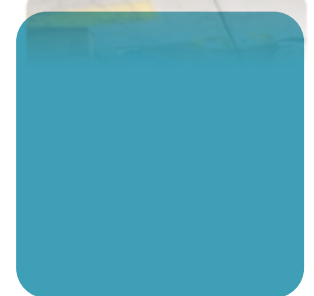


Avoiding Post Process Recontamination – the Importance of a Robust Environmental Monitoring Program

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Modesto, CA June 4, 2015

6-15

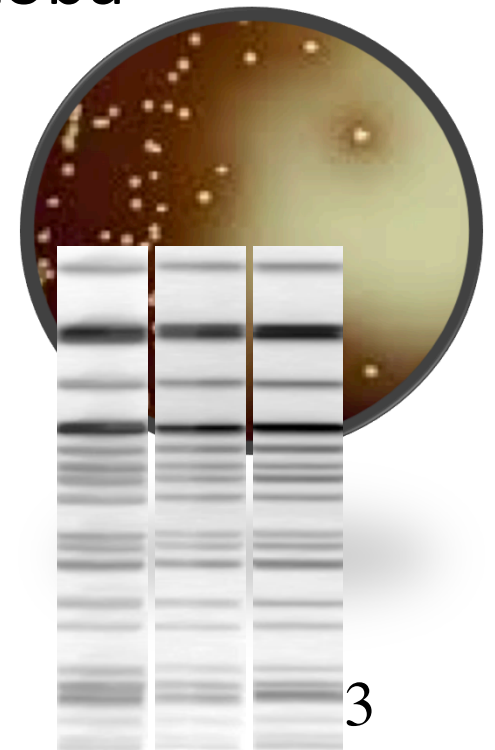


Outline

- Outbreaks/illnesses
 - New methodologies, new approaches
 - Peanut butter, 2014
 - Stone fruits, 2014
 - Caramel apples, 2014
- Environmental persistence of *Salmonella*
- Anticipated regulation/requirements
- Environmental monitoring – anticipated requirements
 - Zone concept
 - Environmental pathogens
 - *Salmonella*

2014 Listeriosis – Caramel Apples

- Commercially produced, prepackaged caramel apples
- Single California packing facility
- 35 illnesses/7 deaths; 12 states; Manitoba
 - Three cases of meningitis in otherwise healthy children
 - aged 5–15 years
- PFGE link outbreak, other product and environmental strains
 - 6 zone 1, 1 zone 3, whole fresh apples in commerce



