Traceability of a Breakthrough Food Science Technology







Russ Miller & Hilary Taylor, SCM 2018

Advisor: Bruce Arntzen

Sponsor Company: Apeel Sciences

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



Sponsor Company - Apeel Sciences

- 45% of produce is wasted due to spoilage \$750B annually
- Food science start-up
- Founded in Santa Barbara, California in 2012





Company Mission

Apeel uses natural plantbased technologies to protect crops and harvested produce, helping to eliminate food spoilage and reduce reliance on chemicals

Company Purpose

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

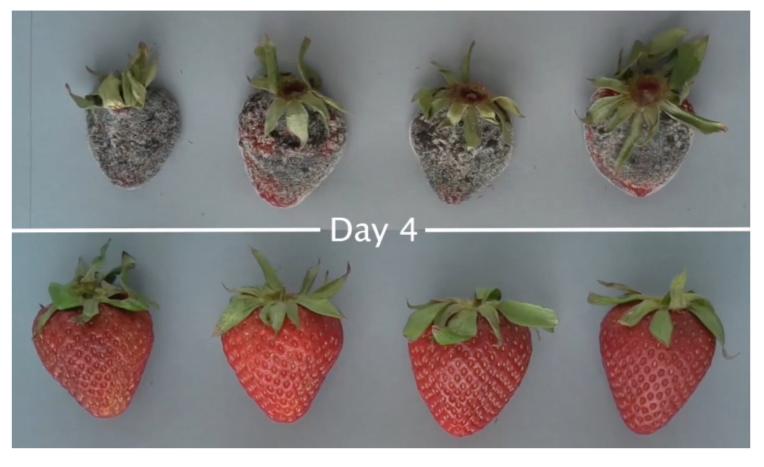
Company Vision

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



Introducing... EdipeelTM

UNTREATED

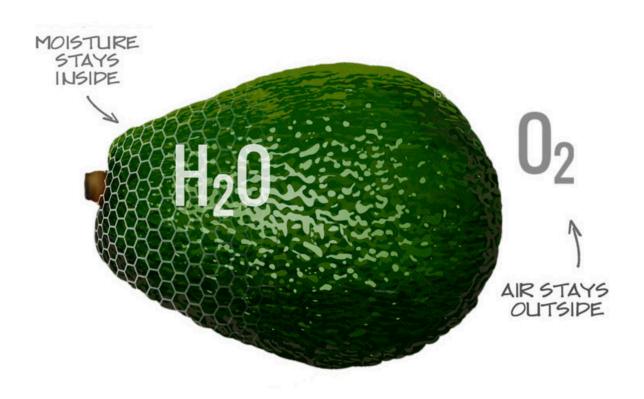


TREATED with Edipeel



|Edipeel^{TM|}

- 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





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

Food & Drug Amendments Act of 2007

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

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 Safety Modernization Act (FSMA) of 2011

