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## Environmental and Occupational Health Protection Law

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### Introduction

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The manufacturing, processing, and use of chemicals, materials, tools, machinery, and equipment in industrial, construction, mining, and agricultural workplaces often cause environmental, health, and safety hazards and risks. Occupational and environmental factors cause or exacerbate major diseases of the respiratory, cardiovascular, reproductive, and nervous systems and cause systemic poisoning and some cancers and birth defects. Occupational and environmental disease and injury place heavy economic and social burdens on workers, employers, community residents, and taxpayers.

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Because voluntary efforts in the unregulated market have not succeeded in reducing the incidence of these diseases and injuries, the public has demanded government intervention into the activities of the private sector. This intervention takes the form of the regulation of environmental health and safety hazards through standard setting, enforcement, and transfer of information authorized by legislation. This article addresses the major regulatory systems (or regimes) designed to protect public and worker health from chemicals discharged from sources that pollute the air, water, ground, and/or workplace. The establishment of standards and other legal requirements in these regulatory regimes has occurred over a more than 30-year period that has seen changes in the use of scientific and technical information in regulatory initiatives and in legal doctrine, including the manner in which science, economics, and technological capability are viewed by the courts. The concepts of risk assessment, cost-benefit analysis, and technology forcing have evolved, both through the development of case law and through changes in the political environment. Often, changes in one of the regulatory regimes has affected the other regulatory regimes as well.

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Standards can be classified in a number of ways. A performance standard is one that specifies a particular outcome – such as a specified emission level above which it is illegal to emit a specified air pollutant – but does not specify how that outcome is to be achieved. A design or specification standard, on the other hand, specifies a particular technology – such as a catalytic converter – that must be used. In either case, the standard can be based on (1) a desired level of protection for human health or environmental quality, (2) some level of presumed technological feasibility, (3) some level of presumed economic feasibility, or (4) some balancing of social costs and social benefits.

Within each of these options, there is a wide spectrum of possible approaches. A human health-based standard, for example, might choose to protect only the average member of the population, or it might choose to protect the most sensitive individual. A technology-based standard might be based on what is deemed feasible for an entire industry, or on what is deemed feasible for each firm within the industry. Moreover, some standards might be based on a combination of these factors. Many standards based on technological feasibility, for example, are also based on some concept of economic feasibility. Other requirements that could be considered ‘standards’ include (1) information-based obligations, such as the disclosure of (and retention of, or provision of access to) exposure, toxicity, chemical content, and production data and (2) requirements to conduct testing or screening of chemical products.

In the United States, toxic substances in the industrial workplace have been regulated primarily through the Occupational Safety and Health Act (OSHAct) of 1970 and the Toxic Substances Control Act (TSCA) of 1976. These federal laws have remained essentially unchanged since their passage, although serious attempts at reform have been made from time to time. Since 1990, sudden and accidental releases of chemicals (chemical accidents), which may affect both workers and community residents, are now regulated under both the Clean Air Act and the OSHAct.

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The OSHAct established the Occupational Safety and Health Administration (OSHA) in the Department of Labor to enforce compliance with the act, the National Institute for Occupational Safety and Health (NIOSH) in the Department of Health and Human Services (under the Centers for Disease Control and Prevention) to perform research and conduct health hazard evaluations, and the independent, quasi-judicial Occupational Safety and Health Review Commission to hear employer contests of OSHA citations. The Office of Pollution Prevention and Toxic Substances in the Environmental Protection Agency (EPA) administers TSCA. The Office of Air, Water, and Solid Waste and the Office of Emergency Response in EPA regulate media-based pollution. The Office of Chemical Preparedness and Emergency Response in EPA is responsible for the chemical safety provisions of the Clean Air Act.

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The evolution of regulatory law under the OSHAct has profoundly influenced other environmental legislation, including the regulation of air, water, and waste, but especially the evolution of TSCA.

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s0010 **Standard Setting and Obligations of  
the Employer and the Manufacturer  
or User of Toxic Substances**

s0015 **The Occupational Safety and Health Act of 1970**

p0035 The OSHAct requires OSHA to (1) encourage employers and employees to reduce hazards in the workplace and to implement new or improved safety and health programs, (2) develop mandatory job safety and health standards and enforce them effectively, (3) establish “separate but dependent responsibilities and rights” for employers and employees for the achievement of better safety and health conditions, (4) establish reporting and record-keeping procedures to monitor job-related injuries and illnesses, and (5) encourage states to assume the fullest responsibility for establishing and administering their own occupational safety and health programs, which must be at least as effective as the federal program.

p0040 OSHA can begin standard-setting procedures either on its own or on petitions from other parties, including the Secretary of Health and Human Services, NIOSH, 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. Under certain conditions, OSHA is authorized to set emergency temporary standards, 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.

s0020 **Key OSHA Standards**

p0045 The OSHAct provides two general means of protection for workers: (1) a general statutory duty to provide a safe and healthful workplace and (2) promulgation of specific

standards to which specified categories of employers must adhere. The act 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 health effects data, as well as on the willingness of a particular OSHA administration to use this as a vehicle for protection.