Caramel apple

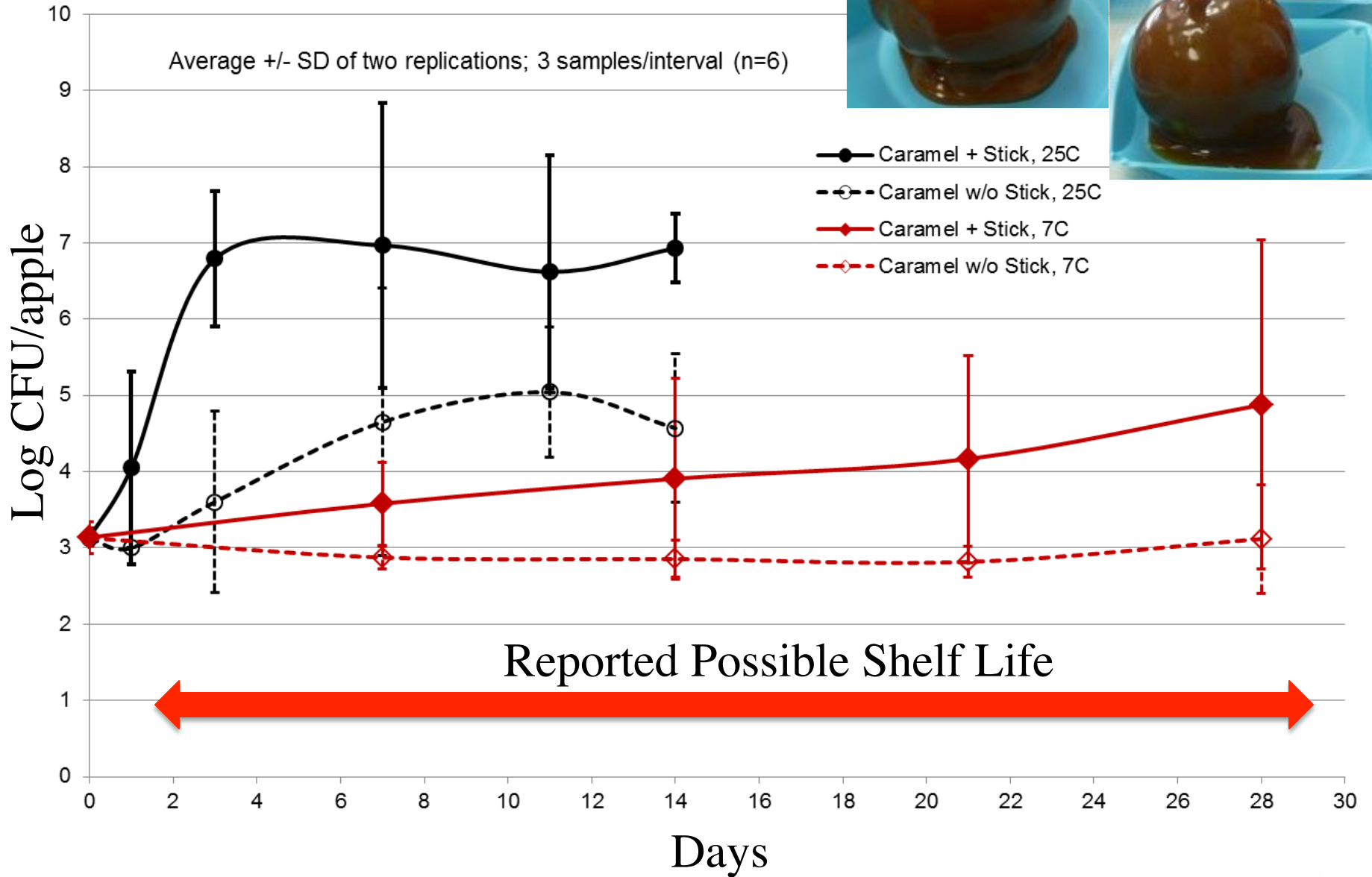


- Unlikely food attribution –
no history
 - Whole apple surface dry
 - pH apple flesh: 3.6 to 4.0
 - A_w caramel: <0.80



- Apples
- Stick/No stick
- Caramel 195°F
 - Dip (stick or tongs)
- Storage
 - 77 and 45°F





Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)



