⁴⁰ Treasury Board, *Privacy Impact Assessment Policy*, May 2002.

⁵⁴¹ Government of Canada, *Draft Government Directive on Regulating*, Consultation Document, November 2005.

One of the major challenges facing the Department will be the need to ensure consistency in the administration and enforcement of any new provisions by a number of Branches and a minimum of three inspection authorities including the HPFB Inspectorate, the Healthy Environment and Consumer Safety Branch's (HECSB) Inspectorate and the Canadian Food Inspection Agency (CFIA).

The department will also have to carry out consultations internally with staff and externally with a wide range of interested parties on different aspects of the legislative proposal, on any regulations being developed or amended, and on the tools, training and information initiatives. The initiative will involve a significant number of different types and levels of consultations in which HC staff from the various affected programs and from CFIA will be asked to participate in or be required to plan, organize and deliver.

Case Study 2: Konjac Jelly Mini-cups – Product Inadequately Regulated

In some cases, an existing regulation does not address all the hazards associated with a consumer product. This situation can occur where:

- The regulatory framework does not provide the authority to address certain types of hazards such as the *Food and Drugs Act* (F&DA) Food Regulations which does not provide the authority to address mechanical hazards related to food;⁵⁴²
- A product has changed due to technical advancements; or
- The product is being used in a manner that was not contemplated when the regulation was developed.

To illustrate this situation and to identify the implications of a GSR for both suppliers and government Konjac Jelly Mini-cup products will be used. These are food products that are covered by the F&DA Food Regulations.

The safety of food is more complex than many other product areas since it involves more than 30 different government departments, agencies (federal, provincial/territorial and/or municipal) depending on the product or problem. At the Federal level, Health Canada is responsible for developing the food safety regulations under the F&DA and the Canadian Food Inspection Agency (CFIA) is responsible for enforcing these regulations. The provinces/territories also develop and enforce statutes to minimize food safety risks in various commodities produced within the province/territory. For example, Ontario administers and enforces standards for the production, safety, labelling, advertising and sale of such products as dairy products, fruits, vegetables, eggs and honey. Municipal Public Health Officials who are often the first to be notified of food safety problems also play an integral role in the food safety system. They can set food safety standards and policies for food premises and have the power to condemn food.

⁵⁴² Department of Justice, *Food and Drugs Act, Part 1, 4*, Sept 2005.

The challenge is for governments at all levels to work cooperatively to reduce the risks and to streamline and enhance the system. CFIA is currently negotiating with provincial and territorial governments a number of federal-provincial agreements to integrate the food safety system. This includes sharing information and expertise and co-coordinating enforcement and inspection activities and emergency response services (e.g., food recalls). CFIA and the provinces/territories promote the use of the Hazard Analysis Critical Control Point (HACCP)-based Quality Management Systems to improve the safety of food.

Current Situation

The Konjac Jelly Mini-cup Jelly products are candies that are traditionally manufactured in South-east Asia and imported into many countries under various brand names. The jellies contain the additive Konjac as the gelling agent in place of gelatine to maintain their shape and firmness. The mini cups are about the size of a coffee creamer with rounded edges. They usually contain a flavoured or fruit centre enclosed in the shell of Konjac jelly. Although no warnings appeared on individual jellies, the outside package often carried a warning such as:

Keep out of the reach of children. Seniors and children should be supervised when consuming the fibre jelly. Make sure to chew slowly and thoroughly. Do not swallow whole. Children under 3 are advised not to eat this product.⁵⁴³

Internationally

During 2001 and 2002, the Konjac Jelly Mini-cups were associated with the choking deaths or near fatalities of a number of children and elderly persons in Japan, Australia⁵⁴⁴, Taiwan, Hong Kong, Canada⁵⁴⁵ and the United States.^{546 547} Due to the fact that these products were slippery and maintained their shape and firmness when placed in the mouth, they could become lodged in the throat and were very difficult to remove due to their size, shape and consistency.

The US Consumer Product Safety Commission (CPSC) in response to a request from the US Food and Drug Administration (FDA) evaluated the potential choking hazard associated with Konjac Jelly Mini-cups. Due to its legislative responsibilities, the CPSC has developed extensive expertise in the physiology and anatomy of the airway and the characteristics of objects involved in fatal choking events among children. These experts concluded that the physical characteristics of the small cup like candies pose a serious choking risk due to their size, shape, texture and consistency.⁵⁴⁸

⁵⁴³ Canadian Food Inspection Agency, *Safety Hazard Alert, Choking Hazard Posed by Mini-Cup Jelly Products*, August 16, 2000

⁵⁴⁴ Australia New Zealand Food Authority, *ANZFA Urges Recall on Jelly Cups with Konjac*, November 16, 2001.

⁵⁴⁵ Canadian Food Inspection Agency, *Safety Hazard Alert, Choking Hazard Posed by Mini-Cup Jelly Products*, August 16, 2000.

⁵⁴⁶ United States Food and Drug Administration, *Import Alert #33-15*, November 16, 2002.

⁵⁴⁷ Public Health Seattle and King County, *Alert, Jelly-fruit cup poses choking hazard*, July 28, 2000.

⁵⁴⁸ United States Food and Drug Administration, *Import Alert #33-15*, November 16, 2002

Under the Food Chemical Codex, Konjac is an additive that is considered to be safe⁵⁴⁹ for human consumption and is used in food in the form of flour, gum/gel or soluble fibre. The same situation applies under Codex Alimentarius standards.

In Canada.

Konjac, a food additive, falls under the purview of the F&DA, which covers “any ingredient that may be mixed with food for any purpose whatever.”⁵⁵⁰ Konjac’s use as an additive is not restricted under the F&DA’s Food Regulations. These regulations prohibit the sale of food that is poisonous, harmful, unfit for human consumption, adulterated or exposed to unsanitary conditions from manufacture to sale.⁵⁵¹ The Act does not prohibit food that due to its physical or mechanical properties adversely affects the health or safety of a consumer. As a result, it was not possible for CFIA to use the F&DA authorities to address the problem of the Konjac Jelly Mini cups.

The size and shape of these jelly candies pose a mechanical choking hazard as defined by regulations under the *Hazardous Products Act (HPA)*⁵⁵². Although the HPA provides Health Canada with the authority to deal with mechanical choking hazards in consumer products, food is specifically exempted from this Act. This meant that the HPA also could not be used to address the problem of the Konjac Jelly Mini cups obstructing a child’s airway.

Since the serious risk associated with the jelly mini-cups could not be addressed by either the F&DA or the HPA, CFIA was forced to explore other options. Initially, CFIA published safety alerts⁵⁵³ in 2000 and 2001. These alerts provided information to consumers about the choking hazard posed by the mini cups and warned against serving them to children and seniors. The alerts were followed by further action in November 2001, when the Minister of Agriculture and Agri-Food Canada announced a mandatory recall of the Konjac Jelly Mini-cups by using the *Canadian Food Inspection Agency Act (CFIA Act)*.⁵⁵⁴ The CFIA Act provides the authority to deal with a broader range of risks than is possible under the F&DA. For example, the Minister of Agriculture and Agri-Food Canada under the CFIA Act may initiate a mandatory recall of a product regulated under an Act for which CFIA is responsible if “the Minister believes on reasonable grounds poses a risk to public, animal or plant health.”⁵⁵⁵ Risk is not specifically defined under the CFIA Act and it was determined that the term covered physical risks.

⁵⁴⁹ Food Chemical Codex, Fourth Edition, 1996, published by the National Academy of Sciences, Washington, D.C., United States.

⁵⁵⁰ Department of Justice, *Food and Drugs Act, Section 2*.

⁵⁵¹ Department of Justice, *Foods and Drug Act, Section 4 Food*.

⁵⁵² Department of Justice, *Hazardous Products (Toy) Regulations Section 7c, Carriages and Strollers Regulations, section 12, 2004*.

⁵⁵³ Canadian Food Inspection Agency, *Safety Hazard Alerts*, August 2001, October 2001

⁵⁵⁴ Canadian Food Inspection Agency, *Safety Hazard Alert, Minister Orders Mandatory Recall of Konjac Mini Cup Jelly Products*, November 21, 2001.

⁵⁵⁵ Department of Justice, *Canadian Food Inspection Agency Act*, Article 19, March 1997.

There are significant gaps in the regulation of food and the onus is on the government to identify hazards and establish standards for each type of product. This reactive approach as occurred with the Konjac Jelly Mini-cups results in significant time delays in addressing adverse health events.

Potential Options to Resolve the Issue

There are a number of options that could be considered to address the problem Konjac Jelly Mini-cups. For example, consideration could be given to revising the F&DA food regulations so that it prohibits not only biological and chemical contamination but also physical characteristics that may cause harm. The European General Food Law⁵⁵⁶ contains such a broad prohibition. This new food law provides the EC with the clear authority to take action against a food causing harm due to its physical characteristics. Moreover, the new European law includes the elements of a General Safety Requirement since it provides the authority to take action against a food conforming to community regulations or standards where it is suspected that the food is unsafe.⁵⁵⁷ The inclusion of physical hazards as a prohibition under the F&DA Food Regulations would also be consistent with the international food standards, guidelines and codes of practice for producers and suppliers developed by the Codex Alimentarius Commission under the Joint FAO/WHO Food Standards Programme.⁵⁵⁸ Under these standards and codes, the definition of hazard includes physical hazards in addition to biological and chemical hazards.⁵⁵⁹

It also could be possible to establish a system that addresses all risks by changing the regulatory framework to a risk based system similar to the Medical Device Regulations⁵⁶⁰. However, this would be a difficult and lengthy process due to the complexity of developing such a system for the wide range of food products. The additional provisions incorporated in a GSR such as mandatory reporting and recall could also be added through regulatory amendment as was done with the F&DA's Medical Device and Natural Health Products Regulations.⁵⁶¹

Another option to be considered, where the existing regulation does not address the hazard in question, is the establishment of a GSR similar to the one in Europe. It is assumed that a GSR would provide the authority to take action against any product that presents a risk to consumers irrespective of whether or not the product meets existing regulations. A GSR containing such a provision would have allowed CFIA to take immediate action to remove the Konjac Jelly Mini-cups from the market although the product complied with the existing

⁵⁵⁶ European Parliament, *Regulation (EC) No. 178/2002 on General Food Law Article 3, Definition 14*, January 28, 2002

⁵⁵⁷ European Parliament, *Regulation (EC) No. 178/2002 on General Food Law Article 14, No. 8., and Article 53*, January 28, 2002

⁵⁵⁸ Codex Alimentarius Commission, 2006. www.codexalimentarius.net

⁵⁵⁹ Codex Alimentarius Commission, *Recommended International Code of Practice: General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4-20031*

⁵⁶⁰ Department of Justice, *Medical Device Regulations*, Dec 2005.

⁵⁶¹ Department of Justice, *Natural Health Products Regulations*, June 2004.

regulation. A GSR in legislation would ensure consistency across all the product areas and cover all products without continual updating or a complex and lengthy amendment. Moreover, the GSR would capture any new innovative product entering the market that posed an adverse health risk. By establishing a general GSR the goal of Health Canada's Legislative Renewal Initiative to better protect consumers by strengthening existing legislation would be met.

Implications of a GSR for Suppliers

From the perspective of a supplier of Konjac Jelly Mini-cups, a GSR would mean that:

- He/she would have to ensure that the product complies not only with any existing regulations but also with the obligations specified by a GSR; and
- The obligations that are normally included in a GSR such as assessing and managing the risks associated with a product, monitoring any problems in the marketplace and reporting problems to the enforcement agency have the potential of significantly impacting on suppliers. It is also assumed that the obligations will be different for producers and distributors since their ability to influence the safety of a product is very different.

If a regulatory option is followed that is based on risk, mandatory reporting could be included and the impact would be similar to the implementation of a GSR

Compliance

Hazard Identification and Risk Analysis

To demonstrate that all reasonable care has been taken to market a safe product and comply with a GSR, a producer would normally be required to assess the product prior to production or importation and take steps to address any problems identified. The procedure to identify hazards and assess risks basically involves responding to four simple questions.

- What can go wrong?
- How likely is it?
- What are the consequences?
- How can it be prevented?

Responding to these questions, however, is not as straightforward as it would appear. The lack of data and research on adverse events caused by the mechanical properties of food makes it difficult for a producer to assess the risk associated with the Konjac Jelly Mini-cups. Moreover, standards, methods for evaluation and available expertise are limited or do not exist. For these reasons, many producers, particularly small and medium sized enterprises are concerned about how they will be able to assess the risks associated with a product like the Konjac mini-cups and to comply with the GSR. Even large companies such as

Nike must rely on external consultants to assess innovative products, which are outside their knowledge base and expertise.⁵⁶²

The risk assessment process that a producer of the Konjac Jelly Mini-cups could follow would be very similar to the process outlined in section 4.3 for bicycles and in Appendix 3. However, in the food area, there are differences due to the involvement of CFIA and its policies related to importation and the enhancement of Canadian food safety. Both policies promote the implementation of Hazard Analysis Critical Control Point (HACCP)-based Quality Management Systems to control the safety of a food product. This approach is consistent with that of the Codex Alimentarius Commission's standards and codes for food are accepted internationally and form the basis of international trade requirements.

There are a number of data sources that a producer can use to help identify hazards and assess associated risks. Information can be obtained from the scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts. To access this information and analyze it, a producer would require very specialized scientific expertise internally or have the financial ability to purchase the expertise externally.

Standards or Codes

No specific test procedures or standards currently exist to evaluate hazards associated with the physical characteristics of Konjac Jelly Mini cups and other food products. Therefore, it would be necessary for a producer to review standards for other products exhibiting similar physical characteristics and either adapt a standard to the Konjac Jelly Mini-cups or develop a new standard to evaluate the mini-cups and to comply with the GSR provisions.

The process of identifying an appropriate standard is not easy since it often requires very specialized expertise to evaluate the applicability of a standard⁵⁶³. Moreover, the number of standards that would need to be reviewed could be extensive and the process time consuming and expensive.

Conformity Assessment

Once a mechanism is found that addresses the hazard identified in the Konjac Jelly Mini-cups the producer should put in place procedures to ensure that the solution is followed during production, distribution and sale. This could take the form of a conformity assessment procedure to determine whether a product, service or system meets the requirements of a particular standard."⁵⁶⁴ There are

⁵⁶² Guy La Salle, Product Safety Director, Nike Europe, *Internalizing the EU Product Safety Agenda in an International Company*, International Workshop on Accident/Injury Data Collection for Non-Food Product and Service Assessment, Feb 20, 2006.

⁵⁶³ See Case Study 1 Section 4.4.1. For additional information on choosing an appropriate standard.

⁵⁶⁴ Standards Council of Canada, National Conformity Assessment Principles for Canada, www.scc.ca/en/publications/index.shtml

many conformity assessment procedures⁵⁶⁵ that could be used. In the food area the one that is being promoted nationally and internationally is the HACCP System.

CFIA through its Food Safety Enhancement Program (FSEP)⁵⁶⁶ and Import Policy⁵⁶⁷ expects all federally inspected processing establishments and importers to implement a HACCP-based Quality Management System. The CFIA uses this to assess domestic and imported food commodities. Where applicable and appropriate, the CFIA will take enforcement action based on the authorities provided by the CFIA Act, the food regulations under the F&D Act or the *Consumer Packaging and Labelling Act*. In the area of federally inspected meat and poultry establishments the HACCP system is mandatory.⁵⁶⁸

To help both food producers and distributors control risks and meet regulatory requirements, CFIA has published a FSEP implementation manual that includes a detailed guide for developing a HACCP program⁵⁶⁹. In addition, it has published a voluntary guideline entitled "Good Importing Practices"⁵⁷⁰ (GIP) based on the *Recommended International Code of Practice - General Principles of Food Hygiene* adopted by the Codex Alimentarius Commission. The GIP describes the key controls necessary for importers to control safety, suitability, labelling and fraud in imported foods sold in Canada. Since it is generic in nature, it can be applied to importers of Konjac Jelly Mini-cups. Elements of the GIP are considered to be the foundation for the development of a system based on HACCP principles for ensuring food safety.

For non-federally registered food processors, the provinces and territories are responsible and many have put in place voluntary HACCP programs. For example, after extensive research, stakeholder discussions, and in-plant testing, the Ontario Government adapted CFIA's FSEP approach to HACCP so it is feasible and practical for Ontario's small and medium-sized enterprises to implement.⁵⁷¹ If Konjac Mini-cups were to be manufactured in Ontario, the producers would be expected to voluntarily implement this program.

A supplier of a Konjac Jelly Mini-cup who establishes a HACCP system would be considered by CFIA, the provinces/territories, and foreign governments to have taken all reasonable care to ensure that the product is safe and complies with

⁵⁶⁵ Information on conformity assessment processes accepted internationally can be found at www.iso.org/iso/en/comms-markets/conformity/iso%2Bconformity.html

⁵⁶⁶ Canadian Food Inspection Agency, *Food Safety Enhancement Program*, 2003.

⁵⁶⁷ www.inspection.gc.ca/english/fssa/polstrat/haccp/manu/vol1/vol1e.shtml

⁵⁶⁸ Canadian Food Inspection Agency, *CFIA Import Policy*, 2001

⁵⁶⁹ www.inspection.gc.ca/english/fssa/polstrat/import/appenae.shtml

⁵⁷⁰ Canadian Food Inspection Agency, *Implementation of Mandatory Food Safety Enhancement Program (FSEP), Meat Inspection Regulations*, Dec. 15, 2004.

⁵⁷¹ Canadian Food Inspection Agency, *FSEP Implementation Manual*, 2001.

⁵⁷² www.inspection.gc.ca/english/fssa/polstrat/haccp/manu/manue.shtml

⁵⁷³ Canadian Food Inspection Agency, *Good Importing Practices: Code of Practice for use by Canadian Food Importers*, 1998. Revised version due to be published April 2006.

⁵⁷⁴ Ontario Ministry of Agriculture, Food and Rural Affairs, *HACCP Advantage*, www.omafra.gov.on.ca/english/food/inspection/haccp/index.html

existing regulations. The question being asked by producers and distributors is whether or not such a system will be accepted as a way to demonstrate compliance with a GSR or new regulatory provisions.

Monitoring and Reporting

Currently, there are no mandatory monitoring and reporting requirements in place for Konjac Jelly Mini-cups or other food products. If Health Canada established such provisions in Canada, a supplier of Konjac Jelly Mini-cups would be required to report any incidents to CFIA. The establishment of a monitoring and reporting system could result in significant financial costs to establish such a system and to hire additional personnel to maintain the system and analyze the data. Moreover, like in the case of bicycles, the provisions of the Personal Information Protection and Electronics Documents Act would have to be respected.

Provision of Information

Most products such as the Konjac Mini-cups are not 100% safe and how it is used can contribute to managing the associated risks. Consumers need and have a right to information about how to assemble, use or maintain a product correctly. Therefore, it is assumed that a GSR or equivalent regulatory amendment will require suppliers to provide consumers with sufficient information to assess the potential product risks and be capable of protecting themselves. The effectiveness of warnings and safety information depends on many factors such as an individual's ability to understand and read the information, their attitude to risk, the quantity of information presented and easy access to the information at the time of use or maintenance. In the case of the Konjac Jelly Mini-cups, where information did exist to warn against feeding this product to children, it was on the outer packing and not on the individual mini-cups themselves. The effectiveness of the warnings on the outer package of these products is in question since a number of children did die due to eating the product. In some cases, the children found the Jelly Mini-cups and ate them without their parents' knowledge.

From the perspective of the producer concerned about complying with a GSR or amended regulation questions arise about how much safety information should be provided, how should it be provided and whether or not it is appropriate to use information to manage residual product risks.

Implications of Failure to Comply

The implications of failing to comply with a GSR or equivalent regulatory amendment could mean fines, product recalls, seizures or a complete ban of the product from the market similar to what occurred with the Konjac Jelly Mini-cups. Moreover, brand images may be tarnished and a producer may be sued for damages.

If a GSR or similar regulatory provisions had been in place when the problem with the Konjac Jelly Mini-cups was identified, it would have been possible for CFIA to take immediate action to remove the product from the market.

Summary

The establishment of a GSR or new regulatory obligations could result in operational and financial impacts for a company producing Konjac Jelly Mini-cups. It would depend on what had already been established in the way of technical expertise to identify and evaluate risks, conformity assessment systems and monitoring and reporting systems. The producer of a product where not all hazards are covered by existing regulations will need to identify any gaps that exist in the skills set of staff, management processes and systems and fill these gaps either internally or externally. If the producer of the Konjac Jelly Mini-cups had carried out such an evaluation and taken steps, for example, to change the size and/or shape of the product so it did not present a suffocation hazard, the product would not have been banned from the market.

Implications of a GSR for Health Canada and Other Government Departments

The implications on government of a GSR or similar regulatory provision for Konjac Jelly Mini-cups, which is regulated but exhibits a hazard not covered by the regulation, will be very similar to that identified for unregulated products. The main difference relates to the fact that the safety of food involves not only Health Canada but also CFIA and other levels of government. CFIA enforces the federal legislation and the provinces/territories have the responsibility for food manufactured and sold within their borders. As a result, there are a number of issues and policies with respect to the implementation of a GSR or new regulatory obligations that will need to be resolved and agreed upon by the different government agencies with responsibilities in this area.

As in the case of bicycles and unregulated products, suppliers will need clarification from Health Canada and the other government agencies involved about:

- Which standards or codes are acceptable as a due diligence defense?
- What role will the establishment of a HACCP- quality management system by a food supplier play as a due diligence defense?
- What process should be used to assess the risks and what level of certainty is expected?
- What level of safety will be considered acceptable or will trigger a report of an adverse health incident?
- What type of safety information, method of presentation and level of detail would be considered to be acceptable?
- What enforcement actions will be taken and will they be consistent across the country and among the different government agencies involved?

The better informed producers and distributors are, about what is expected from them by the various government agencies involved, the more likely they will be able to comply with a GSR or regulatory amendments.

Policies to be Developed and Implemented

Acceptable Level of Safety

ISO/IEC Guide 51, developed to be used by those developing consumer product standards, defines safety as “freedom from unacceptable risk.”⁵⁷² As indicated in this guide, there is no absolutely safe product but only different degrees of safety that are acceptable. This lack of clarity with respect to what is considered a safe or unsafe product could lead to confusion and disagreement between suppliers, consumers and the various governments and/or agencies involved in enforcement of a GSR or similar regulatory framework. Defining the level of safety is one of the key concerns that have been raised by professionals who complain about the vague nature of the GSR in the absence of binding standards.⁵⁷³

With Konjac Jelly Mini-cups, it is important for responsible authorities to provide guidance to suppliers and those responsible for enforcing any new provisions on the meaning of the term unsafe. Such guidance will help suppliers determine whether or not the mini-cups are safe and can be marketed, and whether or not an incident needs to be reported. From the perspective of the regulators, clarification of the term unsafe will assist them in providing advice to suppliers and, more importantly, facilitate consistency in enforcement across the country and among the various government agencies involved. This is particularly critical with Konjac Jelly Mini-cups where it is necessary to develop a consensus among a number of government agencies and levels of government. Agreement on the following questions will have to be reached:

- How the provinces/territories will work with the federal agencies to implement the GSR?
- Whether or not the provinces/territories will be able to draw on the provisions of the GSR for food production and sale within their borders?
- What level of safety will be considered unacceptable and will trigger enforcement action or reporting of an adverse incident?
- What type of information manuals and/or training will need to be developed to assist suppliers and government officials in understanding the policy?

Compliance

In order to comply with the requirement that all reasonable care is taken to ensure the safety of the Konjac Jelly Mini-cups, a supplier must know which instruments or mechanisms are acceptable to demonstrate this. In the case of the Konjac Jelly Mini-cups and other foods, there will be questions about the status of the HACCP – based quality management system as a defence. Not only is HACCP being promoted by CFIA and the provinces/territories as a voluntary initiative, but it has been mandated by CFIA under the Meat Inspection Regulations⁵⁷⁴ and is accepted as an international code of practice in the food trade.

⁵⁷² ISO/IEC, *ISO/IEC Guide 51: Safety Aspects Guidelines for their Inclusion in Standards*, 1999.

⁵⁷³ Centre de Droit de la Consommation, *The practical application of Council Directive 92/59/EEC on General Product Safety*, 2000.

⁵⁷⁴ Justice Canada, *Meat Inspection Regulations, Meat Inspection Act*, February 21, 2006.

Normally, where a regulation does not cover a specific product hazard, it is possible to identify a standard or code for the product or similar product that does. The implementation of the requirements of that standard or code, if deemed to be acceptable, could then demonstrate that all reasonable steps were taken to market a safe product. However, in the case of Konjac Jelly Mini-cups, no standards or codes exist to address the particular hazard in question. Producers will want to know how they will be able to demonstrate compliance under such circumstances, whether or not it will be necessary to develop a new standard or carry out a detailed risk assessment and whether or not a quality management system similar to HACCP or ISO 9000 will be sufficient.

The implication for Health Canada will be the need to develop policies and suitable means of technical assistance in conjunction with the other agencies that share responsibility. CFIA has developed a number of good examples of what will be needed such as its training and manuals on HACCP that were developed by CFIA to assist producers with the implementation of HACCP and CFIA staff in auditing producers' systems.⁵⁷⁵

Monitoring and Reporting

One of the basic elements of any risk assessment and risk management system is:

the element of constant monitoring, analysis of the data obtained and action being taken to address any problems identified. This obligation is normally included in a GSR and could have a significant impact not only on suppliers but also on Health Canada and its partners. The same situation would apply to inclusion of such provisions in regulation. For Konjac Jelly Mini-cups, reports would be provided to the agency responsible for enforcing the regulations that would be CFIA at the federal level or possibly the provinces/territories where a product is manufactured and sold within provincial/territorial borders.

Health Canada and CFIA in conjunction with the provinces/territories will have to make these policy decisions so that there is a consistent approach and to communicate the decisions to suppliers. In addition, agreement should be reached among the enforcement authorities about whether or not there will be one national database that is accessible to all and what enforcement actions should be taken when a report is not made. One of the major issues to be resolved will be how the new reporting system and analytical expertise required will be financed and resourced. It may also be necessary to establish with the provinces/territories a protocol for reporting of food safety problems to CFIA beyond what is already in place.

Responsibilities of Members of the Supply Chain

The responsibilities of the different members of the supply chain for Konjac Jelly Mini-cups differ significantly from one country to another. For example, in

⁵⁷⁵ CFIA, *Food Safety Enhancement Program*,
www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml

Europe, members of the supply chain have been divided into two groups, producers consisting of manufacturers and importers, and distributors consisting of distributors and retailers. In the United States, the responsibilities for all members of the supply chain are the same. Health Canada, in consultation with CFIA, will have to determine whether or not all members of the chain will be required to meet the same obligations. If not, then clear policies will need to be articulated to ensure that all suppliers are fully aware of their obligations.

The other aspect to be considered is the ability of small and medium sized enterprises to comply with the GSR or similar regulatory provisions. Anecdotal information from manufacturers and EU officials appears to suggest that SMEs are not complying with the GSR in Europe due to costs and confusion about what they are required to do.

Impact Assessment

As with the Bicycle case study, a cost/benefit analysis is required to fulfill the requirements of the Directive on Lawmaking and the requirement for a RIAS in the Regulatory Policy. It will have to consider the costs not only to all members of the supply chain but also to Health Canada, CFIA and the provinces/territories.

Operational Changes

Due to the implementation of a GSR or similar regulatory amendment that requires all hazards in products even those in regulated products to be addressed, operational changes will be required. In the case of Konjac Jelly Mini-cups, both Health Canada and CFIA will be involved. It may also involve the provinces/territories depending on the decisions that are made and the agreements that are reached.

The GSR could provide new authorities that result in a greater reliance on standards and codes to achieve policy objectives. In the food area, a great deal of reliance has been already placed on the Codex Alimentarius Commission's standards and codes. Both Health Canada and CFIA participate extensively in the development of these instruments at the international level. Moreover, CFIA is moving forward on promoting and mandating the establishment of HACCP quality systems and auditing these systems. Therefore, unlike what was found in the first case study, the expertise already exists within the organizations responsible for food safety to utilize standards and quality management systems effectively.

Since no mandatory reporting of adverse health incidents related to Konjac Jelly Mini-cups currently exists, systems and expertise to collect and analyse reports of adverse incident will have to be established. However, CFIA through its policies, audits and inspections and sharing of information with other jurisdictions does obtain information on many products that pose a risk to consumers. The mandatory monitoring and reporting of incidents, which is assumed to be part of a GSR or regulatory amendment, should help CFIA in identifying and addressing safety problems in the food supply.

The operational changes that will need to be made to deal with unregulated products have been outlined. The same type of operational changes will have to be made to deal with products that are inadequately regulated. The main difference for Konjac Jelly Mini-cups will be the fact that any operational changes will also involve CFIA and potentially the provinces and territories.

To ensure that the transition from the existing authorities to the new ones is smooth, all the governments responsible for food safety will have to agree on many policies and procedures. Therefore, it is logical that the federal/provincial/territorial working groups that deal with food issues should be involved in drafting these policies and details of the new procedures. If that is not possible, it may be necessary to establish new working groups for this express purpose. The policies and form of any working relationship developed with CFIA and possibly the provinces/territories could be of mutual benefit to all by filling in any gaps in authorities and having a consistent approach for industry.

Case Study 3: Electrical Household Products - Products Subject to Federal and Provincial/Territorial Regulation

The existing Canadian legislative framework governing the safety of consumer products consists of both federal and provincial/territorial statutes. Although effective, the system can be complex and confusing for suppliers, regulators and consumers particularly where the two levels of government have the authority to deal with the same product and the requirements may or may not be consistent across the country. Moreover, due to the distribution of powers under the constitution, the federal and provincial/territorial authorities may not have the authority to deal with certain facets of the problem. Concerns have been raised not only about the gaps that exist in this system but also about the overlap if a General Safety Requirement is implemented. To illustrate these issues household electrical products will be used.

Current Situation

Although the Health Canada has the authority to regulate these products under the *Hazardous Products Act*⁵⁷⁶ (HPA), traditionally the provinces/territories have dealt with them under their legislation and regulations governing the electrical supply system. The fact that no regulations for these products have been developed under the HPA makes it difficult for Health Canada to deal with any potential problems associated with these products. All the provinces and territories, however, have enacted legislation and regulations to deal with the installation and safety of electrical equipment connected to the electrical system including equipment used in and around the home. These regulations mandate the Canadian Electrical Code (CEC) and require that all household electrical products are approved by provincial/territorial authorities or are certified to the product standards referenced in the CEC.

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Justice Canada, *Hazardous Products Act*, Paragraphs 6.1 (a) and (b), March 3, 2006

The electrical code was developed as a model code that could be referenced by all the provinces/territories. This code lays out practical and reasonably predictable sets of rules for the installation and safety of electrical products. Since all provinces and territories in their legislation and/or regulations with only minor deviations reference this model code, the goal of consistency across the country for the most part is achieved. The Canadian Standards Association (CSA) is responsible for developing the code in conjunction with provincial/territorial electrical safety officials, fire authorities, industry and users. It not only drafts the code but also is responsible for the development and/or choice of the standards referenced in the code. Globalization and free trade has led CSA to adopt a number of North American harmonized standards and international standards developed by the International Electro technical Commission (IEC), which is responsible for standards regarding electrical, electronic and related technologies. The time to develop a standard and the four-year period between revisions of the CEC often results in lengthy delays in the adoption of standards that cover new products or unanticipated hazards not addressed by existing standards.

The reliance on IEC standards for household electrical products by provinces or territories and possibly the federal government in the future is to some extent problematic. Canada does not have voting status on the IEC technical committee responsible for the development of the standards for these products. This means that the safety concerns of Canadian consumers may or may not be addressed. The situation has arisen due to the significant reduction in Canadian manufacturers who normally would participate, lack of funding for those representing consumers and the reduction in government funding for standards development work.

Under the current situation, no level of government has the authority to order a mandatory recall of a dangerous household electrical product or to require suppliers to monitor their products and report adverse incidents. Although most household electrical products are imported, the provinces/territories do not have the authority under the constitution to deal with importation and stop dangerous products at the border. In addition, the enforcement powers provided to the provincial and territorial officials are not consistent from one province/territory to another. For example, only Alberta and Saskatchewan have included manufacture in the scope of their legislation and most provinces/territories do not have the power of seizure. As a result, there are a number of gaps in the ability of governments to address risks related to consumer electrical products.

The provincial and territorial legislation/regulations require that all household electrical products sold within their borders be approved or certified to the safety standards under the CEC. Recently, imported products that do not bear a certification label have been sold not only in small retail outlets such as the dollar stores but also in major retail chains in contravention of provincial/territorial statutes⁵⁷⁷. Since the provinces/territories are unable to stop such products from

⁵⁷⁷ CBC Marketplace., "From the Store Shelves: Marketplace shopping test", April 9, 2006.

entering the country and do not have the resources to check every retail outlet, these products, many of which are unsafe, continue to be sold. Moreover, this places suppliers who work to ensure that the products they produce and sell are as safe as possible and comply with provincial/territorial requirements at a real disadvantage.

One of the major safety problems related to electrical products that has garnered recent attention⁵⁷⁸ of suppliers, provincial/authorities, certification bodies and the police⁵⁷⁹ is counterfeiting both of the products and the certification marks on the products. For example, counterfeit extension cords, which melted and caught fire in minutes or power bars, which present fatal shock or fire hazards,⁵⁸⁰ are being sold in Canada placing the public at risk. Due to the inability of the provinces/territories to deal with imported products at the border and the gaps in existing legislation to deal with counterfeiting, this has proven to be a very difficult problem for all levels of government, retailers, certification bodies and the police to deal with.

Potential Options to Resolve the Issue

The establishment of a GSR to act as a safety net that can be used to address safety problems not covered by existing federal or provincial/territorial regulations and includes provisions for mandatory recall and reporting is one way of filling the identified gaps. In situations where a newly identified hazard in a product is not addressed by a standard referenced under the CEC or where no standard exists, it would be possible for the federal government to address the hazard and mitigate the risk to consumers in a timely manner by using the powers under a GSR. In many ways, this would result in a similar situation to what exists in the United States where the individual states mandate the National Electrical Code and provisions exist federally to cover unregulated risks. At the federal level in the USA, Section 15 of the *Consumer Product Safety Act*⁵⁸¹ requires that all adverse incidents including those involving consumer electrical products be reported to the Consumer Product Safety Commission (CPSC). The CPSC evaluates the incidents and a determination is made with respect to whether or not it is a substantial product hazard that requires a recall or corrective action. Moreover, the development of a GSR would address not only any identified problems with consumer electrical products but also with any other group of consumer products regulated by the provinces/territories that can pose risks to the public such as gas appliances.

