Traceability of a Breakthrough Food Science Technology
The Team

Russ Miller

Before MIT, Russ was a Process Engineer in biotech. He has experience with FDA regulations, as well as a deep Good Manufacturing Practices (GMP) knowledge in the pharmaceutical industry.

Hilary Taylor

Before MIT, Hilary was a supply chain systems project lead for a Canadian retailer. She has experience in business process engineering, change management and technology implementation.
Agenda

Introduction
- Apeel’s Supply Chain
- Recommendations
- Q&A
45% of produce is wasted due to spoilage - $750B annually

Food science start-up

Founded in Santa Barbara, California in 2012
Apeel uses **natural plant-based technologies** to protect crops and harvested produce, helping to **eliminate food spoilage** and **reduce reliance on chemicals**

This means we will **waste less food**, water and energy, **helping to preserve our natural ecosystems** while creating economic opportunities for the 500 million small family farms worldwide.

In the future, less food will be wasted, we will use smarter, more natural methods for growing and protecting crops, and there will be **an abundance of fresh food for everyone**

Source: http://apeelsciences.com/apeel-mission.html
Introducing... Edipeel™

UNTREATED

Day 4

TREATED with Edipeel
Edipeel™

- Edible, natural, odorless, flavorless
- Produced as a powder and reconstituted with water
- Mimics the protection of the plant’s natural peel
- **DOUBLES** the viable shelf-life of harvested produce

Source: http://apeelsciences.com/edipeel.html
Project Purpose – Lot Traceability of Edipeel

- Ensure Apeel’s lot traceability program is **compliant** from a **regulatory standpoint** and **scalable**

- Apeel must identify the origin & location of all Edipeel inventory - **current and historic** - upon request

- **Critical data points** from production to applying Edipeel are **logged & linked**

- **Avocados** are the current commercial Edipeel product

- **Lack of standardization** for collecting and communicating data along the supply chain
Regulatory Environment

Code of Federal Regulations

- Establish a **recall plan**
- Packaging requirements – include: lot #, commodity name, date/time, operator signature, supervisor review

Bioterrorism Preparedness & Response Act 2002

- Companies must maintain a record of: “immediate previous sources and the immediate subsequent recipients of food”
- **One up / one down** traceability

Food & Drug Amendments Act of 2007

- **Built** upon one up / one down
- **Reportable Food Registry** (RFR)

Food Safety Modernization Act (FSMA) of 2011

- Shifts focus from reactive to preventative
- Written recall plan, **respond within 4 hours**
- Initiated **Tracking & Tracing Pilots**
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Edipeel Supply Chain

**RAW MATERIALS & MANUFACTURING**
- SUPPLY
- RECEIVING
- MANUFACTURING

**EDIPEEL™ FINISHED GOODS INVENTORY MANAGEMENT**
- INVENTORY (APEEL)
- INVENTORY (CUSTOMER)
- RECONSTITUTION

**TRANSPORT & APPLICATION**
- APPLICATION
- SHIP TO RETAILER

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**SUPPLIER A**
- COMPONENT 1
  - LOT #A1
  - CONTAINER 1

**SUPPLIER B**
- COMPONENT 2
  - LOT #B1
  - CONTAINER 1

**Edipeel™ Lot #1**
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg

**Reconstituted Batch Data #1**
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg
- 1kg

**Sales Order 1**

---

**Shipment to Retailer**
Edipeel Supply Chain

**RAW MATERIALS & MANUFACTURING**
- SUPPLY
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**SUPPLIER A**
- COMPONENT 1
  - LOT #A1
  - CONTAINER 1

**SUPPLIER B**
- COMPONENT 2
  - LOT #B1
  - CONTAINER 1

---

Edipeel™ Lot #1

1kg 1kg 1kg
1kg 1kg 1kg
1kg 1kg 1kg
1kg 1kg 1kg

Reconstituted Batch Data #1

Sales Order 1

Apeel’s Service Model:
- Integrate into customer **packing house**
- Own inventory on customer’s site
- Manage reconstitution and application
- Inventory **title transfer upon application**
Key Data Elements