***Notes from the Field:* Listeriosis Associated with Stone Fruit – United States, 2014**

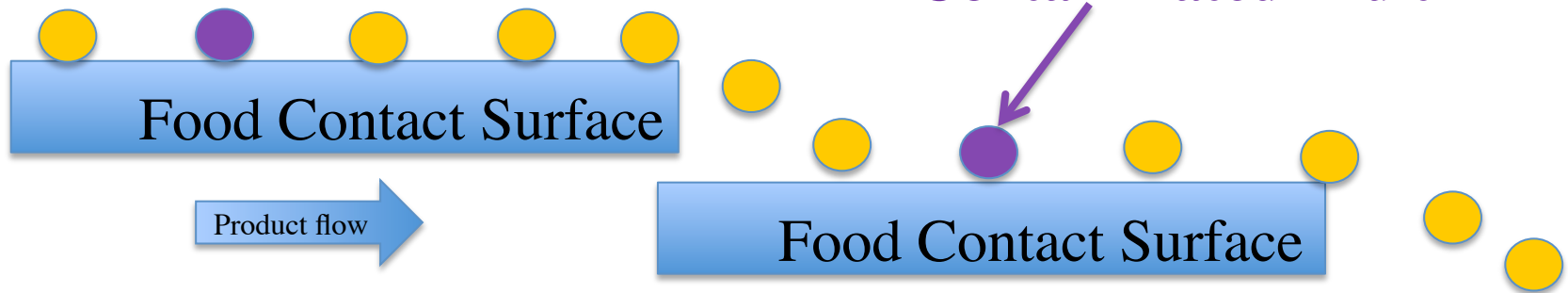
Weekly

March 20, 2015 / 64(10);282-283



Transient vs Resident LM

Transient Lm



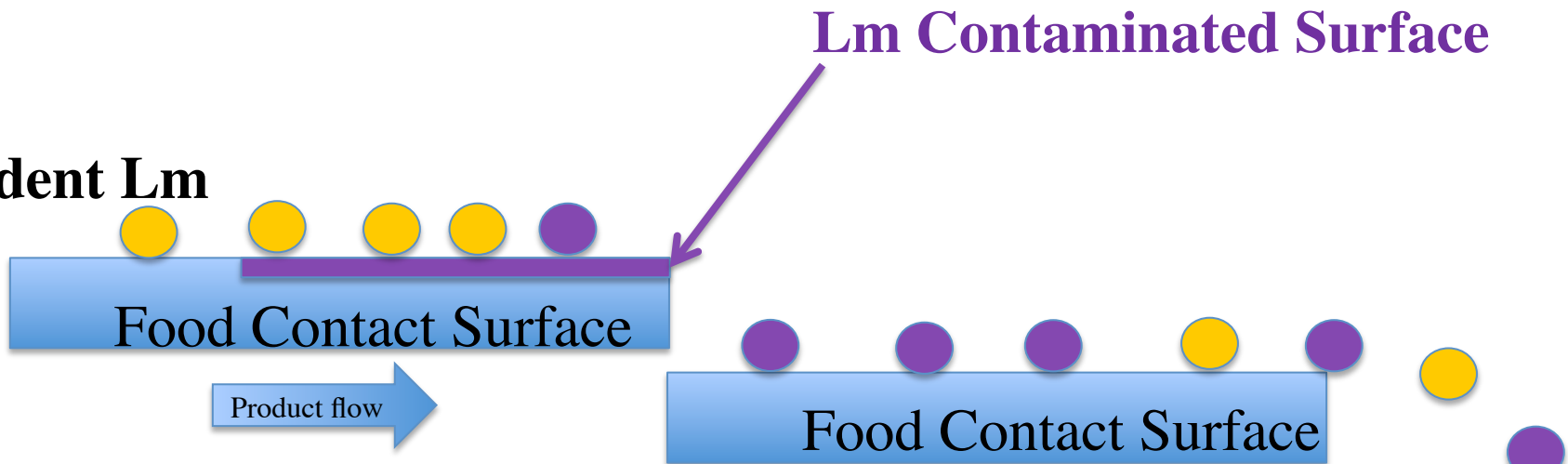
Lm Contaminated Fruit

Food Contact Surface

Product flow

Food Contact Surface

Resident Lm



Lm Contaminated Surface



Food Contact Surface

Product flow

Food Contact Surface

Guidance Resources: RAC's, Fresh-cut, Dry Facilities


Guidance on Environmental
Monitoring and Control of *Listeria*
for the Fresh Produce Industry



United Fresh
PRODUCE ASSOCIATION


Developed by the United Fresh Food Safety & Technology Council

2013



pathogen environmental
monitoring program (PEM)

Presented by the Almond Board of California



<http://www2.unitedfresh.org/forms/store/ProductFormPublic/>

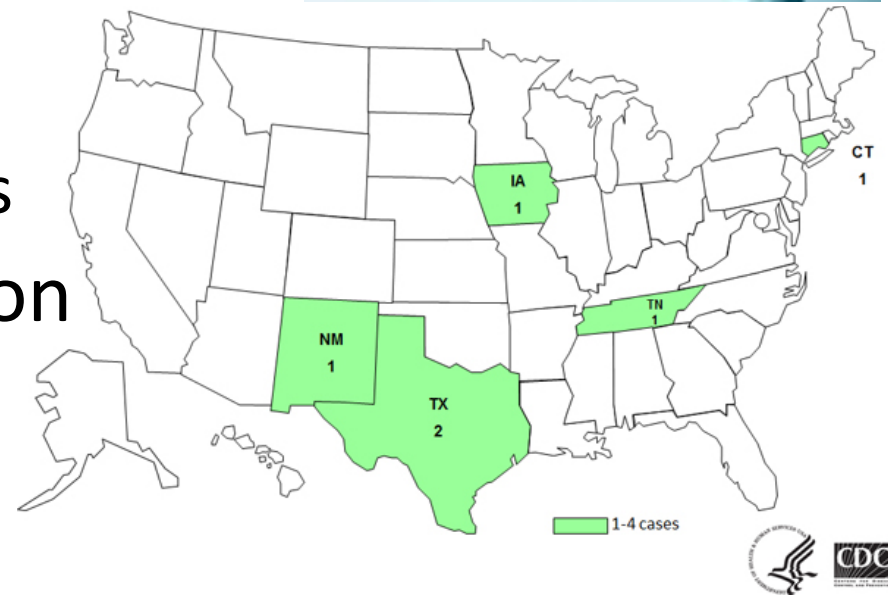
2014 Nut Butter Outbreak - Identification in Reverse

- Routine inspection of facility
 - January 2014
 - Isolates *Salmonella* Braenderup
 - PFGE fingerprinting
 - Whole genome sequencing