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” (emphasis 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.

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/cm<sup>3</sup>. 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-h period) and issued a process safety management (PSM) rule (see the discussion in the section titled ‘The chemical safety provisions of the Clean Air Act: Obligations imposed by EPA and OSHA to prevent the sudden and accidental releases of chemicals’).

p0060 The burden of proving the hazardous nature of a substance is placed on OSHA, as is the requirement that the proposed controls are technologically feasible. The necessarily slow and arduous task of setting standards, substance by substance, makes it impossible to deal realistically with 13 000 toxic substances or approximately 250 suspect carcinogens on NIOSH lists. Efforts were made to streamline the process by (1) proposing generic standards for carcinogens and (2) proposing a generic standard updating the TLVs (PELs). Neither of these efforts was successful.

p0065 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.

p0070 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 h), 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 unclear 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.

p0075 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 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.

### Emergency Temporary Standards

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/cm<sup>3</sup>, it attempted to protect workers by promulgating an ETS at 0.5 fibers/cm<sup>3</sup>. 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.

OSHA has issued nine emergency temporary standards under the OSHAct. Standards for vinyl chloride, dibromo-3-chloropropane (DBCP), and the first ETS on asbestos were not challenged in court and remained in effect until superseded by permanent standards. An ETS for acrylonitrile survived court challenge. ETSs on benzene, commercial diving, pesticides, 14 carcinogens, and asbestos were stayed or vacated by the courts.

Over the past decade, OSHA has avoided setting ETSs and instead has proceeded directly – but slowly – to establishing permanent standards for toxic substances under Section 6(b) (5). Thus, OSHA denied a 1993 request from Public Citizen for a temporary emergency hexavalent chromium standard but promised an advanced notice of rule making for 1995. After a successful court challenge, in October 2004, 9 years after OSHA's promised action, it finally issued a proposed revision of its 8-h exposure limit, lowering the standard to  $1 \mu\text{g}/\text{m}^3$  from the previous 33-year-old standard of  $52 \mu\text{g}/\text{m}^3$ , thus preventing 350 excess cancers annually. A 2001 petition requesting an ETS for beryllium was unsuccessful. However, OSHA is currently planning for a permanent standard.

### Short-Term Exposure Limits

Short-term exposures to higher levels of carcinogens are in general considered more hazardous than longer exposures to lower levels. OSHA issued a new standard for exposure to ethylene oxide in 1984 but excluded a short-term exposure limit (STEL) that had originally been prepared, in deference to objections from the Office of Management and Budget. Ralph Nader's Health Research Group sued the Secretary of Labor in 1986 over OSHA's

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continuing failure to issue the STEL. In 1987, the District of Columbia Circuit Court of Appeals ordered OSHA to establish a STEL for ethylene oxide by March 1988. OSHA complied by setting a STEL of 5 ppm over a 15-min period.

#### s0035 **The Air Contaminants Standard**

p0100 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 all of 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.

p0105 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.

p0110 In the meantime, OSHA could argue that those 164 substances are recognized hazards and enforceable through OSHA's general duty clause, but 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.

#### s0040 **The Toxic Substances Control Act**

p0115 TSCA enables EPA to require data from industry on the production, use, and health and environmental effects of

chemicals. TSCA also requires the manufacturer of new chemicals, or of existing chemicals put to a significant new use, to file a premarket notification with EPA. EPA may regulate chemicals under TSCA – by requiring labeling, setting tolerances, or banning completely and requiring repurchase or recall – where the chemicals present “an unreasonable risk of injury to human health or the environment.” EPA may also order a specific change in chemical process technology. In addition, TSCA gives aggrieved parties, including consumers and workers, specific rights to sue to enforce under the act, with the possibility of awards for attorneys' fees. (This feature was missing in the OSHAct.)

