

Apeel Sciences: Lot Traceability of a Breakthrough in Food Science
Technology

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ABSTRACT

Apeel Sciences has made it their mission to help eliminate food waste. To do so, they are introducing their exciting new product, Edipeel™, to market. Edipeel is an edible, natural, flavorless coating that, when applied to the surfaces of fresh fruit, reduces the rate at which produce spoilage occurs. The product more than doubles the viable shelf life of harvested produce. As a food product, the production of Edipeel must comply with federal regulations for lot traceability. As Apeel prepares to manufacture Edipeel at scale, they have recognized that their current practices for traceability would need to evolve. To ensure their operations were compliant and scalable, Apeel enlisted our support to evaluate their processes and recommend improvements where necessary. Apeel's service model for the application of Edipeel adds complexity to their process and became a key focus area of our evaluation. Through onsite interviews and an end-to-end supply chain review, we were able to verify their compliance with federal regulations for lot traceability and identify the areas of their process most vulnerable to operating at scale. We recommended both process and technological improvements to mitigate risk for the future. These recommendations help Apeel to remain compliant as they pursue their mission to help eliminate food waste.

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1. INTRODUCTION

Motivated by large-scale recalls and consumer demands, expectations for food traceability have increased dramatically in recent years. At the same time, as the complexity of food product supply chains increase, many companies are finding it difficult to document their end-to-end supply chain. (“From Farm to Fork”, 2018) The regulatory landscape in which these companies operate has responded with legislation that puts pressure on companies to establish supply chain transparency. The Bioterrorism Act of 2002 and Food and Drug Amendments Act of 2007 set initial standards for record keeping and reporting, but the Food Safety Modernization Act (FSMA) of 2011 has been the most impactful. FSMA was passed after a number of high-exposure breakdowns in food safety caused public health risks, and highlighted traceability gaps throughout food supply chains. (Deloitte, 2013) The 2008 salmonella outbreak linked to jalapeño peppers and the 2009 outbreak associated with the Peanut Corporation of America are examples of such breakdowns. (Scholten, et al., 2016)

Although collectively these acts establish requirements for traceability, they fail to describe best practices or standard operating procedures. Companies in food production, manufacturing and distribution have had to evaluate their current practices for tracing throughout their supply chain. Apeel Sciences, the focus of this project, has asked us to do just that. As a start-up, they are aware of the current landscape demanding traceability. They are taking a proactive approach to risk management and supply chain transparency and they intend to ensure a clear process for product tracking is in place.

1.1. APEEL SCIENCES

Founded in 2012, Apeel Sciences is a food science startup based in Santa Barbara, California. Apeel was founded by James Rogers, a PhD graduate in Materials, who recognized that the principles behind coating solar panels can also apply to produce as a means to extend shelf life. (Strom, 2018) Apeel’s mission is to “use [their] natural, plant based technologies to protect crops and harvested produce, helping to eliminate food spoilage and reduce reliance on chemicals”. (Apeel Sciences, 2018)

The clock for food spoilage starts when produce is picked. A fruit’s natural peel acts as a barrier to keep water in and oxygen out. Apeel Sciences has developed Edipeel™, an edible,

natural, flavorless coating that, when applied to the surfaces of fresh fruits and vegetables, reduces the rate at which produce spoilage occurs. This is their first commercial product and the focus of our work with Apeel. Edipeel is produced as a powder and reconstituted with water to create a working solution prior to application on harvested fruits and vegetables. Once applied, Edipeel mimics the protection of the plant's natural peel, enhancing its capabilities as a protective barrier. In doing so, Edipeel can prolong the viable shelf life of harvested produce to more than two times the natural life. Such a drastic increase in shelf life has vast supply chain implications for the production and distribution of produce globally. Although the supply chain implications of adjusting shelf-life as a variable is not the purpose of our work with Apeel, it presents an interesting topic for future research.

1.1.1. APEEL SCIENCES' SERVICE MODEL

Produce consumed in the United States is often collected by a distributor in a single location for packaging and redistribution to the end consumer. These distributors are current target customers for Apeel. To serve these customers, Apeel operates a service model in which they manage the reconstitution and application of Edipeel at their customers' packing house. Apeel has established an inventory management, reconstitution, and application process that allows them to integrate into the existing network of produce distributors at the packing house. Apeel uses a mobile unit to apply the reconstituted Edipeel powder. The unit is brought to their customer's packing house and installed into the packing line where Edipeel is then applied. Although this model allows for stricter quality assurance over the application, it extends Apeel's responsibility for lot traceability further downstream in their supply chain. Our work with Apeel ensures that their process for traceability appropriately accommodates for this element of their strategy.

1.2. PROJECT PURPOSE

As a food product, the sourcing, production and distribution of Edipeel is governed by federal regulations for food safety and supply chain traceability. Although current regulations indicate that product traceability is a critical component of continued operations in the food industry, how companies should go about it has not been clearly defined. There is a lack of standardization for collecting and communicating critical data along the supply chain to support traceability. (McEntire, et al., 2012) This lack of clarity is a motivating aspect for this project.

Apeel's service model introduces a complicating factor in that Apeel employees are directly applying Edipeel to their customers' product. The purpose of this project is to ensure that Apeel's lot traceability program is compliant from a regulatory standpoint.

At its simplest, traceability is about connecting information over the lifecycle of a product. Having traceability throughout their supply chain would mean that Apeel is able to identify the origin and whereabouts of all Edipeel inventory - current and historic - upon request. Tactically, this means that all critical data points throughout the process of producing and distributing Edipeel are appropriately logged and linked systematically.

Our role as we analyzed their supply chain was to ask the questions they had not previously considered, thinking objectively about their current process and where future strategies may shift current practices. As a startup, this was especially important given the likelihood that their practices may shift as they enter new partnerships, new markets or grow in size.

1.3. PROJECT SCOPE AND DELIVERABLES

The project scope was established out of an urgency for Apeel to validate that they operate in a compliant manner as they scale their operations. Although the focus of our work is with Edipeel for avocados (their current priority and first product to launch) the process outlined should be viable for all Edipeel varieties following the service model. Apeel Sciences had their first official production run and distribution while this project was still underway.

The scope of this project focused on traceability rather than root cause analysis. A root cause analysis or a traceback investigation would focus on identifying the cause or source of an issue. This activity would precede an action like a product recall. Traceability looks at the ability to gather all the necessary data in the event of a US Food and Drug Administration (FDA) mandated or firm initiated recall. The project scope is outlined in **Figure 1.3.1** and additional detail around scope decisions can be found in **Appendix A**.

Figure 1.3.1: High Level Project Scope Decisions

	In Scope	Out of Scope
Products	Edipeel	Other Apeel products
Produce	Avocados	Other
Geographies	United States	Other
Distribution Model	Service model	Direct-to-customer sales
Project Contributions	Recommendations for updated Operating Procedures and system capabilities; reporting requirements	Technology upgrades and implementation

2. LITERATURE REVIEW

Our research focused on familiarizing ourselves with the current regulations with which Apeel must comply. We looked for a framework with which to evaluate Apeel’s current practices as well as reports of common challenges in the industry. Baseline practices are not readily available, though where possible, we looked for recommendations.

2.1. CODE OF FEDERAL REGULATIONS (CFR)

As a food product producer, Apeel Sciences must comply with the Code of Federal Regulations (CFR) published by the FDA for the manufacture and distribution of Edipeel. Apeel identified three parts of the CFR Title 21 as pertinent to our work (21 CFR, Parts 110, 112, and 117). These regulations stipulate good manufacturing practices (GMP) throughout their operations. (FDA, 2018)

For the purposes of our focus with Apeel, product traceability, the key requirements include:

- Establishing a recall plan describing the steps to be taken during a food recall, inclusive of how effectiveness checks are performed to verify a recall is carried out and how the recalled food is properly disposed of. (FDA, 2017)
- Information requirements for packing. Each packing activity needs to include the following: lot number, commodity name, date/time, signature of operator who performed the activity, and a supervisor review.

Additional detail described in the above mentioned sections of the CFR can be found in **Appendix B**.

2.2. PUBLIC HEALTH SECURITY & BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

The Bioterrorism Act (BT Act) of 2002 gave the FDA the authority to require that companies within the food industry maintain a record of “immediate previous sources and the immediate subsequent recipients of food.” Known as one-up/one-down traceability, this enables companies and investigators to link food throughout the supply chain. (McEntire, et al. 2012) For the purpose of Apeel’s operations, this means the company must document and link supplier raw material lot numbers through to their point of title transfer at the customer.

2.3. FOOD AND DRUG AMENDMENTS ACT OF 2007

The Food and Drug Amendments Act of 2007 added the Reportable Food Registry (RFR) as an improvement to the one-up/one-down system and was adopted under US Code 21 350f. Per this requirement, the responsible party of a reportable food must provide product notice to its immediate upstream sources and immediate downstream recipients. The responsible party must also report information in the RFR portal, such as: manufacturer, description, SKUs, lot numbers, and use-by dates. (McEntire, et al. 2012)

2.4. FOOD SAFETY MODERNIZATION ACT

Following a number of breakdowns in food safety, the Food Safety Modernization Act (FSMA) was introduced as the first major legislation around food safety since the 1930’s. FSMA increases the regulatory reach of the FDA across the food supply chain and emphasizes an increased awareness of the need for traceability processes for food producers. (Deloitte, 2013) This act, signed by President Obama in January 2011, shifts the federal regulators focus from reactive to preventive. (“What is FSMA?”, 2018)

FSMA impacts every segment of the produce supply chain and proposes several large regulations. (“What is FSMA?”, 2018) Most pertinent to our work with Apeel is the introduction of the rules for Preventive Controls for Human Food. These outline the requirements for a company to have a written recall plan. Should the FDA ever initiate a recall of product that has

been treated with Edipeel, Apeel is required to respond in the following manner within four hours. An example document to be completed within the four hour time frame is found in **Appendix C**.