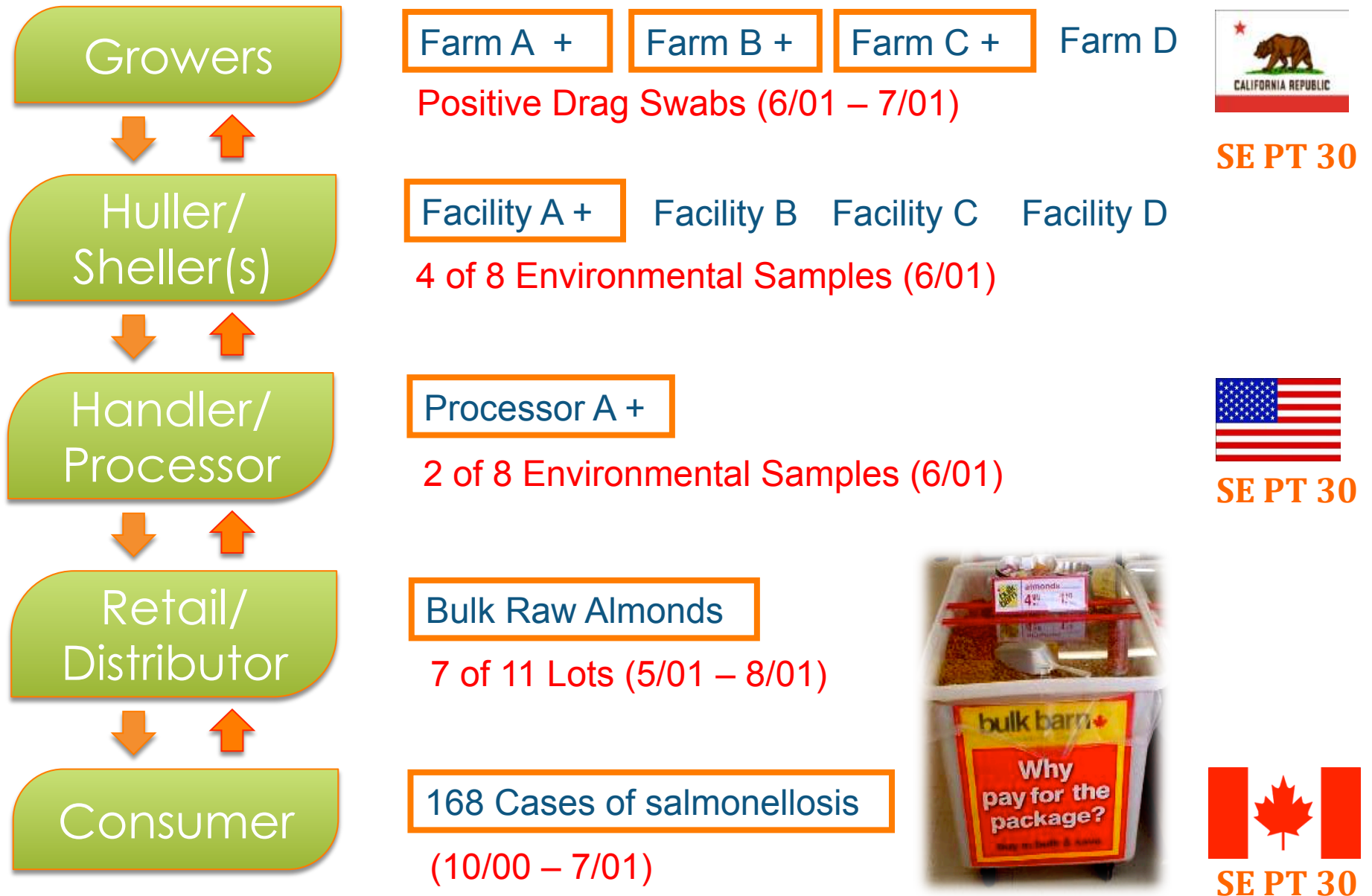


2014 Nut Butter Outbreak - Identification in Reverse

- Search PulseNet for cases
 - January (2), February, March, April, May
- Epidemiology
 - Supportive in some cases
- Re-inspection, re-isolation July 2015
 - *Salmonella* Braenderup
- **6 months product recall**