Under TSCA, EPA must regulate “unreasonable risks of injury to human health or the environment.” EPA has issued a regulation for worker protection from asbestos at the new OSHA limit of 0.2 fibers/cm<sup>3</sup>, which applies to state and local government asbestos abatement workers not covered by OSHA. Although the potential for regulating workplace chemicals is there, EPA has not been aggressive in this area. Between 1977 and 1990, of the 22 regulatory actions taken on existing chemicals, 15 addressed polychlorinated biphenyls (PCBs), which EPA has a specific statutory directive to address under TSCA. Only regulations pertaining to asbestos, hexavalent chromium, and metalworking fluids had a strong occupational exposure component. Although EPA declared formaldehyde a probable carcinogen and the International Agency for Research on Cancer classified it as a confirmed human carcinogen, EPA chose not to take regulatory action on this substance, opting instead to defer to OSHA workplace regulations.

Used together, the OSHAct and TSCA provide potentially comprehensive and effective information-generation and standard-setting authority to protect workers. In particular, the information-generation activities under TSCA can provide the necessary data to have a substance qualify as a recognized hazard that, even in the absence of specific OSHA standards, must be controlled in some way by the employer to meet the general duty obligation under the OSHAct to provide a safe and healthful workplace.

The potentially powerful role of TSCA regulation was seriously challenged by the Fifth Circuit Court of Appeals in 1991, when it overturned the omnibus asbestos phase-out rule that EPA had issued in 1989. The court held that, under TSCA, EPA should not have issued a ban without having first considered alternatives that would have been less burdensome to industry. This would require the agency to perform a more comprehensive, detailed, and resource-intensive analysis. Rightly or wrongly, EPA has viewed this case (which was not appealed to the U.S. Supreme Court) as a significant impediment to future TSCA regulations, and the agency generally regards regulation of chemicals other than PCBs under TSCA to be a

nearly impossible task for now. With an unsympathetic Congress, there have been no successful attempts to resurrect the regulatory authority of TSCA. However, TSCA continues to be important for its surviving authority to require the testing of chemicals and for its information reporting and retaining requirements.

## s0045 **Control of Gradual Pollution in Air, Water, and Waste**

### s0050 **The Clean Air Act**

p0135 The modern Clean Air Act (CAA) came into being in 1970, and although significant changes were made in 1977 and 1990, the basic structure of the act has remained the same, with the addition of provisions for authority over acid rain, chlorofluorocarbons (CFCs), indoor air, and chemical safety, the last of which is discussed in the penultimate section of this article. The CAA regulates both stationary and mobile sources of pollution, taking into account the relative contributions of each to specific air pollution problems, and the relative capacity of different kinds of sources within each category to reduce their emissions. The recognition that sources using newer technology might be able to achieve greater emission reductions than older sources with older technology led to the act's distinction – both in the stationary and mobile source provisions – between new and existing sources. Although driven by equity considerations regarding the relative financial and technical burdens of pollution reduction, however, this approach unwittingly discouraged modernization or replacement of facilities and resulted in the operation of older (especially energy) facilities beyond their expected useful life. For new sources within each industrial sector, there was a recognition of the need for uniformity and also for encouraging technological innovation through technology-forcing inherent in stringent standards. The court decisions recognizing EPA's technology-forcing authority were greatly influenced by OSHA's early technology-forcing approach to worker protection.

p0140 The 1970 CAA directed EPA to establish primary ambient air quality standards that would protect public health with “an adequate margin of safety” (see Section 109(b) (1)). As interpreted by the courts and supported by congressional history, these standards were to be established without consideration of economic or technological feasibility. In addition, secondary ambient air quality standards were to be established to protect “the public welfare . . . within a reasonable time” (see Section 109(b) (2)).

p0145 Both federal and state government were to be involved in protecting the ambient air. Ambient air quality (concentration) standards were to be established by the federal government, and these were to be attained through (1) emission limitations placed on individual existing polluters through permits issued by state government as a part

of their State Implementation Plans (SIPs) (Section 110); (2) emission limitations for new sources, established not by the states but rather by EPA as New Source Performance Standards (Section 111); and (3) by a combination of federal and state restrictions on mobile sources. In specifying compliance with federal emission standards, Congress expressed concern with possible hot spots of localized intense pollution and also with intermittent versus continuous versus sudden and accidental releases of harmful substances. Emission standards, in contrast with ambient concentration standards, are expressed as an emissions rate (milligrams emitted per 100 kg of product, per hour, per day, per week, per quarter, per year, per BTU, per passenger mile, or other unit of measurement).