Of additional importance to our work is FSMA Title II, Sec. 204 “Enhancing Tracking and Tracing of Food and Recordkeeping”. This section states that the FDA was to establish ‘tracking and tracing pilots’ by September 2011. Section 204 does not state additional or amended regulations, but instead initiated new investigations into the current practices and opportunities for improvements of product traceability in food supply chains. The relevant results of the tracking and tracing pilots that were completed are found in **Section 2.5** below.

2.5. PILOT PROJECTS FOR IMPROVING PRODUCT TRACING ALONG THE FOOD SUPPLY SYSTEM

In 2011, the FDA enlisted the Institute of Food Technologists (IFT) to complete product tracing pilots with multiple food product supply chains. Throughout the pilots, the IFT was to “explore and demonstrate methods that enable products in the food continuum to be rapidly and effectively linked from the point of sale back to the point of production/source” (McEntire, et al., 2012). The goal was to analyze current state practices and develop methods for rapid tracking and tracing of food products along a supply chain.

The IFT conducted 14 mock tracebacks and traceforwards in a variety of supply chains. A large obstacle they faced was the wide variety of non-standardized practices and lack of a common language. Ultimately, they urged the FDA to establish and communicate a strict set of rules for the appropriate tracking and tracing of food products.

The IFT defines product tracing as “the ability to follow the movement of a food product and its constituents through the stages of production, processing, and distribution, both backward and forward”. (McEntire, et al., 2012) While food safety measures are considered precautionary to prevent any instance of foodborne illness, product tracing measures are typically utilized in a reactive sense. The IFT distinguishes product tracing from traceability. Product tracing typically considers the entire supply chain, whereas traceability is commonly referring to the actions taken within a firm.

Firms tend to use the term “recall” interchangeably with “traceback”. For clarification, the traceback process is utilized to identify the source of the issue - starting at the point of sale and seeking to identify the timing and source of the problem. The recall, then, may follow the

traceback and is intended to find the products that may in turn be affected. Where necessary, the recall would include the actions to have these goods removed from the supply chain.

The methodology used by the IFT serves as a framework for our evaluation of Apeel. Key concepts and language presented by IFT that we have utilized are outlined in **Figure 2.5.1** below.

Figure 2.5.1 Definitions used in Institute of Food Technology’s 2011 Pilot Projects For Improving Product Tracing

KEY CONCEPT	DESCRIPTION
Key data elements (KDEs)	Data required that captures and communicates critical track and trace information (e.g. lot number, purchase order, etc.)
Critical tracking events (CTEs)	Critical points in the supply chain where data capture is necessary. Key points of product transfer and transformation - eg., transport to facility.
Traceback investigation	Tracing product from the retail shelf to the source. <ul style="list-style-type: none"> • Reviewing the distribution trail of products from multiple locations to identify a common convergence point upstream in the supply chain - e.g. a common harvest date. • Answers key questions like “what do these products have in common?”.
Trace forward investigation	Tracing product forward from farm to the retail store <ul style="list-style-type: none"> • Follows a product from a convergence point towards the point of consumption. • Answers questions like “where did these specific products (eg. lot #'s) go?”. These investigations are often very reliant on company records.
Convergence point	A point in the supply chain where multiple distribution paths of a product converge.
Recall	Typically follows a traceback investigation and may be used interchangeably with “traceforward investigation”. Focuses on identifying products that could have been contaminated at the point identified in the traceback investigation. The recall would include the actions to have these goods identified and removed from the supply chain.

In addition to providing a framework and language for our evaluation of Apeel, the work by the IFT also highlighted common practices that inhibit the speed or accuracy of an investigation. These were taken into consideration as we developed an understanding of Apeel’s operations and mitigating solutions suggested. Select examples of such practices are found in **Figure 2.5.2** below.

Figure 2.5.2: Common challenges as identified by the Institute of Food Technology

PRACTICE	CHALLENGE
Use of one SKU representing multiple products	Quantity in a case frequently caused confusion. Additional confusion linking which product was sent to which firm when multiple case counts are captured under one SKU.
Missing Lots, Brand or Country of Origin Labelling on paperwork	Lot identification was frequently omitted from paperwork.
Lack of clarity around contacts	Common instances of firms not having the “right” employees ready to respond, or multiple contacts identified at a singular facility caused delays and confusion.

3. METHODOLOGY

Our approach parallels that of the IFT product tracing pilots. We reviewed methods that enable products in the chain to be quickly and effectively linked from the point of transfer to the customer back to production. To be able to trace a product through the Apeel supply chain, there are a series of transactions that are to be followed in a logical order. Appropriate records at each transaction point along this trail are what allow for traceability. Because of this, our analysis of the end-to-end process of Edipeel’s production and distribution took three main forms: 1. a high level end-to-end supply chain review; 2. a scenario based review of the product journey; and 3. a Key Data Elements (KDE) review.

Apeel’s current processes can be found in **Section 3.1** below. Here we have captured the high level steps for the production of Edipeel through to Apeel’s end customer - the avocado distributor. Establishing a complete understanding for the purposes of traceability required a deeper look at the of the nuances of their operations. Our second level of review analyzed the possible routes a package of Edipeel may take from raw material through to production. A tool we used to facilitate this discussion was a simplified process map illustrating multiple scenarios for manufacturing and application. An example, inclusive of the key questions asked, can be found in **Appendix E**. This scenario review helped identify the constraints and business decisions that impact how data are created, captured and tracked. A KDE review was our lowest level of analysis of Apeel’s operations. It was critical that we were able to distill their process to a series of connected data points. Understanding how data must be connected, given the constraints identified, allowed us to distill the traceability requirements to five key data connections. What

we uncovered during our scenario reviews and key data element reviews can be found in **Section 4** below.

Our primary point of contact throughout has been Apeel's Sr. Director of Supply Chain. Most of our information gathering for Apeel's current state occurred during an on-site visit at their Santa Barbara headquarters. While onsite, we hosted information gathering sessions with the following teams: Supply Chain, Facilities, Regulatory, Operations, Marketing, Quality, and IT. Throughout these conversations, it was our role to capture as much of the current state as possible and ask the questions they may not have considered. Although our project scope does not include specific recommendations for technology updates, it was also important to understand the tools being used.

3.1. END-TO-END SUPPLY CHAIN REVIEW

An end-to-end process map was provided to us by Apeel. This acted as a high-level guide of their operations and was used to facilitate conversation while onsite. As we reviewed the process and various functional interactions within it, we paid particular attention to the critical points of transfer or transformation (CTEs) of Edipeel along the supply chain. Taking note also of the processes in place to capture and communicate KDEs at each of these points. The remainder of **Section 3.1** details the current state process for the production of Edipeel.

Apeel manufactures Edipeel onsite in Santa Barbara, California. A critical element of their corporate strategy is their service model for the application of Edipeel. As mentioned above, they have developed a process to integrate into the existing distribution of produce. This service model influences their inventory management and data collection process from raw material receipt through application at the packing house. The process maps found in **Appendix D** illustrate raw material ordering and receipt. The maps also show Edipeel production and the movement and reconstitution of Edipeel at the packing house. At a high level they also illustrate the information flow required for lot tracking and inventory management.

3.1.1. LOGISTICS AND SHIPPING

To fulfill a sales order, existing inventory of Edipeel is picked from finished goods inventory (if available, if unavailable skip to manufacturing). Due to Apeel's control over the reconstitution and application steps, the initial transfer of inventory to the customer's packing

house is considered an internal transfer. Apeel still owns the inventory of Edipeel sitting at the packing house. The process in **Appendix D Figure D.2** illustrates that the necessary inventory is “picked, packed, and shipped” physically to a new location, (i.e. packing house), and systematically transferred in their enterprise resource planning (ERP) system to a different Apeel inventory location. The appropriate lot number of the transferred inventory is logged systematically to ensure visibility of all finished goods throughout relocation to the customer.

3.1.2. ON-SITE SERVICE

The customer sales order is a commitment for Apeel to apply Edipeel to an agreed upon volume (cartons or pallets) of produce. A sales order is completed when the committed amount of produce has been coated with Edipeel at the packing house. After the packing house receives the Edipeel inventory, the onsite team will use the local inventory to create the reconstituted mixture for application.

As Edipeel is mixed into a solution the *treatment batch record* is created. This record is a critical component of traceability of Edipeel through to the customer. The lot number for all bags of Edipeel used in creating the solution are captured and a treatment batch data record is created using the sales order, date and customer repack code. The repack code is a data point from the customer and indicates the package of Apeel treated produce that will ultimately be shipped to stores.

At the moment, there is a manual process to capture the Edipeel lot number, generate the treatment batch code with repack number and submit a scan of the document to Apeel’s Regulatory team. The Regulatory team reconciles the now completed sales order with the Edipeel lot numbers used and the resulting treatment batches. This information is logged for the purposes of traceability in their ERP system and the Edipeel inventory is officially charged to the customer.

3.1.3. PLANNING

To date, the majority of Edipeel production has been on a make-to-order basis. However, Apeel also has the option to manufacturer against a forecast. As Apeel scales, this may be required more frequently to build up inventory prior to receiving a customer sales order.