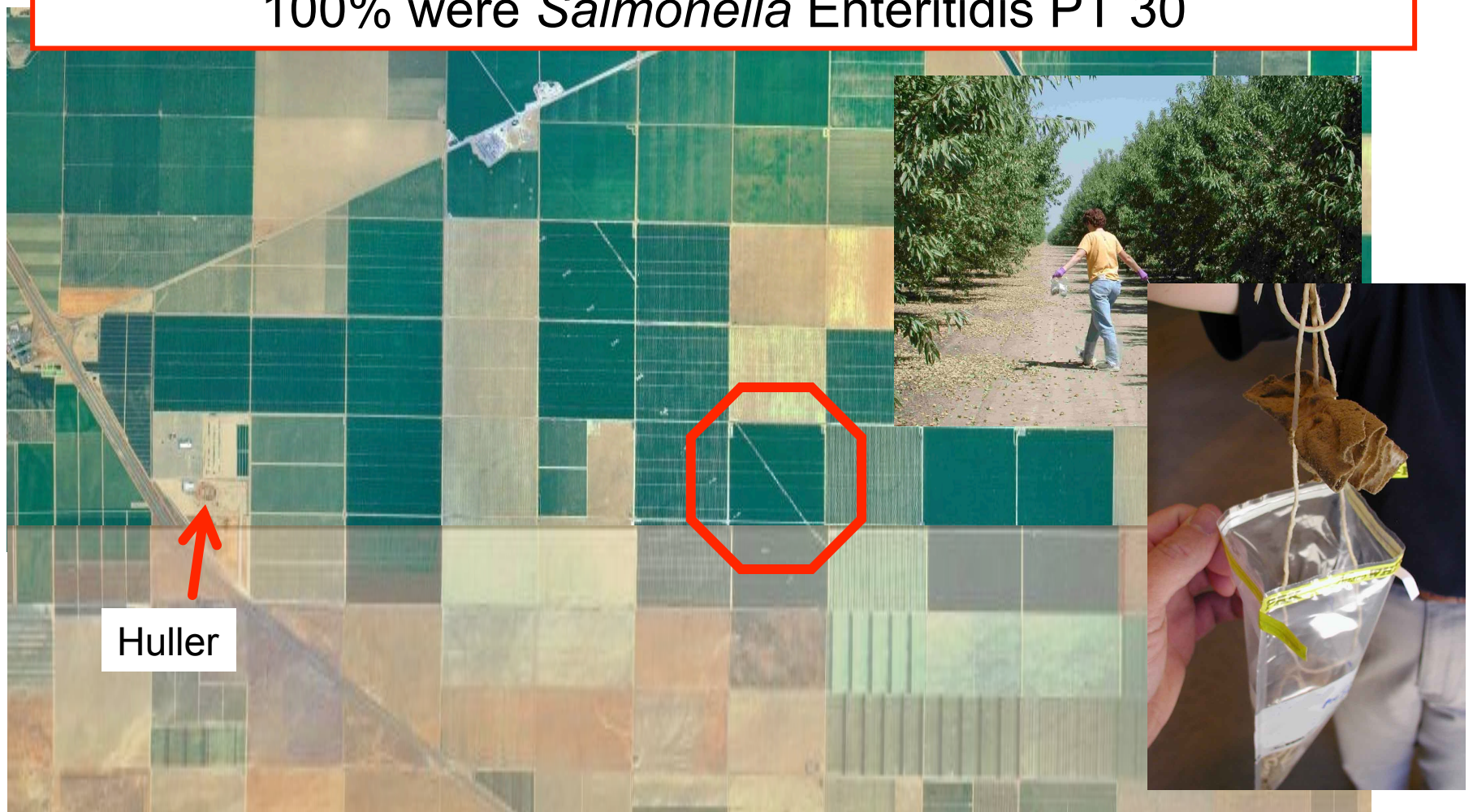


2000-2001 Almond Outbreak Investigation



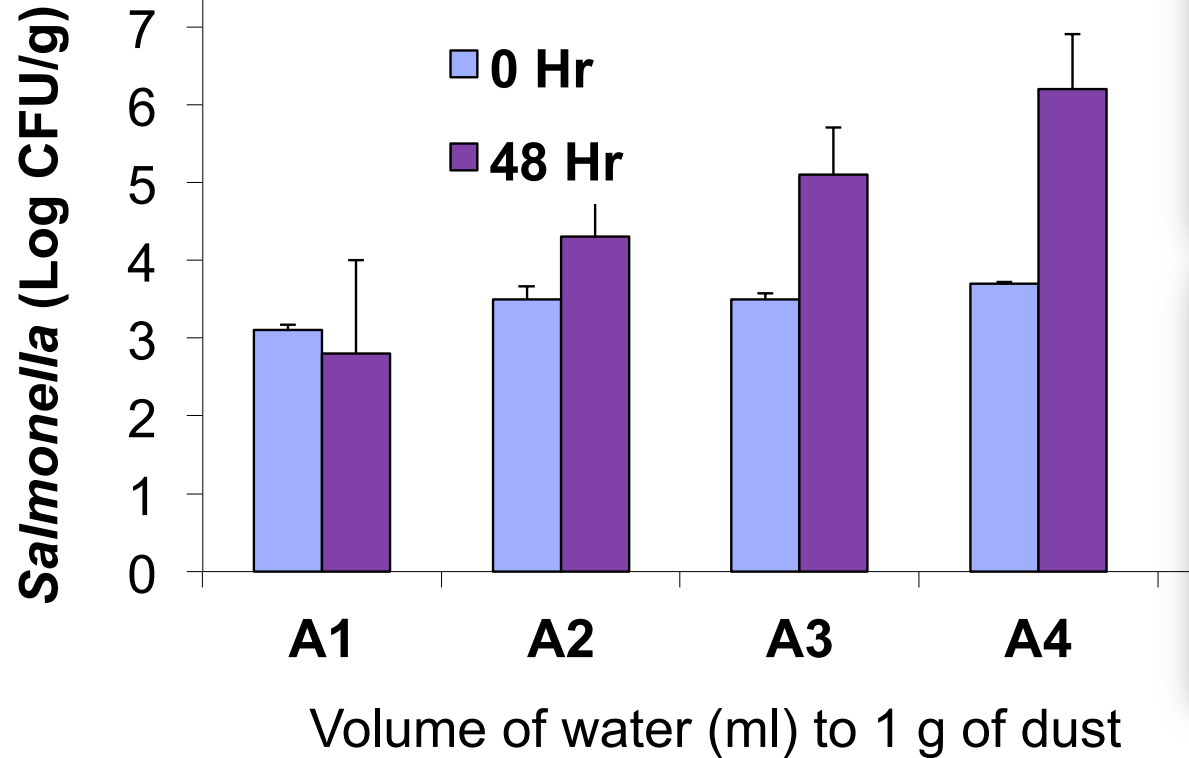
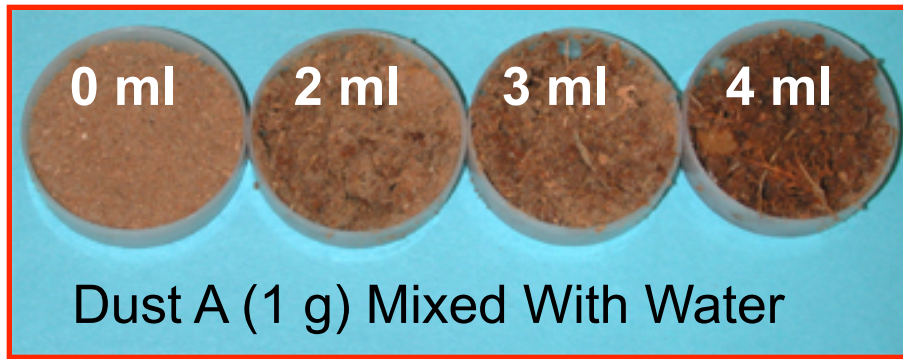
Isolation of *Salmonella* from a single almond orchard, 2001-2006

54 isolates from 230 pooled swabs positive for *Salmonella*
100% were *Salmonella* Enteritidis PT 30



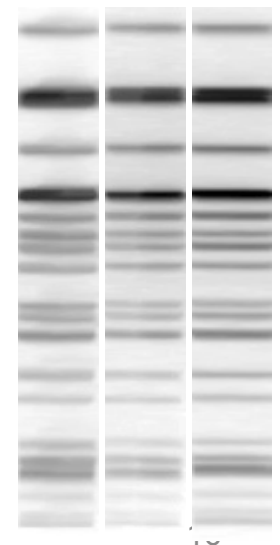
Isaacs et al., 2005; Uesugi et al., 2007

Salmonella Grows in Wet Almond Dust



Cereal Outbreaks

- *Salmonella* Agona
 - April to June 1998
 - Toasted oat cereal - April to June 1998
 - 209 cases/11 states