The 1970 CAA also made a distinction between the federal control of criteria pollutants through ambient air standards and the control of hazardous air pollutants by means of federal emission limitations. Hazardous air pollutants were those recognized as extraordinarily toxic and eventually regarded as non- or low-threshold pollutants. Initially, these were to be regulated to protect public health with “an ample margin of safety” (Section 112) and, as with the standards for primary ambient air pollutants, standards were to be established without consideration of economic burden. These pollutants, Congress determined, were sufficiently dangerous to preclude any reliance on atmospheric dispersion and mixing as a means of reducing their ambient concentrations. Because of their extraordinary toxicity, hot spots were to be avoided, and because ambient concentration air quality standards were considered impractical and of little relevance for sporadic and idiosyncratic sources, uniform federal emission standards were considered necessary. (Note, however, that California did establish an ambient standard as a complement to the federal emission limitation on vinyl chloride.)

In the early stages of the implementation of the stationary source provisions of the Clean Air Act (approximately 1970–1975), EPA focused on (1) the primary and secondary ambient air quality standards and (2) emission standards for both new sources of criteria pollutants and for all sources emitting seven regulated hazardous air pollutants (discussed below). Prior advisory standards for carbon monoxide (CO), sulfur dioxide (SO<sub>2</sub>), oxides of nitrogen (NOX), large particulate matter, and photochemical oxidants were made mandatory. In February 1979, the standard for photochemical oxidants was narrowed to cover only ground-level ozone, and the standard was relaxed from 0.08 ppm to 0.12 ppm averaged over a 1-h period. The standard for coarse particulate matter (PM<sub>10</sub>) – “inhalable” particulates up to 10 µm in diameter – was adopted in 1987. In July 1997, the ozone standard was further revised to 0.08 ppm. At the same time, the particulate standard was altered to place more stringent requirements on smaller (<2.5 µm) “respirable” particles (PM<sub>2.5</sub>) with a 24-h limit

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of 65  $\mu\text{g}/\text{m}^3$ . In 2006, the limit was further lowered to 35  $\mu\text{g}/\text{m}^3$ . A standard for a new criteria pollutant – airborne lead – was promulgated in October 1978. Current primary air quality standards set under Section 109 are found in **Table 1**.

In Section 112, Congress directed the administrator to set emission standards for hazardous air pollutants at a level that protects public health “with an ample margin of safety.” It is likely that this phraseology reflected an early assumption that, though very dangerous, hazardous pollutants did exhibit a finite threshold (a nonzero level of exposure below which no harm would occur). As the 1970s progressed, however, there was a growing recognition that this assumption might be wrong, and that for many hazardous pollutants there was no level of exposure (at least at levels within the limits of detection) below which one could confidently predict that no harmful or irreversible effects (especially cancer or birth defects) would occur.

This presented an implementation challenge for EPA. Arguably, given its mandate to protect public health “with an ample margin of safety,” the agency was required to ban the emission of several hazardous substances. This would, as a practical matter, essentially ban the use of these substances in many industries. Seeking to avoid this result, EPA adopted a policy of setting Section 112 emission standards at the level that could be achieved by technologically feasible technology. (This is the approach then followed by OSHA in setting standards for exposure to workplace chemicals. In the case of carcinogens, OSHA considered no levels to be safe and established control requirements at the limit of technological feasibility.) Using this approach, EPA set finite (nonzero) standards for arsenic, asbestos, benzene, beryllium, coke oven emissions, mercury, vinyl chloride, and radionuclides. The standard-setting process was slow and had to be forced by litigation; it took 4–7 years to establish a final standard for each of these substances. Had EPA continued to set standards for more substances, and had it used the technological feasibility approach to spur the development of cleaner technology, the environmental groups may well have been content to allow the implementation of Section 112 to proceed in this fashion. When the setting of new Section 112 standards all but stalled during the Reagan administration, however, the National Resources Defense Council, an environmental litigation group, was determined to press the issue in court.

*NRDC v. EPA*, decided by the District of Columbia Circuit Court of Appeals in 1987, placed new limitations on EPA’s approach to regulating hazardous air pollutants by requiring the EPA to determine an “acceptable” (usually nonzero) risk level prior to setting a hazardous air pollutant standard. In reaction to this case and to revitalize the moribund standard-setting process, Congress amended Section 112 in 1990 to use a two-tiered approach: the use of technology-based standards initially, with residual risks to be addressed (at a later date) by health-based standards. In the 1990 CAA amendments, Congress listed 189 other substances for which Maximum Achievable Control Technology (MACT) technology-based standards were to be set over 10 years for major sources (defined as those emitting more than 10 tons per year of any single toxin or more than 25 tons combined). EPA was further mandated to issue a new rule, “where appropriate,” adding pollutants “which present or may present . . . a threat of adverse human effects (including, but not limited to, substances which are known to be or may be reasonably anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentration, bioaccumulation, deposition or otherwise.” In addition, for nonmajor (that is, so-called area) sources, restrictions may be less: Generally Achievable Control Technology (GACT) or management practices.