3.1.4. MANUFACTURING

Production of inventory is initiated through a sales order captured in Salesforce. Work orders for manufacturing are generated based on the fulfillment dates detailed in each sales order. Upon receipt of a sales order, current finished goods inventory levels are assessed. For situations where finished goods inventory levels are low, raw materials will be reviewed to confirm available inputs for a new production run. Where necessary, a raw material purchase order will be generated.

Manufacturing will select the containers of raw material that they will use for production. They will capture the quantity of raw material used from the relevant container IDs and assign an Apeel lot number to the production batch. Currently, this process is manually entered into their ERP system to generate a label for packaging.

3.1.5. RAW MATERIAL RECEIPT

Raw materials are quality inspected upon receipt. Multiple drums of raw materials may be delivered under the same supplier lot number. Upon receipt, Apeel's raw material inventory is updated with the appropriate quantities. Apeel captures the suppliers' lot number and generates a container ID to individually identify each drum. The suppliers' lot number, container ID, quantities and receipt dates are entered into the ERP system for tracking purposes.

4. FINDINGS

While the end-to-end process mapping developed our understanding of Apeel's operations, the most critical information for analysis of Apeel's traceability came to light while understanding various scenarios and data requirements. Below we describe the key findings that allowed us to appropriately analyze Apeel's current process for traceability, assess if there are gaps and identify key considerations for future growth.

4.1. SCENARIO-BASED PROCESS REVIEW FINDINGS

Understanding scenarios for how a batch of Edipeel can be created and deposited on produce brings to light any points along the process where lots may be mixed, data points may be added, or inventory visibility may be hindered. We paid particular attention to the CTE we had identified in the high level review:

- raw material receipt
- Edipeel production

- inventory transfer to customer packing house
- reconstitution
- application

A complete understanding for the purposes of traceability requires an understanding of the nuances of their operations. These nuances may come in the form of intentional business decisions, constraints to production for quality assurance, or current limitations of their tools. As mentioned previously, an example of a scenario walk-through and questions asked can be found in **Appendix E**. Our key findings from this walk through - those related to understanding the nature of the tracking data, how they are generated, and what constrains them - are documented below.

Raw Materials & Manufacturing:

- We were able to verify that, for the purpose of production, it is possible that more than one container ID of a single raw material input may be used. A single lot of Edipeel can contain multiple lots of raw material.
- A production run, and therefore the lot size for Edipeel is currently ~48kg. For packaging, this product may be distributed into multiple packs (1kg or 10kg eaches, or a 10 x 1kg case pack) all of which will be marked with the same Apeel Lot #, production date and best before date.
- Whether Edipeel is manufactured to order or to forecast, there will be a sales order (from Salesforce) linked to the work order for production.

Finished Goods Inventory Management:

- Package sizes have been established to minimize unused product on site. A partially used bag of Edipeel cannot be used at a later date and must be disposed of.
- In a service model, Apeel maintains control of their inventory through to application. This means that they will transfer inventory to a different physical location at the customer site, but systematically this is captured as a transfer within their own location master.
- The ultimate transfer of inventory (draw-down) is systematically captured when a sales order is fulfilled. Given the service model, a sales order is considered completed once the agreed upon amount of produce has been treated with Edipeel. The lots and volumes of Edipeel used to complete this sales order are manually captured on-site. They are then scanned to the Regulatory team for entry into the ERP.

Reconstitution and Application:

- Onsite, Edipeel is reconstituted in solution prior to application. The appropriate concentration of Edipeel in the reconstituted batch may differ by produce variety and country of origin. It may be true that different varieties of avocados or those from different origins require small variations in concentration to be most effective.
- Because of their service model, quality testing can take place as batches are being reconstituted and product can be tested.
- We were able to verify that it is possible that more than one lot number of Edipeel may be used during reconstitution.
- It is important to understand what the customer defines as a “lot” of produce. For a current customer, we were able to confirm all avocados processed/packed for a given day were considered to be one lot. However, this may not be the case for other customers.

4.2. KEY DATA ELEMENTS (KDE) REVIEW

Through our key data element review, we distilled their process into a series of connected data points. We reviewed their current lot numbering systems and identified the data elements to be captured at each key tracking event (KTE). Apeel’s tracking numbering systems for raw materials, lot numbers and batch data (reconstituted and applied at packing house) can be found in **Figure 4.2.1** below.

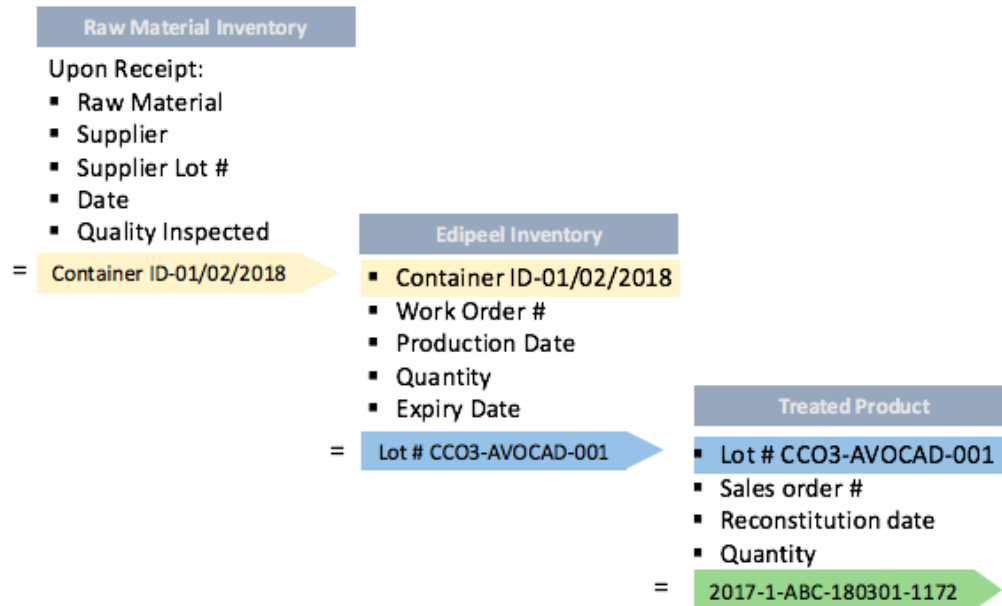
Figure 4.2.1: CURRENT LABELING FORMATS

ID	EXAMPLE	EXPLANATION
Raw Material Container ID	Container ID: 1 OF 2 20180501	Number of Containers shipment (1 of 2) Receipt Date (20180501)
Edipeel Lot #	CC03-AVOCAD-001	Date (CC03) <ul style="list-style-type: none"> - Year (C=17) - Month (C=March) - Day(03) Product Identifier (AVOCAD) <ul style="list-style-type: none"> - Edipeel for Avocado Batch number (001) <ul style="list-style-type: none"> - For given date above
Treatment Batch Data #	2017-1-ABC-180301-1172	Sales Order (2017) Sales Order Line Number (1) Customer ID (ABC) Date (180301) <ul style="list-style-type: none"> - yymmdd Customer Repack No. (1172) <ul style="list-style-type: none"> - Eg. pallet #

The Raw Material Container ID is assigned by Apeel upon receipt. It is possible that they received multiple drums of product from a supplier of the same lot. These are given unique container IDs for tracking purposes. Apeel’s lot number is generated at the point in time of manufacturing and indicates the product code, date and batch number - should there be multiple batches produced in a day. The treatment batch data number is the data point that allows Apeel to track their product through to the batch of produce for which Edipeel was applied. This is one step further than tracking simply the customer receiving the inventory and necessary since Apeel owns the Edipeel inventory until application on the produce.

Figure 4.2.2 below summarizes the data flow of Edipeel across multiple KTEs. Ultimately, Apeel will require that these data linkages exist within their ERP system and are appropriately maintained. The goal is that data can be quickly accessed and a complete picture of product inventory and a particular lot’s whereabouts can be created.

Figure 4.2.2 Data Collection at Key Tracking Events



For illustration purposes, we have also captured these data elements at the most granular level in the form of an Entity Relationship Diagram (ERD). This activity helped further highlight the relationships between multiple data points and can act as a baseline for future reporting schema. See **Appendix F** for this database schema and **Section 4.3** below for a discussion of how these data linkages are used in practice.

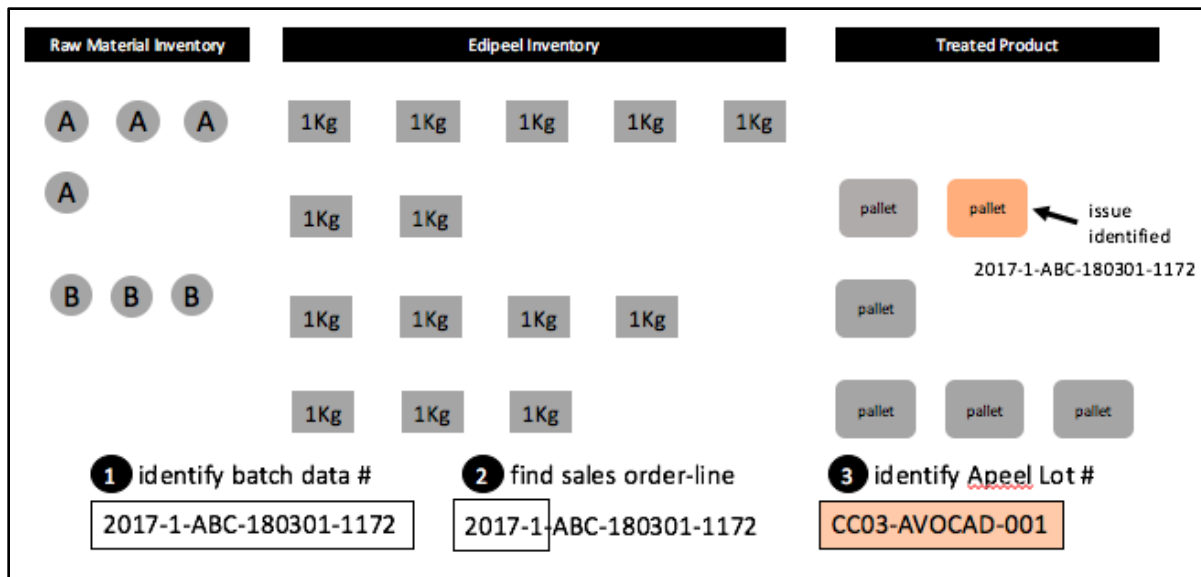
4.3. DATA COLLECTION DURING A RECALL

Based on what we have uncovered about the production and distribution of Edipeel, we have put together a visual representation of data collection in the event of a recall. Depending on where an issue is identified, it is possible that one must trace backwards in the supply chain and then forward to gather the appropriate information necessary to be submitted to the FDA. Because this example illustrates the information gathering process, it is assumed that Apeel is initiating their investigation after identifying at least one impacted data point.