 - January to July 2008
 - Puffed rice and wheat cereals
 - 33 cases/15 states



Same facility and PFGE matched *Salmonella*

1998 response

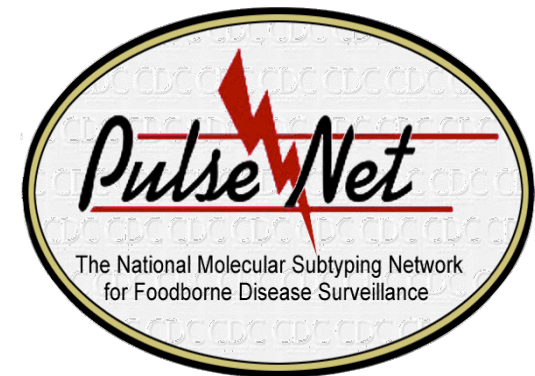
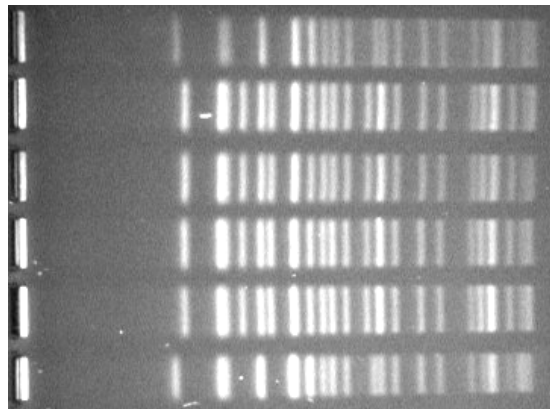
- Implicated production lines:
 - sealed off,
 - all equipment was removed,
 - all surfaces were stripped to bare concrete, decontaminated, and refinished, and new production lines were installed

November 2007

- Maintenance work
 - One wall opened
 - immediately adjacent to section of facility implicated in 1998 outbreak
 - Dust? Wet cleaning? Moist conditions?