**Table 1** National Ambient Air Quality Standards

Carbon monoxide	Primary (1970): 35 ppm averaged over 1 h and 9.0 averaged over 8 h; neither to be exceeded more than once per year Secondary: none
Particulate matter: <sup>a</sup>	
PM <sub>10</sub>	Primary (1970): 150 $\mu\text{g}/\text{m}^3$ averaged over 24 h, with no more than one expected exceedance per calendar year; also, 50 $\mu\text{g}/\text{m}^3$ or less for the expected annual arithmetic mean concentration Secondary: same as primary
PM <sub>2.5</sub>	Prior primary (1997): 65 $\mu\text{g}/\text{m}^3$ averaged over 24 h; 15 $\mu\text{g}/\text{m}^3$ annual maximum Revised primary (2006): 35 $\mu\text{g}/\text{m}^3$ averaged over 24 h
Ozone	Prior primary (1979): 235 $\mu\text{g}/\text{m}^3$ (0.12 ppm) averaged over 1 h, no more than one expected exceedance per calendar year (multiple violations in a day count as one violation). Revoked June 2005. Codified August 2005 Prior secondary: same as primary Revised primary (1997): 0.08 ppm averaged over 8 h
Nitrogen dioxide	Primary (1970): 100 $\mu\text{g}/\text{m}^3$ (0.053 ppm) as an annual arithmetic mean concentration Secondary: same as primary
Sulfur oxides	Primary (1970): 365 $\mu\text{g}/\text{m}^3$ (0.14 ppm) averaged over 24 h, not to be exceeded more than once per year; 80 $\mu\text{g}/\text{m}^3$ (0.03 ppm) annual arithmetic mean Secondary: 1300 $\mu\text{g}/\text{m}^3$ averaged over a 3-h period, not to be exceeded more than once per year
Lead	Primary (1977): 1.5 $\mu\text{g}/\text{m}^3$ arithmetic average over a calendar quarter Secondary: same as primary

<sup>a</sup>Note that PM<sub>xy</sub> below refers to particles equal or less than xy microns in diameter.

More stringent requirements are allowed for all new sources. Emission standards established under MACT must require “the maximum degree of reduction (including a prohibition on emissions, where achievable)” but must reflect “the cost of achieving emissions reduction and any non-air and environmental impact and energy requirements.” For pollutants with a health threshold, EPA could alternatively consider regulating an ample margin of safety in establishing emission levels, essentially the original mandate of the 1970 CAA. Finally, EPA was obligated to issue a report on risk, which it did in 2004. If no new legislation recommended by that report is enacted within 8 years, EPA must issue such additional regulations as are necessary to protect public health with an ample margin of safety – in general – and, specifically for carcinogens, protect against lifetime risks of one-in-a-million or more. EPA did make substantial progress on establishing MACT and GACT standards but has just begun working on risk- or health-based approaches.

an NPDES permit before discharging pollutants to surface waters. In practice, however, many dischargers (mostly smaller ones) still do not. The NPDES permit, which is issued after public notice and an opportunity for comment, is to incorporate all of the various requirements of the act – including discharge limits – that are applicable to the point source in question. Point sources are subjected both to technology-based and water quality-based limits and to the more stringent of the two when they overlap.

The technology-based limits are established by EPA as national standards. To set these standards for industrial dischargers, EPA first divided industry into various industry categories and then established effluent limits for each category based on its assessment of what was technologically and economically feasible for the point sources within that category. Further, as required by the act, EPA set different standards within each industrial category for conventional pollutants (biochemical oxygen demand, fecal coliform, oil and grease, pH, and total suspended solids), toxic pollutants (currently a list of 129 designated chemical compounds), and nonconventional pollutants (which simply are other pollutants, such as total phenols, which are listed neither under the conventional nor the toxic designation).

In recognition of the fact that conventional pollutants usually are amenable to treatment by the types of pollution control equipment that has long been in use at conventional sewage treatment facilities, the standards for conventional pollutants are set according to what can be obtained through the use of the Best Conventional Pollution Control Technology (BCT), taking into account the reasonableness of the cost. The standards for toxic and nonconventional pollutants, on the other hand, are set according to EPA’s determination of the level of pollution reduction that can be achieved through the application of the Best Available Technology Economically Achievable (BAT). Originally, Congress had directed EPA to set health-based standards for toxic pollutants, on a pollutant-by-pollutant basis, but this resulted in only a handful of standards (mostly for pesticide chemicals). The political difficulty of establishing national health-based standards for toxic chemicals led environmental groups, in a suit against EPA to compel regulation, to agree to a schedule for setting technology-based standards for a list of designated toxic pollutants. Congress formally endorsed this approach in 1977 by amending the act to require EPA to set BAT standards for all of the toxic pollutants on that list.