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



Agenda

Introduction

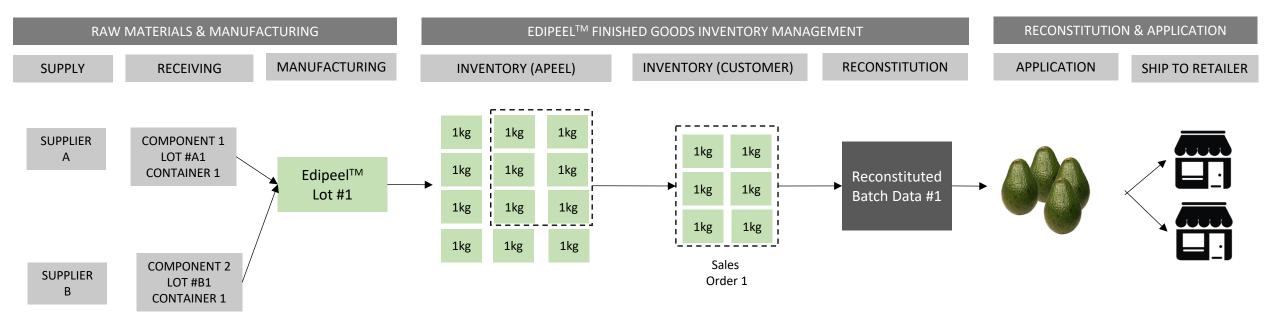


Apeel's Supply Chain

- Recommendations
- Q&A

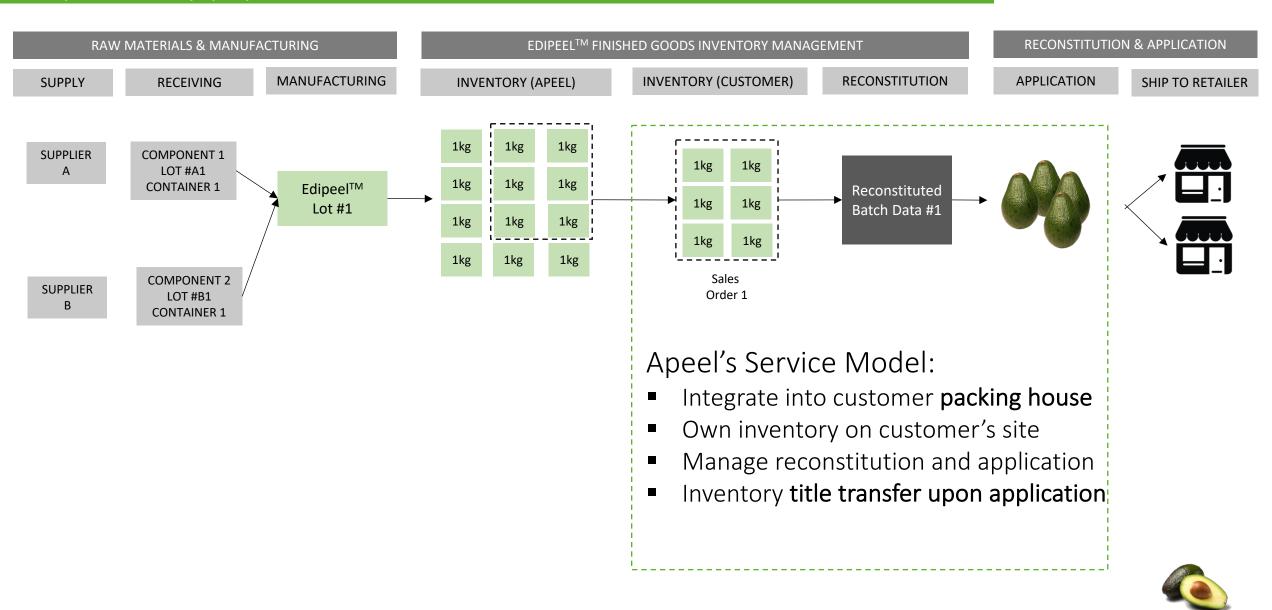


Edipeel Supply Chain

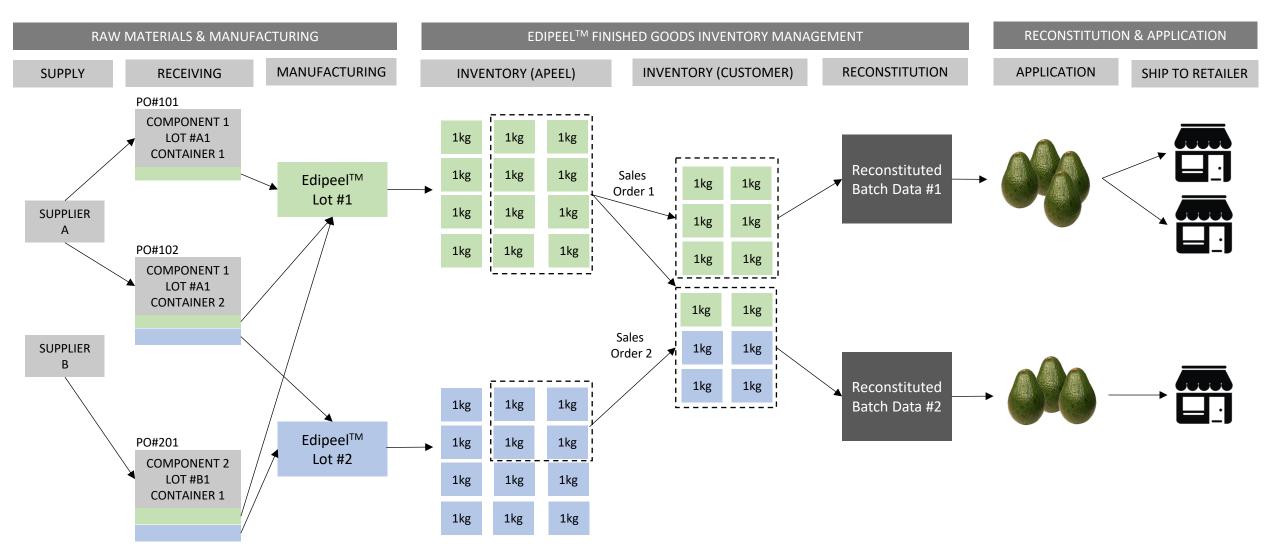




Edipeel Supply Chain



Edipeel Supply Chain – Scenario Review





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

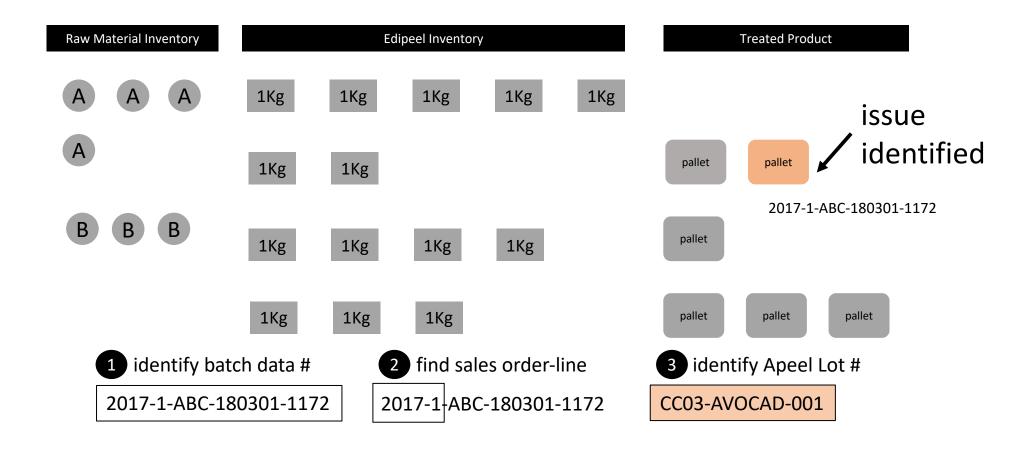
Lot # CCO3-AVOCAD-001

Treated Product

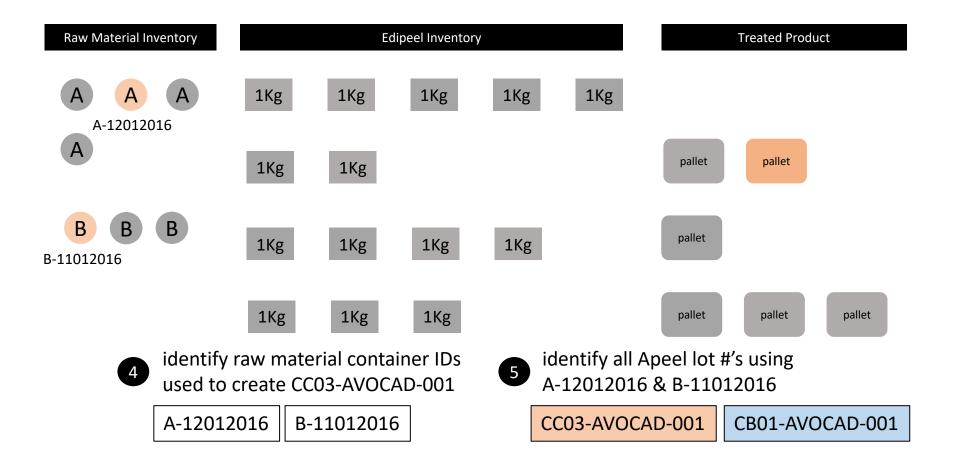
