

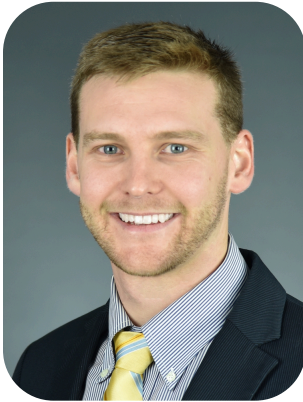
## Lot Traceability of a Break-Through Food Science Technology

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Topic Areas: Distribution, Tracking & Tracing

### Summary:

We had the privilege of working with Apeel Sciences, a food-science start-up based in Santa Barbara, California. Apeel has developed Edipeel™, a natural, edible coating capable of more than doubling the shelf-life of harvested produce. In our work, we evaluated Apeel's lot traceability program with the goal of ensuring their continued compliance with federal regulations as they scale their product to market. Through onsite interviews and a deep analysis of their supply chain, we were able to verify their lot tracing program as compliant with federal regulations and identified areas of opportunity in both process and technology for their consideration as they scale.



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### KEY INSIGHTS

- 1. Apeel's service model adds complexity to their lot tracking process**
- 2. For Apeel, successful identification of relevant inventory in a recall requires five key combinations of data**
- 3. Apeel can maintain a robust lot traceability program by: generating automated reports, implementing a flexible system, and reducing manual data entry**

### 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. The regulatory landscape in which these companies operate has responded with legislation that pressures companies to establish supply chain transparency. Although this legislation sets requirements for traceability, it fails 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, asked us to do just that. Apeel is a start-up based in Santa Barbara. They've invented a new product, Edipeel™, an edible, odorless, tasteless, natural coating that doubles the lifespan of harvested fruit. 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.

The four main regulations Apeel must comply with are:

1. The FDA's Code of Federal Regulations (CFR)
2. The Bioterrorism Act (BT Act) of 2002
3. The Food and Drug Amendments Act of 2007
4. The Food Safety Modernization Act (FSMA)

While these acts cover a broad array of topics, our focus has been on their requirements with regards to lot traceability. Collectively, these regulations require that Apeel maintains records of all transfers and transformations of their inventory and that they establish a recall plan. They are obligated to have visibility one step back and one step forwards in their supply chain. In other words, they must know the

origin of their raw material upon receipt and the customer who purchased their finished good, Edipeel.

### Apeel’s Supply Chain

Apeel manufactures Edipeel onsite in Santa Barbara. Raw material receipt is the first critical tracking event. Upon receipt, raw materials are inspected for quality assurance and systematically logged in the company enterprise resource planning (ERP) software. Edipeel is manufactured both to order and to forecast, and is initiated through a sales order. Manufacturing becomes the second critical tracking event; capturing the raw material lot and quantities used and generating the Apeel lot number for the manufactured batch of Edipeel.

The current variety of Edipeel that Apeel is bringing to market is intended for avocados. Avocados are collected and packaged for distribution at a packing house. A key element of Apeel’s corporate strategy is their service model for the application of Edipeel, whereby they integrate into the existing produce distribution network at the customer’s packing house. Edipeel needs to be reconstituted with a solution in order to be applied to produce. An Apeel engineer reconstitutes Edipeel with a solution and manages the application to the produce as it moves along the packing line. The reconstitution and application marks the third critical tracking event; the onsite employee generates a “treatment batch record” to associate the lots of Edipeel used with the customer repack details. It is at this point that the title transfer of inventory occurs, and the quantity of Edipeel used in application is charged to the customer.

### Findings

Understanding scenarios for how a batch of Edipeel can be created and applied to produce highlighted points along the value chain where lots may be mixed, data points added, or inventory visibility hindered. We paid particular attention to the critical tracking events mentioned above.

In terms of raw material receipt, 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.

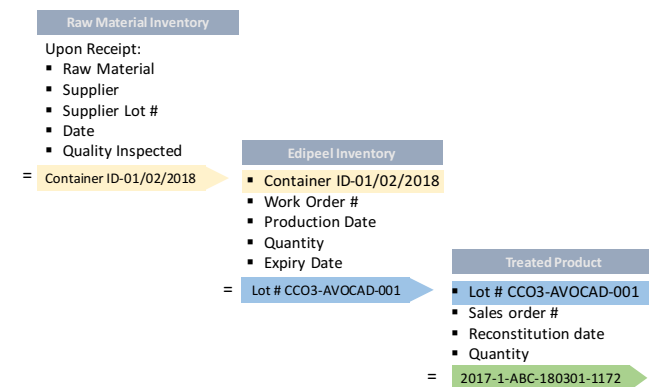
At the point of reconstitution, Edipeel is mixed with a solution prior to application. The concentration of

Edipeel may differ by produce variety and country of origin. Through our interviews, we verified that it is possible that more than one lot number of Edipeel may be used during reconstitution.

For tracking at the point of application, it is important to understand what the customer defines as a “lot” of produce. For a current customer, we were able to confirm that all avocados processed/packed for a given day were considered to be one lot. It is important to acknowledge that this may not be the case for future customers.