April 2008

- Company finds *Salmonella* in finished product
- Recall product
- Outbreak identified through PulseNet



2008 response

- Permanently ceased production of puffed rice and puffed wheat cereals, removed all equipment, and permanently sealed this section of the plant.

Salmonella outbreaks

- In dried food reoccurring themes
 - Water
 - Leaky roof
 - Poor traffic flow
 - Wet sanitation procedures
 - Inadequate follow up
 - Dust
 - Construction
 - Traffic flow

(b) Hazard Identification

- **The hazard identification must consider:**
 - (1) Hazards that include:
 - (i) Biological hazards, including microbiological hazards such as parasites, [environmental pathogens](#), and other pathogens;
 - (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;
and
 - (iii) Physical hazards; and

Hazard Evaluation

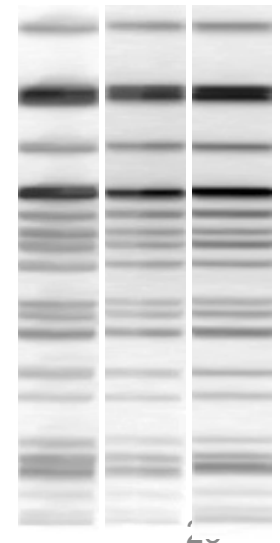
- **(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.**

Environmental pathogen

- means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen.

Dry processes

- Pathogen:
 - *Salmonella*
- Example indicator organism
 - *Enterobacteriaceae*
- Infant formula
 - Pathogen: *Cronobacter sakazakii*
(formerly *Enterobacter sakazakii*)



(3) Sanitation controls

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards.

§ 117.165 Verification of implementation and effectiveness

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples;

§ 117.150 Corrective actions and corrections

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

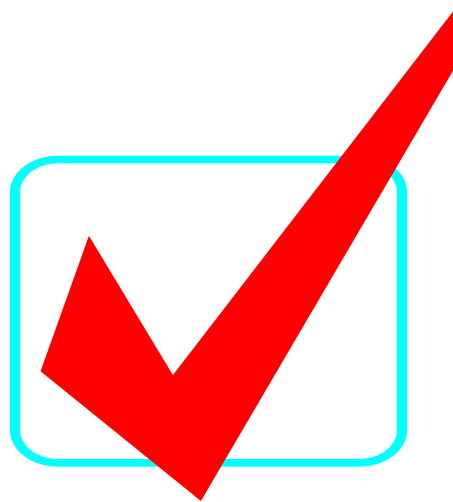
Food Safety Plan

- **Must Consider Environmental Pathogens**
 - In the hazard analysis
 - In sanitation controls
 - In verification activities
 - (environmental monitoring)
 - In corrective actions
 - In the case of pathogen or indicator detection

Environmental Monitoring

Environmental Monitoring

- **A verification step**
 - **Verify** that you are following the procedures you developed (**'compliance'**)
 - **Verify** that the plan is working in practice.



Verification activities include

- **Review** of
 - written policies and procedures
 - quality systems audits, GMP self-audits, etc.
 - records that support the GMP programs
 - E.g., sanitation and training records
- **Observation** of
 - cleaning and sanitation, sanitary conditions,
 - GMP compliance, etc.