In the example below, a treated product batch of avocados is first identified as being potentially affected. The data point associated with this batch is the *treatment batch data* number that would have been assigned on the day Edipeel was applied. **Figure 4.3.1** shows the first three steps where the treatment batch number is associated to the sales order (step 2) from which it was

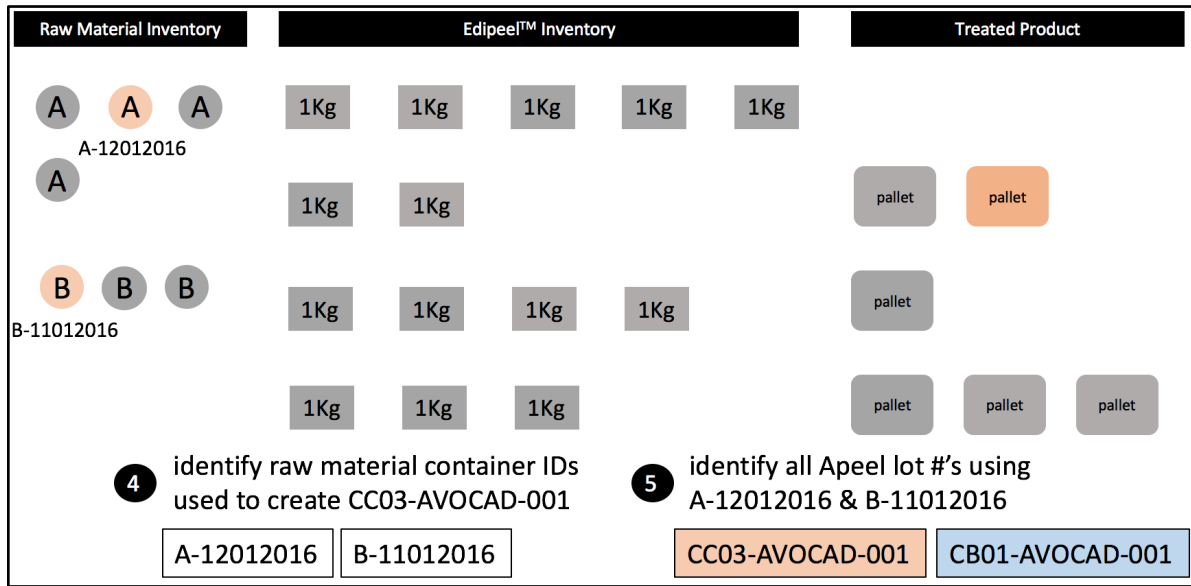
initiated. Upon closing out the sales order, Apeel would have noted the Apeel Lot numbers used - this information can therefore be pulled. A query is performed (step 3) to find the Apeel Lot #(s) associated with that sales order/batch.

Figure 4.3.1. Steps 1-3



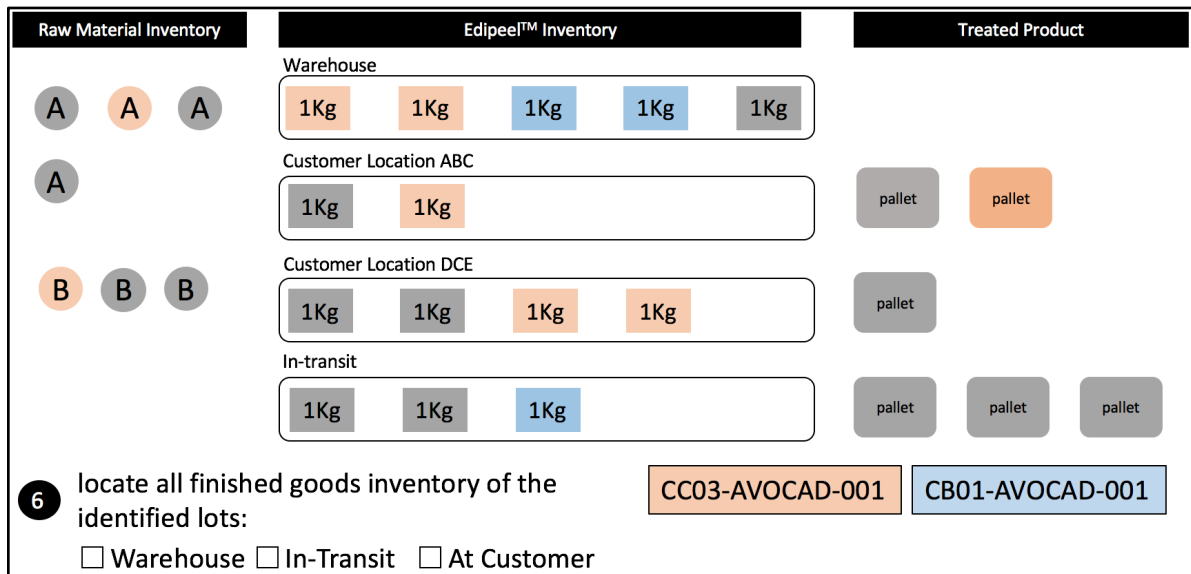
Next, a query is performed (step 4) to identify the raw material container IDs that were used to manufacture the identified Apeel Lot #(s). Once these raw material container IDs have been identified, they are traced back downstream to identify any additional Apeel lot #s in which they were used (step 5).

Figure 4.3.2. Steps 4, 5



Next, all current and historic inventory of the affected Apeel lot #s identified above are located (step 6). It is important at this step to recognize that based on Apeel’s service model, finished goods inventory of Edipeel can be found in multiple locations: physically on hand at their warehouse, in transit to a customer, or in Apeel’s inventory at a customer’s location. All finished goods inventory should be captured at this point.

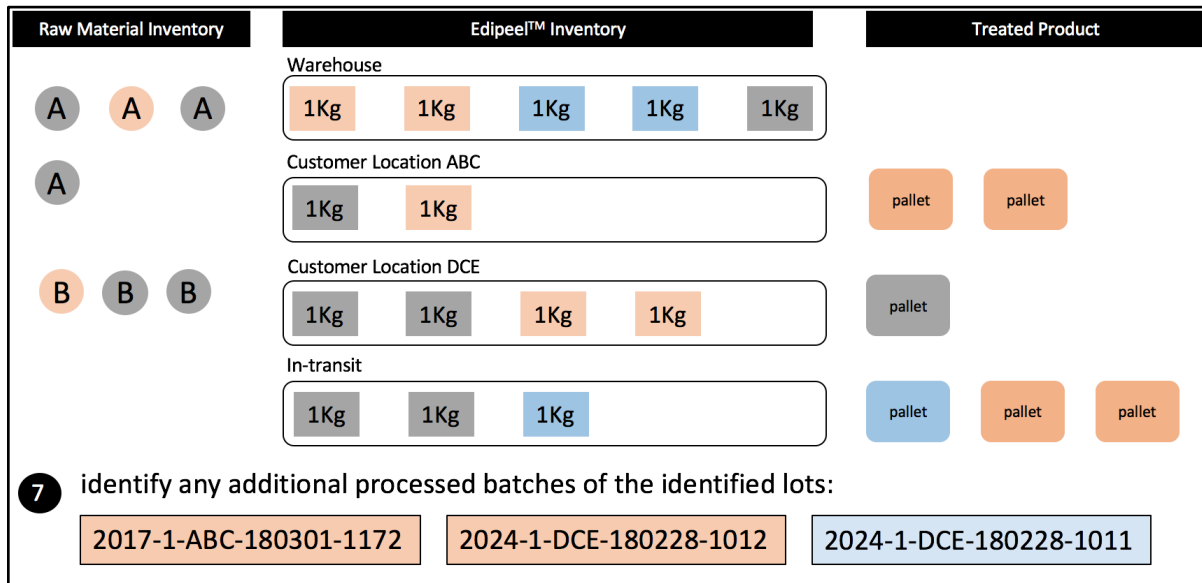
Figure 4.3.3. Step 6



Since it is probable that some or all of the identified Apeel Lot #s have been applied to produce and closed out of Apeel’s inventory. It is critical at this stage that Apeel gather all associated batch

data numbers. This is illustrated in step 7, where all treated product batch #s associated with the affected Apeel lot #s are identified.