Under the CWA, EPA is to consider both control and process technology in setting BAT standards, which are to “result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants” and are to require “the elimination of discharges of all pollutants [where] such elimination is technologically and

## Water Legislation

The two most important federal statutes regulating water pollution are the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). The CWA regulates the discharge of pollutants into navigable surface waters (and into smaller waterways and wetlands that are hydrologically connected to navigable waters), and the SDWA regulates the level of contaminants in public drinking water supplies.

### The Clean Water Act

The modern Clean Water Act has its origins in the Federal Water Pollution Control Act Amendments of 1972. The basic structure of the act was established at that time, although it was refined and refocused by the Clean Water Act Amendments of 1977 (from which it also took its name) and by the Water Quality Act Amendments of 1987. The regulatory focus of the CWA is the discharge of pollutants to surface waters from “point sources,” principally industrial facilities and municipal sewage treatment plants (known under the act as publicly owned treatment works, or POTWs). The CWA flatly prohibits any discharge of a pollutant from a point source to surface waters unless it is done in conformance with the requirements of the act, and the statute has since 1972 retained as an explicit “national goal” the elimination of all point-source discharges to surface waters by 1985. Although the “no discharge” goal may never be attainable in practical terms, it has helped focus the act’s implementation on gradual – but inexorable – pollution reduction, as discharge limits are made more stringent over time.

The centerpiece of this pollution reduction scheme is the National Pollutant Discharge Elimination System (NPDES) permit. In theory, all point sources must have

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economically achievable.” An individual discharger may obtain a cost waiver from BAT standards for nonconventional pollutants if it cannot afford to comply, but no cost waiver is available from the standards for toxic pollutants. For new industrial sources within an industry category, EPA is to set standards based on Best Available Demonstrated Technology (BADT), which can be more stringent than BAT or BCT because of the greater technological flexibility inherent in the design and construction of a new facility. Although industry-wide costs are to be considered by EPA in establishing BADT standards, no waivers are available to individual applicants once the standards are set.

p0205 The CWA also imposes technology-based standards on POTWs, based on the limitations that can be met through the application of secondary sewage treatment technology. In essence, this requires an 85% reduction in biochemical oxygen demand and total suspended solids. In addition, the act imposes limitations on discharges by industrial sources into POTWs. Such discharges are known under the act as indirect discharges (because the pollutants are not discharged directly to surface waters but rather are discharged indirectly to surface waters through a public sewer system). Limitations on indirect discharges are known under the act as pretreatment standards, because they have the effect of requiring the indirect discharger to treat its wastewater before discharging it to the POTW for further treatment. EPA has set national technology-based limitations (known as the categorical pretreatment standards) on indirect discharges of toxic pollutants by firms in certain industrial categories. In addition, the act requires the POTW to set such additional pretreatment limits and requirements as is necessary both to ensure the integrity of the sewage treatment process and to prevent the indirectly discharged pollutants from passing through the sewer system and causing a violation of the POTW’s discharge permit.

p0210 For the first 15–20 years of the act’s implementation, the primary focus was the establishment and implementation of the technology-based limits discussed above. More recently, however, considerably more attention has been given to the act’s system of water quality-based limits, which is equally applicable to industrial sources and POTWs. Since 1972, the CWA has directed the states to establish, and periodically revise, ambient (in-stream) water quality standards for all of the lakes, rivers, streams, bays, and other waterways within their borders and has required EPA to set and revise these standards to the extent that a state declines to do so. Further, the act has required since 1977 that NPDES permits include such additional discharge limits – beyond the national technology-based limits – as may be necessary to meet the ambient water quality standards of the waterway in question.