Another option that could be considered is the addition of provisions, in whole or in part, similar to those that would be included in a GSR in regulations under the HPA. The provisions could be added to individual product-specific regulations

⁵⁷⁸ Canadian Anti-Counterfeiting Network, *Position Paper: The Need for Legal Reform in Canada to Address Intellectual Property Crime*, January 2006. www.cacn.ca

⁵⁷⁹ RCMP, *Police Charge Two Toronto Men with Selling Dangerous Counterfeit Electrical Products*, Press release March 30, 2005. www.rcmp-grc.ca/on/press/2005/2005_mar_30_e.htm

⁵⁸⁰ CSA International, *Counterfeit Products Can Kill, Warn Experts at Anti-Counterfeiting Conference*, April 7, 2005. www.csa-international.org/news/releases

⁵⁸¹ Consumer Product Safety Commission, *Consumer Product Safety Act*, Section 15.

using the authority of paragraph 5(a)⁵⁸² of the HPA or the authority provided by paragraph 6(3)⁵⁸³ in hazard-based regulations. Moreover, it would appear to be possible under paragraph 5 (a) to include in either type of regulatory approach provisions that require the supplier to monitor the market, report any adverse incidents and correct any problems. This approach was taken in Europe where the Low Voltage Directive⁵⁸⁴ (LVD) was designed to cover all risks and categories of risks associated with consumer electrical products. As a result, the General Product Safety Directive does not apply⁵⁸⁵ to the risks associated with consumer electrical products covered by the LVD. It is possible in regulations to covers all risks and to require mandatory reporting of adverse incidents. A Canadian example of this type of regulation is the risk based regulatory framework and mandatory reporting provisions⁵⁸⁶ of the Medical Device Regulations under the *Food and Drug Act*. By requiring suppliers to notify the Health Products and Food Branch Inspectorate of serious incidents that occur in Canada or in another country, the Inspectorate is able to ensure that problematic devices are corrected or recalled in a timely manner. The reporting requirements, which are harmonized with other jurisdictions, enable Canadian participation in an international alert system developed under Mutual Recognition Agreements.

Every Province and Territory has product liability laws that allow a person injured by a product to sue the supplier in a civil action after the injury has occurred. These actions are normally very expensive and take a long time to reach a verdict. If the supplier is found to be negligent about the safety of the product, financial compensation to the victim may result but the product could remain on the market, as a judge does not have the authority to order the removal of an unsafe product.⁵⁸⁷ Criminal law, however, removes many of the problems associated with tort civil actions and a GSR or similar provisions in regulations under federal criminal legislation provides a means for government to act quickly and, where appropriate, remove the product causing the injury from the market.

⁵⁸² “authorizes the advertising, sale or importation of any restricted product and prescribing the circumstances and conditions under which and the persons by whom the restricted product may be advertised, sold or imported”.

⁵⁸³ “may describe a product, material or substance or by reference to any other criteria and any product, material or substance that has those properties or characteristics or meets those criteria shall, for the purposes of this Act, be deemed to have been added by the order of Part I or , as the case may be of Schedule I.”

Directive 72/23/EEC and 93/68/EEC, *Electrical Equipment - Low Voltage Directive*, 1973 amended 1993.

⁵⁸⁵ European Commission’s Directorate General Health and Consumer Protection, *Guidance Document on the Relationship Between the General Product Safety Directive and Certain Sector Directives with Provisions on Product Safety*, November 2003.

⁵⁸⁶ Justice Canada, Sections 59 to 62 of the Medical Device Regulations, *Food and Drugs Act*, February 2006, states “the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada”.

⁵⁸⁷ D.N. Dewees and M.J. Trebilcock, “Study of the Effectiveness of Tort as a Deterrent to the Production and Supply of Hazardous Consumer Products”, January 25, 1994.

Irrespective of the approach followed; there are significant benefits to the implementation of any provisions in cooperation with the provinces/territories. Consideration also may be given to providing them with the authority to enforce any general safety, recall, or mandatory reporting provisions included in federal legislation or regulations that apply to consumer electrical products. The establishment of such agreements could help provincial and territorial authorities in identifying products that pose a danger to the public and having them removed quickly from the market. The policies and the form of any working arrangements developed with the provinces and territories will have a significant impact on whether or not the overlap that will exist between a GSR or similar regulatory requirements and provincial/territorial legal instruments has a negative or positive benefit. The WHMIS Program under the HPA, which is enforced by the provinces/territories, is an example of how governments and other stakeholders can work together to provide mutual benefits. This type of working relationship also benefits industry and consumers by establishing consistent and predictable rules across the country.

Implications of a GSR for Suppliers

The establishment of a GSR in any new legislation or similar provisions in regulations under the HPA could increase the confusion and complexity for those supplying household electrical products to the Canadian marketplace. Not only would suppliers of household electrical products have to comply with provincial/territorial regulatory requirements; but they would also be responsible for complying with any new provisions established at the federal level. Normally, the provisions included in a GSR or similar regulatory initiatives require a producer to assess and manage all risks associated with a product, monitor the product in the marketplace and report any adverse incidents. As a result, a producer could comply with all the standards under the CEC mandated by provincial/territorial regulations and still be at risk of Health Canada taking action against him/her under the criminal code if a hazard not addressed by the standards was identified.

Compliance

In order for a household electrical product to be marketed in Canada, the law requires that it comply with all provincial/territorial regulations. In addition, if a GSR or similar provisions in regulations were implemented, the producer would be required:

- To identify any hazards associated with a product;
- To assess the risk that the hazard presents to the public;
- To determine if the existing standards referenced under the CEC address the potential risk; and
- To take action to eliminate or manage the risks. This could involve reviewing other standards that could be followed to address the risk, making changes to the design of the product, components used, manufacturing processes or accompanying safety information.

An example of the process that a producer could use to assess the risks is presented in Appendix 3. As was the case with Bicycles,⁵⁸⁸ and Konjac Jelly Mini cups,⁵⁸⁹ it can be very difficult to assess the risks due to the lack of data on adverse events and their cause, and the problem of obtaining relevant information about the design, components and manufacture of the product from foreign manufacturers. Since the standards referenced under the CEC, are based on or adopted from international standards, it is unlikely that other standards for the product or similar products exist elsewhere that could be used to address any risks not addressed in the CEC standards.

The actions described above require a producer to have the scientific capacity or the resources necessary to purchase the capacity to assess the risks, evaluate standards and identify what would be required to eliminate or manage the identified risks. However, it may not necessarily be a simple process of making the changes to the product to eliminate the risk if the changes result in a product that does not conform to the existing standards under the CEC.

Provincial/territorial legislation requires that electrical equipment must be approved through certification by qualified third parties to the standards under the CEC⁵⁹⁰. A supplier who has taken steps to comply with a GSR or similar provisions under regulations may find him/herself caught between provincial/territorial requirements and federal requirements. The result may mean that he/she is unable to sell his product in Canada without changes being made to the standards under the CEC or obtaining approval from the individual Provincial/Territorial Electrical Authorities.

The private sector is often affected as much by the implementation and enforcement of new requirements as the requirements themselves. In order to comply with new legislative/regulatory requirements, a company normally has to make changes that have internal financial and operational implications that in the end result in price increases. If new provisions are not enforced equitably across all suppliers, an uneven playing field results making it difficult for responsible suppliers to compete with those who do not comply with new provisions.

Monitoring and Reporting

As indicated earlier, there are no mandatory requirements at either the federal or provincial/territorial levels to monitor the market and report adverse incidents associated with a product as exists in Europe or the United States. In fact, authorities in Canada often obtain information about potential problem products by monitoring the recall information produced by the US CPSC as many of the same products are sold in Canada. From the perspective of a Canadian producer, there could be significant impacts if mandatory monitoring and reporting is implemented in Canada. The impact could be mitigated, in some

⁵⁸⁸ Described in section 4.3. of case study 1

⁵⁸⁹ Described in section 5.2.1 of case study 2.

⁵⁹⁰ For example, the Nova Scotia *Electrical Installation and Inspection Act* states “No corporation, company, or person shall sell, have for sale, display, rent, lease, advertise, install or use any electrical device, appliance or equipment unless it is certified as approved equipment, as defined in the Code, by a certification organization acceptable to the Chief Electrical Inspector”

cases, if the system of reporting and the safety level that triggers reports or recalls is substantially the same as that in the US since many products are sold in both jurisdictions.

The reporting requirement could also significantly impact distributors as well as producers depending on their obligations to report adverse incidents included in any legislative or regulatory changes. It could result in producers and suppliers having to establish incident reporting systems and hire staff to input the data, analyse it and report it to the government. As with bicycles and Konjac Jelly Mini Cups, the provisions of the *Personal Information Protection and Electronics Documents Act* would have to be respected.

Provision of Information

How a household electrical product is used or maintained contributes to managing any risks associated with it. Therefore, it is assumed that a GSR or equivalent regulatory amendment will require suppliers to provide consumers with information about the safe use and maintenance of these products. The effectiveness of warnings and safety information depends on many factors such as an individual's ability to understand and read the information, their attitude to risk, the quantity of information presented and easy access to the information at the time of use or maintenance. In the case of household electrical products, the use and information requirements are normally specified in the standards for the products referenced under the electrical code and suppliers are already supplying the information to the public. As a result any such provisions incorporated in a GSR or HPA regulations should not have an impact on suppliers unless the information required is different than that specified in the existing standards.

Summary

As with the case studies for Bicycles and Konjac Jelly Mini Cups, the establishment of a GSR or GSR like provisions in regulations would result in operational and financial impacts for a supplier. These impacts on producers could be more significant than on distributors depending on the obligations for each specified in any legislative or regulatory changes. The impact would also depend on what is already in place in terms of technical capacity to assess and manage potential risks, and monitoring and reporting systems. The producer of a product where not all hazards are covered by existing regulations will need to identify any gaps that exist in the skills set of staff, management processes and systems and fill these gaps either internally or externally.

The implications of failing to comply with a GSR or HPA regulatory obligation could mean fines, recalls, seizures or a complete ban of a product. The financial costs to the organization and the damage to its brand image would negatively affect the company. In addition, the company could possibly be sued for damages under tort legislation.

Implications of a GSR for Health Canada and Provincial/Territorial Governments

Since the existing legislative/regulatory framework governing the safety of household electrical products consists of both Federal and Provincial/Territorial Statutes, the establishment of a GSR or similar requirements in HPA regulations will impact both levels of government. In many ways the implications for Health Canada will be very similar to those identified in the two previous case studies except that it will have to work with the provinces/territories when developing policies or procedures. Otherwise, there could be a duplication of effort, no consistency in policies or processes between the two levels of government and complexity, confusion and added work and costs for suppliers.

As was the case with bicycles and inadequately regulated products, suppliers will need clarification from Health Canada in a number of areas. For example, they will need to know

- Whether or not HC will accept, like the provinces/territories, certification of a product to the standards under the CEC to demonstrate that all reasonable care was taken to market a safe product? If not, which standards or codes would be acceptable?
- What process should be used to identify the hazards and assess the risks associated with a household electrical product and what level of certainty is expected?
- What level of safety will be considered acceptable or will trigger a report of an adverse incident or recall of a product?
- What type of safety information, method of presentation and level of detail would be considered to be acceptable? Will it be consistent with what all ready exists in the standards under the CEC?
- To whom will reports of adverse incidents be made? To Health Canada in Ottawa, to Health Canada Regional Offices or the Provinces or Territories?
- What enforcement actions will be taken and will they be consistent with those of the different provinces/territories?
- What will happen where action is taken to mitigate a risk but which results in non-compliance with the standards under the CEC?

The decision on these issues and the form of any working arrangements developed with the provinces and territories will determine whether or not duplication exists or there is a negative or positive impact. A working arrangement where the two levels of government agree on the policies and procedures could provide operational and financial benefits for both levels of government and industry.

Policies to be Developed and Implemented

Acceptable Level of Safety

It is a well-recognized fact that there is no absolutely safe product but only different degrees of safety that are acceptable to the public. This lack of clarity with respect to what is considered a safe or unsafe product could lead to

confusion and disagreement between suppliers, consumers and the various governments involved in enforcement of a GSR or a similar regulatory framework that addresses household electrical products. Specification of the safety level that would trigger a report of an adverse incident, a recall or corrective action is one of the key demands of suppliers.

Suppliers assume that compliance with provincial/territorial-mandated standards is the benchmark that is acceptable in Canada. Therefore, in the case of household electrical products, it is very important for responsible authorities to provide guidance to suppliers and those responsible for enforcing any new provisions on the meaning of the term unsafe and how it will be evaluated. Such guidance will help suppliers determine whether or not the electrical products are considered safe and can be marketed, whether corrective action needs to be taken and whether or not an incident needs to be reported. From the perspective of the regulators, clarification of the term unsafe will assist them in providing advice to suppliers and, more importantly, facilitate consistency in enforcement across the country and among the various levels of government. One of the issues that will have to be taken into account is the advantage of having trigger levels for reporting or recalls that are the same as those in the US. This could result in lower implementation and ongoing administrative costs to both government and industry since the same suppliers market many products in both countries.

Agreement with the provinces/territories on the following questions will have to be reached:

- How the provinces/territories will work with the federal agencies to implement the GSR or regulatory provisions?
- Whether or not the provinces/territories will be able to draw on the provisions of the GSR or HPA regulations to identify and take action against products that present a danger to the public?
- What level of safety will be considered unacceptable and will trigger enforcement action or reporting of an adverse incident?
- What type of information manuals and/or training will need to be developed to assist suppliers and government officials in understanding and carrying out their obligations?

Compliance

A supplier, in order to comply with a GSR or similar regulatory provisions, must know which regulations, standards or quality management systems are acceptable to demonstrate conformity. For household electrical products, the main issue will be the status of compliance with the standards referenced in the CEC and mandated by provincial /territorial regulations as a defence.

Normally, a GSR requires that, if an existing regulation or standard does not cover an identified product hazard to which the public can be exposed, action be taken to eliminate or reduce the problem. The implementation of requirements from alternative standards or changes in design, materials or manufacturing that remove the hazard, are examples of some of the actions that could be followed to

demonstrate that all reasonable steps were taken to market a safe product. However, in the case of household electrical products, it will be difficult to identify other standards since the standards referenced in the CEC are adopted or based on those existing internationally. Producers will want to know how they will be able to demonstrate compliance under such circumstances, whether or not it will be necessary to develop a new standard or carry out a detailed risk assessment and whether or not an ISO 9000 management system certified by a third party will be acceptable. Therefore, there will be a need for Health Canada to develop policies and assistance to suppliers in conjunction with the provinces/territories to clarify the issues around acceptable due diligence defences.

Monitoring and Reporting

Constant monitoring, analysis of data and correction of any identified problems are primary elements in any system to assess and manage risks. These obligations are included in GSR or GSR-like provisions in Europe and the United States. If similar requirements are implemented in Canada, they could have a significant impact not only on suppliers of household electrical products but also on Health Canada and possibly the provinces/territories depending on the system established. The same situation would apply to inclusion of such provisions in regulations under the HPA.

Health Canada and/or the provinces/territories will have to make a number of policy decisions so that there is a clear and consistent approach across the country. Moreover, it will be necessary to communicate the decisions to suppliers and the responsible government staff. The decisions that will have to be made around post market surveillance and reporting of adverse incidents include:

- What level of safety will trigger a report of an adverse incident? Will it be the same level that will trigger a recall or corrective action? Will it be consistent across the country and with other countries such as the United States?
- To whom will reports of adverse incidents be made? To Health Canada in Ottawa, to Health Canada Regional Offices or the Provinces or Territories?
- Will there be one national database that is accessible to all?
- How will government finance and resource the new reporting system and the expertise required to analyze the data? Will resources be provided to the provinces/territories if they are involved?
- What information will be required to be included in any report? Will it be consistent with that already required by the US CPSC?
- What system for reporting will be set up? Is there an advantage of basing it on the well-established system within the Health Products and Food Branch?
- What enforcement actions should be taken when a report is not made?

In establishing a system that collects data on adverse incidents, Health Canada will have to address the issues related to its legal obligations about what it is required to do when it becomes aware of a potential problem in the marketplace.

From the experience of the CPSC, the number of reports can run into the thousands each year.⁵⁹¹ The CPSC's Office of Compliance, which reviews the reports and determines the action to be followed, developed criteria to ensure that only essential reports and information are provided in order to reduce the number of reports to a manageable level. It is anticipated that, since many Canadian suppliers are owned by American companies and carry the same products, the number of reports made in Canada could be very similar. The principle of proportionality should be applied to reporting requirements for products that exhibit different levels of adverse health effects. In particular, policy decisions are required that set threshold levels of safety below which notification is required as is the case in Europe.⁵⁹² This would help to ensure that limited resources are focused on addressing the most serious problems and that Health Canada is not overwhelmed by incident reports. In addition, consideration could be given to harmonization with existing reporting system in the United States to help in the sharing of information, the eventual integration of the systems, the usefulness of the data collected and the minimization of the costs for industry and government.

Recalls

The Consumer Product Safety Bureau of Health Canada currently provides general guidance to suppliers about when and how to carry out a recall.⁵⁹³ It states that, a company should initiate a product recall when they become aware:

- Of a defect that makes a product unsafe;
- Of an injury or death to consumers caused by an unsafe product; or
- That a product does not comply with legislative requirements.

Health Canada's Consumer Product Safety Program enforces the *Hazardous Products Act and Regulations*, and the *Cosmetic Regulations* under the *Food and Drugs Act*. Health Canada may request that a company initiate a recall when:

- A product does not comply with applicable legislation: or
- A product poses an unacceptable risk to the health and safety of the consumer or user."

Both Europe⁵⁹⁴ and the United States⁵⁹⁵ provide detailed advice to suppliers on what they consider to be level of hazard that would trigger a product recall. In the future, Health Canada will need to provide greater specificity with respect to the levels that will result in a recall. The development to a risk rating system that is

⁵⁹¹ Mullan John Gibson, Director of Compliance CPSC, *A working Model for Retailer Reporting under Section 15*, ICPHSO Annual Meeting, Orlando, February 23, 2005.

⁵⁹² European Commission, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC*, December 2004.

⁵⁹³ Consumer Product Safety Bureau, Health Canada, *Recalling Consumer Product – a guide for industry*, April 2005. http://www.hc-sc.gc.ca/cps-spc/advisories-avis/child-enfant/recalling-guide-2005-04-rappel_e.html

⁵⁹⁴ UK Consumer Union sponsored by the European Commission, *Product Safety in Europe: A guide to corrective action including recalls*, June 2004.

⁵⁹⁵ US Consumer Product Safety Commission, *Recall Handbook*, May 1999.

compatible with Europe and the US would allow Health Canada to leverage its resources through improved sharing of information on problem products, and reduce the cost to suppliers who may be required to recall products from many different countries. The development of more specific guidance documents, manuals and/or training for suppliers and staff of Health Canada and the provinces/territories will ensure transparency and consistency. Not only will suppliers and government staff understand what is required to comply with any new GSR or regulatory provisions but also responsible officials will be able to provide better advice and enforced the new provisions consistently across the country.

Impact Assessment

In order for Cabinet to decide on whether issues related to the safety of household electrical products should be addressed by new legislation or regulation, it requires accurate, complete and up to date information based on the results of:

- An analysis of the proposal and the alternative solutions considered;
- The consultation with those who have an interest in the matter, including other departments that may be affected by the proposed solution;
- An analysis of the impact of the proposed solution on the operating environment and costs to small, medium and large suppliers; and
- An analysis of the resources that the proposed solution would require, including those needed to implement or enforce it.^{596 597}

Therefore, like the situation with bicycles or Konjac Jelly Mini Cups, consultation with the suppliers of household electrical products and other concerned parties is required. Moreover, a cost/benefit analysis that includes the costs to suppliers and government, and possibly a Business Impact Test would have to be carried out to fulfill these requirements and those for a Regulatory Impact Analysis Statement.

Privacy Impact Assessment

The establishment of any new data collection system such as the collection of information on adverse health incidents must respect the *Privacy Act*.⁵⁹⁸ According to Treasury Board policy a Privacy Impact Assessment will need to be carried out.⁵⁹⁹

Operational Changes

Operational changes will be required if a GSR or similar regulatory amendments are implemented requiring all risks associated with household electrical products to be addressed. Changes may also have to be made by the provinces/territories depending on the decisions that are made and the agreements that are reached.

⁵⁹⁶ Justice Canada, *Cabinet Directive on Lawmaking*, 2003-07-08.

⁵⁹⁷ Privy Council Office, *Regulatory Policy*, June 2000.

⁵⁹⁸ Justice Canada, *Privacy Act*, 1985.

⁵⁹⁹ Treasury Board, *Privacy Impact Assessment Policy*, May 2002.

The GSR or regulatory amendments under the HPA could provide new authorities that result in a greater reliance on standards and codes to achieve policy objectives. A great deal of reliance has already been placed on the standards referenced in the CEC in the case of household electrical products. Although the provinces/territories participate extensively in the development of these standards nationally, Health Canada does not. Moreover, at the international level, Canada is not a member of the IEC technical committee that drafts and maintains these standards and its ability to have the concerns of Canadians addressed is limited. If Health Canada is to adopt a GSR or similar regulatory provisions, it will need to examine its participation in critical committees that develop the standards. In many cases, it may not have the specific expertise required or the resources to participate and may wish to work closely with the provinces/territories to share the added workload that would be required. For example under the CEC, there are more than 50 technical committees and hundreds of subcommittees that draft and maintain the standards for household electrical products nationally and similar numbers of committees at the international level.

Many of the standards in the electrical area reference a number of other standards, which will require substantial monitoring, and/or participation by government officials to ensure that these standards also address the health and safety concerns of Canadians.

The operational changes that will need to be made to deal with unregulated products have been outlined. The same type of operational changes will have to be made to deal with household electrical products that could be regulated by both the federal and provincial/territorial governments. The main difference will be the fact that operational changes will have to be made not only within Health Canada but also within the provinces and territories. To ensure that the transition from the existing authorities to any new ones that are adopted is smooth, consistent nationally and does not result in duplication of effort, all the levels of government responsible will have to work together.

Summary

In conclusion, the establishment of a GSR or similar provisions in regulation has the potential of benefiting both levels of government in carrying out their responsibilities to protect the health and safety of the public. The success will very much depend on the working relationship that is developed between the two levels of government and their ability to influence the development of standards on which so much of the safety of household electrical product are based.

Appendix 1. Equivalent Provisions to GSR in Existing Legislation

	HPA	Food and Drugs Act							RED Act
		Food	Drugs	Med Devices	Biologics	Nat Health	Cosmetics	Vet Drugs	
Pre Market Evaluation			x	x	x	x		x	
Safety of all products covered			x	x	x	x		x	
Mandatory Reporting			x	x	x	x		x	
Voluntary Reporting	x	to CFIA					x		x
Analysis of Reports	x	x	x	x	x	x	x	x	x
Recall			x	x	x	x		x	
Follow up action	HECS	CFIA	HPFB	HPFB	HPFB	HPFB	HECS	HPFB	HECS

Product	Act/Regulation	Obligation of Supplier	Comments
Health Products - Drugs, Natural Health Products, Biologics	<i>Food and Drug Act and Regulations</i>	<p>Mandatory reporting for all products.</p> <p>Health Professionals report on a voluntary basis.</p>	<p>Health Canada's Marketed Health Products Directorate, through the Canadian Adverse Drug Reaction Monitoring Program, is responsible for collecting and assessing reports for these products marketed in Canada with the exception of vaccines.</p> <p>The Public Health Agency of Canada collects case reports on adverse events following immunization from provincial and territorial health departments, health care professionals and the pharmaceutical industry.</p>
Biologics and Genetics	<i>Food and Drug Act and Regulations</i>	<p>Before a biologic is approved, sufficient scientific evidence must be provided by the manufacturer to show that it is safe, efficacious and of suitable quality.</p> <p>Manufacturers must also supply Product Specific Facility Information that outlines the method of manufacture of the biologic.</p>	<p>An inspection of the manufacturing facility is completed to assess the production process and facility</p> <p>With higher risk biologics, each lot is tested before being released for sale in Canada. Moderate risk biologics are periodically tested at the discretion of Health Canada , in collaboration with the Public Health Agency of Canada</p>
Drugs	<i>Food and Drug Act and Regulations</i>	A manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality	Before drug products are authorized for sale in Canada, Health Canada reviews them to assess their safety, efficacy and quality.

Product	Act/Regulation	Obligation of Supplier	Comments
Natural Health Products	Natural Health Products Regulations under <i>Food and Drug Act</i>	Supplier must provide information on - medicinal ingredient, quantity per dosage unit, and its potency in order to obtain a product License that is necessary prior to selling product.	If the Minister has reasonable grounds to believe that a natural health product may no longer be safe when used under the recommended conditions of use. Minister may request that the licensee provide information and documents demonstrating that the natural health product is safe when used under the recommended conditions .
Medical Devices	Medical Devices Regulations of the <i>Food and Drug Act</i> .	Risk Classification System that covers all medical devices. Requirements differ for safety and effectiveness information that needs to be provided for pre-market application for a license depending on risk posed by the product.	.
		Mandatory reporting of any incident involving a medical device that is sold in Canada when the incident occurs either within or outside Canada; relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labeling or in its directions for use (section 59(1)(a)); and has led to the death or a serious deterioration in the state of health of a patient, user or other	Reports sent to Health Product and Food Branch Inspectorate, which analyses the reports and determines what if any action is required.

Product	Act/Regulation	Obligation of Supplier	Comments
		<p>person, or could do so if it were to recur (section 59(1)(b)).</p>	
Cosmetics	<i>Food and Drug Act and Regulations</i>	<p>No person shall sell any cosmetic in Canada that:</p> <ul style="list-style-type: none"> • has in or on it any substance that may cause injury to the health of the user when the cosmetic is used (section 16, FDA) 	<p>Sections 29 and 30 of the <i>Cosmetic Regulations</i> state that evidence of the safety of a cosmetic product must be provided if requested by Health Canada.</p>
		<p>Voluntary reporting of incidents to Consumer Product Safety Offices of Health Canada</p>	
Food	<i>Food and Drugs Act</i>	<p>4. No person shall sell an article of food that</p> <p>(a) has in or on it any poisonous or harmful substance;</p> <p>(b) is unfit for human consumption;</p> <p>(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;</p> <p>(d) is adulterated; or</p> <p>(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.</p> <p>Labelling must not be false, misleading or deceptive or likely to create an erroneous impression.</p> <p>Regulations establish labelling requirements for many products.</p>	

Product	Act/Regulation	Obligation of Supplier	Comments
	<i>Canadian Food Inspection Agency Act.</i>	19. (1) Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister.	
General Consumer Products	<i>Hazardous Products Act</i>	Statute does not provide authority to take action against a non-regulated product.	Action is voluntary – recalls, reporting
	Voluntary Reporting	Reporting to Consumer Product Bureau.	
Radiation Emitting Devices	Radiation Emitting Devices Act	“No person shall sell, lease or import into Canada a radiation emitting device if the device:(a) does not comply with the standards, if any, (b) creates a risk to any person of genetic or personal injury, impairment of health or death from radiation by reason of the fact that it (i) does not perform according to the performance characteristics claimed for it, (ii) does not accomplish its claimed	

Product	Act/Regulation	Obligation of Supplier	Comments
		purpose, or (iii) emits radiation that is not necessary in order for it to accomplish its claimed purpose.	
	Mandatory Reporting	Report any adverse effect related to a radiation-emitting device (for example: ultrasound equipment, X-ray devices, microwave ovens, tanning equipment, or lasers) to the <u>Consumer and Clinical Radiation Protection Bureau</u> .	Reporting of non-radiation type of hazards are not required.

Appendix 2: Some Unregulated Consumer Products that Would Be Caught by a GSR

Acids other than those listed in item 2 of Schedule I
Adhesives, cleaning solvents, thinning agents and dyes that do not contain toluene or acetone
Antifreeze preparations that do not contain ethylene glycol or diethylene glycol
backpack baby carriers (hazard of baby falling out)
bicycle and ski helmets (mechanical hazards)
bicycles (mechanical hazards)
bunk beds (mechanical hazards)
candles (flammability hazards)
chain saws (mechanical hazards)
chest waders (drowning hazard)
children's novelty purses (hazard of petroleum distillates)
children's playground equipment (mechanical hazards)
children's highchairs (mechanical hazard)
children's PVC teething/rattles with DINP plasticizer
children's stationary activity centres (mechanical hazard)
children's clothing with drawstrings (strangulation hazard)
CO detectors
Flammable adhesives
food container (plasticizer)
Gas powered go-karts
halogen lamps (electrical hazard)
hammocks (strangulation hazard to children)
lightweight children's dressers (tipover hazard)
non-factory installed remote car starters (mechanical hazard)
ozone generators (hazardous ozone level)
Products that off-gas resulting in poor indoor-air quality
recliner chairs (entrapment hazard)
soccer goal nets (mechanical hazard)
toboggans (mechanical hazard)
Upholstered furniture (flammability)
utility barbecue lighters (not child-resistant since not for cigarettes, cigars and pipes)
window blind cords (strangulation hazard)

Drinking Water

- 1) devices used in the treatment of water, including filters that remove uranium from water
- 2) components of water systems that come in contact at any time with water destined for human consumption from its collection to its use by the consumer.
- 3) treatment additives (with respect to their effect on the resulting water or on persons that drink or otherwise use the treated water), including disinfectants used in drinking water

Appendix 3: Demonstrating Compliance with a GSR

As with most GSRs, it is assumed that if a product causes harm a government would not have to prove criminal intent or negligence but a supplier would be required to demonstrate that all reasonable care had been exercised to market a safe product. Therefore, a supplier would be required to make certain decisions about what risks are associated with a product; what instrument exists that could be used to address the risks adequately; what design or process controls need to be established to reduce or eliminate the risks; and how controls can be implemented to ensure the consistent production of a safe product.

A number of factors are normally considered⁶⁰⁰ by a government when determining whether or not a supplier has exercised reasonable care. These include:

- The nature and severity of the injury or damage that a product may cause;
- The probability of the adverse incident and the number of people that could be exposed;
- Who will be exposed and how vulnerable are they;
- How the risk compares with historical risks and risks associated with similar products;
- The extent to which safe guards are present to protect against the hazard;
- The knowledge of the user about the risk and how to control it;
- Whether the product was assessed objectively to identify and mitigate any risks;
- The level of safety that can reasonably be expected;
- The extent to which a supplier monitors potential risks after the product is marketed;
- Scientific knowledge and state of technology about the product; and
- The level of expertise one can reasonably expect from the various participants involved in the supply chain and their respective responsibilities.

These factors are similar to those normally considered when carrying out a risk assessment of a product. A number of standards, guidance documents and information on what needs to be considered when carrying out a risk assessment have been published. These include those developed and published by Health Canada⁶⁰¹, the US CPSC⁶⁰², the European Guide to corrective action⁶⁰³, IEC's Advisory Committee on Safety⁶⁰⁴, the University of Nottingham's⁶⁰⁵ work on safe

⁶⁰⁰ based on Consumer Product Safety Commission, *Recall Handbook*, Washington, 1999, European Union, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors In Accordance With Article 5(3) Of Directive 2001/95/EC*, 2005, and Health Canada, *Health Protection Legislative Renewal, Detailed Legislative Proposal*, 2003.

⁶⁰¹ Health Canada, *Decision Making Framework*, August 1, 2000.

⁶⁰² US Consumer Product Safety Commission, *Handbook for Manufacturing Safer Consumer Product*, Washington, August 2005.

⁶⁰³ Intertek Research and Testing Centre and Uk Consumers Association supported by the EC, *Product Safety in Europe: A guide to corrective action including recalls*, June 2004.

⁶⁰⁴ IEC Advisory Committee on Safety, *Development of a standard for Safety Related Risk Assessment in the area of low voltage*, July 29 2005.

design and the Canadian National Standard on Risk Management⁶⁰⁶. All of these documents recommend that data about the design, use, incidents, injuries and harm associated with a product be brought together in order to identify the hazards, assess the risks and identify potential risk reduction measures. By following the practices, a supplier will be able to demonstrate that all reasonable care was taken to identify, eliminate or reduce the risks to an acceptable level and market a safe product.

The Process

What is described in this section is a basic risk assessment/management process. It is based on the models referenced above that could be used by a supplier or safety authorities. The process outlines the questions that need to be considered when identifying, assessing and mitigating any risks.

1. Determine Whether the Act Applies to Product

Initially the producer must determine whether or not the product falls under the scope of any proposed legislation. It must meet the definition for a product and not be exempted from the provisions of the legislation

A determination then has to be made regarding whether or not the product is intended to be marketed in Canada to consumers, or will it foreseeably be marketed in Canada to consumers. Products manufactured for export may or may not be covered under the legislation depending on the provisions included in any new legislation.

2. Identify all Possible Users.

The identification of all possible users means thinking about everyone who might come into contact with the product whether an intended user, potential user or an unintended user. The knowledge and capabilities, which are required by the user to operate the product safely, should be identified. In the case of vulnerable users such as seniors and children, it is important to focus on their physical and psychological characteristics and capabilities. Others who are not direct users of the product may also be exposed and affected. For example, an exercise cycle with unprotected moving parts may result in finger injuries to small children who are in the environment where the product will be used.

3. Identification of all Potential Hazards

In trying to identify all potential hazards, a producer will need to anticipate everything that could go wrong or be dangerous. For example, a product could present a hazard because it exhibits unacceptable side effects, or is adulterated, mechanically defective emits harmful substances or radiation, or it is poisonous, corrosive, flammable, explosive toxic, infectious, or dangerously reactive. In addition, hazards can be caused by product deterioration, maintenance

⁶⁰⁵ Beverly Norris and John R. Wilson, *Designing Safety into Products*, Product Safety and Testing Group, University of Nottingham, Nottingham, October 1997.

⁶⁰⁶ Standards Council of Canada, *CAN/CSA - Q850 - 97 (reaffirmed 2002), Risk Management: Guidelines for Decision Makers*, National Standard of Canada, Ottawa

instructions that are hard to understand, and unusual operating conditions. There are a number of things that a producer can do and sources of information that he/she can use to determine the potential hazards including:

- The intended use and reasonably foreseeable use of the product; a design review against safety criteria which examines the materials, configuration, packaging and labeling;
- The limits of the product such as durability, life span of parts or deterioration due to weather;
- Whether the hazards are visible and well understood by the user (e.g. knife blade);
- Potential hazards that have been identified in regulations, standards, previous risk assessments or guides for the product or similar products;
- Injury scenarios, research and medical literature; and
- Expert opinion.

Once the hazards have been identified, it will then be possible to attempt to determine their cause and to take steps to eliminate or reduce them. In many cases, there will be gaps in the information available to a producer. For example, product-related injury data often does not exist in Canada and information about product design and raw materials may not be made available to an importer by the manufacturer in another country. It may, however, be possible to obtain injury or research data from other countries and information from standards that exist for similar products.

Risk Assessment

Once the hazards are identified, the next step in the process is to evaluate the risks associated with each potential product hazard or hazardous situation. The concept of risk involves a combination of the severity of harm that may result, the likelihood that an adverse health incident will actually occur, the number of users who may potentially be exposed and the technical and human possibilities of avoiding or limiting the harm. This is illustrated below.⁶⁰⁷

⁶⁰⁷ IEC Advisory Committee on Safety, *Development of a standard for Safety Related Risk Assessment in the area of low voltage*, July 29, 2005.