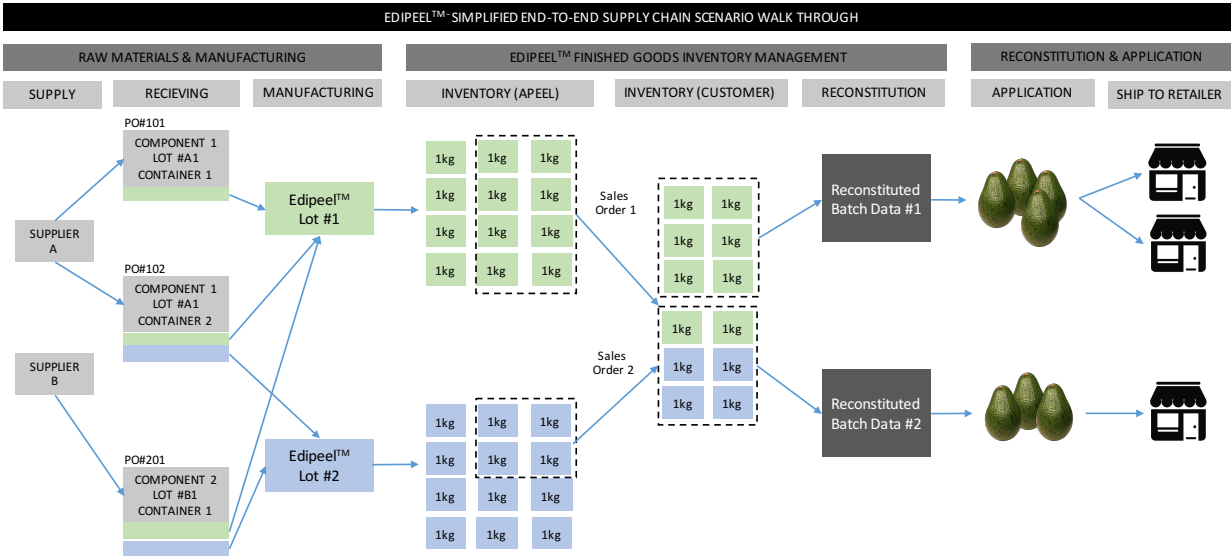
Apeel maintains control of their inventory until application. The ultimate transfer of inventory is captured when a sales order is fulfilled. The lots and volumes of Edipeel used to complete the sales order are manually captured on-site. They are then scanned to the Regulatory Department for entry into the ERP. This method, however, may not be scalable and may be prone to errors.

We distilled the lot traceability process into a series of connected data points. **Figure 1** shows the Key Data Elements (KDEs) at each state of the traceability process.



**Figure 1. Key Data Elements**

During our onsite visit, we mapped out the end-to-end supply chain for the purpose of understanding the scenarios or paths a manufactured batch of Edipeel may take. Though simplistic in nature, the process flow shown in **Figure 2**, allowed us to visualize scenario based information flow from raw material receipt to the end retailer.



**Figure 2. End-to-end supply chain map of Edipeel.**

**Recall Example - Sequential Data Gathering**

In the event of a recall, Apeel must be able to rapidly identify all current and historical inventory that may have been impacted; this can include raw materials, finished goods inventory, or previously treated batches of produce. Based on our understanding of all possible paths a lot of Edipeel may take from raw material through to application, we were able to map out a process for sequential data gathering to do this. The following steps are an example of data gathering for a trace-back:

1. A treated product batch of avocado’s is first identified as being potentially affected
2. The associated treatment batch number is identified via the sales order from which it was initiated
3. A query is performed to find the Apeel Lot #(s) used in the application of the identified batch number
4. A query is performed to identify the raw material container IDs that were used to manufacture the identified Apeel Lot #(s)
5. The raw material container IDs are then traced back downstream to identify any additional Apeel lot #s in which they were used. This creates the complete list of potentially impacted lots.
6. Finally, using this complete list of lots, any additional treatment batch numbers must be identified. It may be the case that there are additional batches impacted at the same packing house or another customer.

During the course of our project, Apeel performed a mock recall and a follow up “post-mortem” to evaluate how it went. Apeel was able to connect one of their raw materials to Edipeel lots and batches, accounting for 100% of the raw material. Though this

indicates that their current traceability program is successful, areas for improvement were identified.

**Recommendations**

While Apeel is well within compliance, they were interested in scalable solutions that can be applied to multiple scenarios. We identified three key recommendations and considerations to support complaint practices as they scale.

First, during after our review of their recall, we identified that their ability to pull all required information requires five critical combinations of data that link inventory from raw material through to application. These are found in **Figure 3**. While the scope of our project did not include developing technical specifications for reporting, Apeel’s reporting capabilities should support pulling all five of these combinations. Generating these reports would be mutually exclusive and collectively exhaustive, allowing full transparency during a recall.

Given:	Identify:
Treatment Batch ID	Any Additional Treatment Batch IDs
	All relevant Apeel Lot #s
Apeel Lot #	All relevant Raw Material Container IDs
	All relevant Treatment Batch IDs
Raw Material Container ID	All relevant Apeel Lot #s

**Figure 3. Reporting: critical data combinations**

Second, a key element of their tracking process is manual. Post application of Edipeel, the current process requires the regulatory team to manually enter batch ID numbers against their appropriate sales order line to close out the transaction and update their inventory records. This manual entry poses two risks: manual entry errors and a temporary gaps in traceability due to timing. We therefore

recommend a more automated solution, such as barcoding to address this risk.

Third, Apeel's current process for data capture and tracking is based on their current service model and type of customer. It is important for Apeel to consider elements of their process that may shift in the future. In this way, their lot traceability program should remain flexible and under frequent review. Should Apeel begin producing their own raw material inputs for Edipeel, they will require the capabilities to track this production. Additionally, Apeel should consider that future customers may manage their repack process differently – this may impact how Apeel lots are linked to treated produce in the future. Finally, 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

## **Conclusion**

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. 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.

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.