Figure 4.3.4. Step 7



4.4. MOCK RECALL RESULTS

During the course of our project, Apeel performed a mock recall and a follow up “post-mortem” to evaluate how it went. Performing mock recalls are essential for ensuring the efficacy of a traceability program. A key aspect of a mock recall is the ability to locate 100% of affected product within 4 hours. (Honigbaum, 2012)

During the recall, Apeel was able to connect one of their raw materials to Edipeel lots and Edipeel batches for both demonstration batches and inventory batches. They were able to account for 100% of this raw material with their traceability program, indicating that their processes to date successfully enable tracking. A key learning was identifying that sales orders and work orders are not linked in their ERP system until the sales order has been closed. That however, did not prevent them from being able to gather the appropriate information. A further improvement that Apeel identified was the need to create automatically generated reports. We discuss the core requirements for these reports below in **Section 5.2**.

5. CONSIDERATIONS AND RECOMMENDATIONS

After only a few minutes of discussion onsite in Santa Barbara, it became clear that a key challenge in establishing a thorough lot-traceability process is an understanding of the title transfer of goods (capturing the “one step down”). Apeel Sciences must maintain traceability of Edipeel one step backwards and one step forwards in their supply chain. Identifying and capturing the source of the raw materials, “one step backwards”, is simplistic. Apeel captures raw material lot information upon receipt. Internally, Apeel links raw material Container IDs to a newly produced lot of Edipeel, another simplistic CTE. Apeel’s service model for application, however, adds a complexity to capturing “one step down”.

Tracking one step down requires that Apeel maintains a record of the pass off of their inventory. This can be termed the ‘title transfer’ and it indicates the point in the process that Apeel is no longer responsible for continuing to trace their product. In a typical direct-to-customer model, Apeel would need to track what lot numbers and associated quantities were shipped to their customer. That would satisfy the requirement for one step down traceability. Apeel’s service model, however, extends their responsibility for tracking inventory into the produce packing process. The title transfer point in a service model is the point at which Edipeel is applied to the produce. Because of this, Apeel is responsible for linking their Edipeel lot numbers with the customer batch data *rather* than just with the customer itself.

5.1. RECALL VS. ROOT CAUSE ANALYSIS

The purpose of our work with Apeel has focused on traceability rather than root cause analysis. Traceability ensures that information can be gathered when required. Traceability ensures appropriate linkages are in place to paint a concise picture of the location of a given lot of Edipeel. This is not a root cause analysis and therefore does not identify where an issue occurred. Typically, this root cause analysis is a part of the traceback investigation initiated by the FDA should an issue arise. In such a scenario, a cross-functional team of subject matter experts (e.g. Manufacturing, Quality, Engineering, etc.) performs the root cause analysis. In this sense, the recall is a step that may follow once an issue has been identified. Quality testing procedures and documentation practices are outside of the scope of this project, but any request for the identification of all related inventory of Edipeel should be enabled by their traceability process.

5.2. INTERNAL REPORTING REQUIREMENTS

As illustrated in **Section 4.3** above, a recall of any form would require a sequential gathering information. The starting point may vary depending on where in the chain the issue was identified. No matter where the issue was discovered (e.g. notified by the raw material supplier about a raw material lot or a customer about a batch), the information Apeel must gather is the same. All relevant raw material quantities, relevant Edipeel quantities (in house and on site), as well as all possible impacted treated product batches must be identified. This collection of information can be generated with 5 key reports as illustrated in **Figure 5.2.1**. The column “used in step” refers to the data gathering steps previously detailed in **Section 4.3**.

Figure 5.2.1. Mock Data Queries

Given:	Identify:	Report #	Used in Step #
Treatment Batch ID	→ Treatment Batch IDs	1	1
	→ All relevant Apeel Lot #s	2	3
Apeel Lot #	→ All relevant Raw Material Container IDs	3	4
	→ All relevant Treatment Batch IDs	4	7
Raw Material Container ID	→ All relevant Apeel Lot #s	5	5

As an example, if a supplier identified a raw material lot number/container ID as an issue, Apeel would follow the following process:

1. Pull report #5 against the given Container ID. Take note of all impacted Apeel Lot #s and their inventory quantity/location.
2. Pull report number 4 against the output of report #5 (all Apeel Lot #s). Take note of all impacted Treatment Batch IDs across all customers.

In both of the above steps it is likely that lot numbers and batch IDs are being pulled for past lots for which there is no more remaining inventory on hand. It is critical then, when collecting specifications for internal reports that the report is not filtered for where inventory is greater than zero.

The above finding that the gathering of information requires the ability to pull a series of five pivots of information was an important realization that further informed the requirements Apeel has developed for reporting. While above, we suggest that the data pulls could come in the form of 5 reports, it is more probable that a user would wish to have a more compact way of pulling the above sets of data. It should be possible to combine reports, but for illustration purposes, it is five combinations of input/output data that we have identified. It is also assumed that in a report pull to identify Apeel lot numbers (eg. report 5), all relevant inventory information for the reported lot numbers is included. Sample report mock-ups can be found in **Appendix G**. The project scope did not include drafting technical specifications for Business Intelligence reporting. To be able to concretely recommend reporting formats or requirements would require business requirements gathering sessions and further work with Apeel's IT team.

5.3. CONSIDERATIONS FOR FUTURE OPERATIONS

Our understanding of Apeel and the production and distribution of Edipeel is rooted in their current practices today. It is critical that Apeel's solution for traceability is flexible in that it is not restricted to current practices should their strategy shift in the future and for future scaling. The process described in **Section 3.1** illustrates their current operating model and strategy for application and distribution. In **Section 3.2**, we introduced factors that define their current best practices, as they pertain to Edipeel. Our key data elements include data from customers that they have currently established today. It is critical to review then, how their solutions for traceability may be required to shift should their process shift from the status quo.

Raw Materials: Apeel currently sources raw materials from a third party. Current raw material receiving and tracking assumes that a lot number is provided from the supplier. Should Apeel produce their own inputs in the future, they will need to be able to generate lot numbers for raw materials and systematically track against their own raw materials.

Manufacturing: Currently, Apeel manufactures Edipeel to order to forecast. For make to forecast inventory, Apeel will generate an internal sales order. It will be important either way that the sales order is ultimately reconciled with the lot(s) of Edipeel used to fulfil it - this action is completed by the regulatory team today.

Reconstitution: Depending on the inventory present on site, multiple lots of Edipeel may be combined in the reconstituted batch for application. Systematically, this requires that multiple data points can be captured against a single treatment batch data number. At the moment a text field is used to capture the Apeel lot number against the treatment batch data. This is a current work around given Apeel's active ERP system and may cause challenges for pulling data through reporting.

Application: For the current customer base, the customer assigns the same code (referred to as a repack number) to the multiple cartons or pallets of avocados that are packaged in a day. For Apeel, this means that they are linking their reconstituted batch data ID to a singular customer repack. Even though the product may end up in multiple locations, the link between batch ID number and repack is likely 1:1. Going forward, though, it is possible that other customers have different processes, or that for different produce this is not the case. Apeel should have systematic flexibility to capture multiple repack (or customer lot numbers) against a single reconstituted batch data ID.

In the current process, an Apeel employee is responsible for application; ensuring the quality and accurate record keeping. Should this change in the future, it will be critical to have governance in place to maintain accurate records.

Inventory Reconciliation: For the service model, the current process requires the Regulatory team to manually enter Batch ID numbers against their appropriate sales order line to close out the transaction. This is the step that systematically solidifies the link between the Apeel lot number used in reconstitution and the customer order / batch data ID that it was applied on. Upon completion of this step, the customer is invoiced and inventory is reconciled. It has been acknowledged that this manual entry poses two risks; manual entry error and a temporary gap in traceability due to timing. This is a current limitation of their tools and noted as an opportunity for future improvement as their customer base grows.

6. CONCLUSION AND NEXT STEPS

Apeel Sciences has taken a proactive approach to establishing supply chain transparency as they prepare to enter the market at large. In its current state, Apeel is within compliance from a lot traceability standpoint. When comparing their program with FDA regulations, the BioTerrorism Preparedness Act, the Food & Drugs Amendments Act, and Food Safety Modernization Act, Apeel meets or exceeds these standards. There are, however, two difficult parts of assessing any traceability program. First, there is a dearth of specific standards set forth by federal regulations. Second, as mentioned in the IFT pilot studies, there is non-standardized terminology, which can occasionally lead to confusion.

As detailed in the project purpose, our role as we analyzed their supply chain was to ask the questions Apeel had not previously considered. By objectively observing their current process, we were able to identify opportunities for improvement today as well as key areas vulnerable to scaling their operations in the future. As a startup, this was especially important given the likelihood that their practices will shift as they enter new partnerships, new markets or grow in size. Apeel is clearly capable of the data gathering and executing a recall, but as they scale, some practices may not be sustainable. Manual processes will become increasingly challenging to manage, and differences between customers' packing houses may require adaptations in their recordkeeping process. As the company grows, it is important that they continue to monitor risk and evolve their best practices. Because Apeel has emphasized lot traceability as a critical aspect of their supply chain, they are cultivating a culture of quality in the company.

Throughout our work with Apeel, it became apparent that the impact to the food industry of a product like Edipeel could be massive. The ability to extend the variable of shelf life in the produce supply chain presents fascinating opportunities for further research. In concluding our project, we are confident that Apeel is well prepared to pursue their mission to eliminate food spoilage and reduce reliance on chemicals.

APPENDIX

APPENDIX A. DETAILS OF PROJECT SCOPE

Location: Apeel's current operations are US based. Although future plans are to operate outside of the USA, the regulations for traceability that we are looking to satisfy will ensure compliant operations within the U.S..

Product: Edipeel

- The avocado variety of product is the current focus of Apeel, so we will reference their distribution of this SKU.
- The solution should be viable for all Edipeel varieties following the same service model
- Outsourced production of Edipeel is considered out of scope.