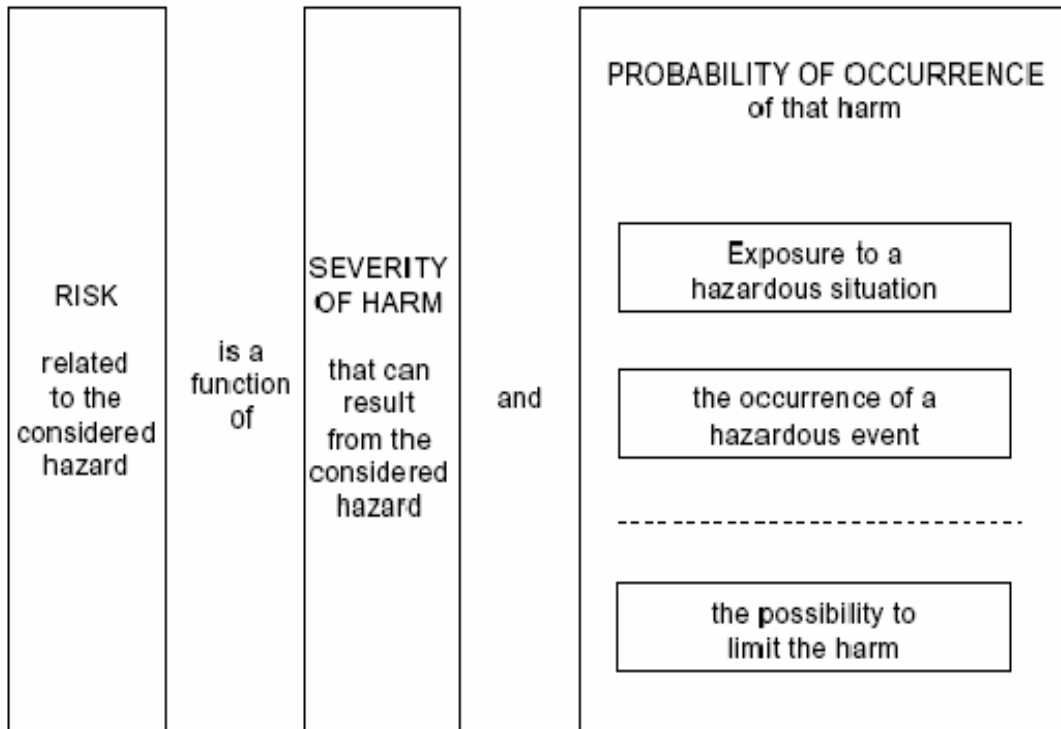


Figure 4. Risk Assessment.

Ultimately, however, any risk assessment will involve not only scientific evidence but also an element of subjective judgment in determining the degree of risk aversion among the population, interpreting evidence and weighting the relative importance given to each of them. The many factors that normally are taken into account when determining whether or not a product presents an unreasonable risk, whether a producer has exercised reasonable care or whether an adverse health incident should be reported to the authorities, include:

- The nature and severity of the injury or damage that the product might cause;
- The probability of an adverse health incident;
- The size of the population potentially exposed to the product, including the extent to which third parties/bystanders may be at risk;
- The comparison of the risk with risks historically judged to be acceptable;
- The physical and psychological characteristics and vulnerability of the likely user and their previous experience with similar products;
- The extent to which the product incorporates safeguards against the hazard;
- The consumer's knowledge of, or control over the risk — how obvious is the hazard and is it possible to take precautions against it;
- The voluntary or involuntary nature of the risk; and
- The utility of the product and the extent to which the hazard is necessary for the function of the product.

The hazards identified and the risks estimated are essential to selecting an appropriate instrument to be used as a due diligence defence. However, these elements can have a more important role to play when no regulations, standards or codes exist that address the problems identified. The knowledge obtained about the hazards and risks associated with a product make it possible for the producer to establish measures such as design changes, manufacturing or distribution controls or improved consumer information that will eliminate or reduce the risk. In this way, the producer will be in a position to demonstrate that all reasonable care was taken to market a safe product.

Evidence about the hazards and risks associated with a product is also valuable in evaluating adverse health incidents, determining whether or not reporting is necessary, and whether immediate corrective action is required. In Europe and the United States, for example, incidents where the hazards cause slight harm, where exposure is rare and it is possible to avoid the hazard are classified as low and reporting is not required. Figure 2, page 18, illustrates the system that Europe uses to make this determination.

Identification and Implementation of Corrective Actions

Having identified the hazards and the risks associated with a product, appropriate corrective action must be taken by the manufacturer or importer to eliminate or minimize the hazards and risks identified. These actions could take the form of changing the design or instructions, reconditioning of the product in the distribution chain, recall, return and replacement of products, establishment of compliance programs to ensure that raw materials and parts meet specifications and that the critical points in production or distribution are controlled, training of staff, and initiating inspection and testing prior to distribution.

Evaluation and Selection of an Acceptable Standard or Instrument.

With the information about potential hazards and the mechanisms that need to be put in place to eliminate or reduce these hazards, it is possible to evaluate and select the most appropriate standard or instrument to demonstrate compliance with the provisions of a GSR. Where a regulation exists that covers a product, compliance is required under the law irrespective of whether or not the regulation addresses the potential hazards associated with the product. If the regulation does not address all the potential risks, the product will not be considered to be safe. Any risk the regulation does not address will fall under the provisions of a GSR and must be dealt with by other means.

Another challenge that a producer must face is that a regulation, standard or instrument could address each hazard or risk associated with a product yet not specify a level of safety that prevents injury and is expected by society. For example, a standard may set a level for lead that is higher than the level that causes or contributes to lead poisoning in children. In such a case, other instruments should be considered that set levels for lead in the range recommended by the medical profession, or the World Health Organization

Monitoring the Product.

In order to meet the objective of reporting adverse health incidents to authorities and taking appropriate action to eliminate or minimize any risks, a GSR would normally require a supplier to monitor adverse health effects throughout the life cycle of the product and take appropriate corrective action. The evidence collected from complaints or injury reports can be used to identify the interventions that need to be taken to resolve any problems. Others in the supply chain such as retailers and distributors in most cases are required to cooperate with the manufacturer and importer in implementing corrective actions and reporting adverse health incidents. Health Canada has published a number of guidance documents related to mandatory reporting of adverse health incidents involving health products^{608 609} and provides guidance on voluntary recalls for consumer products.⁶¹⁰ In other jurisdictions, guidance has been provided to suppliers on when to notify a problem consumer product⁶¹¹ and how to carry out a recall.^{612 613}

The exact type and nature of the system required have not been established at this time.

⁶⁰⁸ Health Products and Food Branch Inspectorate, *DRAFT Guidance Document Mandatory and Voluntary Problem Reporting for Medical Devices*, July 2001.

⁶⁰⁹ Natural Health Products Directorate, *Adverse Reaction Reporting Guidance Document*, Jan. 2004.

⁶¹⁰ **Health Canada's Consumer Product Bureau, Recalling Consumer Products - A Guide For Industry, April 2005, www.hc-sc.gc.ca/cps-spc/advisories-avis/child-enfant/recalling-guide-2005-04-rappel_e.html**

⁶¹¹ European Commission, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities*, Dec 2004, www.europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidelines_en.htm

⁶¹² Intertek Research and Testing Centre and UK Consumers Association supported by the EC, *Product Safety in Europe: A guide to corrective action including recalls*, June 2004.

⁶¹³ US CPSC, *Recall Handbook*, May 1999.

Appendix 4: Regulations and Standards for Bicycles

There are over 200 International and National standards that exist for bicycles or components that are used in bicycles. What are listed below are those standards that specifically deal with the overall safety of a bicycle, are available in Canada and are published in English or French.

Table 1: Regulations and Standards for Bicycles

Country	Type	Title	Comments
Australia	Consumer Safety Standard under the <i>Trade Practices Act</i>	Pedal Bicycles: Safety Requirements, Nov 1999	Mandatory and sets design requirements, performance requirements and assembly and use requirements for all manually powered bicycles.
	Australian and New Zealand National Standard	AS/NZS 1927 – 1998 Pedal Bicycles - Safety requirements	Referenced under Trade Practices Act as above. It differs from the international standard developed by ISO.
CEN – European Committee for Standardization	European Standard	PREN 14764: 2003 Bicycles for use on public roads - Safety requirements and test methods	
	European Standard	PR EN 14765 2003 Bicycles for young children - Safety requirements and test methods; German version prEN	
	European Standard	PREN 14781: 2003 Racing bicycles - Safety requirements and test methods	
	European Standard	PREN 14766:2003 Mountain-bicycles - Safety	

Country	Type	Title	Comments
		requirements and test methods	
	European Standard	PREN 14822 2003 Bicycles - Accessories for bicycles - Luggage carriers	
France	National Standard	NF R30 – 020 Cycles. Safety requirements for bicycles, all terrain bikes and bicycles for young children.	
		NF R30 – 003: Bmx bicycles. Safety requirements.	
International Standards Organization ISO	International standard	ISO 8098: 2002. Safety Requirements for bicycles for young children. 2 nd Edition	
	International Standard	ISO 4210: 1996 Cycles - Safety Requirements for Bicycles, Fourth Edition	
Japan	National Standard	JIS D 9203: Method of Stability Test for Bicycles	English
	National Standard	JIS D 9301: General Specifications for Bicycles	English
	National Standard	JIS D 9302: Bicycles for Young Children	
New Zealand	Regulation	Product Safety	Covers adult bicycles

Country	Type	Title	Comments
	under the <i>Fair Trading Act</i>	Standards (Pedal Bicycles) Regulations	including powered bicycles, it does not cover children's bicycles
	New Zealand National Standard	AS/NZS 1927 – 1998 Pedal Bicycles - Safety requirements	Design, assembly, safety of handlebars, seats, brakes etc.
United Kingdom	Regulation under <i>Consumer Protection Act</i>	Pedal Bicycles (Safety) Regulations 2003 (SI No. 145)	Adult bicycles must be constructed and assembled to comply with BS 6102: 1992 Standard for Pedal Bicycles and BS 6102 Part 2: 1982 for reflectors.
	Road Traffic Act	Pedal Cycles (Construction and Use) Regulations 1983	Cycle (of any sort) must have two braking systems
	Road Traffic Act	Road Vehicles Lighting Regulations 1989 as amended 2005	Pedal cycles to have various lights and reflectors fitted, clean and working properly between sunset and sunrise
	BS 6102 Part 1. National Standard	Cycles Part 1: Specification for Safety Requirements for Bicycles	Safety requirements for adult bicycles, the components and instructions. Mountain cycles are not covered
	BS ISO 8098	Cycles - Safety Requirements for Bicycles for Young Children	
United States	Regulation under <i>Consumer Product Safety Act</i>	Requirements for Bicycles, 16 CFR. Part 1512	Requirements for different components for regular and sidewalk bicycles. e.g. Braking, steering, pedals, chain, guards, tires, wheels, hubs, forks, seat, reflectors

Country	Type	Title	Comments
			and assembly. Test procedures and instructions.
	ASTM US National Standards	F2043 Standard Classification for Bicycle Usage.	Bicycle Usage Conditions
	ASTM US National Standard	F2273 Standard Test Methods for Bicycle Forks	Mechanical tests for compression load, bending load, impact resistance and fatigue life of bicycle forks
	ASTM US National Standard	F 2274 Standard Specification for Condition 3 Bicycle Forks	Standard for Mountain type bicycles to be used on rough terrain.
	ASTM US National Standard	F963 Standard Consumer Safety Specification for Toy Safety	Specifications for Tricycles and children's products.

Annex 2 - Questionnaire on the Quality of Some Existing Standards⁶¹⁴

NOTICE: Standards are the property of national standardisation bodies and can only be obtained from them⁶¹⁵.

Please register yourself:

You are: public authority
 Consumer association
 Producer
 Distributor
 Standardiser
 Other (please specify):

Name:

Address:

Telephone:

and fill-in one questionnaire per standard/product from the Annex.

⁶¹⁴ Please use the list of standards in Annex.

⁶¹⁵ The list of national standardisation bodies can be found in:
<http://www.cenorm.be/cenorm/members/members/index.asp>

QUESTIONNAIRE ON THE QUALITY OF SOME EXISTING STANDARDS⁶¹⁶

NOTICE: Standards are the property of national standardisation bodies and can only be obtained from them⁶¹⁷.

(please fill-in one form per standard/product)

1. Standard: (Please choose from the list in annex)
2. Do you consider that the above standard addresses all the risks /categories of risks associated with the product (risk scope)?
 YES.
 NO. Please specify which risks are not covered.
 DO NOT KNOW.
3. Do you consider that the standard covers in an adequate way the risks /categories of risks associated with the product that it covers (quality of the standard)?
 YES.
 NO. Please specify which risks are not properly covered.
 DO NOT KNOW.
4. Do you consider that the standard ensures a high level of safety?
 YES.
 NO. Is this justified by reasons answered in questions above?
 YES NO. Please justify.
 DO NOT KNOW.
5. Do you know of any statistical data/ information on accidents directly related to the product covered by the standard?
 YES. Please give details and source.
Had the product involved been manufactured according to the relevant standard?
 YES NO DO NOT KNOW
 NO
6. Do you think that the standard(s) should be revised?
 YES.
 NO
 DO NOT KNOW
7. Do you have any proposal of additional safety requirements that should be addressed in a revision of the standard (s)?
 YES. Please specify.
 NO
 DO NOT KNOW

⁶¹⁶ Please use the list of standards in Annex.

⁶¹⁷ The list of national standardisation bodies can be found in:
<http://www.cenorm.be/cenorm/members/members/index.asp>

8. Do you consider that this standard fulfils the general safety requirement of the Directive on General Product Safety and that the Commission should publish its references in the Official Journal of the European Union?
- YES.
 - NO. Please justify.
 - DO NOT KNOW

Annex 3 - Key Factors Affecting Compliance⁶¹⁸

Factors Influencing Voluntary Compliance

1. Knowledge of the Rules

The laws and regulations are clear.

There are relatively few unintentional violations.

Knowledge of the rules is improving satisfactorily under the compliance program.

2. Cost-Benefit (Advantages / Disadvantages of violation vs. compliance)

The time, money, effort and intangible costs, such as loss of reputation, favour compliance by the target group.

3. Level of Acceptance of the Regulatory Scheme

The policy, laws and regulations are perceived to be reasonable; they enjoy wide acceptance in the target group, or

The policy, laws and regulations are not perceived to be reasonable in some situations but the Program is addressing those situations effectively.

4. Loyalty and Obedience of the Target Group

The compliance and enforcement program builds on the basic willingness within the target group to comply, *a priori*, with the laws and regulations established by government. It is administered fairly, efficiently and effectively. It does not detract from base compliance levels, for example, by failing to deal effectively with poor performers.

5. Social Controls / Peer Pressure

Non-compliant behaviour by the target group is likely to be detected and sanctioned by other than government authorities, or by a peer group, because it offends community standards or values.

Informal control is exercised within the target group and its environment: family, friends, fellow workers, or business competitors.

Control Factors

⁶¹⁸ Reproduced from *Enhancing Compliance with Human Rights Objectives, 1999*, Annex A, prepared by Lyle S. Fairbairn, Q.C. and Margot Priest, for the Canadian Human Rights Act Review

6. Informal Reporting of Violations

Violations are likely to come to light even without government intervention, for example, due to third party reporting mechanisms, or an effective complaints process.

7. Likelihood of Detection of Violations

The target group perceives that there is a likelihood of detection.

8. Probability of Official Response

The regulated community is familiar with the Program's compliance and enforcement policies and government practices under them

There is a general perception that non-compliance will attract a timely and appropriate official response.

9. **Selectivity** (Targeting)

There is increased likelihood of government controls or sanctions being imposed due to the targeting of firms and persons likely to violate the rules, as well as actions and areas in which violations are likely to occur.

Sanctions

10. Probability of Sanction

Violations or offences are likely to be met with administrative, civil or criminal sanctions.

11. Severity of Sanction

The sanctions imposed are proportionate to the seriousness of the violations.

Respondents are not re-offending

The target group is not treating sanctions a "cost of doing business."

The sanctions imposed escalate with the seriousness of the offence and for repeat offenders."

Annex 4 – Outline of Issues Discussed with European Union Experts

Evolution of the General Safety Requirement

1. What was the central policy rationale for the adoption of the GSR (or equivalent) in the E.U. / U.S.? Is there a governing regulatory policy in place? What was the case for reform?
2. What were thought to be the GSR's advantages and limitations at the time of its introduction?
3. What has experience in the EU since the promulgation of the original Directive on General Product Safety demonstrated to be the GSR's main advantages and limitations?

Scope of Application

4. How far is the application of the GSR limited to consumer products?
5. What are the considerations / advantages / limitations to making the GSR comprehensively applicable to all products, subject to enumerated policy-based exemptions? (e.g. products used in the workplace, or other products where the risk in question may already be regulated under dedicated legislation)
6. How has the EU circumscribed the scope of operation of the GSR in relation to other, possibly overlapping, legislation regulating consumer products? Are the distinctions clear? If not, what ongoing initiatives are in place to clarify the operation of the GSR?
7. What is the EU's experience under the GSR Directive(s) with the concept of "lifecycle management" of products? For example, UK Guidance Notes, dated July 5, 2005, linked to the implementation of the EU's revised Directive on General Product Safety, refer to implicit obligations on Distributors and Producers to "help ensure that a product remains safe throughout its reasonably foreseeable use." What is the EU's experience with implementing and enforcing lifecycle management of product obligations? What is the position of key stakeholders on these obligations, whether explicit or implicit?

Legislative Experience

8. Following the promulgation of the original Directive on GSR (92/59/EEC), the original Directive and the transposing legislation in Member States has been revised. (2001/95/EC). What were the principal limitations that the revision sought to address? Have these been effectively addressed in transposing legislation enacted on or January 2004, the date for implementing the Revised Directive?

Implementation of the GSR / Operational Considerations

9. Were there any significant delays or complications in implementing the GSR? Did you observe resistance to implementation either on the part of those involved in the traditional regulatory process, or on the part of regulated business, whether in product manufacturing, sales, or importing? Were there any surprises or unanticipated aspects of the implementation experience you consider particularly noteworthy?
10. In order for us to understand the implementation process in greater detail, are there any jurisdictions within the EU whose experience might be particularly instructive? Are there any studies of implementation either completed or currently underway which we should attempt to examine during the course of this project?
11. What are the core resource requirements to implement an effective GSR regime? (e.g. standard setting capabilities, core information needs, communications, training, monitoring and enforcement capabilities) Were any cost/benefit studies, or implementation analyses, undertaken prior to its introduction?
12. What are the legislative and administrative means employed to enable the regulated communities to know when they have complied with the statutory duty to produce only “safe” products? (ie: definitions, interpretation guidelines, deemed compliance provisions, Q’s and A’s, etc.) Are these means considered effective? By Government? By industry and business? By other stakeholders? Are additional measures contemplated?
13. Given the special emphasis in GSR regimes on risk assessment and compliance with identified standards, what is the impact on human resources, and training needs under a GSR regime?. (E.g. Compliance audits require quite different skills than traditional inspections.)
14. Are the additional reporting requirements inherent under a GSR regime accepted as a consequence of the increased flexibility given to industry under this regulatory approach? Or are they regarded, by some, as an unjustifiable regulatory burden?
15. What inter-agency coordination issues had to be addressed in implementing a GSR regime. How, specifically, have they been addressed?

Compliance and Enforcement

16. What are the major reasons for observed non-compliance under the GSR regime? How are the compliance issues being addressed?
17. Does the EU, or Member States, maintain written compliance and enforcement policies, guides to enforcement, or make annual reports on compliance and enforcement experience under the GSR? Are these documents publicly available? Generally, how do the public authorities account to oversight bodies and/or the public for its administration of the GSR

regime?

18. What remedies and sanctions are available to Member States to enforce the GSR? Are criminal sanctions available? What are viewed as the most cost-effective remedies? Are informal processes available to find facts and resolve disputes? What is the relative reliance placed on civil, administrative and criminal processes?
19. What are the conditions precedent to recalling a product under the GSR regime? Could an effective GSR regime be maintained without the recall power?
20. How are penalties modulated under the GSR regime to account for infractions of varying severity and to prevent such penalties being treated as “the cost of doing business”?

Harmonization of Standards

21. The international trade regime embodies a number of initiatives intended to promote harmonization and to alleviate obstacles to trade. These include the Agreement on Technical Barriers to Trade, the Agreement on Sanitary and Phytosanitary Measures, and the Agreement on Trade-Related Aspects of Intellectual Property. Did the EU anticipate or experience any trade-related effects from the adoption of the GSR approach? Is there any indication of the effects of the GSR approach on harmonization of product standards?

Legal Considerations

22. What key legal issues arose, or were considered, in relation to the original or revised Directives, or in relation to their transposing legislation?
23. Have there been any significant legal proceedings, or case law precedents, involving enforcement or liability under the GSR regime? What is the basic legal framework underlying the GSR regime(s)? (Regulatory? Or criminal? Civil Code? Or Common Law?) How has the underlying legal framework in different member States affected the operation of the GSR regime?
24. Is the defence of “due diligence” available in a prosecution under the GSR? How far is the concept of due diligence spelled out in legislation, guidelines or “deemed to comply” provisions?
25. Has the operation of the GSR, in effect, raised the standard of due diligence applicable to the manufacturing, distribution or importation of “safe” products following its introduction? Has the GSR contributed in any significant way to the development of a “comprehensive culture of safety” on the part of manufacturers, distributors, or importers of consumer products, that is, to assess, rectify or report risks before harm occurs?
26. How has the GSR affected the tort liability of the regulated community, if at all? Or the exposure of public authorities to liability for negligence in the administration of the GSR regime?

Stakeholders' Position on Aspects of the GSR

27. Do the various stakeholders under the GSR regime (manufacturers, distributors, importers, consumers, interest groups) understand and support the GSR? If they have concerns about aspects of the GSR regime, what are they? How have they been addressed?

Policy Options

28. Apart from the General Product Safety Requirement, how do Member States deal with new products presenting risks of harm before that harm occurs. What are the preventive strategies they employ?
29. Are obligations placed on manufacturers, distributors and importers to assess, rectify, or report risks of harm in consumer products without necessary intervention by the public authority? How is this achieved?

Supplementary Issues & Endnotes

Supplementary Questions by Chantal Trepanier (HC – Legal Services)

30. Under "Implementation of the GSR - Question 9 - We are particularly interested to learn about the experience of the various Member States within the EU. Are there differences among the Member States on the manner the GSR was implemented? If so, what are the reasons for these differences?
31. Specifically, what was the experience of the UK with the GSR? Why were the UK prohibitions with regard to product safety taken out of the Consumer Protection Act and placed in the regulations as a result of General Product Safety Regulations in 1994 and in 2005? In terms of resources, what has been the impact of introducing the GSR in the UK?
32. Under "Implementation of the GSR" - Question 13 - What was the experience of the EU Member States with respect to the new reporting requirements? On average, how many reports of unsafe products are made by industry in the various EU Member States? Were there more or less reports than originally anticipated? Does each report investigated? Do the EU Member States share information with respect to reports of unsafe products?
33. Under "Legal Considerations" - A concern that was raised by some of our Canadian stakeholders during our consultations related to the use of the terms "under reasonably foreseeable conditions". Some members of the Canadian industry thought that it would be difficult for them to anticipate all the usage that the public may make of their products. Therefore, we are interested to know if there have been similar issues raised by the industry in the EU Member States? These terms appear in the definition of the term "product" in the EU Directive and have been

transposed in the Member State legislation. Is there any case law in the UK or other EU Member States on the interpretation/application of these terms?

Supplementary Issues raised by Jaime Benedickson

34. In the general pre-recall "incident-reporting" process; who receives? Who assembles such information? Is there a threshold of incidents in terms of frequency or severity, which triggers some further consideration of the matter preceding actual recall?
35. What is the nature and frequency of any post-recall claims by manufacturers, distributors etc where they feel the recall was inappropriate and seek to recover some of their losses?
36. What are the issues in the EU experience around what actually happens to products/materials that are recalled: storage only; retrieval; destruction?

Supplementary Issues arising from Research

37. Is there a trend within the EU to make greater use of regulations, relative to Directives?⁶¹⁹ If so, how far will this trend bear on the practice under the General Product Safety Directive in the future?
38. What are the "New Approach" Directives and what is their underlying rationale?
39. What administrative tasks had to be undertaken to implement the GPSD? . . . , How much and what kind of additional resources and new skills were required to undertake these tasks?⁶²⁰

Netherlands

40. Under Dutch administrative law, the Inspectorate for Health Protection requires the approval of the Public Prosecutor before organizing the withdrawal of a product from market. Query, what criteria does the Public Prosecutor bring to bear on this decision?
41. As of 2000, only the Public Prosecutor could impose fines following a report of an economic offence by the Health Protection Inspectorate, with recourse to the Courts only when the violator objected to the fine. It was proposed to give some power to impose fines directly to the Inspectorate. Has this occurred? Under what circumstances? (Relationship to the criminal law process? To economic (regulatory?) offences? Or an administrative

⁶¹⁹ See the Scottish Parliament's Subordinate Legislation Committee Report, 9th Meeting, 2005 (Session 2), 15 March 2005, Associated Written Evidence from the the Food Standards Agency of Scotland under the heading Reform and Simplification

⁶²⁰ The focus here is to determine the nature and kind of resource requirements unique to implementing the GSR and the impact on existing compliance and enforcement personnel.

penalty?)

42. How does the Netherlands deal with the marginal professionals who pay fines as the cost of doing business, or frequently change name or place of business to avoid accountability?
43. Has there been any development at the Community level to achieve some greater consistency amongst Member States in the approach to sanctioning offenders for breaches of consumer protection legislation?⁶²¹
44. What is the rationale for excluding medicines, and medical instruments from the operation of the GSR in the Netherlands?
45. In practice, what use did the Netherlands (which has comprehensive product safety legislation) make of the standards criteria listed in Article 4 of the (92) Directive, if at all? (The Netherlands did not initially transpose Article 4 but apparently used it in practice for some purposes)

Permanent prohibition of a product (as of 2000) can only be done through a Public Prosecutor or by drafting specific legislation. What is the rationale for this under Netherlands law?

⁶²¹ This possibility was alluded to in the Member State (Netherlands) report.

Annex 5 - Experts Interviewed in Europe Nov/Dec 2005

European Commission

BERNARDO DELOGU

Head of Unit
Product and Service Safety
Health and Consumer Protection Directorate-General
European Commission, Brussels, Belgium

ERIK HANSSON

Deputy Head of Unit
Product and Service Safety
Health and Consumer Protection Directorate General
European Commission, Brussels, Belgium

Member States

Belgium

JAN DECONINCK

Office of the Minister for the Environment, Consumer Protection and
Sustainable
Development
Brussels, Belgium

The Netherlands

DIRK MEIJER

Director, Region SW
Food and Consumer Product Safety Authority
Zwijndrecht, The Netherlands

JAN VAN LEENT

Senior Public Health Officer
Food and Consumer Product Safety Authority
Zwijndrecht, The Netherlands

The UK

GRAHAM BARTLETT

Assistant Director
General Product and Services Safety
Department of Trade and Industry, London, UK

ADEBAYO IGE

Policy Advisor and Product Delivery Manager
Health and Safety Executive, London, UK

PHIL PAPARD

Head, Product Safety Section
Health and Safety Executive, Manchester, UK

ARNOLD PINDAR

Head of Consumer Affairs
British Standards Institute, London, UK

ANTHONY ZACHARZEWSKI

Better Regulation Executive, London, UK

Simmons & Simmons Law Firm

MARK DEWAR

Partner
Simmons & Simmons Law Firm, London, UK

MILES ALEXANDER

Partner
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Oxford University

CHRISTOPHER HODGES

Visiting Research Fellow
Centre for Socio-Legal Studies
Oxford University, Oxford, UK

MAGDALENA SENGAYEN

Research Officer in Product Liability and Regulatory Issues
Centre for Socio-Legal Studies
Oxford University, Oxford, UK

Stakeholders

GOTTLLOBE FABISCH

ANEC
Brussels, Belgium

Annex 6 - The European Experience with the General Product Safety Directive: Highlights of the Interviews with European Union Experts

Evolution of the General Safety Requirement

1. Case for Reform

There was a need to harmonize regulations to enable free trade within the European Union. Under the old approach where everything had to be specified within the law, it was impossible to produce enough legislation harmonized amongst the Member States to meet the demand. The Cassis de Dijon decision, which was a free market decision, was the first one where the European Court gave a clear signal that it would assist with the creation of an internal common market without barriers to trade between Member States. About the same time, there was a new directive stating that if a Member State wanted to enact new technical rules, they would have to give notice to the Commission and every other Member State. This made everyone aware of the serious intent and force of the common market on domestic law making.

These challenges led to the development of The New Approach by the European Council in May 1985. It is a tool for technical harmonization, which politically changed the rules and allowed the EU to get into the business of developing domestic laws. The New Approach has variously been referred to as a policy, philosophy, strategy, but is generally regarded as a regulatory technique including an “enforcement measure” or a framework for dialogue. The New Approach is a two tier system in which legislative essential requirements, or the broad principles, related to health, safety and the environment are defined in EU Directives, and the details on how these requirements can be fulfilled are found in standards which are not included in the law.

The 1992 General Product Safety Directive had a GSR and followed the style of the New Approach Directives in that it contained the essential legislative requirements and some common safety denominators with the details on how to meet those requirements specified in standards. Member States were obliged to transpose the requirements of the GPSD into their country legislation. Since many already had a GSR type of approach in their own consumer legislation, the GPSD did not result in major changes in approach although some of the powers in the GPSD differed. In particular, recall was not in the UK legislation and resulted in the UK not transposing the first Directive.

The GPSD was designed as a “final safety net” in case European harmonization was not fully achieved to ensure, at a minimum, that products were “safe” throughout the EU. The second objective was to provide Member States with the obligations and powers to ensure safe products. The purpose and role of the GPSD may be changing from a safety net to an alternative form of regulation⁶²².

⁶²² In Canada, there could be pressure to use the GSR excessively as an alternative mechanism to weak or lacking remedies or sanctions in the sectoral legislation if those remedies are not separately reviewed for their sufficiency – a catchall that could, by default, become an alternative approach to regulating.

It was not designed for this; it was to be a means of bridging an enforcement gap, to prevent harm while a safety issue is being assessed and sometimes, to bridge the gap to formal regulation of the risk.

The GPSD concept did not evolve from the common law; it originated from the EU flowing from the Product Liability Directive, which preceded the General Product Safety Directive.

Some feel that education and border control should be the real focus, not the GPSD⁶²³ particularly since there is no massive evidence of enforcement under this legislation anywhere throughout Europe. It was not under its predecessor, or under national predecessors, but the 2001 Directive places the most impetus on the Member States to get their act together.

There were parallel activities going on in the UK and the EU. Consumer product legislation was started in Member States some time before it got going in the EU.

The UK had consumer product legislation in 1961 and 1978. There was a consultation in 1984 leading to a revised UK Consumer Protection Act in 1987. It seems that it was simply a modernization with no real change in policy. There were some inadequacies in the legal remedies, for example, prohibition, but these were consistent with the need to modernize. There was no evidence of any major safety problems, and it might be questioned what the case for reform was in the UK. In the absence of a General Product Safety Directive, the UK still had its Consumer Protection Act of 1987 that had a general safety requirement provision. A broad policy of standardization was adopted in the UK, which was politically important, especially for industry at that stage. The timing was important though, because a report in 1984 with the act in 1987 is virtually contemporaneous with the adoption of strict liability in the separate area of tort, which was suddenly agreed in 1985. At that point, there was a lot of discussion about unsafe products and a lot of expectation when the product liability Directive came in that there would be a lot of claims and that there were a lot of unsafe products around. It was this background development which underscored the need for modernization of the regulatory legislation... "to control the situation".

Health and Safety and Consumer Product Safety reform have developed separately in the UK although there seem to be commonalities. It was acknowledged that there may have been some cross fertilization of ideas flowing from the Robens Inquiry.

There were other legislative activities occurring in the UK at this time. Thalidomide was another important development in the early 1960's that gave rise to two different strands of legislation in the UK; there was a shift from negligence to strict liability (different definition than the one used in Canada) with a strict liability Directive in 1985. Product liability had never been a large phenomenon in the UK, but politically it was very important at this time because there was a sense that there were large numbers of unsafe products on the market. The other strand was the evolution of regulation. Product regulation would have been inevitable because of the existence of the common market and

⁶²³ Christopher Hodges, *European Regulation of Consumer Product Safety*, 2005, Oxford University Press

the wish to have single rules. Medicines were the first in 1965 and have gone on being amended over time, e.g. human tissue engineering, use of cell tissues, bioengineering etc. Product regulation took a long time to develop even though there was a national statute in place as early as 1961. Medicines have been regulated since 1965 in EU, especially developed in the early seventies, 80's and 90's.

2. Advantages of the GSR and limitations at the time of introduction

The purpose of the GSR specified in the 1992 GPSD was to enable free trade of consumer products within the EU while at the same time ensuring that these products did not present a risk to health and safety. The role of the GPSD was to be a backstop, safety net, long stop to be applied as a last resort when there are no applicable regulations. It was not designed as an alternative to regulation; rather as a means of bridging an enforcement gap, to prevent harm while a safety issue is being assessed and sometimes, to bridge the gap to formal regulation of the risk.

DG Enterprise conducted a study of obstacles to business caused by regulation and found the least obstacles were created by the GPSD. It was viewed as prescribing only what should be common practice. Industry saw it as a kind of checklist of what they should have in place.

In an historical context, a key point that was made was that GPSD was quite late in that it post dated most of the other vertical directives as well as Member State legislation that included a GSR. One interesting point was that all other directives came out of DG Enterprise with the exception of the GPSD which came out of DG SANCO. There was speculation that this might signal greater attention to health and safety.

3. Advantages and limitations based on experience since implementation of the original GPSD

In the EU, a first Directive is testing the water with a view to developing it over time. In an in depth review of the 1992 GPSD, the Catholic University of Louvain concluded that improvements were needed. Details of their review are summarized in Annex 9, Operative Provisions of the European General Product Safety Directive. In general, they found that Member States were unclear as to the application of provisions in the GPSD to their legislation, obligations for suppliers, surveillance, notification, emergency measures, even which products were covered. There was no obligation for suppliers to inform government or consumers when they took action on a product. There were weaknesses in the standard setting, and they did not confer a "presumption of conformity" the way the harmonized standards under the New Approach did. There was uneven enforcement across the Member States. This review led to a revised GPSD in 2001, which became effective in 2004.

The revised Directive seeks to clarify the relationship between the GPSD and other sectoral legislation, extends the scope and gives tools to the EC to deal with Member States that are not performing well enough. It also addresses the other problems identified in the review. Details are provided in Appendix...

The legal profession is much more interested in the new GPSD, in particular the new obligation on business to notify authorities when they have placed non-compliant products on the market. There is not that much case law yet, but more legal practitioners participate in the EC meetings.

The purpose and role of the GPSD may be changing from a safety net to an alternative form of regulation⁶²⁴. There are several reasons for this: firstly, the regulatory policy has a bias against new regulations unless a very strong case can be made out; secondly, the five year targeted period for reviewing standards seems not to be entirely effective, leaving a broader scope for application of the GPSD; thirdly, the GPSD may be relied upon more by new countries entering the EU which do not have comprehensive (or perhaps any) consumer product legislation as a first resort; fourthly, some of the standards developed by the standards groups, by reason of committee make up, industry imperatives or intransigent positions are not effective.

Scope of Application

4. How far is the application of the GSR limited to consumer products?

The GPSD applies to all non-food consumer products and products that are not subject to specific vertical directives. This covers less than 50% of the products on the European market. There are GPSD requirements including labelling, tracking and notification that apply to specific vertical regulations. In addition, the powers in the GPSD can be used across the vertical directives. Cosmetics use some of the powers from the GPSD. Gaps in the vertical directives should be filled by revision, but the GPSD can be used in emergencies. For example, it was used to ban phthalates in toys. The GPSD can be used for life cycle management, although the view is that a product should be unusable before it becomes unsafe.

The scope for GPSD may be diminishing as new product legislation comes on but there is pressure to avoid too much regulation, so there is not much new legislation. The practical scope of the GPSD is different from practice depending upon the subject matter. For technical requirements, it is very limited; but for safety management it is more widely used.

5. Considerations/advantages/limitations to making GSR comprehensively applicable to all products

Since the powers in the GPSD may be used across other vertical directives, it is in effect comprehensively applicable across all products.