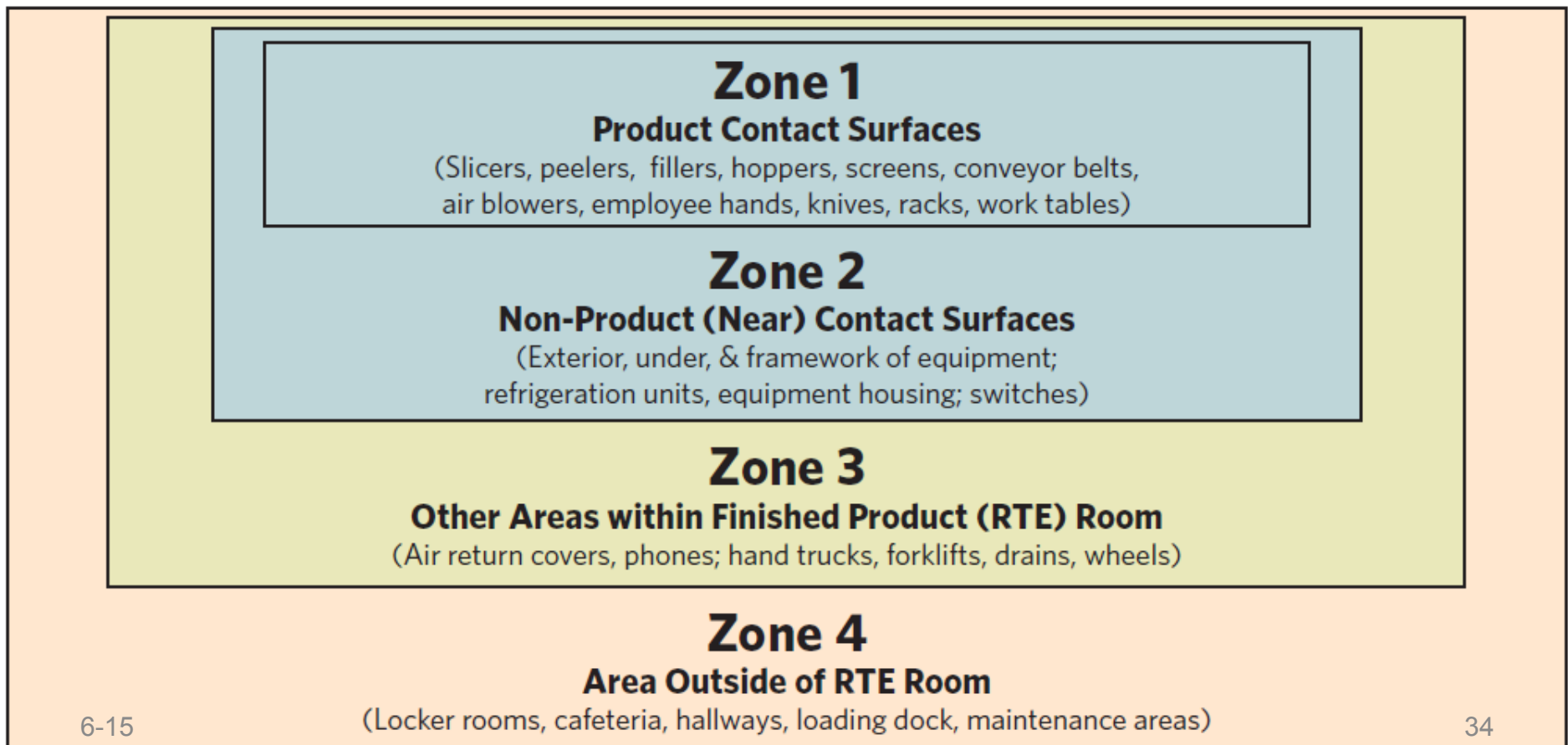


pathogen environmental monitoring program (PEM)

Presented by the Almond Board of California



Zone Concept for Setting Master Schedule Cleaning and Sanitation & Environmental Monitoring Programs



Be the *Salmonella*

- Where would you look?



What about a positive finding?

- You MUST have a written corrective action.
- Transient
 - Not found in repeated testing
- Resident
 - Repeatedly found
- Examine the site, implement appropriate cleaning/sanitation
 - Retest the site and surrounding area
 - Increase routine testing in and around area until several negative results
- If resident *Salmonella* spp. is suspected
 - Form a team
 - Investigate potential cause, implement corrective action, retest
- Document all activities

Special Events

- Enhanced environmental monitoring should be considered when:
 - Construction
 - New equipment installation
 - Major repairs
 - Breaks in operation

Indicator and Pathogen Testing

- Results
 - Understand the limitations.
 - Define Critical Limits **in Writing**
 - What is unacceptable?
 - Define Corrective Action **in Writing**
 - Action for unacceptable result?
 - **Written** data disposition **policy**.

Indicator and Pathogen Testing

- Data processing
 - Keep good records
 - Evaluation of trends
 - Recognizing site-specific deviations
 - Recognizing equipment or practice-specific risks
- Further characterization of isolates
 - *Listeria* spp. to *L. monocytogenes* to fingerprints
 - Genome sequencing
- Whole community analysis

Summary

- Environmental monitoring
 - Is a verification activity that can be used to assess the efficacy of GMPs and a sanitation program
 - For zone 1 surfaces assessing for indicators of reduced organic or microbial load (e.g., ATP, APC) is common
 - For zone 2 to 4 surfaces assessing for a pathogen or pathogen indicator (e.g., *Listeria* spp.) may be appropriate
- Written
 - Environmental monitoring plan and corrective actions
 - Documentation is critical