Distribution Model: Service Model

- Apeel's primary focus is that of a service model for distribution and application of Edipeel. Our focus will be on ensuring appropriate tracking from raw material through to title transfer of Edipeel under the assumption of this service business.

APPENDIX B. CODE OF FEDERAL REGULATIONS TITLE 21

The following CFR sections were identified by Apeel as pertinent to our understanding of the regulatory environment in which Apeel operates with respect to traceability. We have included further detail about these particular subsections of 21 CFR below.

21 CFR Part 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*

Section A of this regulation requires that all individuals performing activities must be qualified. For Apeel Sciences, this would require that all Apeel Engineers applying Edipeel coating on the packing line be qualified.

Part 117 also includes how raw materials must be inspected and segregated when received. In addition, this regulation requires a Recall Plan be established. This Recall Plan must describe the steps to be taken during a food recall, including how effectiveness checks are performed to verify a recall is carried out and how the recalled food is properly disposed of. During a recall, the public must be notified of any potential hazards and the consignee of the food being recalled must be notified.

Section G describes the supply chain program that must be established for a food producer. Some of these requirements include: the use of approved suppliers, execution of supplier verification activities (for example audits performed by qualified auditor), and written procedures for receiving raw materials.

21 CFR Part 112, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*

For raw agricultural commodities (RACs), which includes produce such as avocados, this section includes packing activities and requirements. For example, Subpart K includes testing for and prevention of *Listeria monocytogenes*, a bacterium that's harmful to humans

Per Section O, each packing activities needs to include the following information: Lot number, commodity name, date/time, signature of operator who performed the activity, and a supervisor review.

21 CFR Part 110, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*.

21 CFR Part 110 is considered out of scope for the purposes of this project. This Part includes requirements for buildings, equipment, production controls and defect action levels. These topics are not in the scope of federal requirements for lot traceability.

APPENDIX C. EXAMPLE RECALL PLAN TEMPLATE

The below template was provided by the Food Safety Preventive Controls Alliance for a Recall Action Plan.

Recall Plan Example	PAGE 4 of 12
PLANT NAME:	ISSUE DATE: 08/02/2015
ADDRESS:	SUPPENSEDS: 05/29/2015

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency/ believe your product is causing illness	Assemble recall team and ask agency if recall is recommended		<p>If no recall is needed:</p> <ul style="list-style-type: none"> Document why not and action. <p>If recall is needed:</p> <ul style="list-style-type: none"> Assign responsibilities Gather evidence Analyze evidence Get word out Monitor recall Dispose of product Apply for termination of recall Assemble recall team and debrief Prepare for legal issues
News media story on problem with a type of food you produce	Assemble recall team, review internal records		
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records	Evaluate situation; decide if, what and how much product to recall	
Health Department believes your produce is causing illness	Assemble recall team, contact appropriate regulatory agency		

Recall Plan Example	PAGE 5 of 12
PLANT NAME:	ISSUE DATE: 08/02/2015
ADDRESS:	SUPPENSEDS: 05/29/2015

Information Templates for FDA Communication

PRODUCT INFORMATION:

Modify the "Product Description, Distribution, Consumers and Intended User" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package inserts
- Directions for Use
- Promotional Material (if applicable)

CODES (Lot Identification Numbers):

- UPC code(s) involved: _____
- Lot number(s) involved: _____
- Lot numbers coding system: Describe how to read your product code: -

- Expected shelf life of product: _____

Recall Plan Example	PAGE 6 of 12
PLANT NAME:	ISSUE DATE 08/02/2015
ADDRESS:	SUPERSEDES 05/29/2015

RECALLING FIRM CONTACTS

Provide this information to FDA for clear communication:

Manufacturer name: [Name and address]

Position	Name, Title	Contact Information
RECALL coordinator		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Most responsible individual		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Public contact:	<i>May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator focus on retrieving product and resolving the issue</i>	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx

Recall Plan Example	PAGE 7 of 12
PLANT NAME:	ISSUE DATE 08/02/2015
ADDRESS:	SUPERSEDES 05/29/2015

REASON FOR THE RECALL:

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none"> • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved 	
If a State agency is involved in this recall, identify Agency and contact.	

VOLUME OF RECALLED PRODUCT:

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace	
<ul style="list-style-type: none"> distributor level customer level 	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

DISTRIBUTION PATTERN:

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
<ul style="list-style-type: none"> wholesalers/distributors repackers manufacturers retail consumers (Internet or catalog sales) federal government consignees foreign consignees (specify whether they are wholesaler distributors, retailers or users) Geographic areas of distribution, including foreign countries 	

CONSIGNEE LIST

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

Commercial customers

Name	Street Address	City	State	Recall contact name	Contact phone number	Recalled product was shipped?	Recalled product was sold?	Recalled product may have been shipped or sold

Was product sold under Government Contract?

Yes _____ No _____

If yes, include contact name and information above AND complete information below.

Contracting Agency	Contract Number	Contract date	Implementation date

School Lunch Program:

If product was sold to federal, state or local agency for the school lunch program, complete table and notify "ship to" (so they can retrieve product) and "bill to" customers (so they can initiate the sub-recall).

Consignee	Quantity	Sale date	Shipment date

Recall Plan Example		PAGE 10 of 12	
PLANT NAME:		ISSUE DATE:	08/02/2015
ADDRESS:		SUPPENSEDES:	05/29/2015

RECALL STRATEGY:

Level in the distribution chain

Level	Included		Rationale if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact Info		Phone	Email	Fax	Letter		

Recall Plan Example		PAGE 11 of 12	
PLANT NAME:		ISSUE DATE:	08/02/2015
ADDRESS:		SUPPENSEDES:	05/29/2015

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Product destruction/reconditioning

- o Provide a proposed method of destruction, if applicable.
- o If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- o Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- o It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- o You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA Investigator).
- o Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

Recall Plan Example		PAGE 12 of 12
PLANT NAME:		ISSUE DATE 08/02/2015
ADDRESS:		SUPERSEDES 05/29/2015

DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity] [---No Other Products Affected---]

Contact

Consumer:

1-xxx-xxx-xxx

Media Contact:

xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- [insert lot codes]

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
----------------	-----------------	-----------------

[Company Name] [insert product name(s)] [insert product codes(s)] [insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

APPENDIX D. APEEL SUPPLY CHAIN PROCESS

Below is a sample process map provided to us by Apeel of their current process.