6. Containment of the scope of operation of the GSR in relation to overlapping legislation relating to consumer products

⁶²⁴ In Canada, there could be pressure to use the GPSD excessively as an alternative mechanism to weak or lacking remedies or sanctions in the sectoral legislation if those remedies are not separately reviewed for their sufficiency – a catchall that could, by default, become an alternative approach to regulating.

This does not appear to be a problem since the GPSD is, in essence, residual to the vertical directives.

7. Life Cycle Management

Reasonably foreseeable use conditions are not a big issue in Europe, and there are not many questions on it. In most cases the problem solves itself. If an accident happens outside the normal use of the product, it won't apply. It has to be assessed on a case by case basis and it is impossible to spell it out in advance. In principle, it can be interpreted that a product should become unusable before it becomes unsafe so far as the duration is concerned. Disposal is covered under environmental legislation.

Legislative Experience

8. What were the limitations that the revised GPSD sought to address?

The limitations and the remedies contained in the revised GPSD are outlined in detail in Chapter 6, the Operative Provisions of the European General Product Safety Directive (GPSD).

In discussions in the UK we were informed that there were different intermediate remedies that may provide a framework for discussion, including, improvement notices, prohibition notices, withdrawal and recall. Clearly, the UK had a spectrum of remedies ahead of the GPSD, which enabled a proportionate response to violations of varying degrees of seriousness. It will be important to review the complementary remedies under the Health Canada acts to see if they are adequate to prevent overuse or abuse of a new GPSD remedy.

Words to the effect that "The UK does not have a product safety problem" appeared in the RIAS prepared for the revised Directive. It may be that this is largely "spin", although the UK system does seem more effective, in relative terms, than many in the EU. There was also the view that consumer groups have been largely "neutered" since they have been recently given new responsibilities and funding which makes them unlikely to want to be too aggressive. It was suggested that the UK government does appear to adopt the view that product safety is "done and dusted" in the UK.

Legislated criteria for assessing safety are not transparent. There was a test case in which two groups of Member States used the criteria in the GPSD to determine whether a hypothetical product was "safe". One group found the products safe; the other found it unsafe⁶²⁵.

Implementation of the GPSD/Operational Considerations

9. Were there significant delays or complications in introducing the GSR?

⁶²⁵ Fairbairn: This kind of uncertainty in a penal context could be fatal to a prosecution.

The first GPSD was adopted in 1992, with quite some reluctance in some states. Germany took the EC to the Court of Justice on the basis that it had exceeded its discretion. By 1997, Germany and several other states had still not transposed it. In discussions on the revision, there was still reluctance on the part of some of the business federations: they just wanted it repealed. The process was very useful for both the states and business community; they came to understand it was in the interest of business, to have good laws and good enforcement; it led to a level playing field. Now, business lobbies harder than consumers in ensuring there is effective enforcement

10. Member State Experience with GSR prior to GPSD

UK had the first consumer legislation in 1961; Germany, France, the Netherlands and some others, had legislation about the same time but it was pretty embryonic. The UK Act was partly consumer protection, but also pro-industry in the sense that it facilitated a base for standardization. The UK, Germany, Nordic countries and the Netherlands were seen as the forerunners and by the mid 80's there were GSR provisions in their consumer product safety legislation. The Netherlands also had the possibility to implement the vertical directives for consumer products. Thus the GPSD did not affect their behaviour. Belgium also had legislation that embodied the general provision for product safety. The UK was one of the last to develop transposing legislation for the revised GPSD and resisted recall for a long time. The UK has quite a good enforcement mechanism in the form of the Training Standards Units in the communities.

We were told that the center of gravity within the UK industries has always been the DTI and therefore pro industry. The policies in dealing with what is now the UK General Product Safety Regulations, indeed all product liability, have been careful not to upset industry. One important background reason is that UK industry by and large produces safe products.

Over the past 40 years in the UK, there has developed an industry-made form of self regulation through quality systems in what has become ISO 9000, plus standards to go with it. Therefore the British Standards Institute becomes very important, along with internal quality systems. Importantly, much later, when the EU harmonization got under way to prevent too much diversification, the regulatory systems, which are mainly contained in the New Approach Directives, (20 or so different highly technical Directives) are almost all based upon a quality system approval and use of standards. Under these Directives, EU harmonized standards are given specific legislative or legal standing within the regulation.

Now, the latest GPSD adopts the same procedure by facilitating compliance with a GSR through the introduction of harmonized consumer product safety standards. There have not yet been any harmonized standards for consumer products under the GPSD, and it will probably take some time.

11. Core Resource Requirements

There are three main factors leading to successful implementation of a new regulation⁶²⁶. All of these factors require resources.

a. The first one is the degree to which the target group knows and understands the rules.

The first GPSD was adopted in 1992, and it was not well received. This was due to lack of understanding of what it meant and confusion over what the target group (both industry and Member States) had to do. Consultations on the revisions to the Directive provided a forum to increase the understanding of both the regulated community and the regulators in the EC and Member States. As a result there is greater acceptance of the revised GPSD.

In the EU, it appears that the greatest number of non-compliant products is toys and electrical products, mostly from China⁶²⁷, and even though it is the largest manufacturer of consumer products in the world, the statistics are disproportionately high. Since it appears that small importers may not even be aware of the standards and the Chinese manufacturers even less, the EC is taking the initiative to educate them about the standards with which they should comply and is sending the incidents (RAPEX) reports to China with a view to encouraging the Chinese authorities to follow up internally.

b. The second factor that can influence implementation of a regulation is the degree to which the target group is willing to comply voluntarily. This will be driven not only by the costs to the target group, but also whether it has been consulted before implementation and whether the government is serious about enforcing the regulation to deter non-compliance.

Enforcement (includes monitoring, surveillance and enforcement) results in significant costs to government since implementation of the GPSD results in a switch from a pre-market approach to a post-market one. The EC has made calculations on costs and determined that the GPSD is more costly than the old system. In some cases, some testing costs can be redeemed from business, but the government has to enhance enforcement, custom control, put in place systems to track suspicious goods even at the investigation stage, and collect injury data and share this information with other member states. In addition, the revised GPSD is explicit on requiring recall, although it is considered a last resort and less intrusive action should be taken if possible.

Cost-benefit studies undertaken prior to introduction

It does not appear that there were detailed cost-benefit studies done prior to implementation of the first GPSD in 1992. There was strong political interest in reducing technical barriers to trade within the EU. The first step was the introduction, in 1985, of the New Approach, which was a tool for technical harmonization. This approach was extended to consumer products in the 1992 GPSD. There was an in-depth review done for the EC leading to a subsequent revision of that Directive in 2001. Although there was evidence that a GSR

⁶²⁶ OECD, *Reducing the Risk of Policy Failure: Challenges for Regulatory Compliance*, 2000

⁶²⁷ RAPEX Report 2004

would be more costly than the existing regulatory systems within each of the Member States, these costs were considered to be outweighed by the significant economic benefits emanating from enhanced free trade of European manufactured goods within the EU. The costs of implementing a GSR in Canada are likely to be similar to those in Europe, but the benefits may be significantly different.

Business, it seems has accepted the costs of complying with a GPSD as simply the kind of things that business should do as a common practice to protect themselves from being sued. For government, there are some studies which indicate that the costs are outweighed by the reduction in lost income and hospital costs resulting from accidents. The part of government benefiting from this is Health Services, not the group responsible for implementation of the GPSD.

It seems that many Member States are moving away from strict cost benefit analyses and focusing now on whether a new regulation is a worthwhile policy using the Dutch Table of 11, and how likely is the regulation to be voluntarily complied with.

Organizational Structure

At the time the 2001 GPSD was negotiated, everyone knew that the system needed to evolve further. There was a lot of discussion with US Consumer Product Safety Commission (CPSC), and much of the new Directive was based on the CPSC model, without there being a proper centralized control. Although it is unlikely that the EC could establish a central agency, industry made a case for a one. The mandate could be postulated, and if it were to be effective, the next step would be to provide what the CPSC did, that is quick access to information with a huge population data base centralized through an agency. There are a number of models in existence in Europe including the European Medicines Agency, which along with the WHO has a large database, the Pharmacovigilance Post-marketing system that allows rapid action if there are health problems with a pharmaceutical. Unfortunately a central agency for consumer products seems to be a step too far for the Member States at this point.

There is a proposal to create a Consumer Trading Standards Agency in the UK that would be concerned with safety issues, although its specific mandate and location are unclear. There is disagreement between the Office of Fair Trading (competition regulator) and the Office of Consumer Trading, which wants to take this function. It has been recommended that the Consumer Trading Standards Agency should have a central control over the international companies because prosecutions by the local trading standards department office have been dropped due to lack of funds.

Cost Implications for Government for Enforcement

There are significant resource implications both at the EC and the Member State levels. The EC is funding the upgrade of RAPEX, the PROSAFE initiative and CEN.

The Netherlands coped with the need for increased resources for enforcement in a stepwise fashion. They have their own laboratories to test products and in the

overall product safety area, the resources include fair grounds, toys, machinery, electric, personal protective equipment, etc. They now have about 120 full time equivalent personnel and a budget of 15 million Euros, which compared to other European countries, is quite high (this includes some activities beyond enforcement of the GPSD). There are about 1 million additional Euros for implementation of the new GPSD, which will be used to improve RAPEX, and to do the increased number of anticipated investigations resulting from inclusion of notification and recall in the new GPSD.

The observation in Belgium is that since the GPSD is a “safe guard for products not covered by a specific vertical Directive, it makes planning difficult. It also has significant resource implications because the government has to be responsive to complaints and the 50 million Euro budget is insufficient to handle it. This is further exacerbated by the government responsibilities in administering the GPSD.

c. The third factor influencing implementation is the degree to which the target group is able to comply. This will be influenced by their skills and capacity and by the information and guidance provided by government. The legal profession was concerned about how to interpret the Directive in practice, what kind of guidance could be found to design and produce a product, what standards and documents were available and what assistance was available to business.

Standards

The introduction of new systems, both legal systems and standards can, depending upon the sector or the product, cause enormous burdens and small businesses have gone out of business with the introduction of new regulations. But all businesses should be able to meet the “basic safety requirements” as a cost of being in business. The UK industry, including small industry, has not had any difficulty keeping up to speed with standards – given the enforcement policy. There is some balance achieved through grant programs to encourage innovation. The GPSD does not set the standard too high; it requires that only safe products be produced and leaves it up to industry to determine what that entails. It should also be noted that in the EU, the requirements vary according to size, capacity and volume of the supplier and an administrative discretion is applied to the circumstances of the distributor. The UK situation does reinforce the need to help small business under a self regulatory scheme. Since SMEs have difficulties in developing standards, the government helps them do it.

“The New Approach entrusted private organizations, namely the European standardization organizations with the task of defining European safety standards, or in other words, the European level of safety, on the basis of defined safety objectives. This delegation of powers from the legislator, this privatization of law-making was both its key to success, because it simplified law-making and its drawback because it induced a democratic deficit”⁶²⁸. Under the New Approach of the EU, legislative harmonization is limited to essential requirements related safety, health, consumer and environmental protection. Manufacturers are free to use any technical solution provided that the product complies with the essential requirements. Only those products that comply with Directives can be placed on the EU market and bear the CE marking. It is the

⁶²⁸ Fabisch, ANEC2005/GA/044, 30 November 2005

responsibility of Member States to allow only complying products to be placed on the market through their market surveillance activities. Harmonized European standards are technical specifications adopted by the European Standardization Bodies (CEN, CENELEC and ESTI) through a stakeholder driven consensus building process and are considered to be voluntary standards. The GPSD builds on this and introduces the concept of presumption of conformity with the European standards⁶²⁹. There is no concept of minimum standards in the GPSD. More frequently, situations are seen where there are no standards, usually for novel products. In some cases existing standards are changed to account for new risks.

Given the role of voluntary standards, it is important to understand how they are set. In the UK, the BSI (British Standards Institute which is the National Standards Agency) has responsibility for creation, coordination and dissemination of standards. It has a number of technical committees, primarily drawn from the relevant industrial sector. They are faced with issues concerning whether they should have consumer representation, or government representation if there are highly technical issues in a particular regulatory area. Today, the focus is mostly on the pan-European context, so the BSI is simply one national agency feeding into one of the European Standardization Bodies (CEN, CENELEC or ESTI). This causes difficulties in operation and coordination since it involves traveling long distances and getting the right people there. There have been criticisms the standard setting system does not operate quickly enough. The latest GPSD adopts the same procedures as developed by the BSI with the intent of facilitating compliance by introducing a number of consumer product safety standards. That has yet to happen and will probably take some time.

Concern was raised that available resources were not sufficient to do the maintenance on old standards and keep up with the new. In practice the five-year review cycle was not considered sufficient.

There are differing views on the use of standards. Some feel that the origin of standards was not for product safety, and although there is movement towards safety, the process is still governed by the producers and not the safety experts. Thus, there is reluctance to give standards a big role given this lack of influence on the process. On the positive side, 80-90% of the standards used on a daily basis as reference sources do not provide problems. But in difficult areas there is a large burden on the Member States, which is made more complicated by the GPSD because there are two types of standards, those issued by European standards organizations and a higher category called community standards that are published in the official journal of the EC. Concern was also expressed about the use of ISO standards. Others feel that even though the 2001 Directive introduced the possibility of standards for consumer products, not much has happened. However, for the standards for all the other industrial products covered under the New Approach or National legislation, there has been huge activity and the standards have worked very well. Today, some of it is put into global standardization. The view of the EC is that the standardization process means all parties should be involved and make their voices heard, and the mandate given to the standard setting agencies is to find the "essential safety

⁶²⁹ Hansson, Presentation, Appendix....

requirements". If EC did not regard a resulting standard as credible, it would not publish it and would refer it back.

Although reasonably well accepted in the EU for the purpose of promoting internal trade, the New Approach which "privatizes the regulatory process" still causes some problems, especially with ANEC and other consumer interest groups which may feel that their modest influence is overwhelmed by industry interests and that the standards, once published can be difficult to amend or place under review. There is pressure from ANEC for equal representation for consumers on Standardization Committees⁶³⁰.

The standards process is not transparent, although efforts to make it more so are proceeding.

Consumer groups always say they have very little influence and while probably true, it is the view of some that it is unlikely to have made any real difference in the output. Consumer groups now have improved access to experts who are capable of sitting on these standardization bodies although they may not feel it is enough. Industry has its own problems in locating sufficient experts to do the work. Nevertheless there does not appear to be evidence that the resulting standards are biased or ineffective. The more interesting observations may be to note the impact on public participation in an expert dominated process as well as how far are the bodies moving beyond strictly technical to more subjective issues where direct input may be quite relevant.

One observation is that the main activities in Europe have been to emphasize the ability to use standards for compliance and not the development of new standards, which is more important. The application of standards across all sectors will have variable impacts. Big enterprises have the resources to explore and use innovative methods whereas SMEs are more inclined to look for a precise standard to follow to gain confidence that their products are safe and to be sure to have the benefit of the presumption of conformity. In practical terms, there should not normally be a difference between the producers and importers. SMEs generally do not have the technical ability to demonstrate that the essential requirements can be met by another means and are better advised to follow the standards as a blueprint. SMEs constitute ~60% of the industry in Europe.

12. Legislative and administrative means employed to enable regulated communities to know when they have complied with statutory duty

There is a need for consistency in standard setting and the assessment of product conformity with the standard. The EC has developed numerous guidance documents to assist industry including Product Safety in Europe- A guide to corrective action including recalls⁶³¹. Despite these efforts by the EC, conformity is not always transparent.

⁶³⁰ This resonates with the evolution of labour representation on Workplace Safety Committees. Labour demands for equal representation on such Committees fuelled industry concerns about a labour move toward "co-management" of corporate enterprises, especially when legal entitlement to refuse to work in an unsafe environment came into issue.

⁶³¹ <http://europa.eu.int/comm/consumers>

Uncertainty by companies as to whether their products are in compliance with the standards has led many to submit their products to independent testing bodies called Notified Bodies (NB). In the case of toys and electrical products, it is a requirement to send the products for such testing to Notified Bodies. It also helps build a defence in the case of enforcement action. This third party certification is a growing industry.

“A NB is an inspection body or organization (private company) which is competent to perform tasks relating to the conformity assessment mentioned in certain Directives. This authority is designated by the Member State on the territory where it is established if it satisfies the criteria with regard to competence and the requirements established in the relevant Directive and is notified to the Commission and to the other Member States. It could be called an approved laboratory,⁶³² authorized by the government, in the country in which it exists to do testing within the GPSD for approval for the CE marking for example. This information has to be provided to the regulatory authority as part of the technical file. A complication is that in the NL, since the NB is considered by the judiciary to be part of the public legislation, government and the NB have to agree on the position before taking action on the product.

One criticism of NBs is that they only test what the company asks even though it may not be a complete testing of the safety of the product. If the product meets the standard, the authority would have problems prosecuting despite the incomplete testing. Concern about the independence of the NB from industry was also expressed by the Dutch. The U.S. FDA and other U.S. authorities have been scathing in their criticism of these bodies. These are industry experts in the main, working in the NBs. NBs may also be influenced by industry and “shopping” for sympathetic NBs, while prohibited, appears to occur sometimes.

For products where there are no standards, no regulations, no laws, the authority submits the product for testing and the test house determines what sort of criteria should be used to determine whether or not the product is safe. Relevant standards will be referenced as well. It appears that for SMEs who do not know how to do a risk assessment on their product in the absence of a standard, the UK transfers the responsibility for the products for which there is no standard to the local authority. It appears that this is done in other (unnamed) Member States.

There seems to be a general regard for having a GSR that requires any product that is put on the market to be safe and for the due diligence on the part of the producer as a more efficient way of enforcing safety than making lots and lots of different regulations about safety in particular product areas. That said, the take up of GSRs is nowhere nearly as extensive as the general support for it appears to suggest. The UK chose the GSR method a long time ago because the minister does not have to be involved every time something appears to be wrong with a product and having to make orders or make emergency regulations. The local enforcement authorities can go out, look at a product, and if they think it

⁶³² Ministry of Economic Affairs, Belgium, Quality and Safety Administrator, Safety Division, Product Safety Department, Nov.1999. CE What? Why? How? Introduction to Technical in the Area of Product Safety in the European Union p. 19

might be unsafe, issue a suspension notice under their own authority, have it tested under whatever terms that the test house may determine. Then they will come to a conclusion whether or not they think it is safe or unsafe. If they conclude that it is unsafe, they can issue a withdrawal notice. The trader can apply to the courts if they disagree with the determination of the local authority. Then the courts decide. That is the method used in the UK.

13. Impact of emphasis on risk assessment and compliance with identified standards on human resources and training needs

Given the subjective nature of the determination of safe, the EC concluded that it needed to take a concrete decision about safety. It is developing risk assessment procedures that should be used for determination of severity of the injury data in the RAPEX system and for product recall. It is important that there be consistency in determining what level of risk the product has caused so that all Member States may take similar action in restricting, removing or recalling the product from the market.

In practice, the Member State asks the producer for more information, what tests have been carried out and what tests have been applied. Based on that, it might be decided that further tests might be needed, and these would be done in house or through certification houses. Normally there would be a dialogue with the company, usually with a representative present. For low priced Chinese exports, there would not be such a dialogue since the retailer might not know much about the testing done, if any. The practices vary from State to State. In the Nordic countries the tendency is to negotiate more; in France there is a more formal judicial system. They move more quickly to a formal decision. In the Nordic countries they would reach an agreement which might never be formalized if the company does what they need to do. In the end, if there are inconsistent decisions, there might be an appeal.

14. Acceptance of the additional reporting requirements

The additional reporting requirements were met with mixed reactions by industry. There was quite an evolution. There were early objections by some but not the trend setters. They saw it as an expression of good business practice as well as a tool to get rid of the non-compliers. Product safety has a higher profile and, because of the reporting requirements, they have been pro-active. More and more big companies are organizing themselves with proper compliance plans, and they have determined that even recalls can work to the benefit of their reputation if handled appropriately. There are probably small companies that have no knowledge of or position on such practices.

Effective market surveillance is an important component of enforcement. According to the UK Consumers' Association, approximately 7% of consumer products in the UK are unsafe, and enforcement officers in the Netherlands have identified 15-20% unsafe products. RAPEX, the existing notification system for cases of serious risk, supports this, identifying such hazards as choking, suffocation and electric shock⁶³³. Under RAPEX, the Member States are obliged to notify the Commission when they adopt measures to prevent, restrict or

⁶³³ Fabisch, ANEC2005/GA/044, 30 November 2005

impose conditions on the marketing or use of a consumer product and when industry takes voluntary measures on products in cases of serious risks. The current level of reporting under RAPEX is extremely variable as is the capacity to identify cases of serious risk from products on the market and to notify other Member States.

The EC has been concerned about the robustness of the notification process and as a result, is now developing an information technology application where notification can be made by and to all EU Member States. According to the EC, the notification content should include information enabling precise identification, a full description of the risk, information for tracing the product and actions undertaken to prevent the risks. There are challenges involved in this because there are inconsistencies in the information required by various Members.

CPSC was asked to participate in RAPEX but was unable because they could not share the information as is done in EU.

The need for trace back was emphasized during the crisis when it was found that there was dioxin contamination in chocolates. Since producers in other countries are not covered by Belgian law, the distributors who are Belgian are turned to when information is needed.

15. Interagency Coordination

In the EU, responsibility for enforcement rests with the Member States, and currently, there is considerable variation in the enforcement structures amongst Member States. Some have one person responsible for a range of products; others have specialists dealing with toys, electrical products, etc. Some enforce at the regional level; the UK does it at the local level. As a result, the EC is financing a project, to be carried out by PROSAFE over three years, on a common approach to enforcement, to develop guidelines and best practices on surveillance and enforcement. Prosafe⁶³⁴ is an informal network that allows discussion (not at an official level) amongst market surveillance officers across the EU on issues arising on products, and sharing of what worked and what did not work. It is currently chaired by Dr. Dirk Meijer of the Netherlands. They are looking to establish a rapid advice forum consisting of experts on market surveillance acting on their own behalf, not the Member State. The target is to provide the advice within 48 hours and no longer than one week.

Some feel it is possible that this strong movement toward the harmonization of national enforcement mechanisms will be a big problem because of the difference in approaches and resources. In particular, there is a big North / South divide: the Germans, French, Swedish, British and Dutch have long established consumer regulation and good national enforcement coupled with a lot of practice and much consistency of approach. The southern countries sometimes have no people, budget or expertise so it can be quite arbitrary, if any action is taken at all. The imminent arrival into the EU of central Europe, where there was virtually no consumer product legislation, emphasized the need for a framework; thus the second Directive has requirements for authorities, for people, budgets, standards, powers, annual reports, surveillance.

⁶³⁴ <http://www.prosafe.org/background.htm>

Compliance and Enforcement

16. Major reasons for observed non-compliance and how these are being addressed

As discussed under implementation, the main reasons seem to be lack of awareness of the GPSD, and incapacity to do the risk assessment. The EC has signed an MOU with the Chinese consumer product regulatory authorities to assist them in raising the compliance of their industry.

17. Documentation and administration

Businesses see highly variable performance from local authorities on the same type of decisions. The difference is not transparent. LACORS has a role to try and get consistency but has not done well; its principle function is as a lobbying organization with central government. They have many lobbying groups, consumer protection, environment, health industry groups, but very little coordination. An example of the inconsistency was the use of the terms chocolate flavour, or chocolate flavoured. One supermarket labelled one way at the suggestion of a local authority; six months later another authority ordered it labelled the other way.

The UK Better Regulation Office has just been just created to do the things LACORS is supposed to do (definitions, performance assessment, etc), but is not doing. The Concordat is just being revised, and it is at an early stage.

Effect of legislating the Concordat – It has not yet been decided whether to make it statutory, and it could be a while before a decision is taken. There are pros and cons. The regulators would have to show consistency with the code of practice; otherwise they would be liable to judicial review; their performance assessment would be based on conformity with the code. In prosecutions, a judge could use failure to follow the code as a mitigating factor. It is possible that something may be done ahead of judicial review, like the US fairness courts.

Enforcement – The Concordat has had mixed results. It had quite an impact initially, but it is now largely worn off since it does not really have the teeth to make things happen, and it does not have the definitions within it to enable people to know what they must do. Ninety-six per cent of regulators have signed up, but the practice has not really changed since there is no stick behind it. Changes in the Concordat prompted by Hampton report and Less is More Report, might include: a proper definition of risk assessment. LACORS standard of risk assessment is 50/50. Fifty per cent based on criteria, 50 per cent on whether local authority thinks the business is a bit “dodgy” Now however, they want risk assessment to drive regulatory resources.

The best local authorities are the largest, because they are taking the time to step back to reflect on why they are doing what they are doing. Their conviction rate per number of inspections is much higher.

18. Remedies and Sanctions

Remedies/Sanctions/Recall. The inclusion of recall in the revised Directive caused anxiety in some of the Member States which felt that there were other less draconian ways of removing unsafe products. Relevant to the issue of recall in the EU is the proportionality principle. In the latest European Treaty, proportionality is mentioned as a broad principle where steps should not be taken that are disproportionate to the needs or seriousness of the issue. The inclusion of the Precautionary Principle in the GPSD appears to be in conflict with the proportionality principle. Another complication in Europe is the principle of subsidiarity meaning that a matter cannot be legislated on a European law basis where unnecessary, and it should be left to the Member States to legislate for themselves. The Member States have the residual or original jurisdiction. Clearly, there is a balance between Community and National Sovereignty. Given all the issues, the EC is proceeding carefully in terms of developing guidelines on recall so as not to upset the balance between proportionality, subsidiarity and precautionary principles.

The EC considers that recall is a last resort and that less intrusive action (than full recall) should be taken if possible, although there may be some increase in recalls because of the attention paid to it in the revised Directive. In the UK, section 11 of the Consumer Protection Act allows the Secretary of State to make regulations in respect of the product. He can do that on an emergency basis without consulting or on a general basis with consultation (the emergency regulation). The action can last for 12 months, and if it needs to be extended there has to be a proper consultation. The recall power does not appear to have been abused. In one case in the European court, not under the GPSD, but some other Directive, the court found the action was correct.

19. Conditions precedent to recall and impact of a lack of recall powers on an effective GSR regime

In the UK, over 90 per cent of the recalls under the original Directive were "voluntary". (Given the teeth in the UK / EU regime, and the natural pressures on companies to produce safe products, this is perhaps not surprising.) Since the UK did not interpret the 1992 Directive as requiring a recall, it was made explicit in the revised Directive. There is EC guidance on recall, and it has worked smoothly in all the other States. The EC considers that recall is a last resort and less intrusive action (than full recall) should be taken if possible, although there may be some increase in recalls because of the attention paid to it in the revised Directive. In the UK, section 11 of the Consumer Protection Act allows the Secretary of State to make regulations in respect to the product. He can do that on an emergency basis without consulting or on a general basis with consultation (the emergency regulation). The action can last for 12 months, and if it needs to be extended there has to be a proper consultation. The recall power does not appear to have been abused. In one case in the European court, not under the GPSD, but some other Directive the court found the action was correct.

In summary⁶³⁵, recall is very much a topical area that is evolving quite quickly now. Recall, in Europe, was almost unheard of 20 years ago. Industry

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developed recall as standardization took hold during globalization. The car and food industries have quite effective operating systems for recall. Recall was half mentioned in the first Directive, and is now fully mentioned in the revised Directives. Europe has a couple of guidelines on recall, one based on guidelines developed, initially, in the UK.

The UK guidelines were developed collaboratively by the Department of Trade and Industry and the consumers association (their technical people did most of the work), and the Confederation of British Industry and a large British Retail Association. So, the four relevant big players got together and wrote the recall guideline, which was adopted as a European guideline. It tells “how to”; it doesn’t answer the very difficult question of “when to”. This question can be very difficult, getting into complex scientific modeling and data against which no baseline or criteria exist. The problem has been around for decades.

20. Modulation of penalties under a GSR Regime

Some believe that the penalties should be higher. In the UK, there is an ongoing debate as to whether there should be a “corporate manslaughter” offence, that is, the company, as well as the Directors, may be prosecuted. This is an area that has been fiercely fought for a long time, and the Government has only made a few tentative steps into that arena for the moment.

Harmonization of Standards

21. Trade-related effects of the GSR Harmonization of Standards

Standard setting is complicated in the EU. There is a push to have harmonized or Community standards that would enhance trade amongst Member States. The early approach to harmonization was slowed down by too much detail at the political level, aggravated by the need for unanimity. Later, 70 per cent became the voting consensus in the EU, although the Standardization Bodies always strive for consensus standards. As a pragmatic matter, the process of separating essential requirements from technical detail was beginning to happen at the level of standardization committees; partly because the political dialogue, in many cases, had become quite uncivil, and there was difficulty in moving matters forward; it took 6 years to get agreement on the allowable lead levels from ceramic dishes in the early years.

The cost of establishing new standards is mainly paid for by industry. However for standard setting through CEN, the EC R&D program puts up 50 % of the money for development of methods of analysis, and the EC funds the secretariat. Everyone who participates pays for his/her own time and travel costs. The EC pays for travel costs for consumer representatives, but not the work time. In most standardization committees, there are may be 10 industry representatives and only 2 consumer representatives. Nevertheless the standards still have to be accepted by the Member States and the EC. There has to be a proper outcome. (Based on this process in the EU, there are implications that the Canadian government might have to consider assuming an oversight and approving role as well as a financial role.)

There are additional financial implications. Standards are developed at the general (product sector) level, not on the basis of individual products. SMEs require considerable help under a standards regime including, often, testing by the public authority and compliance advice on a case by case basis. The capacity to participate effectively in international and intergovernmental standards setting processes incurs costs for such items as travel and accommodation, publication of resulting standards and assistance for consumer groups to participate meaningfully.

There may be some national standards not covered by harmonized standards (e.g. flammability of mattresses). Some of the national standards could be harmonized by being adopted at the EU level. That in fact is the source of many of the harmonized standards, although there is often much internal discussion before this occurs. Once harmonized standards are in place, further national standards might be viewed as a trade barrier unless it falls within one of several exceptions such as ones that are necessary to ensure local safety (e.g. car bumpers in Finland to deal with car moose collisions).

Some feel that the answer to these global issues is to press for ISO standards. The EU has evolved from national to harmonized European standards and there is some movement towards harmonization between European and International standards.

(Canada has some reservations about adopting ISO as a default position. Also, there are other North American standards, which are not ISO standards that Canada must take into account.)

*Voluntary Standards - Industry Bias*⁶³⁶ There is concern in Europe by some enforcement authorities about the degree of industry influence and control of voluntary standards under a trade-driven regime. The concerns include:

- Lack of balance in standardization committees
 - The consumer and government perspectives are not always well represented.
 - Government may not have the capacity to monitor, or participate in, the work of standardization committees to the degree considered appropriate. Industry may effectively control the agenda of some standardization committees, or refuse to consider developing a standard for a product, even when requested. (e.g for lighters.)
 - The standardization committees are more vulnerable than government to influence from big business or industry, even from outside the committee.
 - There is pressure from ANEC for equal representation for consumers on Standardization Committees. (This resonates with the evolution of labour representation on Workplace Safety Committees. Labour demands for equal representation on such Committees fuelled industry concerns about a labour move toward “co-management” of corporate enterprises,

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especially when legal entitlement to refuse to work in an unsafe environment came into issue.

- Notified Bodies may also be influenced by industry and “shopping” for sympathetic notifying authorities, while prohibited, appears to occur sometimes.
- The competence of accreditation agencies is sometimes questioned.
- Safety issues may suffer in a trade-oriented regime.

Legal Considerations

22. What legal issues arose?

The key legal issues that arose or were considered include: the nature of GSR and how to interpret in practice (what kind of guidance can be found to design and produce a product; what standards exist and documents are available; what kind of assistance is available); delegation of legislative responsibility – ministerial responsibility; due diligence; liability creep; interface between tort and GSR (two aspects are the government liability e.g. for responding effectively to complaints and the industry side e.g. the possibility of liability creep; safeguards in recall; and the European principle of proportionality and how it is applied.

Another area of concern is executive decision making power, and the fact that the criteria on which it is based are not transparent. The EC also does not wish to give up its power to issue authorizations. For example, although the European Medicines Agency is evolving as a very high quality, fast, efficient technical body, with good expertise making reliable decisions, it does not have the authority to issue authorizations of pharmaceuticals even though it is responsible for evaluating the data upon which the decision to register is made. The Food Agency came about as a reaction to the Mad Cow crises of the 1990s and is mainly a figure head since food regulation relies more on local inspection of facilities as opposed to close evaluation of the product.

23. Case law precedents

Experience under prosecutions is limited. In the UK, there is very little experience in the courts because so few cases go to prosecution, and those that do are often heard in Magistrate’s Court and unreported. There are a number of disincentives to prosecution, namely:

- *Expense* - it is very costly to prosecute cases, in the thousands of pounds when opportunity costs including salaries are taken into account.
- *Orientation of the regulations* – the regulations under the Directive are drafted in a way to facilitate discussion and settlement and to discourage confrontation, which can be injurious to trade
- *Enforcement posture* – regulatory policy and the enforcement concordat encourage a “light touch” approach to enforcement, with formal enforcement in the background if the company is disinclined to

comply. (“Voluntary” compliance may be a bit of a euphemism given the tension present in settlement or remediation discussions.

- *Proportionality* – enforcement actions, when disproportionate to the risk involved, can expose the public authority to criticism and judicial review. Proportionality is an aspect of “light touch” enforcement practices.
- *Business disruption* - more effective than criminal prosecutions are remedies and sanctions which impair an industry’s capacity to market its product. Notification to a Notifying Body (required under the Directive in some circumstances) could result in a product being removed from the EU market and even banned for export to non-EU countries. Accordingly, there is a leverage impact of a violation in the EU in the sense that a problem in one Member State can quickly become a problem for marketing the product in all EU States given the Notification procedures and the responsibilities and powers of the Commission in relation to such transgressions.
- *Reputation* – reputable businesses do not want negative publicity associated with their products and, in any event, have a natural incentive to build safe products if they are to stay in business.
- *Working relationships* – inspectors and businesses interface over time; a collaborative approach to safety makes long term relationships.
- *Exposure to product liability* – a successful prosecution can have product liability consequences far greater than any fine imposed. (Note: the Cabinet office mentioned the possibility of greatly increased fines, including a provision for removing illicit profits in the process, along the lines of US practice.

The number of cases under the 1987 UK Consumer Protection Act is quite limited. There are statistics on this. Some enforcement mechanisms are used; others are not. This is based on the conclusion in the UK that most products are safe and thus a “light touch” is justified. Nevertheless a “big stick” is needed to wield for a relatively small number of companies. Occasionally a larger industry might be involved, but that is unusual. Unfortunately, few European statistics are kept; they would take some of the sting out of the overheated discussion about the importance of the legislation.

24. Defence of Due Diligence

In the UK, the due diligence defence has almost the same wording in the Health and Safety at Work Act and the Consumer Protection Act, Part II, carried over into the General Product Safety Directives of 1995 and 2001. It is very difficult for that defence to succeed since it has to be shown that the defendant was reasonably competent and that all the necessary steps were taken. The courts have shown that “all” means “pretty high”. That is entirely consistent with having a generally low key regulatory approach. The perception is that U.S. regulatory authorities are much more aggressive, in which case HC might want a different balance, for constitutional reasons, that is, a broader defence⁶³⁷.

Due diligence is a very difficult defence to make in the UK and has been for 30 to

⁶³⁷ Fairbairn: The scheme is highly self-regulatory, so there is a rationale for higher penalties and a higher burden on the defence.