p0215 To help call attention to these water quality requirements, Congress in 1987 added what became known as the

toxic hot spot provision of the CWA, which directed EPA and the states to identify those waters that were in violation of ambient water quality standards because of toxic pollution, to identify those point sources whose discharges of toxic pollutants were contributing to those violations, and to develop an “individual control strategy” for that source (which almost always meant a revision of the source’s NPDES permit to add or tighten limits on toxic pollutants). Another provision of the act that has prompted the addition or tightening of water quality-based discharge limits has been the requirement that the states (and, if they decline, the EPA) to calculate a total maximum daily load (TMDL) for all waters that are in violation of ambient water quality standards. For any particular body of water, the TMDL for a particular pollutant is the total amount of that pollutant that may be discharged to the water body in a day without violating the relevant ambient water quality standard. When a TMDL is set, it often leads inexorably to a tightening of the NPDES permits of those point sources whose discharges are contributing to the particular violation of water quality standards. Although the TMDL requirement has been in the act since 1972, the states and EPA have been slow to implement it. Over the past 10 years or so, however, as a result of several successful suits by environmental groups seeking to compel EPA to set TMDLs in the face of state inaction, the TMDL requirement has come considerably more to the fore. Consequently, the inclusion of water quality-based limits in NPDES permits has become considerably more commonplace.

### ***The Safe Drinking Water Act***

Although some sources of drinking water are also regulated as surface waters under the CWA, the legislation specifically designed to protect the safety of the drinking water delivered to the public from public water systems is the SDWA. Passed in 1974 after a series of well-publicized stories about the number of potential carcinogens in the Mississippi River water used as drinking water by the City of New Orleans, it contains very little that is designed to address the sources of drinking water pollution. Instead, the SDWA directs EPA to set national health-based goals – known as maximum contaminant level goals (MCL goals) – for various drinking water contaminants and to set MCLs that are as close to the MCL goals as is technologically and economically feasible. All public water systems, defined as those with at least 15 service connections or that serve at least 25 people, are required to meet the MCLs.

Over the act’s first 8 years, EPA set only 23 federal drinking water standards. Dissatisfied with the pace of implementation, Congress amended the act in 1986 to spur the agency into action. It directed EPA to set standards (MCLs and MCL goals) for 83 specified

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contaminants within 3 years and to set standards for 25 additional contaminants every 3 years thereafter. Ten years later, with scores of MCLs and MCL goals now on the books, Congress scaled back. In a 1996 compromise endorsed by environmental groups and water suppliers alike, Congress eliminated the requirement for 25 new standards every 3 years. At the same time, it added provisions that effectively ensured both that the standards that had been set would largely be allowed to remain in place and that new standards would be far slower in coming (and likely would be – because of the addition of a cost–benefit requirement – relatively weaker).

p0230 Since then, the primary focus of the SDWA program has been bringing public water systems throughout the country into compliance with the existing standards. Although the MCLs are set at a level deemed to be technologically and economically feasible, many water systems have had difficulty affording the cost of meeting, and monitoring for, the MCLs. To attempt to ameliorate the financial burden on municipal water systems, the SDWA has periodically made federal funds available for technology upgrades and infrastructure improvements. The task, however, remains a daunting one. In 2002, EPA estimated that approximately \$151 billion would be needed over the next 20 years to upgrade the nation's 55 000 community water systems.

### s0070 **The Regulation of Hazardous Waste**

p0235 Broadly speaking, the generation, handling, and disposal of hazardous wastes are regulated by the interaction of two federal statutes. The primary federal law regulating hazardous wastes is officially known as the Solid Waste Disposal Act. In 1970, Congress amended that statute with the Resource Conservation and Recovery Act (RCRA), and the law has come to be popularly known by that name. RCRA was given regulatory teeth with a set of 1976 amendments under which EPA, in 1980, promulgated regulations establishing a cradle-to-grave system for hazardous wastes that tracks the generation, transportation, and disposal of such wastes and establishes standards for their disposal. Initially, however, EPA's disposal standards were minimal to nonexistent and did little to discourage the landfilling of chemical wastes. This led Congress, in 1984, to pass sweeping amendments to RCRA that (1) established a clear federal policy against the landfilling of hazardous wastes unless they have first been treated to reduce their toxicity and (2) gave EPA a specific timetable by which it had to either set treatment standards for various categories of waste or ban the landfilling of such waste altogether. Consequently, EPA has set treatment standards – which are commonly known as the land disposal restrictions (LDRs) – for hundreds of types of hazardous wastes. These standards are based on

EPA's assessment of the Best Demonstrated Available Technology for treating the waste in question.