Figure D.1

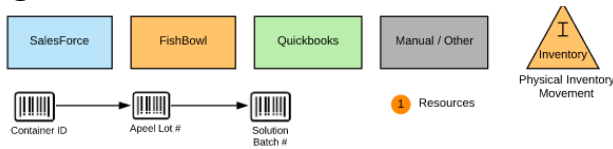


Figure D.2 Apeel current state shipping and logistics

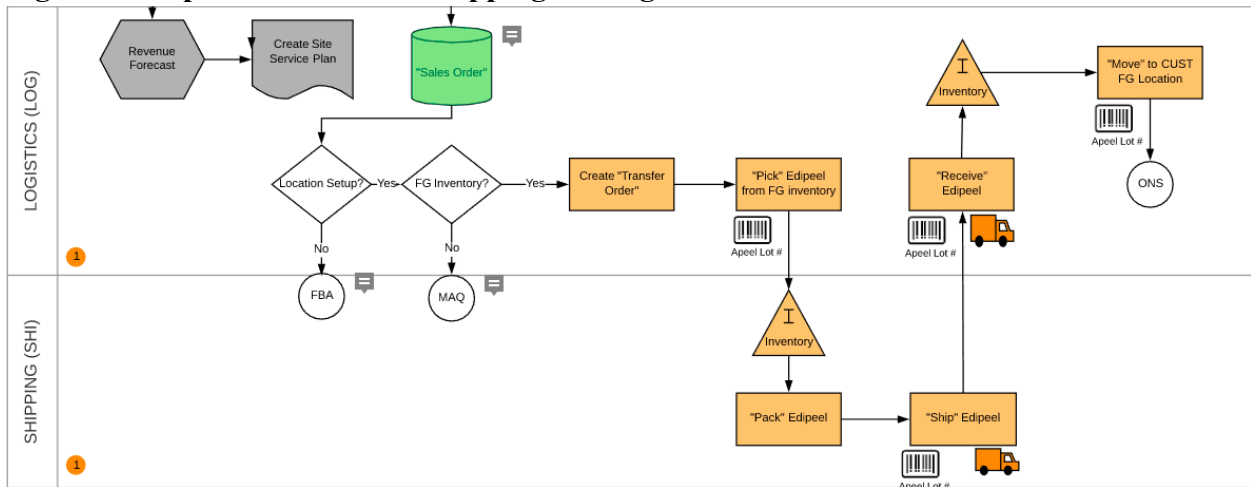


Figure D.3 Apeel current regulatory and on-site service

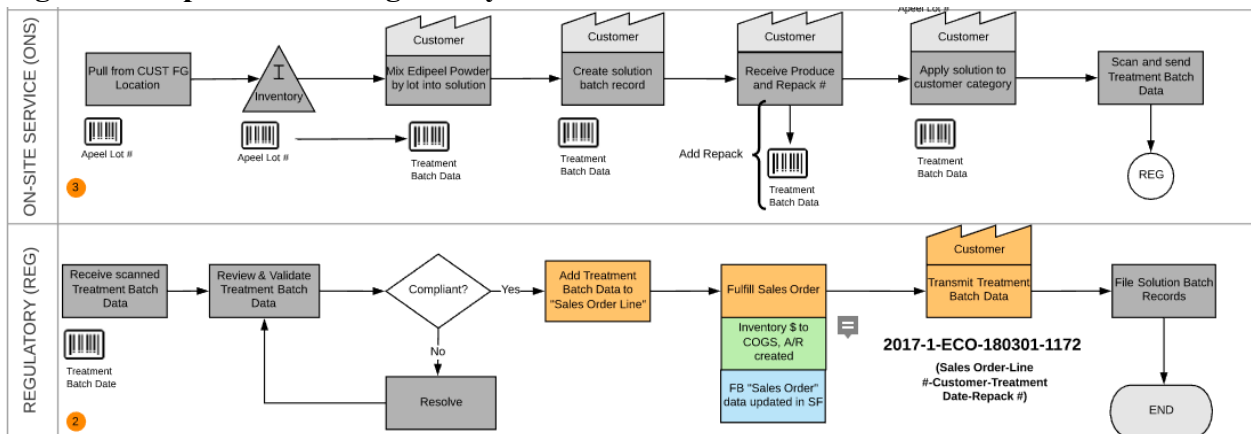
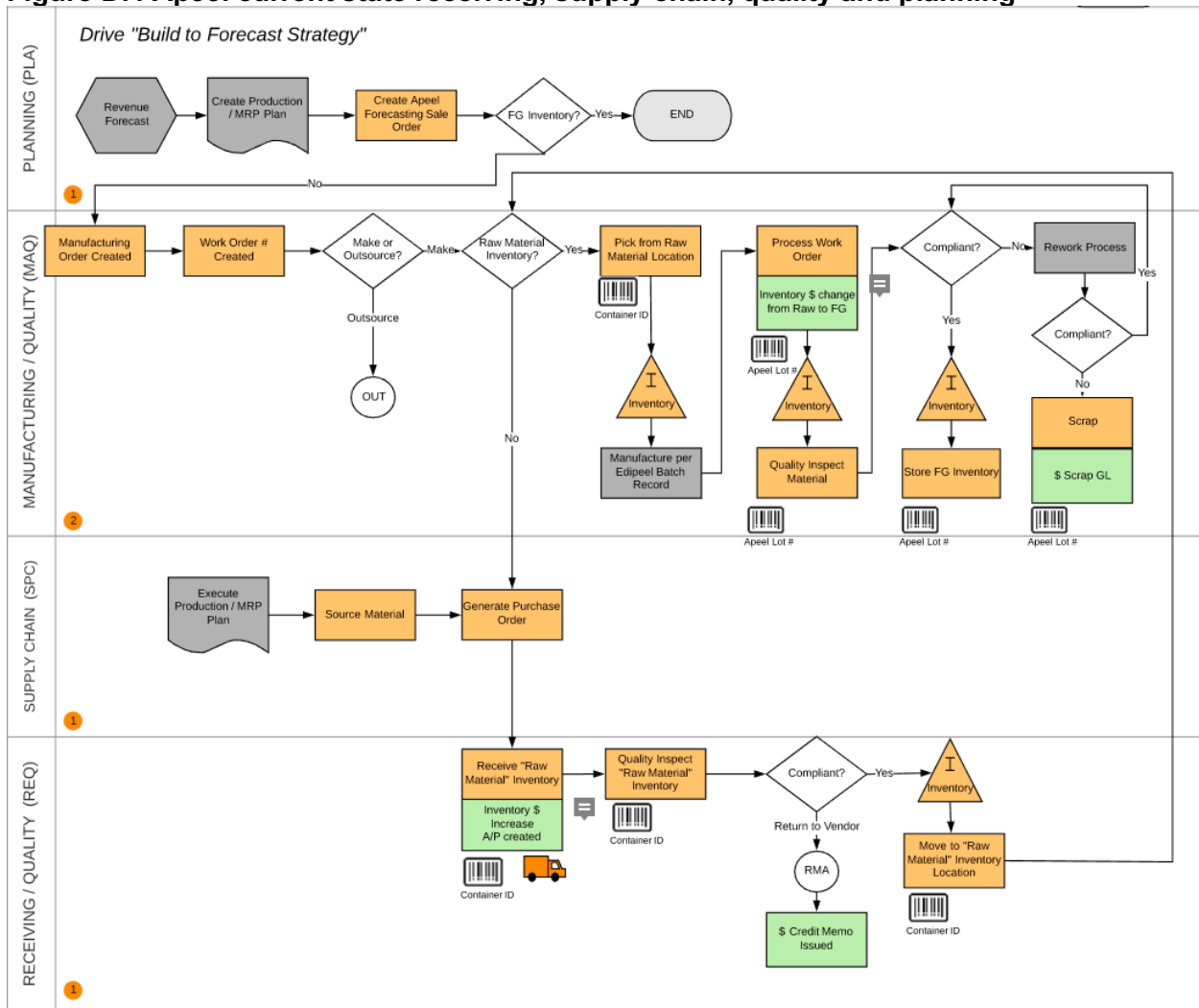
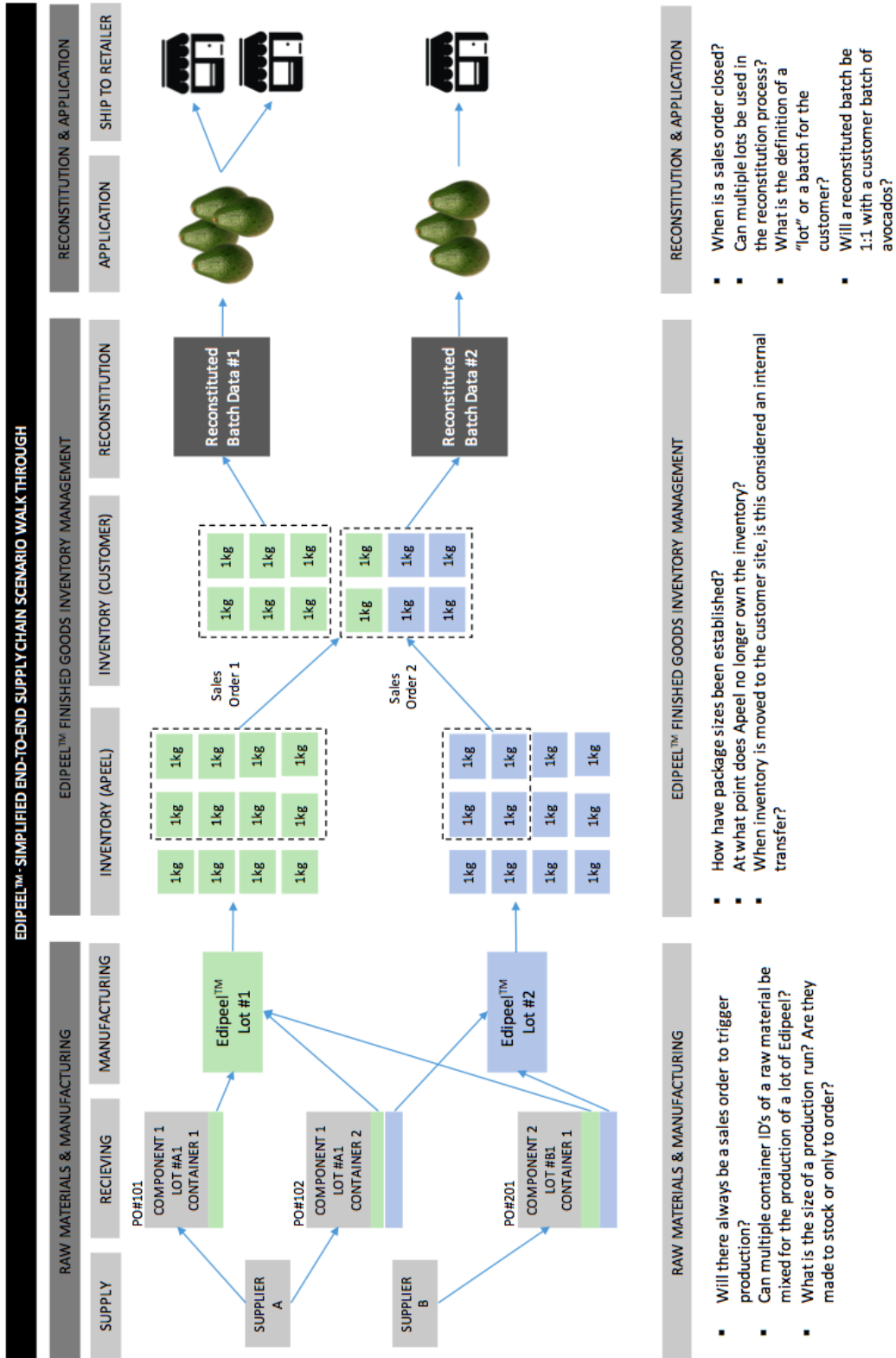