40 years. That is a quid pro quo for a highly self regulatory system which, of course, preceded the GSPD for some time. The wording has been copied into successive statutes. It is arguably inconsistent with the EU policy under the GSPD Directive. Technically, it isn't, because the GSPD does not legislate "on that point".

If industry is putting all its faith on due diligence, it is probably on the wrong point. It does not appear that the UK industry, including small industry, has had any difficulty keeping up to speed with standards given the enforcement policy. Some small businesses have gone out of business with the introduction of the new regulation. But all businesses should be able to meet the "basic safety requirements" as part of the cost of being in business. There is some balance achieved, of course, through grant programs to encourage innovation. It is not felt that the GSPD sets the standard too high as it says almost nothing just that the supplier has to produce safe products⁶³⁸.

There is a technical issue about an inconsistency between the absolute liability regulatory regime and the product liability regime, also one of absolute liability. It is argued, usually in product liability cases. Industry has been mounting a defence that there should be a defence, in the product liability context, for regulatory compliance. That argument gains force with the more regulation there is and the clearer the regulatory and conduct standards are. This argument is not likely to gain much credence in Europe just now (presumably because of the state of consumer product legislation and standards).

The very limited case law on the GSPD makes it difficult to assess the impact of new and improving standards on the standard of care required to be shown to establish a due diligence defence. There seems to be a presumption that the natural result of new and improving standards will inevitably raise the bar on a due diligence defence, but the same might have been true no matter the reason standards were improved.

There seems to be general agreement that the words "took all the necessary steps to prevent the offence" and exercised due diligence, makes a due diligence defence very difficult to advance, especially in view of the absolute liability thrust of the Directive. The "all necessary steps" may be used to refer to improving standards of risk assessment and advanced process requirements in relation to new products. The UK is probably the only country in the EU to insist upon the due diligence defence which sits uncomfortably alongside the absolute liability posture of the Directive. The main use of the due diligence standard, likely, is to illustrate to clients what they may/must do to position themselves well to avoid a successful prosecution (i.e. by demonstrating that risk assessment has taken place, compliance plans have been drawn up, etc.) To that extent, the defence has some preventive value where clients may be expected to consult lawyers.

For harmonization purposes (i.e. to be published as an approved EU standard engaging the presumption of conformity), all harmonized standards must meet "essential requirements" under the relevant Directive. To the extent that this means "essential *safety* requirements", this may reasonably equate to minimum safety requirements being met within the due diligence test. ISO standards,

⁶³⁸ Fairbairn: This reinforces the need to help small business under a self regulatory scheme.

ironically, may tend to be lower than national standards simply by reason of the degree of compromise required to achieve a consensus at the international level. Standards developed for trade purposes when led by a major company may be protectionist in nature, or constitute a barrier to entry or survival of smaller firms.

25. Increase in the standard of Due Diligence and the development of a Culture of Safety

It is difficult to assess whether there has been an increase in the standard of due diligence since all kinds of dangers of a product cannot be covered (e.g. a knife is inherently dangerous, but necessarily so to be useful). What is looked for is whether the product is over represented in the number of accidents (based on data and reports from consumers and business federations). Then the first step might be to develop a new standard since standards developed 10 years ago do not represent the state of the art, new technologies have developed, often they become cheaper and more affordable. There is no concept of minimum standards in the GPSD.

The impact of standards on the tort standard of care is almost impossible to identify. It is clear however, that standards in practice have improved greatly over 40 years. A theoretical argument can be made that if there is a regulatory standard – an official standard – that it will affect the standard of care in the law of negligence over time. But what drives negligence is the end result of an injury. If there is an injury and you have contractual liability, fault liability and what the UK calls strict liability, the fact of a shift in the standard of care is not going to make a lot of practical difference. (In Canada, maybe more so, given the absence of an absolute liability component.⁶³⁹)

In Holland, the notification regulations were not implemented because there was concern about self-incrimination. This was not the case in the UK. Notification is seen to be one of the more important aspects of the regulations, certainly far more important than recall because it aids transparency. It means that where there is a risk people know about it. The UK enforcement authorities are not inclined to prosecute people if they put their hands up and say actually we've got a problem here and this is what we're doing about it. The authorities are trying to build relationships with businesses in their areas so that they can work jointly together to deal with problems. Prosecution means the system has failed largely; the intent is to make sure there is cooperation and voluntary action where it is necessary. So prosecution danger is meaningless in the UK.

Deterrent Nature of the GPSD

Since the Directive requires that there be an opportunity for business to state its case and that business does not want to appear in public to be obstructive, they might take remedial measures even if they disagree. The role of the GPSD in improving the behaviour of industry may be no more of a deterrent than the common law of negligence. Since the vast majority of products are safe, there is no need for overregulation or an aggressive enforcement policy. An important part of the UK's enforcement philosophy is encouraging compliance rather than using a big stick, although the big stick needs to be available. In the UK,

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historically, the only real problem has been with cheap electrical products from the Far East, some toys and children's clothing. Counterfeit goods are, now, a large problem.

26. Regulatory Liability of the regulated community and public authorities

This issue was not discussed at length, the opinion was that any attempt to sue a public authority in negligence for failing to react appropriately to complaints or notifications, would be a "wash". This, presumably, is a reference to the case law that modified the results of the *Anns* case that gave rise to this concern and which has been largely overturned in the UK, although the approach continues to influence Canadian law.

As for the regulatory liability of public authorities, the *Anns* case was the high point, but there have been some more recent cases modifying the effect of *Anns*. There are some academic articles as well. There have been a couple quite recently where the House of Lords said, quite frankly that people should assume some personal responsibility. There are very few cases against product regulatory authorities and none based on negligence.

Stakeholders' Position on Aspects of the GSR

27. Stakeholder reactions to GPSD

Consumers were generally very positive about GPSD, especially its wide scope. One specific problem was where the EC wanted to introduce child resistant lighters. They tried to develop a standard and planned to publish a reference to that standard in the Journal – resulting in a presumption of conformity. The problem was how to get rid of all the non-child resistant lighters. Several Member States and consumer organizations found this too weak. They wanted specific prescriptive legislation. The EC view was that a specific product, child resistant lighters, had too narrow a scope to warrant legislation. As a result, the EC has taken the view that all lighters must conform to the standard. Consumers might have wished for a stronger instrument.

Consumer groups say they have very little influence, and that is probably true. The view was that it is not clear whether that has made any real difference in the output. Consumer groups now have improved access to experts who are capable of sitting on these standardization bodies. Industry has its own problems in locating sufficient experts to do the work. There does not appear to be any evidence that the resulting standards are biased or ineffective. (Note the impact on public participation in an expert dominated process. Also, how far are the bodies moving beyond strictly technical to more subjective issues where direct input may be quite relevant⁶⁴⁰.)

Trade-driven international standards may not adequately address local safety concerns or local risk tolerances.

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Annex 7 - Case Law Related to the GPSD

Notwithstanding a paucity of case law related to the GPSD, there are a few noteworthy decisions concerning:

- The jurisdictional underpinnings of the GPSD in Europe;⁶⁴¹
- The scope of the European Commission's 'direct' authority to act against specific products and hazards;⁶⁴²
- The jurisdictional constraints against enacting Directives for the sole, or primary, purpose of protecting public health and safety (Challenge to EU's Tobacco Directive);⁶⁴³
- The interface between the GPSD and Member State legislation dealing with similar products or hazards (Second-hand car);⁶⁴⁴
- The exercise of the public authority's power to warn the public of dangerous products (Baby Walkers);⁶⁴⁵
- The extent to which the element of 'causation' in tort law is relevant, if at all, under a general product safety provision in assigning responsibility for successive failures to meet obligations imposed by the GPSD throughout the supply chain (for example, as an excuse for retailers seeking to escape their obligations under the GPSD where producers and distributors failed earlier to meet their own product testing obligations.) (Claw hammers imported from China);⁶⁴⁶
- The application of the defence of due diligence in a UK Criminal Court (toy caps for cap pistols);⁶⁴⁷

⁶⁴¹ *Federal Republic of Germany v Council of the European Union*, Case C-359/92.

European Court reports 1994 Page I-03681; accessed on September, 17, 2006, at: <http://www.bailii.org/cgi-bin/markup.cgi?doc=eu/cases/EUECJ/1994/C35992.html&query=%22general%20product%20safety%20%22>

⁶⁴² *Ibid.*, see also ECJ, Case C-376-98 dealing with directive 98/43/EC, banning tobacco advertising and sponsorship of tobacco products., European Court reports 1994 Page I-03681

⁶⁴³ *Ibid.*

⁶⁴⁴ *Caerphilly County Borough v. Stripp* [2000] E.W.J. No. 1779.

⁶⁴⁵ *Baby Products Assn. V. Liverpool City Council*, [1999] E.W.J. No. 6012; Case No: CO/3733/99, Also reported at: [2000] L.G.R. 171

⁶⁴⁶ See, *Padgett Brothers (A-Z) Limited vs The Coventry City Council*, CO/3892/97, H.C.J. (Queen's Bench, Divisional Court); accessed on September, 17, 2006 at <http://www.bailii.org/cgi-bin/markup.cgi?doc=ew/cases/EWHC/Admin/1998/20.html&query=%22general%20product%20safety%20%22>

⁶⁴⁷ *Powys County Council v. David Halsall International Limited*, CO/9162/2005 [2006] EWHC 613 (Admin), High Court of Justice Queen's Bench Division Divisional Court

- An approach to dealing with an alleged regulatory gap in the context of an application to amend pleadings (Felt Pen caps – childrens’ choking hazard);⁶⁴⁸
- The importance of leading evidence as to the degree of hazard presented by a product in a prosecution under GPSD regulations (Shaggy Dog soft toy);⁶⁴⁹ and
- Uncertainty in the formulation of a ‘Secondary’ Offence Under the GPSD (Laser Pointers).⁶⁵⁰

Jurisdictional Issues

In the *Federal Republic of Germany v Council of the European Union*,⁶⁵¹ the Court considered the jurisdictional basis of the General Product Safety Directive. Germany challenged the European Council’s authority under Article 9 of the GPSD ((92/59/EEC) to require Member States to take temporary remedial or corrective measures from among those listed in Article 6.⁶⁵² Germany argued that Council had no authority to apply the law *to individual cases* in the place of the national authorities, as permitted by Article 9 of the Directive.

The Court found that Article 100a(1) of the EC Treaty (now Article 95) provided the legal authority for the GPSD. That Article empowered the Council to adopt measures having as their object the abolition of barriers to trade arising from differences between the provisions laid down by law, regulation or administrative action in Member States. The harmonization effected by the GPSD was unique in that it provided for a form of "horizontal" harmonization.

Since the authority for the GPSD was trade-based, some linkage had to be made between product safety and establishing an internal European common market to sustain the European Council’s authority to act under Article 9. Articles 7 and 8 of the GPSD, the Court found, “entrusted the Commission with the task of supervising measures taken by Member States which are likely to hinder trade.”⁶⁵³ The Court summarized its position as follows:

⁶⁴⁸ *R. v. Newcastleupon Tyne Magistrate’s Court (Ex parte Poundstretcher Limited,)* [1998] EWHC Admin 251 (3rd March, 1998), accessed on September, 17, 2006, <http://www.bailii.org/cgi-bin/markup.cgi?doc=ew/cases/EWHC/Admin/1998/251.html&query=%22general%20product%20safety%20%22>

⁶⁴⁹ *The Queen v. The West Midlands Magistrates, Ex Parte PMS International Group PLC*, [1993] E.W.J. No. 3485, CO 1446/92

⁶⁵⁰ *R. v. Thames Magistrates Court (Ex Parte Academy International PLC)*, H.C.J. C.O. C.).-293-99, [1999] EWHC Admin 548 (June 14, 1999)

⁶⁵¹ European Court reports 1994 Page I-03681, accessed on September 13 at <http://www.bailii.org/cgi-bin/markup.cgi?doc=eu/cases/EUECJ/1994/C35992.html&query=%22general%20product%20safety%20%22>

⁶⁵² The measures include such matters as imposing conditions of marketing particular products, public warnings, prohibiting supply, and organizing withdrawal of the product.

⁶⁵³ *Ibid.*, para. 27 Under Article 7, Member States must inform the Commission of measures which restrict the placing of a product or product batch on the market or require its withdrawal from the market, specifying their reasons for adopting them. Under Article 8, Member States must as a matter of urgency inform the Commission of emergency measures which they have adopted or decided to adopt in order to prevent, restrict or impose specific conditions on the possible marketing or use, within their territory, of a

As is apparent from the eighteenth, nineteenth and twentieth recitals of the preamble to the Directive and from the structure of Article 9, the purpose of that provision is to enable the Commission to adopt, as promptly as possible, temporary measures applicable throughout the Community with respect to a product which presents a serious and immediate risk to the health and safety of consumers, so as to ensure compliance with the objectives of the Directive. *The free movement of goods can be secured only if product safety requirements do not differ significantly from one Member State to another.* A high level of protection can be achieved only if dangerous products are subject to appropriate measures in all the Member States.⁶⁵⁴

The Court concluded, therefore, that Council action under Article 9 of the GPSD was not contrary to Article 100a(1) of the Treaty establishing the European Union. The measures which the Council is empowered to take under that provision, it stated, are aimed at "the establishment and functioning of the internal market". In certain fields, and particularly in that of product safety "the approximation of general laws alone may not be sufficient to ensure the unity of the market." The Court also found that the concept of "measures for the approximation" of legislation must be interpreted as encompassing the Council's power to lay down measures relating to a specific products or class of products and, if necessary, individual measures concerning those products."⁶⁵⁵

Trade? Or Public Health and Safety? The Dominant Purpose Consideration (Tobacco Advertising)

While the protection of public health and safety may properly be an *incidental* purpose of the GPSD, actions taken under the GPSD having no real or substantial connection to establishing or enhancing internal trade will be found to be void in Europe. This is clear from Germany's challenge⁶⁵⁶ to an EC Directive banning advertising and sponsorship of tobacco products throughout the Community. The challenge was based on various grounds, including that:

- The Directive presented no appreciable obstacles to trade in tobacco advertising media or to the exercise by advertising agencies of their freedom to provide services and that there was no appreciable distortion of competition between such agencies, and
- That recourse to Article 100a (the legal authority underpinning the GPSD) was not possible *where the 'centre of gravity of a measure is focused not on promoting the internal market but on protecting public health.*

With respect to Article 100a of the Treaty, Germany submitted, firstly, that Article 100a granted the Community legislature competence to harmonize national legislation to the extent to which harmonization is necessary in order to promote the internal market. *But a mere reference to that article in the preamble to the*

product or product batch by reason of a serious and immediate risk presented by the said product or product batch to the health and safety of consumers. Member States may also pass on to the Commission any information in their possession regarding the existence of a serious and immediate risk before deciding to adopt the measures in question.

⁶⁵⁴ *Ibid.*, para. 34

⁶⁵⁵ *Ibid.*, para. 37

⁶⁵⁶ ECJ, Case C-376-98 dealing with directive 98/43/EC, banning tobacco advertising and sponsorship of tobacco products.

measure adopted is not sufficient, otherwise judicial review of the selection of Article 100a as a legal basis would be rendered impossible. *The measure must actually contribute to the improvement of the internal market.*⁶⁵⁷ Germany argued that the Directive had the contrary effect in that it had “the sole result of introducing new permanent obstacles to trade, whether immediately or in the future.”⁶⁵⁸

The Court found for Germany and voided the Tobacco Advertising Directive notwithstanding a vigorous defence by the European Parliament and Council and a series of supportive interveners, including France, the United Kingdom, Finland and the Commission of the European Communities.

The Court stated that a measure adopted on the basis of Article 100a of the EC Treaty *must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market*. The Court, nevertheless, noted that, if the conditions for recourse to Articles 100a, 57(2) and 66 as a legal basis were fulfilled, the Community legislature could not be prevented from relying on that legal basis *on the ground that public health protection is a decisive factor in the choices to be made* because the third paragraph of Article 129(1) provided that health requirements were to form a constituent part of the Community's *other* policies and Article 100a(3) expressly required that, in the process of harmonization, a high level of human health protection is to be ensured.⁶⁵⁹

In brief, the dominant purpose of a Directive under the section of the EC Treaty upon which the GPSD is founded (Article 100a) must be the ‘improvement of the conditions for the establishment and functioning of the internal market’, although a public health and safety objective may be considered as an *ancillary*, albeit sometimes decisive, factor in a particular case.

In this case, however, the court found that, for numerous types of advertising prohibited by the Tobacco Advertising Directive, the prohibition could not be justified by any need to eliminate obstacles to the free movement of advertising media or the freedom to provide services in the field of advertising.⁶⁶⁰ Implicitly, the Court found that the Tobacco Advertising Directive - founded on the same authority as the General Product Safety Directive - had the protection of health and safety as its *dominant* purpose and was, therefore, invalid.

To North Americans, this may seem a somewhat convoluted approach to dealing with safety issues, but it is clearly an inescapable ‘fact of life’ in Europe in order to meet jurisdictional requirements. For what seemed so clearly a public health and safety initiative, it is instructive to read the ingenious, detailed, and trade-based arguments, both for and against the validity of Europe’s Tobacco Advertising Directive. It is difficult to determine how far European safety initiatives are adversely affected by the ‘trade and industry’ focus, but is the

⁶⁵⁷ *Ibid.* para 23

⁶⁵⁸ *Ibid.* para. 27

⁶⁵⁹ *Ibid.*, para 84

⁶⁶⁰ For example, the prohibition of advertising on posters, parasols, ashtrays and other articles used in hotels, restaurants and cafés, and the prohibition of advertising spots in cinemas, prohibitions which in no way helped to facilitate trade in the products concerned.

subject of some comment in this Paper under the heading *Implementation and Operational Experience*.

Interface with Sectoral Regulations

In this case, the respondent, a car dealer, was charged with supplying a second-hand VW Golf motor car found to be a dangerous product, contrary to Regulation 13(b) of the *UK General Product Safety Regulations 1994* and Section 2 of the *European Communities Act 1972*. The Respondent objected that the applicant authority had not pleaded, as it might have done, that the offence also constituted an offence under the *Road Traffic Act, 1988*.

The essential question was whether, in circumstances where the prosecution wished to proceed against a motor trader who has offered to supply a second-hand car which it was alleged to be so defective as to be in a dangerous condition, the prosecuting authority may, if they choose, proceed under the 1994 UK General Product Safety Regulations, or whether they are *obliged* to proceed, if at all, under the provisions of the *Road Traffic Act 1988*.

The choice in the manner of proceeding was significant to the Retailer because the penalties under the *Road Traffic Act* were considerably less and involved no possibility of imprisonment. There were, however, some important practical advantages to the Appellant Public Authority in terms of available sanctions, reduced inspection costs and administrative expediency in proceeding under the General Product Safety Requirement:

The two provisions plainly complement each other to a very large extent. As might be expected, however, there is a practical reason why the appellants wish to bring proceedings under the Regulations rather than the Act. By Section 77 of the 1988 Act, authorised examiners are empowered to enter premises to inspect the condition of motor vehicles offered for sale. However, only qualified vehicle examiners are so authorised under the 1988 Act. Different considerations apply to enforcement of the provisions of the 1994 Regulations which grant powers of entry, search and inspection to local authority officials who are not qualified vehicle examiners. It is thus easier and cheaper for the local authority to use its own inhouse officials rather than using the powers under the 1988 Act.

No doubt that is what happened in this case, and it explains why there was no application to amend the summons to allege an offence under the 1988 Act. If the evidence of alleged defects had been obtained by inspectors exercising their powers under the 1994 Regulations, there would be plain evidential difficulties in the way of the prosecution.

The Court concluded that the definition of “dangerous product” in the General Safety Regulations was very broad and included the observed defects presented by the second-hand Volkswagen in question. The Court noted that the General Product Safety regulations did not apply, however, to “any product where there are specific provisions *in rules of Community law* governing all aspects of the safety of the product.” Since the national Road Traffic Act was domestic law, and not a rule of Community law within the meaning of the Regulation, the Court found that the prosecution had discretion to proceed under the General Product Safety Regulations.

Exercise of the Public Authority's Power to Warn the Public of Dangerous Products

In *Baby Products Assn. V. Liverpool City Council*, the court examined a public authority's power to warn of dangerous products under the GPSD. In this case, the Court found that the Authority's press release was contrary to law by reason of the Authority's failure to comply with statutory conditions precedent to the exercise of the power, which conditions provided for important legal safeguards for the producer.⁶⁶¹

On 28 April 1998 Liverpool City Council issued a press release concerning some models of babywalker, which were said to fail standard tests of safety. The issue on this application was whether, in issuing that press release, the Council acted unlawfully. The ground of challenge was not that the Council acted irrationally or in bad faith or with any improper motive, nor was the Council accused of procedural unfairness. The sole ground of challenge was that, having regard to the legislative scheme governing regulation of the safety of consumer products, it was beyond the power of the Council to issue the press release which it did.

On 28 April 1998 the Council issued the disputed press release announcing that samples of ten models of babywalkers had been tested and found not to comply with the British Standard Safety specification. In the previous month, Council had warned the applicant (unincorporated trade association representing the interests of manufacturers and importers of baby products) of its intention to issue the press release. Solicitors for the applicant had strongly contested alleged non-compliance and challenged the Council's authority to issue the proposed release, which, nevertheless, proceeded.

At the time of this case, the enforcement provisions for the General Product Safety Regulations were those contained in the *Consumer Protection Act, 1987*. In reviewing the provisions governing suspension, prohibition and warning notices, carefully noted the safeguard provisions against the arbitrary exercise of the Authority's power to notify the public directly of dangerous goods, including the producers rights to make oral and written representations to the Authority, rights of further appeal, rights to compensation in some circumstances.

In the result, the Court found that the Council had attempted to do indirectly with a prematurely released warning notice, what it should have done directly using formal powers of suspension and prohibition after giving the producers an opportunity contest the Council's actions:

Mr Fordham accepted that, generally speaking, it was open to local authorities to publish information relating to their activities, at any rate within their areas. Had the Council issued suspension notices in accordance with section 14 of the Act, that fact could (he accepted) have been announced to the public. Had the Council initiated any criminal proceedings that fact, and the outcome of such proceedings, could similarly have been announced to the public. Sections 142(2) and 111(1) gave authority to make such announcements if statutory authority was needed. *What, however, was impermissible was to make a public announcement having an intention and effect which could only be achieved by implementation of clear and particular procedures prescribed in an Act of*

⁶⁶¹ 1999] E.W.J. No. 6012; Case No: CO/3733/99, Also reported at: [2000] L.G.R. 171

*Parliament when the effect of the announcement was to deny the companies the rights and protections which Parliament had enacted they should enjoy. So to act was to circumvent the provisions of the legislation and to act unlawfully*⁶⁶²
(emphasis added)

Throughout this Paper, reference is made to the enormous discretion given to officials under a General Safety Requirement and the corresponding need to balance these new powers with appropriate legal safeguards. This case illustrates the manner in which the UK has sought to achieve that balance.

Whether Failure of Producer and Distributor in Duty of Care Excuses Retailer

In *Padgett Brothers (A-Z) Limited vs The Coventry City Council*,⁶⁶³ the facts found and were these.

In 1995 Padgett imported a consignment of something over 12,000 claw hammers from China. A term of the contract for the supply had been that they must meet British Safety Standards. When they arrived, an employee of Padgetts tested a number of these hammers by striking them against the ground and, as they did not break, he concluded that the tools fulfilled the contractual requirement. No more rigorous tests were carried out.

Some of these hammers were subsequently sold to a wholesaler (Westcliffe), with a oral assurance that they were safe. That wholesaler could have demanded written evidence that they met the relevant British Safety Standard or could have had safety tests conducted itself, but in fact the wholesaler did neither of these things.

The wholesaler then sold some of the hammers on to the retailer (Forum), and that retailer likewise could have demanded evidence that the hammers were safe or could have had them tested, but in fact did neither.

On 13th March 1996 the retailer sold three of the hammers to a trading standards officer, a Mr Robinson, employed by the Respondent authority. When tested later against the requirements of the applicable safety standard (BS 876: 1995), all three of the hammers became distorted and the heads began to detach, thus failing the tests. When this was reported to the Appellant company, they made efforts to recall all of the hammers that they had supplied for sale.

No specific act or default by Padgetts (the retailer) was alleged other than the supply by them of the hammers into the distribution chain. The retailer asserted that there was no causal connection between that act and the commission of the offences by Forum (the wholesaler).

What the Appellants are saying here, as I understand it, is that the Appellants could perhaps have been properly convicted under Regulation 13(a) (placing on the market) but not under 13(b) (supply), because, so as far as the latter is concerned, failures further down the chain of supply, for example by the wholesaler or retailer, break the chain of causation.

It is, therefore, a straightforward submission that the Appellants make, and none

⁶⁶² *Ibid.*, para 22.

⁶⁶³ CO/3892/97, H.C.J. (Queen's Bench, Divisional Court); accessed on September, 17, 2006

the worse for that reason. However, as we shall see, the equally straightforward answer, in my judgment, on the facts of this case is that the chain of causation was not broken at all. The Appellants' act in supplying the unsafe hammer was, at the very least, an operative cause, I find, of the supply of the dangerous hammers later on by Forum to the prosecutor.⁶⁶⁴

The Court, however, agreed with the Respondents position that the GSP Regulations expressly anticipate that more than one person may be guilty of an offence in relation to the supply of an item to which the regulations apply.⁶⁶⁵ The Court agreed with Council that this reflects the overall scheme of the Regulations which places duties upon *both* the producer of the item (in this case the Appellants) and any distributor, effectively negating 'causal chain' arguments in tort.

In coming to this conclusion, the Court also relied on *Lamb v Sunderland and District Creamery, Limited*⁶⁶⁶ where there had been a supply by the Respondents to a retailer of deficient or defective milk. The Court in that case found that the mere selling of the defective milk constituted an act or default, and, furthermore, that two people may be convicted in such circumstances, namely the supplier and the retailer himself, if he has not used all due diligence.

Due Diligence

Powys County Council v. David Halsall International Limited,⁶⁶⁷ provides a recent, isolated, example of a successful due diligence defence under the UK General Product Safety Provision.

In *Powys*, the prosecution alleged that the accused supplied 'Sure Shot' ring caps (a Category One firework imported from Taiwan) that did not comply with the relevant requirements of Part 2 of British Standard 7114, when tested in accordance with the appropriate test method in Part 3 of BS7114 contrary to Regulation 3(1) of the *Fireworks (Safety) Regulations 1997* and section 12 of the *Consumer Protection Act, 1987*.

The respondent had imported from Taiwan Sure Shot 96 Ring Caps ("the caps") and supplied Builth Bargain Centre with this product. The caps were supplied in plastic rings of eight caps per ring, but packaged in two different ways. A different product code was allocated, dependent on the packaging: product code 40388 as a pack of two tubes, each tube containing 6 rings; product code 40389 in a blister pack card, containing 15 rings.

Tests were conducted by the County Trading Council following a complaint by a member of the Institute of Quality Assurance.that the sampled caps were defective. They did not meet the construction and performance criteria of part 2

⁶⁶⁴ *Ibid.*,

⁶⁶⁵ Regulation 15 of the General Product Safety Regulation, 1994, provided:

"Where the commission by any person of an offence to which regulation 14 [the due diligence regulation] above applies is due to the act or default committed by some other person in the course of a commercial activity of his, the other person shall be guilty of an offence and may be proceeded against and punished by virtue of this paragraph whether or not proceedings are taken against the first-mentioned person."

⁶⁶⁶ [1951] 1 KB 923,

⁶⁶⁷ CO/9162/2005, [2006] EWHC 613 (Admin), High Court of Justice Queen's Bench Division Divisional Court

of BS7114, in that: they failed to meet the construction and performance criteria as two of the primary packs contained more than five patches of exposed composition, and upon test firing a cap in each pack, five of the caps tested communicated the explosive reaction to more than 50 per cent of the remaining caps in the pack;

The tests conducted by the company differed from those conducted by the Council. The respondent had not arranged independent laboratory testing for 40388 or 40389, but had relied upon a report from Intertek Taiwan's test that 40389 met BS7114. (Intertek Taiwan is a worldwide testing company independent of retailers or manufacturers). The products coded 40388 and 40389 were almost identical. The packaged product 40389 was British standard compliant and tests in the UK were not necessary. There was no UK company at that time available to undertake independent testing on caps. The respondent was aware of this and made in-house testing arrangements.

The details of the Company's defence of due diligence, ultimately approved at trial and on appeal, were pleaded as follows:

1. Being aware that there was not an accredited UK laboratory, the company established procedures whereby each shipment of product 40388 was tested by in-house procedures, which were reasonable and sufficient in all the circumstances.

2. By developing staff training and quality control standards, and applying those standards and compiling manuals for reference.

3. The product 40389 was tested by an independent foreign testing house and found to comply with BS7114. Product 40388 and 40389 differ only in type of packaging and number of rings in each pack. Therefore by implication product 40388 was also compliant.

4. The respondent company employed a statistician to develop statistical sampling techniques for both products coded 40388 and 40389. Upon receipt of each and every shipment sampling for quality and safety of the product would take place.

5. The statistician developed a formula to calculate the number of products to be sampled from each consignment:

2,400 received -- 16.5 tested.

18,000 received -- 16.8 tested.

The sample figures were rounded up.

A test sample of 17 would apply to shipments varying from 2,400 to 150,000.

6. The in-house testing comprised: recording the dates of the product deliveries; recording the date tested; checking the quantity delivered; checking the manufacturer's grade assigned by the respondent ie: grade B (UK); checking the wording of warnings on packaging; checking the print is in English; a visual check to ensure there was no loose powder within the packaging of the caps; the caps were fired using a cap gun.

7. The in-house tests above were the same as BS7114 composition tests. The communications test within BS7114 was not the same as the firing test, but was directly comparable. Had the product sample tested by Mr North been subject to the in-house procedures, the defect would have been identified and the product

withdrawn from supply.

8. Whilst it is accepted that testing was not carried out to BS7114, the in-house testing procedure established by the statistician and administered by the quality control manager ensured the product was safe for supply to the public.”

On appeal, Council had strongly challenged the Company’s claim (paragraph 7, above) that the in-house ‘composition’ test and the BS 7114 ‘communications’ test were ‘comparable’.

14 In his skeleton argument, on behalf of the appellant, Mr Crowther submitted that there was no evidence before the justices from which they could properly come to the view that the respondent’s firing test was directly comparable with the ignition test in BS7114. He further submitted that the preponderance of the evidence suggested significant differences, not least that one test was carried out in packaging and another with the ring caps installed in the cap gun. There was no evidence before the justices from which they could conclude that the firing tests adopted would ensure the supply of a safe product; rather, the evidence showed incontrovertibly that there had been no safety testing of the supplied caps in their packaging. There was no evidence before the justices from which they could properly conclude that the results of the manufacturer’s tests on ring caps 40389 would apply equally to ring caps 40388, as the test was carried out on packaging, and the packaging was different, holding the rings of caps in contact with each other in 40388 but separate and apart in 40389. There was no evidence upon which the justices could properly conclude that members of the public were granted the same level of protection as though BS7114 tests had been undertaken, as no equivalent testing had been undertaken. It was accordingly submitted that the justices erred in finding that the company had acted with all due diligence and had taken reasonable precautions.

As compelling as those arguments might have been, the appeal was in the form of a ‘stated case’ on questions of law and the Council had neglected to pose a question as to whether there was sufficient evidence on the question of comparability of the tests, or to order the trial transcripts for the Appellate Court to review. The Appellate Court, therefore, was left with the findings of the Magistrates below that the tests were comparable.

While the value of this case suffers from procedural defects, it does provide an excellent, though isolated, example of just how difficult it is for a defendant to establish a defence of due diligence in the U.K under the General Product Safety regime. Notwithstanding the detailed efforts made by the Company in its in-house testing program, and the absence of any independent testing laboratories in the UK to undertake such testing, the Company’s successful result in this decision must be qualified as a ‘close call’. Had a question been posed on the sufficiency of the evidence establishing the comparability of the tests, the decision might easily have gone the other way.

Use of the GPSD to Deal with Regulatory Gaps

In *R. v. Newcastle Upon Tyne Magistrate’s Court (Ex parte Poundstretcher Limited.)*,⁶⁶⁸ the central issue was whether a charge should have been laid under

⁶⁶⁸ [1998] EWHC Admin 251 (3rd March, 1998), accessed on September, 17, 2006, accessed on September, 18, 2006 at <http://www.bailii.org/cgi-bin/markup.cgi?doc=ew/cases/EWHC/Admin/1998/251.html&query=%22general%20product%20safety%20%22>

the General Product Safety Regulations, or as regulations under the Toys Directive. Council had sought to amend the charge and the respondent retrailer objected, on the grounds that a six month limitation period had expired and no new charges could be laid.

In *Poundstretcher*, the facts were as follows:

The applicant is a retailer of various goods including children's toys. On 16 July 1996 a Trading Standards Enforcement Officer employed by the Newcastle upon Tyne City Council entered the applicant's trading premises at Kingston Park Shopping Centre, Newcastle upon Tyne and purchased four "Kids Collection" art sets. Each of these sets included three coloured fibre-tipped pens. The sets were subsequently forwarded to the public analyst's laboratory for testing in accordance with British Standard 7272 of 1990, which is the British Standard specification for safety caps for writing and marking instruments, in order to determine the air flow through the caps of the fibre-tipped pens. Paragraph 3.4 of the specification provides that caps shall permit a minimum air flow of 8 litres a minute. The ten caps that were tested failed to meet this requirement. The air flow achieved in each case was less than one litre a minute. A report to this effect was produced to the City Council on 11 September 1996. In addition to this report, in December 1996 the City Council obtained a statement from an ear, nose and throat surgeon to the effect that any pen top which is readily accessible to small children, and which does not conform to British Standards 7272, represents an asphyxiation hazard to a child and if inhaled will cause irreversible brain damage within a few minutes."

On the basis of this information, the Council laid an information alleging a contravention of regulation 7 of the General Products Safety Regulations 1994, which provided that no producer shall place a product on the market unless the product is safe. Regulation 3(c) provided that the 1994 regulations *do not apply* to any where there are specific provisions in rules of Community law governing all aspects of the safety of the product. Regulation 4 provided that:

The requirements of these Regulations apply to a product where the product is the subject of provisions of Community law other than the GPS Directive *insofar as those provisions do not make specific provision governing an aspect of the safety of the product.*

In fact, the broad risk in question (suffocation) was covered in 1995 regulations enacted under the E.U.'s Toys Directive, the essential requirements of which were that:

Toys and their parts and the packaging in which they are contained for retail sale must not present risk of strangulation or suffocation.

The enforcement officers were aware of the existence and significance of both the Toys and the General Product Safety regulations. They decided that it was not appropriate to lay the information under the Toys regulations for two reasons:

First, they were aware that testing for compliance with the 1995 (Toys) regulations is usually done by reference to British Standard 5665, the British Standard relating to the safety of toys. The specific risk of inhalation of pen tops

is not covered by this standard. For that reason, therefore, they thought that the 1995 regulations did not make relevant specific provisions such as to exclude the 1994 regulations. Secondly, they had regard to paragraph 1(d) of section 2 of Schedule 2 to the 1995 (Toys) regulations, which states:

‘Toys and their component parts and any detachable parts of toys which are clearly intended for use by children under 36 months old must be of such dimensions as to prevent their being swallowed and/or inhaled.’”

The enforcement officers therefore considered that there was a gap in the 1995 (Toys) regulations, in that the specific risk of swallowing and inhaling was only covered in respect of children under 36 months old. The 1995 regulations made no provision in respect of this specific risk for children over 36 months old. Since a product must, however, be generally safe, the officers laid an information under the provisions of the 1994 (General Product Safety) regulations. The applicant, argued that insufficient air flow through pen tops fell within Schedule 2 of the 1995 (Toys) regulations; that it was therefore a risk specifically covered by those regulations; and that consequently the 1994 regulations could not apply.