- Lot # CCO3-AVOCAD-001
- Sales order #
- Reconstitution date
- Quantity

2017-1-ABC-180301-1172

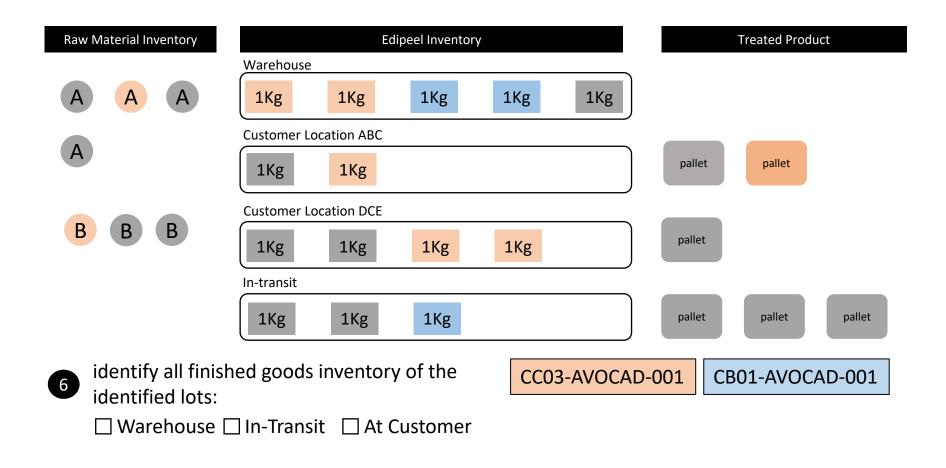




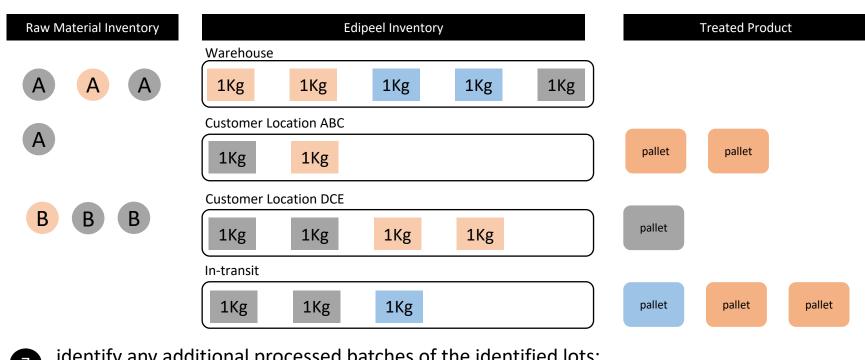












identify any additional processed batches of the identified lots:

2017-1-ABC-180301-1172

2024-1-DCE-180228-1012

2024-1-DCE-180228-1011



Reporting Requirements

| 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 |



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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