Figure D.4 Apeel current state receiving, supply chain, quality and planning

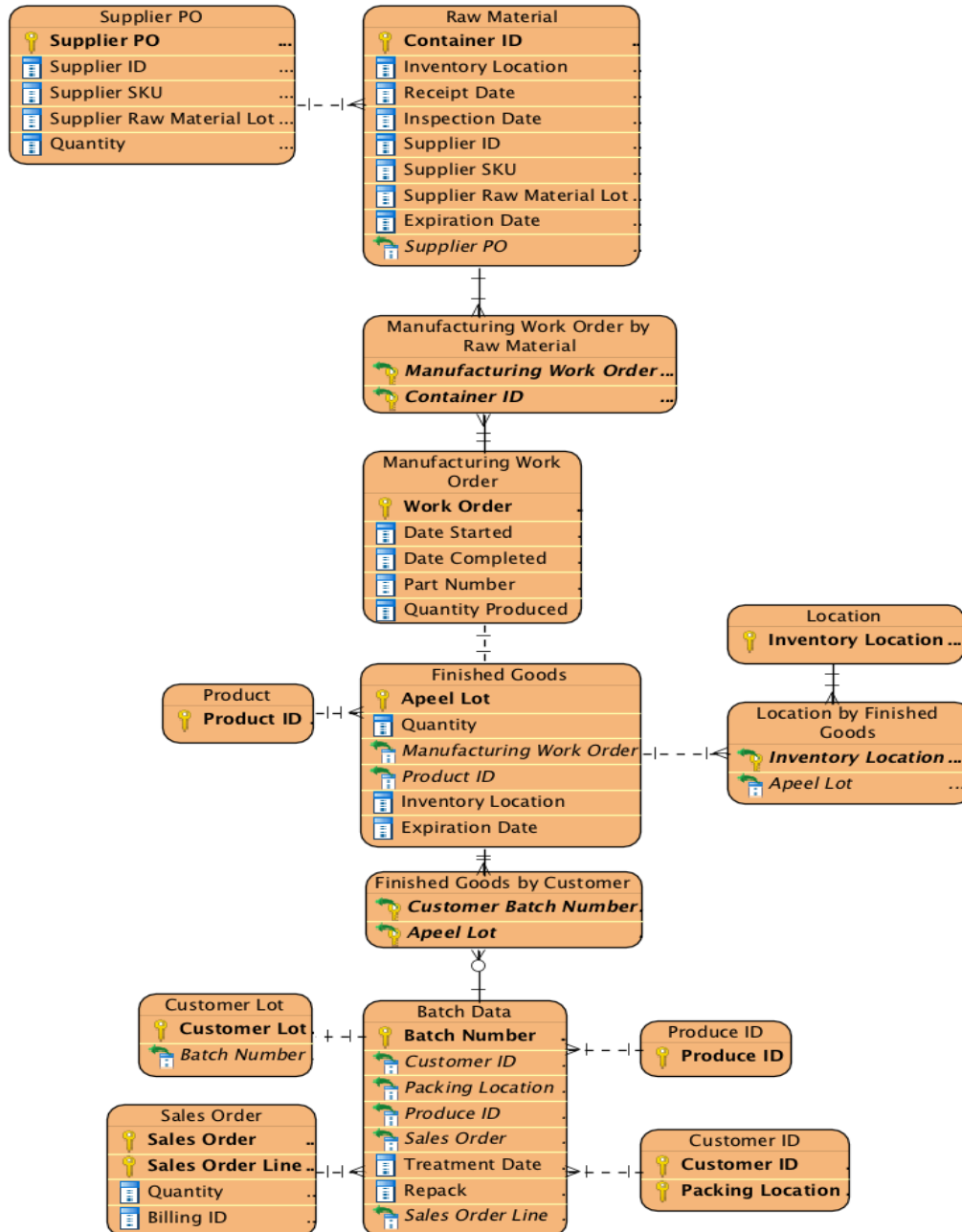


APPENDIX E. EXAMPLE SCENARIO WALK-THROUGH



APPENDIX F. EXAMPLE SCHEMA

The ERD diagram below shows the key linkages and relationship (eg. 1:1 of 1:many) of critical components of Apeel’s process.



APPENDIX G. EXAMPLE MOCK REPORTS

As mentioned, we established that Apeel needs to be able to pull the following 5 key data associations.

Figure G.1 Mock Data Queries

Given:	Identify:	Report #	Used in Step #
Treatment Batch ID	→ Treatment Batch IDs	1	1
	→ All relevant Apeel Lot #s	2	3
Apeel Lot #	→ All relevant Raw Material Container IDs	3	4
	→ All relevant Treatment Batch IDs	4	7
Raw Material Container ID	→ All relevant Apeel Lot #s	5	5

Below are a simple illustration of how that data may appear in a report. These are not official specifications. Mock ups 1-3 were provided to us by Apeel, and the other two were developed for us for illustration purposes and to facilitate a conversation around the above 5 linkages.

Figure G.2 Mock up reports 1 through 3

<p>REPORT MOCK UP #1 (External to Customer)</p> <p>Treatment Batch Data 2017-2-ECO-180302-11072 2017-4-ECO-180314-11073 2017-6-180320-11074</p>	<p>REPORT MOCK UP #2 (Internal report in FishBowl)</p> <p>Treatment Batch Data 2017-2-ECO-180302-11072</p> <table border="0"> <tr> <td style="text-align: right;">A lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-001</td> <td style="text-align: right;">2</td> </tr> <tr> <td style="text-align: right;">Total</td> <td style="text-align: right;">2</td> </tr> </table> <p>2017-4-ECO-180314-11073</p> <table border="0"> <tr> <td style="text-align: right;">A lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-002</td> <td style="text-align: right;">1</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-003</td> <td style="text-align: right;">1</td> </tr> <tr> <td style="text-align: right;">Ttotal</td> <td style="text-align: right;">2</td> </tr> </table> <p>2017-6-ECO-180320-11074</p> <table border="0"> <tr> <td style="text-align: right;">A Lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-004</td> <td style="text-align: right;">2</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-005</td> <td style="text-align: right;">1</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-006</td> <td style="text-align: right;">1</td> </tr> <tr> <td style="text-align: right;">CC03-AVOCAD-007</td> <td style="text-align: right;">1</td> </tr> <tr> <td style="text-align: right;">Total</td> <td style="text-align: right;">5</td> </tr> </table>	A lot#	Quantity	CC03-AVOCAD-001	2	Total	2	A lot#	Quantity	CC03-AVOCAD-002	1	CC03-AVOCAD-003	1	Ttotal	2	A Lot#	Quantity	CC03-AVOCAD-004	2	CC03-AVOCAD-005	1	CC03-AVOCAD-006	1	CC03-AVOCAD-007	1	Total	5	<p>REPORT MOCK UP #3 (Internal Report)</p> <p>Apeel Lot # CC03-AVOCAD-001</p> <table border="0"> <tr> <td style="text-align: right;">Raw Material SKU</td> <td style="text-align: right;">Raw Material Lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-OXY</td> <td style="text-align: right;">2016-OXY-30154</td> <td style="text-align: right;">1 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">1 KG</td> </tr> </table> <p>Raw Material SKU</p> <table border="0"> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-TYP</td> <td style="text-align: right;">2015-TYP-78534</td> <td style="text-align: right;">2 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">2 KG</td> </tr> </table> <p>CC03-AVOCAD-002</p> <table border="0"> <tr> <td style="text-align: right;">Raw Material SKU</td> <td style="text-align: right;">Raw Material Lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-OXY</td> <td style="text-align: right;">2016-OXY-30154</td> <td style="text-align: right;">1 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">1 KG</td> </tr> </table> <p>Raw Material SKU</p> <table border="0"> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-TYP</td> <td style="text-align: right;">2015-TYP-78534</td> <td style="text-align: right;">2 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">2 KG</td> </tr> </table> <p>CC03-AVOCAD-003</p> <table border="0"> <tr> <td style="text-align: right;">Raw Material SKU</td> <td style="text-align: right;">Raw Material Lot#</td> <td style="text-align: right;">Quantity</td> </tr> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-OXY</td> <td style="text-align: right;">2016-OXY-30154</td> <td style="text-align: right;">1 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">1 KG</td> </tr> </table> <p>Raw Material SKU</p> <table border="0"> <tr> <td style="text-align: right;">FAKE-RAW-MATERIAL-TYP</td> <td style="text-align: right;">2015-TYP-78534</td> <td style="text-align: right;">2 KG</td> </tr> <tr> <td style="text-align: right;">Total</td> <td></td> <td style="text-align: right;">2 KG</td> </tr> </table>	Raw Material SKU	Raw Material Lot#	Quantity	FAKE-RAW-MATERIAL-OXY	2016-OXY-30154	1 KG	Total		1 KG	FAKE-RAW-MATERIAL-TYP	2015-TYP-78534	2 KG	Total		2 KG	Raw Material SKU	Raw Material Lot#	Quantity	FAKE-RAW-MATERIAL-OXY	2016-OXY-30154	1 KG	Total		1 KG	FAKE-RAW-MATERIAL-TYP	2015-TYP-78534	2 KG	Total		2 KG	Raw Material SKU	Raw Material Lot#	Quantity	FAKE-RAW-MATERIAL-OXY	2016-OXY-30154	1 KG	Total		1 KG	FAKE-RAW-MATERIAL-TYP	2015-TYP-78534	2 KG	Total		2 KG
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Figure G.3 Mock up reports 4 through 5

REPORT MOCK UP #4
(Internal Report)

Apeel Lot #
CC03-AVOCAD-001

Treatment Batch#
2017-2-ECO-180302-11072
2017-6-ECO-181334-11063
2016-3-DEL-184532-13423

Location	Quantity
SB.2.3.14	32 KG
ECO.34.2.1	2 KG

CC03-AVOCAD-002

Treatment Batch#
2017-4-ECO-180314-11073
2017-6-ECO-183294-10782
2016-3-DEL-184532-13423

Location	Quantity
SB.2.3.15	32 KG
ECO.34.2.3	2 KG
DEL.34.2.5.9	1 KG

REPORT MOCK UP #5
(Internal Report)

Raw Material Lot #
2016-OXY-30154

Apeel Lot #
CC03-AVOCAD-001
CC03-AVOCAD-002
CC03-AVOCAD-003

Location	Quantity
S.B.34.5.1	455 KG
S.B.34.3.2	122 KG

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