Without acknowledging the validity of the (retailer) applicant’s position on the correct charge, the enforcement authority sought leave to amend the information to include a charge under the Toys regulation largely because retailer’s own evidence (which had been served on the Council) showed that the pens were unsafe because of the risk associated with insufficient air flow through the pen tops.

The issue of the correct charge was not ultimately dealt with in this case, except in so far as to determine the enforcement authority’s application to amend the information after the expiration of a six month limitation period for laying an information. The Court allowed the amendment, noting that the offences charged were not materially different, and there would be no prejudice to the retailer in doing so.

Importance of Leading Evidence on the Degree of Hazard Presented by a Product

In *The Queen vs. The West Midlands Magistrates, Ex Parte PMS International Group PLC*,⁶⁶⁹ a toy importer was charged under the GPSD regulations in relation to a ‘Shaggy Dog’ soft toy. A Trading Standards officer had purchased an example of the toy from a wholesale outlet for testing purposes.

The ‘Shaggy Dog’ was allegedly unsafe because its hair came out easily and could therefore choke its young owner. In the course of the hearing the Importer’s lawyer wished to cross-examine and lead evidence which included the attitude of the trade and other manufacturers to the risk involved in this type of toy, the opinion of British standards or those involved with British standards as to the risk involved in this type of toy being on the market, and evidence about whether or not there had been incidents of the kind alleged to constitute the risk here involving similar toys.

⁶⁶⁹ [1993] E.W.J. No. 3485, CO 1446/92

The Magistrates refused to allow the proposed cross examination and, though requested to do so, refused to state a case for an Appellate Court on the grounds that the application was frivolous.

The Appellate Court, in ordering the Magistrates to state a case for their consideration, emphasized the importance of the evidence which the Importer had sought to present:

No doubt there are cases where the question of the admissibility of the evidence, which is always a question of law, is of such minimal importance to the real issues in the case and its outcome, that the Justices would be justified in refusing to state a case. But in my judgment that obviously is not the case here. This was a substantial point. It clearly did affect the conduct of the Applicant's defence to the charge and there can be no basis upon which the Magistrates, properly directing themselves could have concluded that the application to state a case was frivolous. Indeed, in the affidavit they do not say why they considered it to be frivolous. In my judgment it was not a frivolous application and therefore the application for mandamus should be granted.

Uncertainty in the formulation of a 'Secondary' Offence Under the GPSD / Due Diligence

R. v. Thames Magistrates Court (Ex Parte Academy International PLC),⁶⁷⁰ involved an application by an importer of laser pointers for judicial review of a decision of the Metropolitan Magistrate at Thames Magistrates' Court that a prosecution of it for a "secondary" or "bypass" offence contrary to Regulation 13(b) of the General Product Safety Regulations 1994 was not time-barred by virtue of a six month limitation period in the *Magistrates' Courts Act 1980*.

Regulation 13(b) of the UK's GPSD regulation makes it an offence for a producer or distributor to possess for supply a dangerous various product. Regulation 14 provides a defence of due diligence which, if it involves an allegation that the offence was another's fault, the alleged primary offender must notify the prosecutor at least 7 days before the hearing of the proceedings. Regulation 15 provides for what the Court called a "secondary" or "bypass" offence by that other where a Regulation 14 defence applied. It provides:

Where the commission by any person of an offence to which regulation 14 above applies is due to the act or default committed by some other person in the course of a commercial activity of his, the other person shall be guilty of an offence and may be proceeded against and punished by virtue of this paragraph whether or not proceedings are taken against the first-mentioned person.

Under the 1994 GPS regulations, a penalty was provided for a breach of the General Product Safety provision, but no separate penalty was provided for regulation 15. The importer argued that it was unclear by reason of the wording of regulation 15 and the absence of any specified penalty, whether the regulation 15 (secondary) offence was a separate offence from that created by the GPS provision (in which case the limitation period had expired), or was simply a provision deeming the GPS offence to have been committed by the third party. The importer argued that certainty was a cardinal requirement of penal legislation

⁶⁷⁰ H.C.J. C.O. C.).-293-99, [1999] EWHC Admin 548 (June 14, 1999)

and, due to the uncertainty alleged in relation to the by pass offence, the charge should be dismissed.

Mr de Haan emphasised that a statutory provision should not be interpreted as having a penal effect so as to deem a person guilty of a criminal offence committed by another *in the absence of very clear language*. He prayed in aid *the need for certainty in penal legislation, not only a cardinal principle of our domestic law but as recognised by European Union law and enshrined in Article 7 of the European Convention of Human Rights*. He cited as applications of the general principle in those regimes: *R v Kirk* [1984] ECR 2689; *Westminster City Council v Blenheim Leisure (Restaurants) Limited*, 12 February 1999 (unreported); *Kokkinakis v Greece* (1993) EHRR 397; and *Hertel v Switzerland* (59/1997/843/1049). As Mr De Haan acknowledged, those regimes state general principles, which are familiar in English domestic law, and the particular factual applications of them in the authorities to which he referred are of little assistance on the issue of interpretation arising in this case. (emphasis added)

The Court concluded that, in reading the GPS regulation as a whole, there was no uncertainty. There was a clear and certain provision by Regulation 15 (the secondary offence) in the circumstances specified for guilt under Regulation 13 (the primary GPS offence) for which Regulation 17 (the penalty provision) expressly provided a penalty. For that reason Regulation 16 operated expressly to extend the time limit to such a prosecution, from the usual six months under the Magistrate's Court Act to 12 months under the 1994 UK *General Product Safety Regulation*. In concluding, the Court stated:

I am reassured by the good sense of the outcome, for I can see no good reason why the draftsman of the Act would have wished to differentiate between the two types of offender in this respect. The Regulation 15 procedure may often only be engaged after the alleged principal offender is the subject of proceedings and has served the requisite notice on the prosecutor, which may be up to 7 days before the hearing of the case. There could be an argument for giving the prosecution longer time in which to institute proceedings against the secondary offender than against the principal offender. Mr de Haan suggested that this is merely a theoretical possibility, since prosecuting local authorities are normally likely to be put on notice of a possible secondary offender at an early stage of their investigation. Whether or not that is so, the machinery of the Regulations contemplates that the Regulation 14 procedure may be initiated by the primary offender at a late stage in the proceedings which could be well into the limitation period.

Annex 8 - Reporting Obligations and Notification Requirements

Reporting Obligations:

Legislative commentary prepared by the department anticipates that suppliers (“any person who manufactures, imports, distributes, promotes or markets a product or an activity”) would be responsible for “reporting adverse health incidents, as prescribed by regulation.” (B3.2.3) In addressing offences or prohibitions, the legislation is expected to establish that “no person shall fail to report adverse health incidents, as prescribed by regulation.”(B2.7)

An initial observation with regard to the reporting requirement is that it serves, even within the context of a general safety requirement, as a residual safety net. It exists to provide a systematic basis to identify and where appropriate to respond to situations in which an unsafe consumer product may have entered the market-place either because pre-market assessment failed to identify the existence of some form of risk, under-estimated the likelihood or severity of a risk, or because such assessment was not, in fact, ever undertaken.

What is involved in fulfilling the reporting obligation then falls to be determined. In general, we can identify several components of the reporting obligation:

- The threshold or trigger: What degree of severity is required to constitute an adverse incident of a reportable nature?
- Form of reporting: What information is required in a report? In what manner is it to be presented? To whom is it to be provided?
- Timeliness: Within what period of time from the moment a supplier has knowledge of an adverse incident should the report be provided?

There is clearly room for variation in relation to each of these elements. If the threshold is set too low, there is a risk that minor or trivial incidents might overwhelm the capacity of officials to perform review functions effectively. The information provided needs to be responsive to the nature of the hazard while respecting victim privacy and other elements of the legal process. With regard to the latter, it may be worth highlighting that suppliers are required to report adverse incidents; they are not required to report that they have or may have committed an offence relating to an unsafe product or products. As Elizabeth notes in the Implementation Case Study Report, it must also be determined whether reports would be submitted to Health Canada in Ottawa, to regional offices, or to provincial or territorial officials. Reports should be provided in a timely manner but requirements must permit some reasonable compliance period, bearing in mind the varied capacities of those subject to the reporting requirement and the existence of a penalty for failure to comply.

In connection with timing, for example, several options would appear to be available. Reports might be required on a uniformly fixed delivery schedule, either at fixed intervals, or within a fixed number of days of a reportable incident. Or, reporting requirements might vary depending upon the severity of the incident, with injury reporting allowing for a longer delay than in circumstances involving death. Generic or notional requirements are also possible, taking the form of “forthwith,” “immediately,” or “without delay.”

While each of these matters remains to be determined, we can nonetheless look to experience in other settings for some guidance as to what might be involved. Sources of such guidance include the European and American contexts where similar issues have already been addressed and other Canadian legislation where adverse incident reporting requirements presently exist. Each of these is briefly discussed in turn.

Europe:

The reporting obligations of producers and distributors within the European context are described in the current Directive (Article 5.3) as follows:

“Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof ...”

Annex 1 to the Directive sets out in more detail the manner in which this reporting obligation is to be carried out, noting in particular that in the context of “serious risks” the information provided shall address at least the following matters:

- Information enabling a precise identification of the product or batch of products in question;
- A full description of the risk that the products in question present;
- All available information relevant for tracing the product;
- A description of the action undertaken to prevent risks to consumers.⁶⁷¹

United States:

Reporting requirements under the US Consumer Product Safety Act will be addressed to some degree by Professor Nick Ashford in Annex 12. Here, for convenience are the reporting provisions of what is conveniently referred to as section 15 of the U.S. CPSA:

- (a) For purposes of this section, the term “substantial product hazard” means—
- (1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or
 - (2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.
- (b) Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product—
- (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9;
 - (2) contains a defect which could create a substantial product hazard described in subsection (a)(2); or

⁶⁷¹ See also: European Commission, *Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC*, December 2004.:

http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf

(3) creates an unreasonable risk of serious injury or death, shall immediately inform the Commission of such failure to comply, of such defect, or of such risk, unless such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such defect, failure to comply, or such risk.

[*Consumer Product Safety Act*, 15 USC §2064(b).]⁶⁷²

Canada:

Many Canadian statutes currently require those involved in an operational capacity in a wide range of industries and activities to provide information or to report adverse incidents to officials. These generally provide the foundation for follow-up action either by government or the responsible parties in order to prevent or minimize injury to health or the environment.

In the environmental context, CEPA, 1999 contains general and specific provisions concerning information gathering. A general authority over information gathering is set out in CEPA, 1999 sec. 46 where the Minister, for such purposes as conducting research, creating a data base or inventory, issuing guidelines, or reporting on the state of the environment may, on the basis of a notice in the *Canada Gazette* or elsewhere require “any person described in the notice to provide the Minister with any information that may be in the possession of that person or to which that person may reasonably be expected to have access.” The types of information required to be provided under this authority include information relating to a wide range of substances governed by the legislation. The information obtained pursuant to sec. 46 constitutes the basis for a *National Pollutant Release Inventory* which the Minister is required to establish. Further information and discussion on NPRI, timeliness of reporting, confidentiality requests, etc. is available: Commission for Environmental Co-operation, *North American Environmental Law and Policy*, Vol. 10, *Public Access to Government-held Environmental Information and The Precautionary Principle in North American and International Law*.⁶⁷³

In connection with Toxic Substances addressed in CEPA, provides that:

Where a person (a) imports, manufactures, transports, processes or distributes a substance for commercial purposes, or (b) uses a substance in a commercial manufacturing or processing activity, and obtains information that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic, the person shall without delay provide the information to the Minister unless the person has actual knowledge that the Minister has the information.⁶⁷⁴

Canada’s new Pest Control Products Act (2002) also provides for more formal post-registration control of pesticides. In particular requirements are included for reporting new information concerning health and environmental risks of registered pesticides. In response to such reports, the Minister may initiate a Special Review and must alert the public concerning significant risks. In cases where data has not been provided, the Minister may remove pesticides from the market.

⁶⁷² See also: US Consumer Product Safety Commission, *Regulated Products Handbook*, 3rd Edition, January 2005, Washington, DC: <http://www.cpsc.gov/BUSINFO/8001.pdf>

⁶⁷³ (Montreal: Yvon Blais, 2003) 63-5; see also Molly Grindley

⁶⁷⁴ 1999 Part V, section 70

It is also noteworthy that a range of adverse reporting requirements are now found in relation to a range of regulated products within the general mandate of Health Canada. For convenience, these and some supplementary documentation are reviewed here.

In respect of adverse reporting, the *Food and Drug Regulations*⁶⁷⁵ require that:

(1) No manufacturer shall sell a drug unless the manufacturer, with respect to any adverse drug reaction or any serious adverse drug reaction known to the manufacturer that occurs after this section comes into force, *furnishes to the Director*

(a) a report of *all information in respect of any serious adverse drug reaction that has occurred in Canada with respect to the drug*, within 15 days after receiving the information; and

(b) a report of *all information in respect of any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug*, within 15 days after receiving the information.

(2) The manufacturer shall, *on an annual basis* and whenever requested to do so by the Director, *conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions* to a drug referred to in subsection (1) and prepare a summary report in respect of the reports received during the previous twelve months or received during such period of time as the Director may specify.

(3) Where, after reviewing any report furnished pursuant to subsection (1) and any available safety data relating to the drug, the Director considers that the drug may not be safe when used under the recommended conditions of use, the Director may, for the purpose of assessing the safety of the drug, request in writing, that the manufacturer submit

(a) case reports of all adverse drug reactions and serious adverse drug reactions to that drug that are known to the manufacturer; and

(b) a summary report prepared pursuant to subsection (2).

(4) The manufacturer shall submit the case reports and summary report referred to in subsection (3) within 30 days after receiving the request from the Director.⁶⁷⁶

Similar requirements exist under the *Natural Health Products Regulations*.⁶⁷⁷

24. (1) A licensee *shall provide the Minister with*

(a) *a case report for each serious adverse reaction to the natural health product that occurs inside Canada*, within 15 days after the day on which the licensee becomes aware of the reaction; and

(b) *a case report for each serious unexpected adverse reaction to the natural health product that occurs inside or outside Canada*, within 15 days after the day on which the licensee becomes aware of the reaction.

⁶⁷⁵ *Food and Drug Regulations*, C.R.C., c. 870.

⁶⁷⁶ *Ibid.*, at para. C.01.016 *et seq.* as am. by: SOR/95-521, s. 2. [Emphasis added.]

⁶⁷⁷ SOR 2003-196

(2) A licensee who sells a natural health product shall annually prepare and maintain a *summary report* that contains a concise and critical analysis of

(a) *all adverse reactions to the natural health product* that have occurred inside Canada; and

(b) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(i) during the previous 12 months, and

(ii) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

(3) If after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the natural health product, the Minister has reasonable grounds to believe that the natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that, within 30 days after the day on which the request is received, the licensee

(a) provide to the Minister a copy of any summary report prepared under subsection (2); or

(b) prepare and provide to the Minister an interim summary report containing a concise and critical analysis of

(i) all adverse reactions to the natural health product that have occurred inside Canada, and

(ii) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(A) since the date of the most recent summary report prepared under subsection (2), and

(B) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.⁶⁷⁸

Again, under the *Medical Devices Regulations*:⁶⁷⁹

60. (1) *A preliminary report shall be submitted to the Minister*

(a) *in respect of an incident that occurs in Canada*

(i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, *if the incident has led to the death or a serious deterioration in the state of health* of a patient, user or other person, or

(ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, *if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur*; and

(b) *in respect of an incident that occurs outside Canada*, as soon as possible after the manufacturer has indicated, to the regulatory agency

⁶⁷⁸ *Ibid.*, at s. 24 *et seq.* [Emphasis added.]

⁶⁷⁹ SOR/98-282.

referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.⁶⁸⁰

As the Case Study report indicated, the Health Product and Food Branch Inspectorate, has prepared a guidance document outlining expectations in relation to voluntary and mandatory reporting for medical devices. The guidance document is in respect of the *Medical Devices Regulations*,⁶⁸¹ promulgated under the *Food and Drugs Act*. The purpose of the *Regulation* is to compel manufacturers and importers of medical devices to disclose adverse incidents to Health Canada, in a timely⁶⁸² and standard⁶⁸³ manner.

The guidance document is particularly relevant for present purposes in light of its definition of "serious deterioration in the state of health" which serves as a trigger or threshold.

"Serious deterioration in the state of health" means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.⁶⁸⁴

The guidance document, more generally sets out to explain the requirements for manufacturers and importers of "medical devices."⁶⁸⁵ As the guidance document states:

Use of this guidance document will help to assure that all adverse incident reports are comprehensive and accurate. Please note that the guidance document is a supplement to the *Regulations* and not a replacement. If there are

⁶⁸⁰ *Ibid.*, at s. 60.

⁶⁸¹ SOR/98-282. [Regulation]

⁶⁸² For incidents occurring *within* Canada a "preliminary" report is required within 10 days of a manufacturer or importer becoming aware of an adverse incident where the patient dies, or suffers "a serious deterioration in the state of health" (s. 60(1)(a)(i)); and 30 days of an incident where the patient affected did not die or so suffer, but *could* were the incident to recur. (s. 60(1)(a)(ii)). For incidents occurring *outside* Canada, the manufacturer or importer is required to negotiate a time frame with Health Canada for reporting, but *only if* the incident prompted the manufacturer elected, or the foreign regulator required the manufacturer, to take "corrective action." (See *Regulation* at s. 60(1)(b) and Guidance Document at s. 2.3.3)

⁶⁸³ While a "standard form" has not yet been produced for "final reports." A standard form for preliminary reports is appended to the Guidance Document, and final reports are instructed to mirror that standard form.

⁶⁸⁴ *Ibid.*, at s. 1.

⁶⁸⁵ "Medical device" should be a defined term. The *regulation* defines the term as having the same meaning as in the *Food and Drugs Act*. However, "medical device" is not defined in the *Act*, nor does it even appear. "Device" is defined in the *Act* as:

any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
- (c) the diagnosis of pregnancy in human beings or animals, or
- (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug

any conflicts between the *Regulations* and this guidance document, the *Regulations* take precedence.⁶⁸⁶

The *Regulation* and the Guidance Document also provide for the *voluntary disclosure* of adverse incidents. The Guidance Document explains how manufacturers and importers of medical devices may do so.⁶⁸⁷

Existing reporting requirements attached to regulated products and incident reports that may eventually be made available for consumer products that have not been subject to pre-market regulatory approval will ordinarily be associated with specific product-related risks. To the extent, however, that there may be a broader policy interest in overall injury data it may be observed that reporting under a general safety requirement may make such a contribution as well.

Injury Data

It has recently been suggested that, “The disease that should be of most concern, especially to individuals under the age of 45, is a disease about which most people know very few facts – injury.”⁶⁸⁸ Although injuries, certainly the most severe of these, result in medical examination and treatment, comprehensive information as to the extent of the injury problem in Canada is lacking. Instead there is considerable reliance on extrapolation from selected data sources, for example, the Canadian Hospitals Injury Reporting and Prevention Program.⁶⁸⁹

Although medical reporting, in contrast with supplier reporting, is not central to this report, it is appropriate to mention elements of the inter-relationship. The central consideration is perhaps the extent to which – as we have noted in connection with principles of regulatory effectiveness and, in particular, compliance – a public policy problem has been clearly identified and understood, not only by regulators, but by members of the public and of the regulated community or communities. In the absence of reliable documentation concerning the extent of a consumer product safety problem in Canada, it may be difficult to summon sufficient political will and public support for a vigorous response such as the general safety requirement would represent.

One factor contributing to the lack of comprehensive data on consumer injury rates in Canada may be appreciated on the basis of the following observation:

In the course of treating patients, particularly in emergency wards, public health personnel may gather information about whether individuals were victims of crime, perpetrators of offences, or witnesses to crimes. Caregivers may not only obtain information, but may come into custody of physical evidence, ranging from bodily samples to instrumentalities of crime. While public health workers, like other citizens, may have a natural inclination to co-operate with the authorities in the investigation of offences, the basic rule is that public health workers and facilities must keep information and bodily samples gathered during treatment

⁶⁸⁶ Guidance Document, at s. 1.1.

⁶⁸⁷ See also: Health Canada’s Therapeutic Products Directorate, *Guidelines for the Canadian Pharmaceutical Industry on Reporting Adverse Reactions to Market Drugs (Vaccines Excluded)*, Revised July 2001. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/guide-ldir_indust_e.pdf

⁶⁸⁸ Ries et al, 219. For some indication of the burden of injury (said to be overwhelmingly associated with vehicles, falls and poisonings,) see Ries et al, 221-2

⁶⁸⁹ Ries et al, 269

confidential unless the patient provides informed consent, or the law otherwise permits or requires disclosure.⁶⁹⁰

The Role of Consumer Organizations

Consumer organizations potentially represent another source of more systematic access to product safety information. As reported by the European Commission in the context of the review of experience under EEC Directive 92/59 on General Product Safety, consumer organizations play varying roles:

In four countries consumer organizations play a special role in the field of product safety: France (lobbying and suing), Denmark (market surveillance), Austria (market surveillance and information on the law), and the Netherlands (safety tests, awareness-raising and training of professionals, drafting of a code of conduct on the emergency procedures). In the other countries the consumer organizations' role is normally confined to performing comparative tests, whose results are published in the magazines, and to collecting consumer complaints. In Ireland, Greece, Sweden, Finland, Portugal and Luxembourg consumer associations play a relatively minor role in the field of product safety at least.⁶⁹¹

Inter-jurisdictional Information Exchange and Responsibilities

Within the context of the European Union, where a Directive calling for general safety requirement legislation by Member States was introduced nearly fifteen years ago, concern for the well-being of other members of the community is unremarkable. It is notable, however, that at the time of the review of experience under this original Directive, the European Commission reported to Parliament and the Council that uncertainty and delays had arisen in connection with obligations to exchange information between Member States and that, despite general satisfaction, a number of difficulties had arisen in connection with emergency situations and the Rapid Exchange of Information System (RAPEX).⁶⁹²

Chapter IV of the revised Directive sets out the obligations and powers of Member States with Article 10 (2) (a) specifically addressing administrative cooperation around such issues as “ the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities.” Chapter V establishes the foundations for the exchange of information within the community concerning product safety and for provides for rapid intervention.

The small size of the Canadian marketplace suggest that consumer product safety information will limited, certainly in comparison with the more heavily-populated jurisdictions encompassed by the European Union and the United States. Thus it will be highly beneficial to maintain or establish arrangements for information exchange around product safety. In the case of the United States, that country's Consumer Product Safety Commission already contributes importantly to consumer safety in Canada: children's products recalled in the

⁶⁹⁰ Ries et al. 436 See also re significance of authorization/duty to disclose information about health incidents Ries et al. 436-9

⁶⁹¹ Commission report to the European Parliament and the Council on the experience acquired in the application of Directive 92/59/EEC on general product safety

⁶⁹² Commission Report to the European Parliament and the Council on the Experience Acquired in the Application of Directive 92/59/EEC on General Product Safety, COM/2000/0140 final

U.S. are automatically recalled in Canada. In the eighteen month period to June 2006, at least three quarters of the forty major recalls in Canada were initiated on this basis.⁶⁹³

The revised EU Directive also anticipates such relationships:

Access to RAPEX shall be open to applicant countries, third countries or international organizations, within the framework of agreements between the Community and those countries or international organizations, according to arrangements defined in these agreements. Any such agreements shall be based on reciprocity and include provisions of confidentiality corresponding to those applicable in the Community.⁶⁹⁴

The Community's recognition of the interests of third parties extends beyond reciprocal information exchange to affirmative measures of protection:

Export from the Community of dangerous products, which have been the subject of a decision, [at the Community level in relation to products posing serious risk to health and safety] shall be prohibited unless the decision provides otherwise.⁶⁹⁵

⁶⁹³ Carly Weeks, "Health Canada unable to ensure product safety" Ottawa Citizen 4 July 2006, p.5

⁶⁹⁴ Chapter V, Article 12 (4)

⁶⁹⁵ Chapter V, Article 13 (4)]

Annex 9 - Comment on Proposed (1994) Regulatory Efficiency Act

Excerpts from a Discussion Paper of the Law Reform Committee of the Parliament of Victoria, May 1997, on proposed "Regulatory Efficiency Legislation" similar to failed Canadian legislation⁶⁹⁶

Canadian Regulatory Efficiency Bill (C-62)

"3.4 The Committee believes that the first legislative embodiment of the concept of alternative compliance mechanisms is contained in the (Canadian) Regulatory Efficiency Bill (C-62) (the Canadian Bill). Under this Bill, which was introduced into the Canadian Parliament in 1994, Ministers would be able to approve alternative methods of complying with regulations applying to a particular business or industry.

3.6 Under the scheme proposed by the Canadian Bill, the Governor in Council, on the recommendation of the President of the Treasury Board and the Minister responsible for a particular set of regulations, would be able to make regulations designating:

(a) that the particular set of regulations may be subject to compliance plans;

(b) that any Act or regulation may be subject to 'administrative arrangements'; or

(c) that a Minister or other person or body act as the regulatory authority for approving proposed compliance plans or changes to approved compliance plans or for entering into administrative agreements.

Problems with the Canadian Bill (Regulatory Efficiency Act)

3.13 The Committee's current information is that the Canadian Bill lapsed and is unlikely to be reintroduced in the short term. It is useful to set out some of the reasons for this outcome, as they have relevance to elements of the Victorian proposal, which is set out in Chapter 4.

3.14 It appears to the Committee that one of the most significant reasons why the Canadian Bill has not received a smooth and speedy passage through the Canadian Parliament is that it was the subject of a fairly scathing report by the Standing Joint Committee for the Scrutiny of Regulations (the Canadian Scrutiny Committee). While taking no issue with the goals of the Canadian Bill (that is, to relieve the public, especially businesses, from the effects of unnecessarily burdensome or costly regulations and the like), the Canadian Scrutiny Committee stated that the Bill represented 'a major departure from traditions of

⁶⁹⁶ See Discussion Paper on Regulatory Efficiency Legislation by the Law Reform Committee of the Parliament of Victoria, accessed on September 25, 2006, at :

http://www.parliament.vic.gov.au/lawreform/Regulatory_Efficiency/ref/may97/default.htm#TopOfPage

law and government' and, as a result, 'ought to be very carefully examined and tested'.

3.15 The Committee believes that it is important to set out the concerns of the Canadian Scrutiny Committee in detail because of the likelihood that similar concerns will be expressed in relation to the Victorian proposals. Those proposals will then have to be examined against the Canadian concerns, to see whether (and to what extent) the Victorian proposals warrant similar concern.

3.16 The particular problems that the Canadian Scrutiny Committee identified were:

(a) that it would give the Executive a discretion to grant dispensations from the operation of subordinate laws in favour of individuals; and

(b) that it was inconsistent with other constitutional values.

3.17 In relation to the first of these issues, the Canadian Scrutiny Committee said that the scheme proposed by the Canadian Bill amounted to a partial abrogation of the Bill of Rights of 1689, which declared illegal the exercise of a power of dispensation by the Crown. If the Executive was given the power to grant dispensations from subordinate laws, the Committee questioned how long it would be before another government sought to extend its authority to the ability to grant dispensations from not just regulations but statutes themselves in the name of efficiency.

3.18 In relation to the second issue, the Canadian Scrutiny Committee stated that the Canadian Bill was contrary to the Rule of Law, because:

It would put into place a system whereby governmental authorities have an uncontrolled and unreviewable discretion to set aside the law in particular instances and substitute for it a private agreement that is not legislative in nature but that would nevertheless be made binding on persons who are not parties to it. For the first time in this country, citizens could be convicted and fined or imprisoned, not because they disobeyed a law, but because they disobeyed a private agreement between a designated regulatory authority ... and their employer. Such a system can hardly be said to be consistent with the Rule of Law or with the principles of equity and fairness which are derived from it.

3.19 The Canadian Scrutiny Committee also expressed concerns that the Bill was contrary to the principles of equity and fairness. The Committee felt that the compliance scheme plan offended the principle of equality before the law as it put forward a system where there could eventually be 'as many different rules as there were persons initially subject to a particular Regulation. The Committee expressed the view that while it could be theoretically argued that the scheme allowed for equality of opportunity, giving all people an equal opportunity to seek a dispensation from regulations, practical reality dictated that those with greater financial resources would have better opportunities to gain approval of a compliance plan.

3.20 The Canadian Scrutiny Committee felt that the fairness of a system where large corporations could easily obtain dispensations from regulations while

smaller competitors due to their lack of resources continued to be bound by regulations, had to be questioned. They further questioned the fairness of a system where public officials did not have to justify their refusal of dispensations and where laws enacted by parliament could be set aside as a result of private negotiations without prior notice to other concerned people.

3.21 Finally, the Canadian Scrutiny Committee suggested that the proposals contained in the Canadian Bill were contrary to the principles of government accountability. This suggestion was made on the basis of an assessment that, under the operation of administrative arrangements, there would be no Minister answerable to the Parliament for a dispensation from the operation of a law. The Canadian Scrutiny Committee also stated that the tabling provisions in the Bill were 'ineffective'."

Annex 10 - Recall Under the UK General Product Safety Regulations, 2005 S.I. No. 1803

15. — (1) Subject to paragraph (4), where an enforcement authority has reasonable grounds for believing that a product is a dangerous product and that it has already been supplied or made available to consumers, the authority may serve a notice ("a recall notice") requiring the person on whom it is served to use his reasonable endeavours to organize the return of the product from consumers to that person or to such other person as is specified in the notice.

(2) A recall notice may require—

(a) the recall to be effected in accordance with a code of practice applicable to the product concerned, or

(b) the recipient of the recall notice to—

(i) contact consumers who have purchased the product in order to inform them of the recall, where and to the extent it is practicable to do so,

(ii) publish a notice in such form and such manner as is likely to bring to the attention of purchasers of the product the risk the product poses and the fact of the recall, or

(iii) make arrangements for the collection or return of the product from consumers who have purchased it or for its disposal,

and may impose such additional requirements on the recipient of the notice as are reasonable and practicable with a view to achieving the return of the product from consumers to the person specified in the notice or its disposal.

(3) In determining what requirements to include in a recall notice, the enforcement authority shall take into consideration the need to encourage distributors, users and consumers to contribute to its implementation.

(4) A recall notice may only be issued by an enforcement authority where—

(a) other action which it may require under these Regulations would not suffice to prevent the risks concerned to the health and safety of persons,

(b) the action being undertaken by the producer or the distributor concerned in fulfillment of his obligations under these Regulations is unsatisfactory or insufficient to prevent the risks concerned to the health and safety of persons, and

(c) the authority has given not less than seven days notice to the

person on whom the recall notice is to be served of its intention to serve such a notice and where that person has before the expiry of that period by notice required the authority to seek the advice of such person as the Institute determines on the questions of—

- (i) whether the product is a dangerous product,
- (ii) whether the issue of a recall notice is proportionate to the seriousness of the risk, and
- (iii) the authority has taken account of such advice.

(5) Paragraphs (4)(b) and (c) shall not apply in the case of a product posing a serious risk requiring, in the view of the enforcement authority, urgent action.

(6) Where a person requires an enforcement authority to seek advice as referred to in paragraph (4)(c), that person shall be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the authority.

(7) In paragraphs 4(c) and (6) "the Institute" means the charitable organization with registered number 803725 and known as the Chartered Institute of Arbitrators.

(8) A recall notice served by an enforcement authority in relation to a product may require the person on whom it is served to keep the authority informed of the whereabouts of any such product to which the recall notice relates, so far as he is able to do so.

(9) Where the conditions in paragraph (1) for serving a recall notice are satisfied and either the enforcement authority has been unable to identify any person on whom to serve a recall notice, or the person on whom such a notice has been served has failed to comply with it, then the authority may itself take such action as could have been required by a recall notice.

(10) Where—

- (a) an authority has complied with the requirements of paragraph (4); and
- (b) the authority has exercised its powers under paragraph (9) to take action following the failure of the person on whom the recall notice has been served to comply with that notice,

then the authority may recover from the person on whom the notice was served summarily as a civil debt, any costs or expenses reasonably incurred by it in undertaking the action referred to in sub-paragraph (b).

(11) A civil debt recoverable under the preceding paragraph may be recovered—

- (a) in England and Wales by way of complaint (as mentioned in section 58 of the Magistrates' Courts Act 1980,

(b) in Northern Ireland in proceedings under Article 62 of the Magistrate's Court (Northern Ireland) Order 1981.

Annex 11 - Interim Order Provision – *The Hazardous Products Act*⁶⁹⁷

5.1 (1) The Minister may make an *interim order that contains any provision that may be contained in a regulation made under this Part* if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health or safety.

5.2

(2) The Minister may make an interim order in which any power referred to in section 6 is deemed to be exercised, *if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health or safety.*

(3) An interim order has effect from the time that it is made but *ceases to have effect* on the earliest of

(a) 14 days after it is made, unless it is approved by the Governor in Council,

(b) the day on which it is repealed,

(c) in the case of an interim order made under subsection (1), the day on which a regulation made under this Part that has the same effect as the interim order comes into force and, in the case of an interim order made under subsection (2), the day on which an order made by the Governor in Council under this Part that has the same effect as the interim order comes into force, and

(d) one year after the interim order is made or any shorter period that may be specified in the interim order.

(4) *No person shall be convicted of an offence consisting of a contravention of an interim order that, at the time of the alleged contravention, had not been published in the Canada Gazette unless it is proved that, at the time of the alleged contravention, the person had been notified of the interim order or reasonable steps had been taken to bring the purport of the interim order to the notice of those persons likely to be affected by it.*

(5) An interim order

(a) is exempt from the application of sections 3, 5 and 11 of the *Statutory Instruments Act*; and

(b) shall be *published* in the *Canada Gazette* within 23 days after it is made.

(6) For the purpose of any provision of this Part other than this section, any reference to regulations made under this Act is deemed to include interim orders, and any reference to a regulation made under a specified provision of this Act is deemed to include a reference to the portion of an interim order

⁶⁹⁷ (S.C. 2004, c. 15, s. 67)

containing any provision that may be contained in a regulation made under the specified provision.

(7) A copy of each interim order must be tabled in each House of Parliament within 15 days after it is made

8) In order to comply with subsection (7), the interim order may be sent to the Clerk of the House if the House is not sitting. (emphasis added)

Annex 12 – Nicholas A. Ashford

Options for a Statutory General Safety Requirement (GSR): Lessons from Selected Experiences in the United States

Introduction: The Legal and Policy Framework for Consumer Protection

Product Safety in the US Legal System

The safety of consumer products, devices, materials, chemicals, pharmaceuticals, cosmetics, food, equipment, machinery and motor vehicles -- hereafter collectively called 'products' -- for consumers and users is addressed in advanced economies through both common-law traditions and legislation. In the United States, common-law protection is generally provided through the case-developed state law, sometimes later codified in state statutes, reflected in tort traditions and the availability of injunctive relief to protect consumers from harmful products.

Federal statutory protection for consumer products is provided by the Federal Consumer Product Safety Act and for hazardous substances through the Federal Hazardous Substances Act, both administered by the U.S. Consumer Product Safety Commission. Excluded from both acts are pesticides, tobacco, pharmaceuticals, food, medical devices, cosmetics, motor vehicles and firearms. Harms from those categories are protected by their own particularized statutes. Other countries' jurisdictions may differ as to what is protected under general, as opposed to particularized product safety.