Thus, RCRA directly regulates the handling and disposal of hazardous wastes. And by establishing a set of requirements that must be followed once hazardous waste is generated, it also indirectly regulates the generation of hazardous wastes. RCRA regulations have increased the cost of disposing of most types of waste by two orders of magnitude over the past 25 years. In this sense, RCRA operates as a *de facto* tax on the generation of hazardous waste. p0240

Another statute that acts as an indirect check on hazardous waste generation (and that provides additional incentive to ensure that one's waste is safely disposed) is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as the federal Superfund law). The primary focus of this law is the remediation (cleanup) of hazardous waste contamination resulting from imprudent handling and disposal practices of the past and the recovery of remediation costs from those designated as “responsible parties” under the act. CERCLA imposes liability for the costs of remediating a hazardous waste site both on the owners and operators of the site and on those generators of hazardous waste that sent waste to the site. Because the owners and operators are often business entities that are no longer financially viable, CERCLA liability often falls most heavily on the generators. And CERCLA liability is strict liability, meaning that the exercise of reasonable care by the generator is not a defense. Further, unless the generator can establish a convincing factual basis for distinguishing its waste from all or part of the contamination being remediated, CERCLA liability is joint and several, meaning that each responsible party is potentially liable for the full cost of remediation. As a practical matter, this means that the cost of remediation will be borne by those among the responsible parties who are financially solvent. p0245

The prudent business entity, then, has a strong financial incentive to take such actions as will minimize the likelihood that it will face CERCLA liability in the future. As the only certain way to avoid such liability is to refrain from generating the waste in the first instance, CERCLA does provide a rationale for pollution prevention. Further, it provides firms with an incentive to meet – or perhaps to go beyond – RCRA regulations in dealing with such wastes as they do generate. p0250

This is not to say, of course, that substantial amounts of hazardous waste are no longer generated in the United States, that all hazardous wastes are adequately treated and safely disposed, or that all instances of hazardous waste contamination are being adequately addressed (or addressed at all). RCRA and CERCLA both contain what might reasonably be called loopholes and gaps in coverage, and hazardous waste contamination remains an ongoing issue. Further, the most common treatment methodology p0255

incorporated into EPA's RCRA treatment standards is incineration, which has brought with it a release of airborne contaminants that has yet to be comprehensively addressed by regulation. There is no question, however, that the country has made considerable progress from the late 1970s, when disposal of chemical wastes in unlined landfills – at a cost of roughly \$15 per ton – was the common practice.

s0075 **The Chemical Safety Provisions of the Clean Air Act: Obligations Imposed by EPA and OSHA to Prevent the Sudden and Accidental Releases of Chemicals**

p0260 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.

p0265 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 Amendments of 1990 directed OSHA to promulgate a Process Safety Management (PSM) standard under the OSHAct.

p0270 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.

p0275 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* case, 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.

The Clean Air Act also requires each state to establish programs to provide small business with technical assistance in addressing chemical safety. These programs could provide information on alternative technologies, process changes, products, and methods of operation that help reduce emissions to air. However, these state mandates are unfunded and may not be uniformly implemented. Where they are established, linkage with state offices of technical assistance, especially those that provide guidance on pollution prevention, could be particularly beneficial.

Finally, the 1990 amendments established an independent Chemical Safety and Hazard Investigation Board (CSHIB). The board is to investigate the causes of accidents, conduct 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 prestart-up 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.

p0295 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 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 been ignored. 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.

## s0080 Environmental Regulation in the European Union

p0300 Europe, once behind the United States in environmental legislation, now often surpasses the United States in its

environmental initiatives. European Union directives form an overarching regulatory structure under which individual member states implement the broad general requirements of the directives. The most recent examples are the Water Framework Directive and the REACH, (Registration, Evaluation and Authorization of Chemicals) system, focused on improving the production and assessment of risk information and regulation of industrial chemicals, the counterpart to TSCA in the United States.

See also: (00272); (00275); (00276); (00279); (00280); (00281); (00283); (00294); (00295).

## Further Reading

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## Non-Print Items

### Abstract:

The manufacturing, processing, and use of chemicals and materials in industrial workplaces are often accompanied by environmental, health, and safety hazards and risks. Occupational and environmental factors cause or exacerbate major diseases of the respiratory, cardiovascular, reproductive, and nervous systems and cause systemic poisoning and some cancers and birth defects. Occupational and environmental disease and injury place heavy economic and social burdens on workers, employers, citizens, and taxpayers. Government intervention to address those issues largely takes the form of regulatory standards promulgated under the authority of federal legislation. This article addresses the major regulatory systems (or regimes) designed to protect public and worker health from chemicals discharged from sources that pollute the air, water, ground, and/or workplace in the United States. The European Union and other developed countries use similar approaches.

**Keywords:** Clean Air Act; Clean Water Act; Comprehensive Environmental Response, Compensation, and Liability Act; Environmental health; Environmental legislation; Hazardous waste; Occupational health; Occupational safety; Occupational Safety and Health Act; Pollution; Resource Conservation and Recovery Act; Safe Drinking Water Act; Toxic substances; Toxic Substances Control Act; Worker health and safety

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