**Raw Material Inventory**
Upon Receipt:
- Raw Material
- Supplier
- Supplier Lot #
- Date
- Quality Inspected

= Container ID-01/02/2018

**Edipeel Inventory**
- Container ID-01/02/2018
- Work Order #
- Production Date
- Quantity
- Expiry Date

= Lot # CCO3-AVOCAD-001

**Treated Product**
- Lot # CCO3-AVOCAD-001
- Sales order #
- Reconstitution date
- Quantity

= 2017-1-ABC-180301-1172
## Recall Traceback – example

<table>
<thead>
<tr>
<th>Raw Material Inventory</th>
<th>Edipeel Inventory</th>
<th>Treated Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>A A A A</td>
<td>1Kg 1Kg 1Kg 1Kg</td>
<td>pallet</td>
</tr>
<tr>
<td>A</td>
<td>1Kg 1Kg</td>
<td>pallet</td>
</tr>
<tr>
<td>B B B B</td>
<td>1Kg 1Kg 1Kg</td>
<td>pallet</td>
</tr>
</tbody>
</table>

1. Identify batch data #
   - 2017-1-ABC-180301-1172

2. Find sales order-line
   - 2017-1-ABC-180301-1172

3. Identify Apeel Lot #
   - CC03-AVOCAD-001

The product identified for recall is the lot 2017-1-ABC-180301-1172 of Apeel with Lot CC03-AVOCAD-001.
Recall Traceback – example

4. Identify raw material container IDs used to create CC03-AVOCAD-001
   - A-12012016
   - B-11012016

5. Identify all Apeel lot #’s using A-12012016 & B-11012016
   - CC03-AVOCAD-001
   - CB01-AVOCAD-001
### Recall Traceback – example

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<td></td>
<td></td>
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</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>B</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Warehouse

<table>
<thead>
<tr>
<th></th>
<th>1Kg</th>
<th>1Kg</th>
<th>1Kg</th>
<th>1Kg</th>
<th>1Kg</th>
</tr>
</thead>
</table>
| Customer Location ABC
| 1Kg     |     | 1Kg |     |     |     |
| Customer Location DCE
| 1Kg     | 1Kg | 1Kg | 1Kg |     |     |
| In-transit
| 1Kg     | 1Kg | 1Kg |     |     |     |

#### Identify all finished goods inventory of the identified lots:

- [ ] Warehouse
- [ ] In-Transit
- [ ] At Customer

**CC03-AVOCAD-001**

**CB01-AVOCAD-001**
### Recall Traceback – example

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</tr>
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<td>Customer Location ABC</td>
<td></td>
<td>pallet</td>
</tr>
<tr>
<td>1Kg</td>
<td>1Kg</td>
<td>pallet</td>
</tr>
<tr>
<td>Customer Location DCE</td>
<td></td>
<td>pallet</td>
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<td>1Kg</td>
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</tr>
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<td>pallet</td>
</tr>
<tr>
<td>In-transit</td>
<td></td>
<td>pallet</td>
</tr>
<tr>
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<td>1Kg</td>
<td>pallet</td>
</tr>
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<td>1Kg</td>
<td>1Kg</td>
<td>pallet</td>
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</table>

7. Identify any additional processed batches of the identified lots:

| 2017-1-ABC-180301-1172 | 2024-1-DCE-180228-1012 | 2024-1-DCE-180228-1011 |
## Reporting Requirements

<table>
<thead>
<tr>
<th>Given:</th>
<th>Identify:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Batch ID</td>
<td>Any Additional Treatment Batch IDs</td>
</tr>
<tr>
<td></td>
<td>All relevant Apeel Lot #s</td>
</tr>
<tr>
<td>Apeel Lot #</td>
<td>All relevant Raw Material Container IDs</td>
</tr>
<tr>
<td></td>
<td>All relevant Treatment Batch IDs</td>
</tr>
<tr>
<td>Raw Material Container ID</td>
<td>All relevant Apeel Lot #s</td>
</tr>
</tbody>
</table>
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# Recommendations and Considerations

## Recommendations
- Reporting requirements – 5 reports
- Minimize manually generating batch data number when applying Edipeel
- Automate inventory reconciliation after Edipeel is applied
- Address limitations of current ERP system

## Considerations for Operating at Scale
- Vertical integration – consider raw material lot tracking
- Future customers – different inventory tracking processes must integrate with Apeel tracking
- Future products – may require different steps
- Cost of Apeel Engineer applying Edipeel
Questions?