Activities Relevant to Product Safety

The plethora of activities relevant to product safety include:

- Designing a safe product at the outset;
- Choosing to market or use a safely-designed – or safer designed -- product from readily available options (off-the-shelf);
- Establishing guidelines or mandatory standards for the safety of some aspect of a product – including product characteristics, labels, and product bans, recalls, & seizures;
- Controlling the hazardous or harmful aspects of a product;
- Providing meaningful warnings, instructions and antidotes;
- Mitigating the harm from a dangerous product;
- Monitoring and tracking the harms once the product is in commerce (data collection);
- Reporting harm/harmful incidents from a product, if known;
- Recalling a product; and
- Compensating those harmed/injured.

The first two activities – developing or adopting a safe/safer product – are proactive or preventive in nature. Activities falling into the third activity – standards and guidelines -- are preventive/proactive only to the extent that they encourage technical improvements in product safety; requirements reflecting existing technological options may foster diffusion of best practices, but are much less likely to encourage product technology innovation. Actions falling into the fourth

activity include secondary prevention approaches such as cut-off electrical devices, blade shields, and the like. These approaches are acknowledged as reactive, rather than proactive; they might be described as 'end-of-pipe' approaches in that they do not require changes in the functioning concept of the product or in the fundamental product design. The fifth activity shifts the avoidance of injury onto the user. The remaining activities are mitigating or minimizing damage, rather than preventing harm in the first place. In examining or developing options for government intervention, one important criterion is the extent to which a particular intervention mainly fosters primary prevention, secondary prevention, or mitigation.

Not all of these activities are backed up by statutory Directives, and not all statutory Directives appear in the same legislation. Statutory provisions may create an affirmative duty on the part of government or those that introduce the product into commerce – or they may simply encourage one or more of these practices. Standards may be nothing more than voluntary guidelines, or they may be requirements for voluntary commercial certification, or they take the form of mandatory requirements/regulations. Adherence to, or departures from, these varying requirements have different consequences for common-law or statutory liability as to both the admissibility as evidence and as to the creation of presumptions of guilt or innocence of violations of legal duties and liabilities.

Since the 1980's in the United States, two somewhat contrary trends are visible: (1) the movement of producer responsibility from the *control* of risk to the *prevention* of possible harm and (2) the trend towards greater reliance on voluntary action, rather than on government imposition of responsibilities. In Europe, these two trends are also visible, and volunteerism characterized most early European approaches, but recently the need for stronger government has been recognized and the rise of the importance of environment in the European Union's legal structure has caused Europe and the EU to "trade places" with regard to regulatory aggressiveness and the creation of mandatory standards in environmental, health and safety regulation⁶⁹⁸. Within Europe, philosophical tensions continue between some EU bureaucrats who tend to favor voluntary approaches involving all the stakeholders, characteristic of the "corporatist state", and some 'northern' EU members who press for more Directive, mandatory standards. In spite of these political waves, lessons relevant to a GSR can be learned from both arenas.

Terminology

Terminology turns out to be important and in need of clarification. Regrettably, in the European realm, 'standards' sometimes mean mandatory requirements and sometimes, voluntary guidelines. This confusion is accelerated by the activities of the ISO and other private 'standard'- setting bodies. The term 'Regulation' tends to be unambiguously mandatory.

Another confusion attends the label 'performance'. It is an adjective-label that is both attached to the term 'standard' and is found in the term 'performance-based approach.' For our purposes, a performance standard is one that specifies compliance with a safety aspect of a product describing it's safety-relevant

⁶⁹⁸ Vogel, David (2003) The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe, *British Journal of Political Science* 33: 557-580.

characteristics, e.g., 'being able to withstand a pressure of 250 lbs/square inch' or 'not containing phthalates'. Performance standards are preferred by the CPSC. They are distinguished from 'specification standards' that usually specify content/product characteristics in a positive sense – e.g., 'made of chromium steel' or 'wood treated with anti-fungal chemicals'. (The line is not always a sharp one, e.g., is requiring a transformer to have an output of 6 volts with an operating input of 110-240 volts a performance or specification standard?) Performance standards give more leeway to the product provider or user, while specification standards tend to be more restrictive in choices. That is one reason they are favored by product manufacturers and users. On the other hand, commercial actors – especially small ones or those in developing countries -- are not always in a position to make informed choices and welcome clarity associated with specification standards. In the context of trade, exporters from developing countries suspect that specification standards – indeed the entire ISO regime -- are being used to minimize competition. WTO Trade disputes are scrupulous about examining whether standards are masquerading as non-tariff trade barriers. Other standards include product bans and labels describing contents, articulating warnings, and providing instructions as to product use.

Voluntary Versus Mandatory Approaches

So-called 'performance-based approaches' to ensuring product safety are used in two different senses. One is to encourage performance standards, rather than overly-detailed specification standards. The other meaning is as a euphemism for voluntary, rather than mandatory requirements, be they performance or specification in nature.⁶⁹⁹ The literature is unfortunately mixed on the usage. Terms such as "common-sense approaches," "regulatory reinvention" "incentive-based compliance evaluation," etc. should raise a red-flag as emphasizing voluntary approaches and the discouragement of mandatory requirements, reflecting a laissez-faire approach to product safety. Of course, and combination of mandatory and voluntary approaches might be indicated in a specific jurisdiction or system. Two different questions should be kept in mind when comparing (or choosing) approaches: (1) which approaches or combinations of approaches are favored in achieving compliance with existing guidelines? and (2) which approaches or combinations of approaches are more likely to favor 'a culture of safety' that fosters inherently-safer⁷⁰⁰ design, marketing and use of product? These different questions suggest different evaluation criteria and philosophies.

Incentives and Disincentives

The government, producers and consumers all have potentially important roles in advancing product safety. The government may be committed to a strong Directive role if it has an emboldened sense of its responsibility under the 'social contract'. Otherwise, government action appears reactively in support of strong government involvement only after some social disaster such as that which followed the occurrence of asbestos-related harms, the Ford Pinto automobile injuries, BSD/mad cow disease, the VIOXX problem, and the like. Note that government does not attempt to sell voluntary programs following these kinds of disasters and events.

⁶⁹⁹ See Coglianesi, Cary and Jennifer Nash (eds.) (2001) Regulating from the Inside, Resources for the Future, Washington DC.

⁷⁰⁰ See the discussion of inherent safety in Section 4 *infra*.

Producers may be motivated by cost considerations that flow directly marketing unsafe products or by enlightened self-interest to avoid product recalls, withdrawals, or tort litigation, but it would be a stretch to say this latter motivation is sufficient to ensure the public safety – especially where advertising and re-branding products can mitigate the losses brought about by harm to reputation, such as with the Ford Explorer and renaming Firestone Tires. In the U.S., the tendency of courts of appeals to dramatically reduce punitive damages has taken the bite out of tort as a financial deterrent. It is true that some producers – e.g., Volvo in automobiles and Fisher-Price in toys – do actively market product safety, but this is a rare occurrence. Mandatory and voluntary standards do have an evidentiary role to play in tort, depending on the particular state or jurisdiction in which suit is brought or in the U.S. which state laws are followed in federal diversity cases, but since tort is generally acknowledged to be a waning deterrent in the U.S., the differences may not be all that important. At a minimum, violation of either a mandatory or voluntary industry standard is evidence of negligence.

Consumers may be safety conscious on their own, but usually an organization – such as the Consumers Union, The National Consumers League, the National Coalition Against the Misuse of Pesticides, the Center for Auto Safety, or Ralph Nader’s Health Research Group (on pharmaceuticals) – can be traced to fostering increased consumer awareness through their activities, publications, and lawsuits. Readily-available information on product-related injuries provided by either government (for example the CPSC’s product injury tracking system – the National Electronic Injury Surveillance System) or NGOs is essential for fostering active participation of consumers in product safety. Some consumer groups participate in private standard-setting organizations such as the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM), or the National Fire Protection Association (NFPA). Individuals (citizens or academics) may participate in ‘professional’ organizations that influence worker health and safety such as the American Conference of Governmental Industrial Hygienists (ACGIH) concerned with the toxic effects of chemicals or the American Society of Safety Engineers (ASSE).

Life-cycle Considerations and Extended Producer Responsibility

In a real sense, developing policies focusing only on the consumer safety aspects of products is out-of-date. Environmental pollution and safety risks from the extraction of materials, their transformation into feedstocks and starting materials for product manufacturing, product manufacturing, transportation, product use, and product disposal are all part of the life-cycle of products⁷⁰¹. While the EU Integrated Product Policy (discussed later) focuses mostly on environmental impact, it does pay some attention to consumer safety associated with products. Partial attempts to integrate various stages of a product’s life are reflected in the developing laws implementing extended producer responsibility, whereby producers of industrial chemicals have obligations to ensure safe use by their industrial customers, buy-back provisions are established as with used motor-oil in Germany, and the EU WEEE Initiative for electronics establishes a complex system linking producers and users. The essential point, of course, is

⁷⁰¹ See Geiser, Kenneth (2001) Materials Matter: Towards a Sustainable Materials Policy, MIT Press, Cambridge, MA, 479 pages.

that these various health, safety, and environmental concerns ideally should be taken into account at the design stage, where the choice of materials, manufacturing methods, safety, and disposal consequences must be considered. The design of sustainable products is an important part of sustainable development.

In the remainder of this paper, we address important features of the U.S. and EU regulatory systems that suggest options for a GSR, the role of standards and guidelines in tort and product liability in ensuring product safety, prevention and inherent safety: technological innovation in product and process design, and compatibility of a GSR with U.S. regulatory traditions and practice.

The Regulatory System

In this section, we not only review authorities and practices of the U.S. Consumer Product Safety Commission, we also explore the possible contributions of the authorities under (1) the 'general duty' requirement to provide a safe workplace under the US Occupational Safety and Health Act, (2) the 'general duty' requirement to design and maintain a safe (chemical) plant under the US Clean Air Act Section 112r, (3) the US Pollution Prevention Act, (4) the EU Seveso Directives for chemical plant safety, and (5) the EU Integrated Product Policy (emphasizing eco-design) in support of creating an affirmative duty to design, maintain, and periodically review the safety of consumer products in a General Safety Requirement in order to promote a 'culture of safety'.

The interplay between the regulation of product safety and liability for harmful and/or defective products is important but very different in the United States and the EU. For an insightful treatment, see Geraint G. Howells, *International Torts: A Comparative Study: The Relationship Between Product Liability and Product Safety -- Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position*, Spring, 2000, 39 *Washburn L.J.* 305-346.

Product Safety Regulation under the U.S. Consumer Product Safety Act (CPSA) of 1972 as amended and the Federal Hazardous Substances Act (FHSA)

Section 4 (15 U.S.C. Sec. 2053) of the CPSA establishes the Consumer Product Safety Commission and provides: that the Commission is a five-member "independent regulatory commission" headed by a chairperson. The members are appointed by the President, but with limitations on presidential power: (a) no more than three can come from the same political party; (b) there is a seven year fixed term; (c) removal is allowed only for "neglect of duty or malfeasance in office;" (d) no member can have a direct tie with the industry.

The CPSA 15 U.S.C. Section 2051 et seq. states as its purposes:

- (1) to protect the public against unreasonable risks of injury associated with consumer products;
- (2) to assist consumers in evaluating the comparative safety of consumer products;

- (3) to develop uniform safety standards for consumer products...; and
- (4) to promote research and investigation into the causes of product-related deaths, illnesses, and injuries.

On its face, and in regulatory practice, the term ‘unreasonable risks’ in the first purpose anticipates a social balancing/cost-benefit approach between providing consumer protection and minimizing the burden to industry. Indeed preparation of a “regulatory analysis” is a statutory requirement precedent to establishing a consumer product safety rule.⁷⁰² Predating the emergence of the ‘precautionary principle,’ the strength of evidence justifying the existence of risks before CPSC imposing regulations has varied with Administrations. However, in the area of toxic substances, the Fifth Circuit Court of Appeals review of CPSC’s proposed standard for Urea Formaldehyde Foam,⁷⁰³ resulted in the court’s invalidating the standard because carcinogenicity in one animal species was deemed insufficient to justify the standard. As in other environmental law cases, decisions of the Fifth Circuit – the geographical location of the U.S. petrochemical industry -- are a variance with those of the other circuit courts on the burden that environmental agencies need to bear to justify their actions.

In the early 1980s following the “Reagan Revolution,” CPSC authority for designating and regulating a substance (or article/product containing that substance) as a “hazardous substance” was transferred from the CPSA to the FHSA (15 U.S.C. Sections 1261–1278). Authority over such substance is retained “only if the Commission by rule finds that it is in the public interest to regulate such risk of injury...” A regulatory analysis identical to that required by Section 9(f)(2) of the CPSA is required before the CPSC can classify an article or substance as a banned hazardous substance or issue a regulation of toys or articles intended for use by children under the FHSA.

Legislative Authority Relevant to Product Safety: Promulgation of Mandatory Consumer Product Safety Standards, Labeling, Recalls, Bans, Seizures, and Data Collection

CPSA

Section 5 (15 U.S.C. Sec. 2054): CPSC “shall” perform a data-gathering function.

Section 7 (15 U.S.C. Sec. 2056): CPSC “may” promulgate consumer product safety standards (in accordance with the procedures set forth in section 9), which may be one or both of two types:

- (a) performance requirements; or
- (b) warnings or instructions.

Section 9(d)(2) [15 U.S.C. Sec. 2058(d)(2)]: a rule establishing a consumer product safety standard is to be promulgated according to notice-and-comment rulemaking, except that “an opportunity for the oral presentation of data, views, or arguments” is to be provided.

⁷⁰² Section 9(f)(2); 15 U.S.C. Sec. 2058(f)(2)

⁷⁰³ *Gulf South Insulation v. Consumer Product Safety Commission*, 701 Fed. Rep. 2nd ser. 1137 (Fifth Circuit Court, 1983).

Section 9(f)(3)(A) [15 U.S.C. Sec. 2058(f)(3)(A)]: CPSC cannot promulgate a consumer product safety standard unless it finds “that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury.”

However, as discussed below, there is now a preference stated in the act for voluntary (industry) standards over the promulgation of agency standards [Section 7b (15 U.S.C. Sec. 2056b)].

Section 8 (15 U.S.C. Sec. 2057): CPSC “may” ban a consumer product where:

- (a) the product presents an “unreasonable risk of injury,” and
- (b) a consumer product safety rule would not adequately address that risk.

CPSC must follow the procedural requirements of section 9 in promulgating such a ban.

Section 12 (15 U.S.C. Sec. 2061): Where there is an imminent and unreasonable risk of death, serious illness, or severe bodily injury, CPSC “may” seek appropriate relief (including seizure of the product) in the appropriate U.S. District Court.

Section 15 (15 U.S.C. Sec. 2064): Where there is a substantial risk of injury to the public, either because of a violation of a consumer product safety standard or because of a product “defect,” CPSC may require that notices of the risk be given, and may, after providing an opportunity for a hearing, order conformity, replacement, or rebate.

Section 30(d) [15 U.S.C. Sec. 2079(d)]: There is a “pass through” to the Federal Hazardous Substances Act [as well as the Poison Prevention Act (15 U.S.C. 1191 et seq.) and the Flammable Fabrics Act (Section 1191 et seq.)] for consumer products that (i) are (or contain) hazardous substances, and (ii) can be addressed adequately under that statute.

FHSA

Section 2(f) [15 U.S.C. Sec. 1261(f)] states that:

The term “hazardous substance” means:

- (1)(A) Any substance or mixture which is (i) toxic, (ii) corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or by other means, if such substance or mixture may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use...

Section 2(f) [15 U.S.C. Sec. 1261(f)]: any substance or mixture that meets one of the statutory definitions, or that is designated as hazardous by CPSC under the first statutory definition.

Exclusions: pesticides, drugs, food, and cosmetics, containerized fuels, tobacco products, and nuclear material regulated under the Atomic Energy Act.

Section 2(p) [15 U.S.C. Sec. 1261(p)]: A “misbranded hazardous substance” is any hazardous substance “intended, or packaged in a form suitable, for use in the household or by children,” which

- (i) fails to comply with an applicable labeling regulation issued by CPSC under the Poison Prevention Packaging Act; or
- (ii) fails to comply with the labeling requirements set forth in this section of the statute (or with more specific labeling requirements for this substance established by CPSC under section 3 of the FHSA).

Section 2(q)(1): A “banned hazardous substance” is

(A) any “toy, or other article intended for use by children,” which is or “bears or contains” a hazardous substance that is “susceptible to access by a child” to whom it is entrusted (although items such as chemistry sets are exempted); or

(B) a hazardous substance “intended, or packaged in a form suitable, for use in the household,” that the CPSC classifies as a banned hazardous substance after a finding that “notwithstanding such cautionary labeling as is or may be required under this Act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce.”

Section 3 (15 U.S.C. Sec. 1262) provides:

- (a) CPSC can, following designated Food Drug and Cosmetic Act (FDCA) procedures, declare a substance to be “hazardous” under the section 2(f)(A) definition.
- (b) CPSC can, if it finds that the labeling requirements of section 2(p) “are not adequate for the protection of public health and safety” from a particular hazardous substance, promulgate more specific labeling requirements for that substance.
- (c) & (d) If CPSC finds that full compliance with (some or all) the act’s labeling requirements “is impracticable or is not necessary for the protection of public health and safety,” or that the substance “is adequately regulated by other provisions of the law,” CPSC must (in the first case) and may (in the second case) exempt the substance from those labeling requirements.
- (f), (g) & (h) impose extensive procedural requirements on CPSC’s designation of a “banned” hazardous substance, give “any person” the

right to propose an existing standard (or develop a voluntary standard) meant to regulate the use of the substance rather than ban it, and require CPSC to promulgate such a standard (in lieu of a ban) if it finds that the standard will be adequate. Subsection (i) prohibits CPSC from banning a substance unless it first finds that the benefits of such a ban “bear a reasonable relationship to its costs,” and that the ban is “the least burdensome requirement which prevents or adequately reduces the risk.”

In classifying a substance as “hazardous,” or in banning a hazardous substance, CPSC must also follow certain procedures of the FDCA applicable to the establishment of a “standard of identity” for a food. These procedures give an objecting party the right to an evidentiary hearing.

Section 4 (15 U.S.C. Sec. 1263): The following acts are prohibited: (a) the introduction or delivery for introduction into commerce of a banned or misbranded hazardous substance; (b) the alteration, obliteration, etc., of a hazardous substance label so as to make the substance a “misbranded” hazardous substance.

Judicial Review of CPSC Decisions

Section 12 (15 U.S.C. Sec. 2061) of the CPSA: Judicial review is in the appropriate U.S. Court of Appeals; consumer product safety standards are subject to the “substantial evidence” standard; and attorney and expert witness fees are available to a prevailing party.

CPSC’s classification of a substance under the FHSA as a “hazardous substance” under the act is governed by section 409(g) of the FDCA – the agency’s findings and conclusions must be “based upon a fair evaluation of the entire record,” after a hearing.

Citizen’s Roles

Citizens may appeal, as above, if they are adversely affected by a CPSC rule issued under the CPSA or the FHSA.

Section 9(i) [15 U.S.C. Sec. 2058(i)] of the CPSA provides: citizens may petition for rulemaking under the APA, and CPSC must consider and respond.

Section 24 (15 U.S.C. Sec. 2073) of the CPSA provides: citizens may sue to enforce a consumer product safety standard, and may recover fees if they prevail.

Section 23 (15 U.S.C. Sec. 2072) of the CPSA provides: there is a private cause of action, for monetary damages, for injury caused by a violation of a consumer product safety standard; prevailing plaintiffs may recover fees.

Section 3(j) (15 U.S.C. 1262(j) of the FHSA provides: Anyone may petition CPSC for a rulemaking, and the agency must grant or deny the request within a “reasonable” time.

Voluntary Standards and Guidelines in the CPSC

Section 7b (15 U.S.C. Sec. 2056b): CPSC “shall rely upon voluntary consumer product safety standards rather than promulgate a consumer product safety ... whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed with such voluntary standards.” The origin of this section lies in the 1981 changes to the CPSC during the anti-regulatory period heralded by the election of Ronald Reagan.

Howells *supra* comments on the different attitudes towards voluntary standards in the U.S. and the EU:

[There is a] different nature of [voluntary] standards in the U.S. and Europe. Whereas in the U.S. these remain very much voluntary standards, established by private actors, in Europe, at least in areas covered by "New Approach Directives," their use has become quasi-mandatory.

The CPSC now works on eight to fourteen mandatory standards per year and forty to fifty voluntary standards. There are numerous standards writing organizations. The three with which the CPSC works most closely are the American National Standards Institute ("ANSI"), American Society for Testing and Materials ("ASTM"), and the Underwriters Laboratories, Inc. ("UL").

Voluntary standards have no legal effect as such. Although industry is often eager to develop voluntary standards and to comply with them, not only to help defend products liability claims and stave off any remaining threat of mandatory regulation, but also to use compliance as a marketing tool both at home and increasingly in the international marketplace. Also, if a producer inaccurately claims that its product conforms to a product safety standard when it does not, then it will be in breach of the truth and labeling laws administered by the Federal Trade Commission.

In the U.S., however, there is no bridge between mandatory and voluntary standards. Except in extreme cases, the U.S. system has forgone mandatory regulations and is left to rely upon freestanding voluntary standards. In contrast, in Europe, the legislatures have managed to keep a hand on the tiller of product safety regulation by developing Directives, which establish a framework that integrates voluntary standards. This integration is an effort to achieve those levels of safety considered politically desirable by means with which industry is comfortable. The integration of the standards into the legal framework has also permitted greater public participation in the formation of standards.

The extent of public or other stakeholder participation in the EU should not be overstated. As in the U.S., large manufacturers tend to dominate SMEs and consumer/citizen groups both of which have less time and ability to defray the costs of participation.

Finally, in both the U.S. and the EU context, one could argue that there has been a "privatization of the regulation," although perhaps to a different extent. Should Canada adopt either approach, care would have to be taken to ensure the changes are compatible with Canadian legal tradition.

Section 7b (15 U.S.C. Sec. 2056b): provides that for “any person [who] participates with the Commission in the development of a consumer product safety standard, the Commission may agree to contribute to that person’s cost...”

Originally, the obligation to report a consumer product safety problem obligation arose only when a person obtained information that the product failed to comply with an applicable consumer product safety rule or contained a defect which could create a substantial product hazard. In an attempt to increase the rate of reporting, the basis for reporting was extended by the Consumer Product Safety Improvement Act of 1990. The obligation to report is now triggered when a product fails to comply with a voluntary product safety standard relied upon by the CPSC and by situations where the product creates an unreasonable risk of serious injury or death [Section 15b (15 U.S.C. Sec. 2064(b))].

Dealing with Emerging, Unregulated or Orphan Risks

Either on its own initiative (described under the section on Legislative Authority above), or in response to a citizen petition (described under the CPSA and FHSA in the section on Citizens’ Roles above), the CPSC can take regulatory action.¹⁴

Extended Producer Responsibility

Manufacturers have no formalized responsibility under the CPSA or FHSA beyond the initial transmission of control to a buyer or recipient. However, should they become knowledgeable about a product defect or harmful product in the line of commercial/personal usage, responsibilities could ‘run with the product’. If the product is used in an unforeseeable and unintended way, product liability may not attend, but products may none-the-less be recalled by the CPSC.

Other Relevant U.S. Regulatory Regimes

The Occupational Safety and Health Act (the OSHA Act) of 1970

The OSHA Act of 1970 envisioned two routes to the creation of permanent worker safety and health standards: (1) the administrative adoption of so-called (industry) consensus standards, the adoption being restricted to a two year period at the beginning of the act’s implementation, and (2) the promulgation of permanent standards after a notice-and-comment period. The act also established a general duty on the part of employers to provide a ‘safe and healthful workplace.’ The OSHA experience with consensus standards, permanent standards and with the general duty obligation may be instructive in devising a General Safety Requirement or other means for advancing consumer product safety.

The consensus standards, while voluntary in their creation, were mandatory on employers under the law. The general purpose of the act was “to assure every working man and woman a safe and healthful workplace and place of employment as far as possible”. Thus, unlike the CPSA, the statute was to provide extensive protection, limited only by feasibility, and not subject to a cost-

benefit balancing. The technology-forcing aspects of OSHA standards are well-known and served as a model for other U.S. environmental regimes⁷⁰⁴.

OSHA can begin the promulgation of standards either on its own or in response to petitions from other parties, including the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health (NIOSH) under the Centers for Disease Control, state and local governments, any nationally-recognized standards-producing organization, employer or labor representatives, or any other interested person. The standard-setting process involves input from advisory committees and from NIOSH. When OSHA develops plans to propose, amend, or delete a standard, it publishes these intentions in the *Federal Register*. Subsequently, interested parties have opportunities to present arguments and pertinent evidence in writing or at public hearings. NIOSH, a non-regulatory scientific organization in CDC, has played a very significant role in OSHA standards development. There is no counterpart in the U.S. or in Europe for independent scientific advise on the safety of products.

Under certain conditions, OSHA is also authorized to set emergency temporary standards⁷⁰⁵, which take effect immediately, but which are to be followed by the establishment of permanent standards within 6 months. To set an emergency temporary standard, OSHA must first determine that workers are in grave danger from exposure to toxic substances or new hazards and are not adequately protected by existing standards. Both emergency temporary and permanent standards can be appealed through the federal courts, but filing an appeals petition does not delay the enforcement of the standard unless a court of appeals specifically orders it. Employers may make application to OSHA for a temporary variance from a standard or regulation if they lack the means to comply readily with it, or for a permanent variance if they can prove that their facilities or methods of operation provide employee protection that is at least as effective as that required by OSHA. The legal provision of variances could be important in the consumer product safety realm.

The OSHAct specifically addresses the subject of toxic materials. It states, in Section 6(b)(5) of the act, that the Secretary of Labor (through OSHA), in promulgating standards dealing with toxic materials or harmful physical agents, shall set the standard that “most adequately assures, *to the extent feasible*, on the basis of the *best available evidence* that no employee will suffer material impairment of health or functional capacity, even if such employee has a regular exposure to the hazard dealt with by such standard for the period of his working life” (emphases added). These words indicate that the issue of exposure to toxic chemicals or carcinogens that have long latency periods, as well as to reproductive hazards, is covered by the act in specific terms.

Under Section 6(b) of the OSHAct, new health standards dealing with toxic substances were to be established using the mechanism of an open hearing and subject to review by the U.S. Circuit Courts of Appeals. The evolution of case law associated with the handful of standards that OSHA promulgated through this

⁷⁰⁴ See Ashford, N. A. and Caldart, C.C. (1996). *Technology, Law and the Working Environment*. Washington, DC: Island Press.

⁷⁰⁵ This power is likened to the Canadian Minister’s power under the Canadian Hazardous Products Act to issue interim orders with respect to any matter that might be appropriate for a regulation (See *Hazardous Product Act*. 1985 section 5.1).

section of the OSHAct is worth considering in detail. The courts addressed the difficult issue of what is adequate scientific information necessary to sustain the requirement that the standards be supported by “substantial evidence on the record as a whole.” The cases also addressed the extent to which economic factors were permitted or required to be considered in the setting of the standards, the meaning of “feasibility,” OSHA’s technology-forcing authority, the question of whether a cost–benefit analysis was required or permitted, and, finally, the extent of the jurisdiction of OSHAct in addressing different degrees of risk.

In Section 6(c), the OSHAct authorizes OSHA to set, on publication in the *Federal Register* and without recourse to a formal hearing; *emergency temporary* (6-month) *standards* (ETSs) for toxic exposures constituting a “grave danger.” Before OSHA lowered its permanent standard for asbestos from 2.0 to 0.2 fibers/cm³, it attempted to protect workers by promulgating an ETS at 0.5 fibers/cm³. In 1984, the Fifth Circuit Court of Appeals denied OSHA the ETS, arguing that the cost involved defeated the requirement that the ETS be “necessary” to protect workers. Attempts by OSHA to establish an ETS for hexavalent chromium likewise failed court review.

In addition to requiring employers to comply with specific standards, the OSHAct imposes on virtually every employer in the private sector a general duty “to furnish to each of his employees employment and a place of employment which are free from *recognized hazards* that are causing or are likely to cause death or serious physical harm...” (emphasis added). A recognized hazard may be a substance for which the likelihood of harm has been the subject of research, giving rise to reasonable suspicion, or a substance for which an OSHA standard may or may not have been promulgated. The burden of proving that a particular substance is a recognized hazard and that industrial exposure to it results in a significant degree of exposure is placed on OSHA. Because standard setting is a slow process, protection of workers through the employer’s general duty obligation could be especially important, but it is crucially dependent on the existence of reliable safety or health effects data, as well as on the willingness of a particular OSHA administration to use this as a vehicle for protection.

In 1971, under Section 6(a) of the act, allowing for their adoption without critical review, OSHA initially adopted as standards the so-called *permissible exposure limits* (PELs): the 450 threshold limit values (TLVs) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) as guidelines for protection against the toxic effects of these materials. In the 1970s, under Section 6(b), OSHA set formal standards for asbestos, vinyl chloride, arsenic, dibromochloropropane, coke oven emissions, acrylonitrile, lead, cotton dust, and a group of 14 carcinogens. In the 1980s, OSHA regulated benzene, ethylene oxide, and formaldehyde as carcinogens and regulated asbestos more rigidly as a carcinogen at 0.2 fibers/cm³. In the early 1990s, OSHA regulated cadmium, bloodborne pathogens, glycol ethers, and confined spaces. OSHA also lowered the PEL for formaldehyde from 1 to 0.75 parts per million (ppm; averaged over an 8-hour period) and issued a *process safety management* (PSM) rule (see the discussion in the next section).

The inadequacy of the 450 TLVs adopted under Section 6(a) of the act is widely known. The TLVs originated as guidelines recommended by the ACGIH to

protect the *average* worker from either recognized acute effects or easily recognized chronic effects. The standards were based on animal toxicity data or the limited epidemiologic evidence available at the time (1969) of the establishment of the TLVs. They do not address sensitive populations within the workforce or those with prior exposure or existing disease, nor do they address the issues of carcinogenicity, mutagenicity, and teratogenicity. These standards were adopted en masse in 1971 as a part of the consensus standards that OSHA adopted along with those dealing primarily with safety. Many of these ANSI standards were purged after their adoption, on the urging of industry.

An example of the inadequacy of protection offered by the TLVs is the 1971 TLV for vinyl chloride, which was set at 250 ppm, whereas the later protective standard (see below) recommended no greater exposure than 1 ppm (as an average over 8 hours)—a level still recognized as unsafe, but the limit that the technology could detect. Another example is the TLV for lead, which was established at 200 $\mu\text{g}/\text{m}^3$, whereas the later lead standard was established at 50 $\mu\text{g}/\text{m}^3$, also recognizing that that level was not safe for all populations, such as pregnant women or those with prior lead exposure. In 1997, OSHA promulgated a new PEL for methylene chloride of 25 ppm, replacing the prior TLV of 500 ppm. The ACGIH updates its TLV list every 2 years. Although useful, an updated list would have little legal significance unless formally adopted by OSHA. OSHA did try, unsuccessfully, to adopt an updated and new list of PELs in its Air Contaminants Standard in 1989 (see later discussion). However, OSHA continues to maintain that it is intent on revising the list. The fact that the official OSHA TLVs are more than 30 years out of date compared with industry's own "voluntary" consensus standards is not welcomed, especially by the more modern firms in industry.

It is obvious that the slow, arduous process of promulgating individual health standards under Section 6(b)(5) of the OSHAct could never catch up with advances in scientific knowledge concerning the toxicity of chemicals. The ACGIH has updated its TLV list every 2 years, and although not as protective as workers and their unions would have liked, the recent updated lists did advance protection over the 1969 list that OSHA adopted into law in 1971. In 1989, OSHA decided to update the original list in a single rule-making effort through the 6(b) standard revision route. The agency issued more protective limits for 212 substances and established limits for 164 chemicals that were previously unregulated. Neither industry nor labor was satisfied with the standards. Industry, although giving general support, objected to the stringency of some of the PELs. Labor objected to their laxity, citing NIOSH recommendations not adopted, and generally objected to the rush-it-through process. The Eleventh Circuit Court of Appeals vacated the standard in 1992, ruling that OSHA failed to establish that a significant risk of material health impairment existed for each regulated substance (required by the benzene decision) and that the new exposure limit for each substance was feasible for the affected industry. OSHA decided not to appeal the decision to what it perceived as a conservative Supreme Court. Thus, the original and inadequate TLV list remains in effect, and 164 new substances remain unregulated. OSHA periodically expresses its intent on updating the list through new rule making, but no new action has been forthcoming. In the meantime, OSHA could argue that those 164 substances are "recognized hazards" and enforceable through OSHA's general duty clause, but conservative OSHA administrations have not been willing to emphasize this approach in the

case of the TLVs, although OSHA has used the general duty obligation to force compliance with good ergonomic practices in nursing homes. In 20 years, OSHA has issued only about a dozen general duty citations for substances covered by the original TLV list. Recently, OSHA's reluctance to use the general duty obligation in the case of the outdated TLVs was in part due to the many congressional attempts to pass legislation prohibiting such use.

A testimonial to the possibly potential significant impact the general duty clause is the fact that OSHA inspectors were ordered not to issue general duty violation citations to employers when the Reagan Administration came in, and that there were constant attempts to limit its use by a anti-regulatory Republican congress. The reasons for this are clear. In the waning years of the Carter Administration (1976-1980), the number of general duty citations began to increase, and industry was fearful of the uncertainty associated with the discretion of the OSHA inspectors to issue citations if they found the workplace unsafe, regardless of the absence of violations of specific standards. OSHA inspectors viewed their ability to issue general duty citations as their most important leveraging tool in conservative administrations which had promised to "keep government off of industry's backs."

The Chemical Safety Provisions of the Clean Air Act

Although the first congressional response to the concern generated by the deadly industrial accident in Bhopal, India, was the Emergency Planning and Community Right to Know Act of 1986, the chemical safety provisions of that law are focused almost solely on mitigation and not on accident prevention. A much greater potential for a direct focus on accident prevention can be found in the 1990 amendments to the Clean Air Act, although that potential has yet to be realized by EPA and OSHA.

As amended in 1990, Section 112 of the Clean Air Act directs the EPA to develop regulations regarding the prevention and detection of accidental chemical releases and to publish a list of at least 100 chemical substances (with associated threshold quantities) to be covered by the regulations. The regulations must include requirements for the development of *risk-management plans* (RMPs) by facilities using any of the regulated substances in amounts above the relevant threshold. These RMPs must include a hazard assessment, an accident prevention program, and an emergency release program. Similarly, Section 304 of the Clean Air Act Amendments of 1990 directed OSHA to promulgate a *Process Safety Management (PSM) standard* under the OSHA Act.

Section 112(r) of the revised Clean Air Act also imposes a "general duty" on all "owners and operators of stationary sources," regardless of the particular identity or quantity of the chemicals used on site. These parties have a duty to:

“... *identify hazards* that may result from [accidental chemical] releases using appropriate hazard assessment techniques,
... *design and maintain a safe facility* taking such steps as are necessary to prevent releases, and
... *minimize the consequences* of accidental releases which do occur.” [emphases added]

Thus, firms are now under a general duty to anticipate, prevent, and mitigate accidental releases. In defining the nature of this duty, Section 112(r) specifies

that it is “a general duty in the same manner and to the same extent as” that imposed by Section 5 of the OSHAct. Because Section 112(r) specifically ties its general duty obligation to the general duty clause of the OSHAct, case law interpreting the OSHAct provision should be directly relevant. In the 1987 *General Dynamics* case⁷⁰⁶, the District of Columbia Circuit Court of Appeals held that OSHA standards and the general duty obligation are distinct and independent requirements and that compliance with a standard does not discharge an employer’s duty to comply with the general duty obligation. Similarly, compliance with other Clean Air act chemical safety requirements should not relieve a firm’s duty to comply with the act’s general duty clause. Further, the requirement that owners and operators “design and maintain” a safe facility would seem to extend the obligation into the area of primary prevention, rather than merely hazard control.

Finally, the 1990 amendments established an independent Chemical Safety and Hazard Investigation Board (CSHIB). The board is to investigate the causes of accidents, perform research on prevention, and make recommendations for preventive approaches, much like the Air Transportation Safety Board does with regard to airplane safety.

As required by the 1990 Clean Air Amendments, OSHA promulgated a workplace Process Safety Management (PSM) standard in 1992. The PSM standard is designed to protect employees working in facilities that use “highly hazardous chemicals,” and employees working in facilities with more than 10,000 pounds of flammable liquids or gases present in one location. The list of highly hazardous chemicals in the standard includes acutely toxic, highly flammable, and reactive substances. The PSM standard requires employers to compile safety information (including process flow information) on chemicals and processes used in the workplace, complete a workplace process hazard analysis every 5 years, conduct triennial compliance safety audits, develop and implement written operating procedures, conduct extensive worker training, develop and implement plans to maintain the integrity of process equipment, perform pre-startup reviews for new (and significantly modified) facilities, develop and implement written procedures to manage changes in production methods, establish an emergency action plan, and investigate accidents and near-misses at their facilities. Many aspects of chemical safety are not covered by specific workplace standards. Most OSHA standards that do apply to chemical safety have their origin in the consensus standards adopted under Section 6(a) of the OSHAct in 1971, and hence are greatly out of date. Arguably, the general duty obligation of the OSHAct imposes a continuing duty on employers to seek out technological improvements that would improve safety for workers.

In 1996, the EPA promulgated regulations setting forth requirements for the RMPs specified in the Clean Air Act. The RMP rule is modeled after the OSHA PSM standard and is estimated to affect some 66,000 facilities. The rule requires a hazard assessment (involving an offsite consequence analysis—including worst-case risk scenarios— and compilation of a 5-year accident history), a prevention program to address the hazards identified, and an emergency response program. In 2003, the Chemical Safety and Hazard Investigation Board urged OSHA to amend its 1996 regulations in order to achieve more

⁷⁰⁶ 815 F.2nd 626 (D.C.Cir. 1987).

comprehensive control of “reactive hazards” that could have catastrophic consequences and asked OSHA to define and record information on reactive chemical incidents that it investigates or is required to investigate. These recommendations have largely fallen on deaf ears. The board also expressed concern that the *material safety data sheets* (MSDSs) issued by OSHA do not adequately identify the reactive potential of chemicals. Legislation is being promoted to require OSHA to prepare or revise MSDSs for the list of chemicals in the PSM standard, and to generally strengthen OSHA’s approach to chemical safety. Despite the fact that a memorandum of understanding between EPA and OSHA had been signed in 1996, in 2001 the U.S. General Accounting Office (GAO) issued a report indicating the need for better coordination between EPA, OSHA, the CSHIB, and other agencies.

The Pollution Prevention Act of 1990

The Pollution Prevention Act (PPA) of 1990 breaks with U.S. regulatory tradition in its proactive approach to preventing *at the source* rather than controlling pollution at end-of-pipe in the hierarchy of regulatory options. While never really implemented, the act also requires the Administrator to examine every regulation issued under the media-based (air, water, waste) legislation – for both gradual pollution and sudden and accidental release of chemicals – and regulations issued under toxic substances and pesticide legislation to ensure that pollution prevention initiatives were fashioned as the preferred choice of interventions.

Taken together, the regulation of chemical safety under the Clean Air Act and the PPA impose a duty on manufacturers to *design and prevent sudden and accidental releases from chemical production, use and storage facilities*. The *design and prevent* approach is one that could be embodied in a GSR for consumer products. Commentators on U.S. and EU regulation of consumer product safety conclude that in neither jurisdiction is consumer product protection as effective as it could be [see Howells *supra*]. A design-and-prevent approach would make either system more effective.

Relevant EU Initiatives Other Than Consumer Product Safety

In the EU, a combination of Directives and Policies represents a similar legislated preference for design-and-prevent as U.S. regulation of chemical plant safety and pollution prevention through the EU Seveso Directives for Chemical Safety, the Integrated Pollution Prevention and Control (IPPC) Directive, and the European Integrated Product Policy.

The EU Seveso Directives for Chemical Safety

In response to the chemical accident at Bhopal, India, EU Directive (82/501/EEC) on Major Accident Hazards of Certain Industrial Activities, the so-called ‘Seveso Directive’, was first adopted in 1982, and required EU member states to ensure that all manufacturers prove to a ‘competent authority’ that major hazards have been identified in their industrial activities, that appropriate safety measures – including emergency plans – have been adopted, and that information, training, and safety equipment have been provided to on-site employees. A revised version of the Seveso Directive, the Seveso II Directive, came into effect in February 1997 (96/82/EEC). Seveso II strengthens the original provisions and coverage of accident-prevention activities, as well as broadens the types of installations, which must comply. Particularly worthy of note is the mention of

inherent safety as a preferred approach to preventing chemical accidents in the accompanying guidance document for the preparation of the safety report required by the revised Directive. Other updates include a revision and extension of the scope, the introduction of new requirements relating to safety management systems, emergency planning and land-use planning and a reinforcement of the provisions on inspections to be carried out by Member States.

The Integrated Pollution Prevention and Control (IPPC) Directive

The purpose of the European Union's Integrated Pollution Prevention and Control Directive (IPPC), adopted in 1996, was to provide a high level of environmental protection by *preventing* wherever practicable, or otherwise reducing (controlling) emissions to air, water, and land (i.e., waste) from a range of industrial processes, such as the energy sector, the production and processing of metals, the mineral and chemical industries, waste management facilities, food production and intensive livestock farming. Like the U.S. Pollution Prevention Act of 1990, the EU IPPC Directive clearly favors prevention over end-of-pipe control and recycling as preferred approaches. Around 60,000 installations across the European Union will be required to operate with IPPC permits by October 2007. The permits are to be 'coordinated' in addressing together all waste and pollution streams and are to be based on the concept of Best Available Techniques (BAT) for minimizing pollution from various point sources. In many cases, BAT means radical environmental improvements within the industries, and it is expected that sometimes it may be costly for companies to adapt their plants to BAT.⁷⁰⁷ The implementation of these new and considerably tougher BAT rules on all existing installations in the European Union could be expensive and thus the Directive grants the covered installations an eleven-year long transition period counting from the day that the Directive entered into force. Identification of required performance levels achievable by BAT is undertaken by the EU Center in Seville, Spain. As is the custom in the EU, the Directive has to be 'transposed' into the National Law of the member states.

The European Integrated Product Policy

While the EU Directives discussed above deal with environmental emissions and waste the EU Commission is pursuing a strategy for strengthening product-related environmental policies with a view to promoting the development of a market for greener products. This strategy focuses mainly on environmental impacts throughout the life-cycle of products and envisions the use of eco-labels both to serve as a voluntary market-focused screening mechanism (through the exercise of consumer choice) and to transmit important information about products. It is linked to the EU New Approach.

In commenting on the Integrated Product Policy, the European Consumers' Organization BEUC based in Brussels, representing a federation of national consumer organizations from the EU and other European countries, believes

⁷⁰⁷ Note that BAT in the European context can include performance requirements for technology that anticipate innovation, and not just levels of control achievable by existing technology that the US use of the term 'best available technology' implies. In other words, BAT requirements can involve technology forcing.

product safety is one of the key issues and BEUC wants information about chemicals used in every-day consumer products to be made available to the public.⁷⁰⁸

Taken together, these three initiatives support inherently-safer and environmentally-souder production and products.

The Role of Tort and Product Liability in Ensuring Product Safety

For an insightful comparison of product liability in encouraging product safety in the U.S. and EU treatment, see Geraint G. Howells, *International Torts: A Comparative Study*. Howells writes:⁷⁰⁹

The main reason for the greater impact of products liability litigation in the U.S. is the level of damages. American damage awards are considerably higher -- this in itself acts as a magnet for litigants. These high awards are due to the lack of a social security system to cushion the impact of accidents, the high costs of medical treatment, the lack of public healthcare services, generous awards of pain and suffering damages, and the availability of punitive damages.

... The role of punitive damages in the U.S. suggests that the regulatory function of litigation is important. Moreover, the threat of wide scale products liability litigation can be seen as an incentive for producers to improve the quality of their products, often with fiscal incentives from insurers. Although civil liability rules have a regulatory dimension in Europe, my impression is that products liability is more responsive to the compensatory needs of accident victims than to the regulatory aspects. Many Americans consider Europe to have a weak products liability litigation culture, but I gain the impression that there is sometimes a failure to appreciate the depth of the product safety regulatory regimes, which may explain why there is less need for products liability litigation as a means of regulatory control.

The FHSA expressly preempts any state labeling (warning) requirement for a substance that is more stringent than a labeling (warning) requirement established for that substance under the FHSA. Many courts have held that this applies to "failure to warn" tort claims for money damages as well as to state statutes and regulations. However, a state tort law claim may be based on a failure to follow the labeling requirements of the FHSA.

Violations of Mandatory Requirements

Violation of a mandatory standard in the majority of states is conclusive evidence of the defective nature of a product, while a minority of states regards it as a rebuttal presumption or mere evidence of negligence. [See Mathias Reimann, *Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?* Fall, 2003, 51 *Am. J. Comp. L.* 751.] Similarly, compliance with a standard creates a presumption of due care, but one that can be overcome by the specifics of the case.

⁷⁰⁸ see http://ec.europa.eu/environment/ipp/pdf/study_final_clean_report.pdf). Safety aspects of products as well as environmental impact is to be included in life-cycle analysis.

⁷⁰⁹ Geraint G. Howells, *International Torts: A Comparative Study: The Relationship Between Product Liability and Product Safety -- Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position*, Spring, 2000, 39 *Washburn L.J.* 305-346.

Violations of Voluntary Standards and Guidelines

Violation of a voluntary standard is evidence of the defective nature of a product, but the presumption can be overcome.

Prevention and Inherent Safety: Technological Innovation in Process and Product Design⁷¹⁰

The concept of inherent safety

Inherent safety as a concept similar to – or a natural extension of -- pollution prevention or cleaner production. The Pollution Prevention Act of 1990 (discussed earlier) covers both. The common thread linking the two concepts is that they both attempt to prevent the possibility of harm, rather than to reduce the probability of harm -- from accidents, pollution, or products -- by eliminating the problem *at its source*. Both typically involve fundamental changes in production technology: substitution of inputs, process redesign and re-engineering, and/or final product reformulation or redesign.

Inherent safety is an approach to chemical accident prevention that differs fundamentally from secondary accident prevention and accident mitigation. Sometimes also referred to as “primary prevention,” inherent safety relies on the development and deployment of technologies that prevent the *possibility* of a chemical accident. In contrast, “secondary prevention” reduces the *probability* of a chemical accident⁷¹¹, and “mitigation” and emergency responses seek to reduce the seriousness of injuries, property damage, and environmental damage resulting from chemical accidents.

Secondary prevention and mitigation, by themselves, are unable to eliminate the risk of serious or catastrophic chemical accidents, although improved process safety management can reduce their probability and severity. Most chemical production involves “transformation” processes, which are inherently complex and tightly coupled. Specific industries use many different processes. In many cases, alternative chemical processes exist which completely or almost completely eliminate the use of highly toxic, volatile, or flammable chemicals. So-called “normal accidents” arising in these systems result in significantly less harmful chemical reactions or releases. Replacement of existing production systems with such benign chemical processes a practice sometimes called

⁷¹⁰ Much of this discussion is taken from N.A. Ashford and G. Zwetsloot, "Encouraging Inherently Safer Production in European Firms: A Report from the Field" *Journal of Hazardous Materials*, Special Issue on Risk Assessment and Environmental Decision Making, A. Amendola and D. Wilkinson (eds.), 1999, pp 123-144.

⁷¹¹ In the accident prevention literature in the traditional chemical engineering journals, there is much attention given to the concept of the “root cause” of accidents. Enquiry into root causes has stimulated mostly secondary prevention by attempting to make production technology more “fail-safe,” that is, stronger vessels and piping able to sustain higher pressures, neutralizing baths, and automatic shut-off devices. A different tradition of analyzing accidents comes from tort and compensation law, where the “but-for” test is used to apportion responsibility between faulty technology and alleged careless workers. If the technology is not “fool-proof”, that is, it is not impossible for a human to initiate an event leading to an accident, then the firm is held at least partially liable -- because, “but-for faulty design, the accident would not have occurred.” Primary prevention promotes “fool-proof”, rather than “fail-safe” technology. Another formulation is “error tolerant”.

“green chemistry,” as well as nonchemical approaches, are examples of primary accident prevention.

Secondary prevention and mitigation are similar in concept to pollution control and remediation measures, respectively, in that each involves only minimal change to the core production system. In particular, secondary accident prevention focuses on improving the structural integrity of production vessels and piping, neutralising escaped gases and liquids, and shut-off devices rather than changing the basic production methods. When plants expand beyond the capacity they were initially designed for, secondary prevention capacities may be exceeded. Sometimes, overconfidence in these added-on safety measures may invite an expansion of production capacity. Accidents, of course, may also disable secondary safety technology, leading to runaway chemical reactions.

The superiority of pollution prevention and cleaner production as a tool of environmental policy has been recognised for more than a decade in both Europe and North America. International meetings of the Cleaner Production Roundtables and the Pollution Prevention Roundtables are held annually in Europe and North America, respectively. The United Nations Environment Programme has spearheaded an aggressive cleaner production program. The U.S. EPA has established a hierarchy of policy choices, with pollution prevention given the highest priority over reuse or recycling, treatment, or disposal. In 1990, the U.S. Congress codified, as national environmental policy, a preference for pollution prevention over pollution control, when it passed the Pollution Prevention Act. The EU supports its Directive on Integrated Pollution Prevention and Control (IPPC) by funding research in Seville, Spain for the identification of Best Available Techniques (BAT).

Incentives, Barriers, and Opportunities for the Adoption of Inherently Safer Technology

Although they are conceptually similar, however, pollution prevention and accident prevention differ in the response they have thus far received from industry. While many firms are embracing pollution prevention (some enthusiastically, some more tentatively), far fewer are moving to primary accident prevention. In all likelihood, this disparity is due to a difference in incentives.

The reasons that firms are embracing pollution prevention and cleaner production today are because of (1) the increased costs of continuing the current practices of waste transport/treatment and pollution control, (2) liability for environmental damage due to industrial releases of toxic substances, (3) increasingly available information about pollution and toxic releases to the public, and (4) the EU IPPC Directive (and possibly the EMAS and ISO 14000 requirements), and to a lesser extent the Pollution Prevention Act of 1996 in the United States, force increased attention to changing production technology, rather than relying solely on end-of-pipe, add-on technologies. Thus, both economic and informational mechanisms are causing a gradual cultural shift away from pollution control and waste treatment and towards pollution prevention and cleaner production.

With regard to primary accident prevention, the same economic signals are not really there. Firms do not pay the full social costs of injuries to workers (or to the public) and firms are under-insured. Unlike pollution, which has to be reckoned

with as a part of production planning, accidents are rare events and their consequences are not factored into the planning process. Thus, firms may anticipate accidents, and may be motivated to take some steps to avoid them, but they do not feel a strong financial incentive to invest in primary accident prevention. Further, while some of the information reportable under EPCRA is relevant to chemical accidents, this information alone—without detailed and plant-specific data on production processes—does not allow the firm, or the public, to assess the accident potential of a particular facility.

Furthermore, an organisation's gradual emissions or wastes can be observed and calculated for any given time period, and this information can be used to measure the effectiveness of the organisation's pollution prevention efforts. Because acute chemical accidents are relatively rare events, an organisation implementing an effective chemical safety program may therefore receive no form of positive feedback whatsoever. Because the safety system is working, accidents do not occur. Of course, a hazardous chemical plant may eventually receive negative feedback, but only when it is too late to take preventive measures.

Ashford⁷¹² has summarized the barriers to primary prevention:

These include: (1) inadequate information about the potential for catastrophic accidents, the significant costs of secondary prevention and mitigation and the costs of chemical accidents, and the existence of inherently-safe[r] alternatives; (2) insufficient economic incentives - in the form of workers' compensation, the tort system, regulatory fines, and insurance; (3) organisational and managerial barriers -- linked to corporate attitudes, objectives, structure, and internal incentives, and the lack of a labour-management dialogue on safety; (4) a lack of managerial awareness and expertise about inherently safe[r] technologies; (5) inadequate worker knowledge about primary accident prevention; (6) technological barriers limiting primary accident prevention; and (7) regulatory problems. Primary prevention shares some of these barriers with secondary prevention and mitigation, but these barriers are of different importance.

Many of these barriers are present in the case of designing inherently-safer and environmentally-sounder products

Although firms sometimes do anticipate accidents and try to avoid them, the expenditures for adequate prevention have not been, and are not likely to be, invested without the right incentives. To the extent that the firm *knows* that the costs of maintenance and the inflexibility of traditional safety approaches are greater than using more reliable inherently safer approaches, the firm may respond by changing its technology.

One way of providing firms with *more visible* economic incentives would be to encourage them to exploit the opportunity to prevent accidents and accidental releases (1) by identifying *where* in the production process changes to inherently safer inputs, processes, and final products could be made and (2) by identifying the *specific inherently safer technologies that could be substituted*. The former

⁷¹² Ashford, N. A., Gobbel, J. V., Lachman, J., Matthiesen, M., Minzner, A. and R. F. Stone. (1993), The Encouragement of Technological Change for Preventing Chemical Accidents: Moving Firms from Secondary Prevention and Mitigation to Primary Prevention. Cambridge, Massachusetts: Center for Technology, Policy and Industrial Development, Massachusetts Institute of Technology, Boston.

we call Inherent Safety Opportunity Audits (ISOAs). The latter we call Technology Options Analysis (TOAs). Unlike a hazard, risk, or technology assessment, these techniques seek to identify *where and what superior technologies could be adopted* to eliminate the possibility,⁷¹³ or to dramatically reduce the probability, of accidents and accidental releases.

From a general safety perspective, it is widely recognised that safety performance is determined by three elements:

- management and organisational factors;
- technological factors; and
- behavioural factors (also referred to as the human dimension, i.e: people)

These three factors interact and influence the safety of industrial manufacturing and production processes through their effects on the *willingness, opportunity, and capability* of organisations and people to change.

In some approaches that promote the adoption of inherent safety, the emphasis is on mainly technological factors, i.e., on identifying and disseminating information on superior technologies. In the current approaches to safety management -- especially those falling under the rubric of Safety Management Systems -- the emphasis is on management and organisational factors, and also on the human dimension, addressing the management of safety; these approaches assume minimal technological change, implicitly leaving the core and secondary production technologies essentially unchanged. Both of these distinct approaches are by themselves insufficient to maximize the adoption of desirable inherently safer technologies and frustrate further progress in safety performance and continual progress in safety management. There is therefore a clear need, both from a technical point of view and from an industrial practice perspective, for a generally accepted approach that bridges traditional safety management with inherent safer technology.

What is needed is to encourage complementary managerial and technological changes aiming at making companies more willing *and* able to identify and use (or develop) inherently safer technologies for achieving *Inherently Safer Production and Products*.

⁷¹³ A [risk] assessment, in practice, is generally limited to an evaluation of the risks associated with the firm's established production technology and does not include the identification or consideration of alternative production technologies that may be inherently safer than the ones currently being employed. Consequently, [risk] assessments tend to emphasize secondary accident prevention and mitigation strategies, which impose engineering and administrative controls on an existing production technology, rather than primary accident prevention strategies, which utilize input substitution and process redesign to modify a production technology. In contrast to a [risk] assessment, a technology options analysis would expand the evaluation to include alternative production technologies and would facilitate the development of primary accident prevention strategies.

Inherently-safer and Environmentally-sounder Products

While not originally applied to product safety, the fundamental concepts of inherent safety are directly applicable and transferable to products. We have already extended the concept of pollution prevention (what the Europeans call clean technology) to products. Green products, sustainable products, and environmentally-sound products are just some of the names characterizing this extension. The EU Integrated Product Policy (discussed above) relies on the concepts of cleaner and environmentally-sound products. It is no artificial stretch to conceive of inherently-safer products that eliminate the possibility or significantly reduce the probability of harm to consumers. Of course innovation may be required. The holistic approach to health, safety and environmental improvements would be to encourage or require *the development and use of inherently-safer and environmentally-sounder products and processes*. For this to become a reality, single-purposes improvements to industrial technology have to be replaced with multi-dimensional technological change.

Compatibility of a GSR with U.S. Regulatory Traditions and Practice

General Discussion

The EU 2001 Directive establishing a General Safety Requirement follows other EU approaches to regulating health, safety and the environment: a general statement of responsibilities (here for product safety) followed by some particularized regulations (as for child toys) and some general reference to 'voluntary standards' developed by one of three European standards organizations. Compliance with these 'voluntary standards' creates a presumption of safety to satisfy the general obligation under the GSR; thus, there is some considerable pressure on industry to comply. In the United States, the CPSC works with the private standard-setting organizations and lists/publicizes those standards it deems acceptable or compliant with the CPSA's statutory requirements. Compliance with voluntary standards in the United States that CPSC does not have a role in developing or standards that are not listed/publicized does not create a strict legal presumption, but in practice they may well deter an inadequately-funded CPSC from taking up the issue in the context of a particular consumer complaint about a product. The nature of standard-setting organizations in the U.S. and the EU are very different (see the discussion below).

In this section, we outline what shape an effective GSR requirement would take as a complement to the CPSA. Other, complementary amendments may be indicated as well. Inasmuch as (1) consumer product safety regulation is regarded as one of many examples of the exercise of federal power under the Commerce Clause of the U. S. Constitution – and not part of the federal criminal law *per se* -- and (2) judicial review is provided explicitly or through the reach of the Administrative Procedures Act (5 U.S.C. §551, *et seq.*) – whereas its use in Canada may be different -- straightforward import into Canadian Law would no doubt present some challenges. Nonetheless, the holistic approach explored here should be considered.

In order to maximize its effectiveness, the GSR has to be much more than a generalized duty/responsibility for product safety, and in that sense, a simple

addition of the authority found in the European context to the CPSA would miss an opportunity to create an operationally-meaningful 'culture of safety.' It has to be particularized and complement (1) the producer's duty to adhere to mandatory standards, (2) mechanisms to report and track product-related injuries, (3) the existence of voluntary industry guidelines and practices, and (4) government's authority for banning, recalling and seizing dangerous products, or requiring that existing products be brought into conformity.

It has already been mentioned that the interplay between the regulation of product safety and liability for harmful and/or defective products is important but very different in the United States and the EU. Thus, whether for the purposes of examining the suitability of a GSR in the U.S. context, or in the Canadian context, this has to be taken into account. Howells *supra* writes:

I think American readers will be surprised by the sophistication of the rules and the strength of the enforcement culture [in Europe]... What is most striking is the extent to which European standardization has been integrated into the legal regime. This is not an eulogy for the American system. There are still some regulatory aspects in which the U.S. is a world leader, including the accident data collection and recall powers. When established in the 1970's the U.S. Consumer Product Safety Commission ("CPSC") was seen as a model for an integrated consumer product safety agency, which Europe has never been able to emulate. There are also many problems with the European system. However, my purpose is to emphasize the European commitment to regulation, rather than, litigation as a means of promoting product safety. It will be for the American reader to determine whether it is desirable or even possible for the U.S. to develop similar regulatory controls.

Describing the current regulatory system in the EU, Howells continues:

The EC's Council Resolution in 1985 on the *New Approach to Technical Harmonization and Standards* marked a move away from detailed product-specific rules to broadly categorized Directives. These Directives lay down essential safety requirements but leave the details to be fleshed out by European standards. The linchpin of the system is the standardization process. Additionally, there has been the development of a global approach to certification and testing. The new and global approaches have three limbs: (i) more flexible legislation, (ii) a prominent role for standardization, and (iii) reliance on conformity assessment procedures (leading to the award of the CE mark which allows access to the European market).

The "New Approach" was intended to be both flexible, leaving a lot of the detailed work to the European standardization bodies, and at the same time attempting total harmonization of all safety aspects in order to reassure member states that they could safely permit free circulation of conforming products. The basic principles of the New Approach to technical harmonization are set out in the 1985 Resolution as being:

- Harmonizing legislation should be limited to adopting essential safety requirements to which products should conform, and which if they do so conform, should be their passport to free movement throughout the Community.
- Standardization organizations should be entrusted with the task of drawing up the technical specifications needed for the production and

placing on the market of products conforming to the essential requirements.

- The technical specification should be voluntary.
- National authorities are compelled to recognize that products conforming to the harmonized standards are presumed to comply with the essential requirements. Manufacturers should have the choice of not manufacturing in conformity with the standards, but in this case they are obliged to prove that their products conform to the essential requirements (and third party conformity assessment is usually required).

The presumption of conformity's purpose is to prevent both the routine testing of products and requirements that documentation be produced once the product has been found to conform to the Directive. Conformity is typically signified by the CE mark, which is the effective passport for products to circulate within Europe.

What is especially important to realize is that the actual standardization process is not undertaken by private standard-setting organizations, but rather under contract between the EU and the CEN (the European Committee for Standardization). In 1991, the CEN received 70% of its funding to work on harmonizing standards in the EU. Consumer organizations play an active role in the CEN, and the CEN's activities are well-integrated into the EU regulatory process. The website <http://www.cenorm.be> describes its process as follows: “formal adoption of European Standards is decided by a weighted majority vote of the CEN National Members and is binding on all of them. They must implement the standards at national level and withdraw conflicting standards”

The U.S. preference for voluntary standards – over promulgated mandatory standards -- is not a faithful replication of the EU New Approach. The private standard-setting organizations ANSI (American National Standards Institute), ASTM (American Society for Testing and Materials) and NFPA (National Fire Protection Association) have very weak stakeholder participation⁷¹⁴ and the standards are not binding upon their members. Voluntary standards actually have no legal regulatory import; they serve to stave off regulation through the CPSC's Section 30 “escape clause”. Perhaps the label “voluntary” in the EU context is a misnomer; negotiated standards might be closer to the mark⁷¹⁵. Negotiation in US standards-setting organizations should not be construed as meaningful; it is not negotiation among key stakeholders, but rather among industry participants.⁷¹⁶

⁷¹⁴ While after 1981, the CPSC allowed for reimbursement by CPSC of “persons” to participate in standards-setting, little has actually been realized. See Carl Tobias, cited in Howells at footnote 63.

⁷¹⁵ Note, however, that historically the EU experience with negotiated standards in the environmental and energy areas are acknowledge to lead to less technological innovation in the technologies of concern than mandatory command-and-control regulations. See Carraro, Carlo and Francois Leveque, “Introduction: the Rationale and Potential of Voluntary Approaches” in *Voluntary Approaches in Environmental Policy*, Kluwer, Boston (1999).

⁷¹⁶ There is U.S. experience with negotiated standards between industry, government, and key stakeholders (unions and environmental groups) in the areas of occupational health & safety and the environment. Most was conducted in conservative administrations and all were judged to be less protective and less technology forcing than strict application of the law would have resulted in. See Ashford, Nicholas A. and Charles C. Caldart (2005) “Negotiated Regulation, Implementation and Compliance in the United States”, in *The Handbook of Environmental Voluntary Agreements* Croci, Eduardo (ed.), Kluwer Academic

In examining whether a GSR would be a welcome addition to the U.S. Regulatory armament, the duty created under a GSR should address the producers'/marketers'/users' duties:

- To design an inherently safer product at the outset (primary prevention);
- To choose to market or use a safely-designed – or safer designed -- product from among those readily available;
- To adhere to mandatory standards;
- To adhere to voluntary industry guidelines/standards or explain/justify departure from recommended practices;
- To control the [remaining] hazardous or harmful aspects of a product (secondary prevention);
- To provide meaningful warnings, instructions and antidotes;
- To mitigate the harm from a dangerous product;
- To monitor and track the harms once the product is in commerce (data collection);
- To report harm/harmful incidents from a product, if known;
- To recall a product; and
- To participate in efforts to compensate those harmed/injured.

In addition, the concept of 'extended producer responsibility' through the supply chain from production to disposal should be considered.

For a general, but particularized to be meaningful, the duty placed on the manufacturer/importer should promote inherently-safer products through the design, management, periodic review, and redesign of consumer products as a proactive measure and it should complement the duty to assess and reduce the risk of consumer products. Second-best is the duty to design (or re-design) secondary prevention measures, e.g., involving add-on devices – such as electrical cut-off switches or blade shields -- or chemical antidotes.

It could be argued that since the CPSC's premarket controls have been effectively weakened, that its post-market powers – such as notification of affected consumers (15 U.S.C. Section 2046c); or manufacturer recalls or requirements to repair, bring into conformity, or replace (15 U.S.C. Section 2046d); or requiring manufacturers to compensate, etc. -- should be strengthened. However, these post-market interventions come late in the game. Alternatively, a more prevention-oriented intervention, a premarket GSR requirement to conduct options analysis to design or re-design questionable products could strengthen consumer protection.

The Fashioning of an Effective GSR

The integration of a GSR into the current U.S. regulatory scheme is suggested by various regulatory and legislative innovations in both U.S. and EU regimes other than those addressing consumer product safety. Adopting a general duty to promote inherently-safer products borrows from the previously described use of a general duty obligation in U.S. worker health & safety legislation and in the prevention of chemical accidents in the U.S. Clean Air Act. The concept of

inherent safety is promoted not only in the U.S. Pollution Prevention Act – where pollution prevention is viewed broadly as both the prevention of gradual pollution and the prevention of sudden and accidental releases of chemicals – but also in the EU Seveso Directives where inherent safety is at the top of the list of the preferred hierarchy of interventions to prevent chemical accidents.

While not historically applied to products, inherent safety is a necessary focus if consumer product safety is to be seriously addressed. Secondary prevention measures are poor substitutes. These measures – summarily called ‘safety devices’ -- can be easily bypassed or disabled, rendering the product unsafe. Setting mandatory product-by-product standards, while exemplary and fostering of the importance of product safety, can not by itself adequately address the myriad of existing or expected future product problems, e.g., from nanomaterials or electronic and biotechnology products. Nor is an increase in the reach of voluntary standards likely to suffice. Unlike a GSR tied to more voluntary standards – or “privatization of regulation” -- a GSR tied to a premarket duty to design or redesign inherently-safer and environmentally-sounder products should be seriously considered.

A change in the culture of safety requires strong Directives to focus on product design and redesign, applying holistic approaches than cover more not only product safety, but public health and environmental concerns, and permeate the life cycle of products, augmenting the approach reflected in the Integrated Product Policy. The goal needs to be the replacement of existing products and advent of new products that are *inherently-safer and environmentally-sounder*. A shift in focus from traditional product safety toward a goal of achieving a ‘modernization of products and production methods’ is central.

Borrowing from the EU model, this general duty GSR should require manufacturers/producers/marketers of products to:

1. *Identify hazards* that may result from the expected and foreseeable manufacture, use, and disposal of products using appropriate hazard assessment techniques;
2. *Undertake an inherent safety opportunity analysis (ISOA)* to identify what aspects of the product [and the process by which it is made] need to be changed so that the product [and the associated manufacturing/production process] is [are] inherently-safer and environmentally-sounder;⁷¹⁷.
3. *Undertake a technology options analysis (TOA)* to identify *specific inherently-safer and environmentally-sounder options* that will advance the design and adoption of products [and production systems] that are less inherently unsafe and environmentally unsound;
4. *To the extent feasible, design and redesign products so that they are inherently-safer and environmentally-sounder; and*

⁷¹⁷ The text in square brackets here and in the next item broadens the scope of government activity beyond product safety to process interventions. This may not be practical in the political process that still focuses on narrow problems, one at a time.

5. *Minimize the adverse consequences* of manufacture, use, and disposal of products that do occur and that are infeasible to eliminate or significantly reduce.

At the same time, authority should exist to promulgate mandatory consumer product standards that promote *inherently-safer and environmentally-sounder* products. The current formulation in U.S. product safety that products not present “an unreasonable risk of injury” [i.e., be reasonably safe] requires a reinterpretation of the word unreasonable. What is ‘reasonable’ where the producer is expected only to make easily-achievable and low-cost minor changes to its products is different than expectations that the design (and redesign) of products address a multitude of health, safety and environmental problems that provide significant advances in protection, but also change result in economic benefits. The history of pollution prevention activities undertaken by polluting firms has demonstrated the significant long term environmental *and* economic benefits of a more holistic, even if radical, approach to product and process improvement.⁷¹⁸ One should expect no less a result from the design (and redesign) of inherently-safer and environmentally-sounder products.

As under the U.S. OSHA Act, the existence of mandatory standards should not lessen a manufacturer’s responsibility under the GSR. These obligations should be co-terminus. Providing that consumer (and environmental and labor) groups are given meaningful opportunities for participation in developing consensus standards, multi-stakeholder negotiation can speed up the standard-setting process, but the use of voluntary standards in the U.S. sense (they are not really consensus standards) should not be part of the regulatory armament. The EU example of relegating standard-setting to an independent body can not easily be copied in the U.S. context for many reasons having to do with the nature of private standard-setting organizations and the inadequacy of public participation.

The GSR cannot merely be a non-particularized duty to produce and market safe products. It works in the EU context because it is backed up by standards that are quasi-mandatory in nature. The reason for requiring industry, for example, to undertake an inherent safety opportunity analysis (ISOA) and a technology options analysis (TOA) articulated above is to attach meaning and specifics to what would otherwise be a *de facto* voluntary and essentially unenforceable requirement.⁷¹⁹

The third element of the GSR: *undertake a technology options analysis* (TOA) to identify *specific inherently-safer and environmentally-sounder options* is especially important. The ability to conduct a risk or hazard assessment can be time-consuming and beset by uncertainties. To the extent that the GSR

⁷¹⁸ Ashford, Nicholas (2002) “Government And Innovation in Europe And North America”, A Special Issue on Ecological Modernization, Sonnenfeld, David and Mol, Arthur, (Eds.) *American Behavioral Scientist*, Volume 45, No. 9, pp. 1417-1434.

⁷¹⁹ For a discussion on the use of ISOAs and TOAs in the context of chemical plant safety, see Zwetsloot, G.I.J.M. and N. Askounes Ashford (2003) “The Feasibility of Encouraging Inherently Safer Production in Industrial Firms”, in a Special Issue on Safety and Design, *Safety Science*, 41(2/3):219-240. Fadier, E, Guest Editor.

encourages a *search for alternatives*, a full fledged risk assessment might be avoided. Comparative risk (and cost) assessments are much easier to do and attended by less uncertainty. In fact, it might be much easier to identify alternatives that had never before been contemplated – because the question was never asked – than to become embroiled in controversial risk assessment. This approach represents a shift from a risk-oriented inquiry to a solutions-oriented inquiry.⁷²⁰

Creating a meaningful general duty GSR could be a serendipitous opportunity for integrating environmental, health and safety concerns for products, but it may also have a profound impact on process and production technology as well.

⁷²⁰ See Koch, Lars and Ashford, Nicholas (2006) “Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH”, *Journal of Cleaner Production* 14(1): 31-46 2006 for a related and detailed approach in the context of the EU REACH initiative for chemicals.