



growing

ADVANTAGE

The Almond Conference



# Food Safety: The Regulations are Closer

Thursday, 12:15 – 1:25pm

# The U.S. Food Safety Modernization Act (FSMA)

- Sweeping change for U.S. food safety legislation
- Focus on **prevention**
- Court-ordered dates to finalize, implement rules
- Currently in 2nd round of comments for supplemental proposals
  - Produce Safety
  - Preventive Controls (Humans, Animals)
  - Foreign Supplier Verification

|                                | Final Rule Deadline | Compliance : Not-Small                          | Compliance : Small                            | Compliance : Very Small                       |
|--------------------------------|---------------------|---|---|---|
| <u>PC Human Food</u>           | 8/30/2015           | 1 Year  | 2 Years                                       | 3 Years                                       |
| <u>PC Animal Food</u>          | 8/30/2015           | 1 Year  | 2 Years                                       | 3 Years                                       |
| <u>FSVP</u>                    | 10/31/2015          | 6 Months After PC Final Rules becomes effective | 2 Years After PC Final Rule becomes effective | 2 Years After PC Final Rule becomes effective |
| <u>Produce Safety</u>          | 10/31/2015          | 2 Years   | 3 Years                                       | 4 Years                                       |
| <u>Food Defense</u>            | 5/31/2016           | 1 Year  | 2 Years                                       | 3 Years                                       |
| <u>Sanitary Transport</u>      | 3/31/2016           | 1 Year  | 2 Years                                       | N/A   |
| <u>3rd Party Accreditation</u> | 10/31/2015          | N/A   | N/A   | N/A   |

# How Can Almonds Leverage our Achievements?

- Previous food safety events = **proactive** action
- Avoid duplication (reinventing the wheel...)
- Recognition for **validated** and **audited** procedures that are already operating
- Going forward, how do we build on success?



# Food Safety: The Regulations are Closer

Julie Adams, ABC (Moderator)

Jennifer McEntire, The Acheson Group

Tim Birmingham, ABC

Following presentations, open discussion  
and Q&A





# Comments from Jeff Farrar, FDA

A close-up photograph of several green almonds on a branch, with vibrant green leaves. The background is softly blurred, showing more of the tree and a hint of a person in the distance. The lighting is bright and natural, highlighting the texture of the almonds and the sheen on the leaves.

**Jennifer McEntire**  
**The Acheson Group**

# Impact of FSMA Supplements on the Almond Industry

Jennifer McEntire, Ph.D

VP & Chief Science Officer

The Acheson Group

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# Key Points

- Hullers/shellers exempt from GMPs
  - Illogical to require food safety plan/ preventive controls
- Human food byproducts produced under cGMPs are exempt from the animal food rule
  - Where does this leave human food byproducts not produced under cGMPs?
- Processors will likely need to conduct environmental monitoring
- Produce Safety Rule eased water testing requirements for generic *E. coli*
  - Still a little confusing



A close-up photograph of several green almonds on a branch, with vibrant green leaves. The background is softly blurred, showing more of the tree and a hint of a person in the distance. A solid red vertical bar is positioned on the left side of the image, partially overlapping the text.

# Preventive Controls

## GMP Exemptions

- (iii) The holding or transportation of one or more “raw agricultural commodities,” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act;
  - (iv) Activities of “farm mixed-type facilities” (as defined in § 1.227) that fall within the definition of “farm”; or
  - **(v) Hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts).**
- “hulling, shelling and drying are...activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in § 110.19.”



# Preventive Controls for Human Food

- No more RLTO! Replaced by “Significant Hazards.”
  - Known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing packing or holding of food would based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrective actions, verification and records) as appropriate to the food, the facility and the nature of the preventive control.
- This was to make it clear that this rule is **not about HACCP** and having critical control points for all significant hazards.

## Finished Product Testing

- Used as a means to verify the adequacy of preventive controls.
  - For pathogens or indicator organisms.
- Note the language used: “testing programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.”
  - The Agency says “could” which indicating not a mandate.
  - Given the use of a validated kill step, **the value of FPT for almonds is questionable**
- If finished product testing is used, a facility will need to have a written plan, corrective action procedures and keep records

# Environmental Monitoring

- Environmental monitoring would be required in the specific circumstances where RTE product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed.
  - In short, RTE product where post process contamination is a significant hazard- **this applies to almonds!**
- Where required, must have records, written procedures of your program / what you are testing and corrective action procedures.



# Supplier Controls

- Establish a risk-based written supplier verification program for raw materials and ingredients when the receiving facility's hazard analysis has identified a significant hazard that is being controlled by the supplier (before receipt of the raw material/ingredient)
- Receiving firm may determine appropriate verification activity (e.g. testing of raw materials, review supplier food safety plans, etc.)
  - EXCEPT an annual onsite audit is required when there is a reasonable probability that exposure to the hazard will result in SAHCDH- unless the receiving facility documents that other verification activities and/or less frequent onsite auditing of the supplier provides adequate assurance that the hazards are controlled.
  - Sampling, testing of ingredients, review suppliers food safety records, etc.
  - DC vs Supplier's suppliers

## Preventive Controls For Animals

- New GMP section for human food facilities that hold and distribute human food byproducts for animal food
  - Cannot be commingled with garbage
  - Must protect from chemical and physical hazards
  - HARPC will not apply to human food byproducts
  - Rationale: if a food is originally produced under human food GMPs and FSP, the facility does not need to consider animal-specific hazards
    - **Hulling/shelling is exempt from human GMPs...**
- FDA made other changes to GMPs including several wording changes and omitting areas applicable only to human food.







# Produce Safety Rule

## Produce Safety Rule

- Revisions to the definitions of “covered activity,” “harvesting,” “holding,” and “packing”. Keeping these as farms
- Updated the microbial quality standard for water that is used during growing of produce (not sprouts) using a direct application method in a way that is consistent with EPA recreational water standards
- Farm may meet agricultural water testing requirements using the farm’s own test results or data collected by a third party
- Removal of the 9-month minimum application interval for use of raw manure



# Produce Safety Rule: not addressed

- Did not address comment on huller/sheller being an extension of the farm
- Did not address list of “rarely consumed raw”

## FSMA Status Summary - “The 7 Pillars”

| Proposed Rule             | Final Deadline   |
|---------------------------|------------------|
| PC- Human Food            | August 30, 2015  |
| PC- Animal Food           | August 30, 2015  |
| Produce Safety            | October 31, 2015 |
| FSVP                      | October 31, 2015 |
| Third Party Accreditation | October 31, 2015 |
| Sanitary Transport        | March 31, 2016   |
| Food Defense              | May 31, 2016     |

## What we're doing

Submitting comments by Dec. 15

What have you heard?

What are you concerned about?



## OPERATIONAL RISK

## REPUTATIONAL RISK

## REGULATORY RISK

- Supply Chain Risk
- Internal Operations
- Crisis and Recall Preparedness
- Environmental & Testing Strategies

- Social Media
- Development of Communication Strategies & Programs
- Strengthen stakeholder relationships

- Food Regulations and Compliance
- Expertise on FSMA
- Crisis Response to regulatory issues, crisis and recalls



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**Tim Birmingham, ABC**

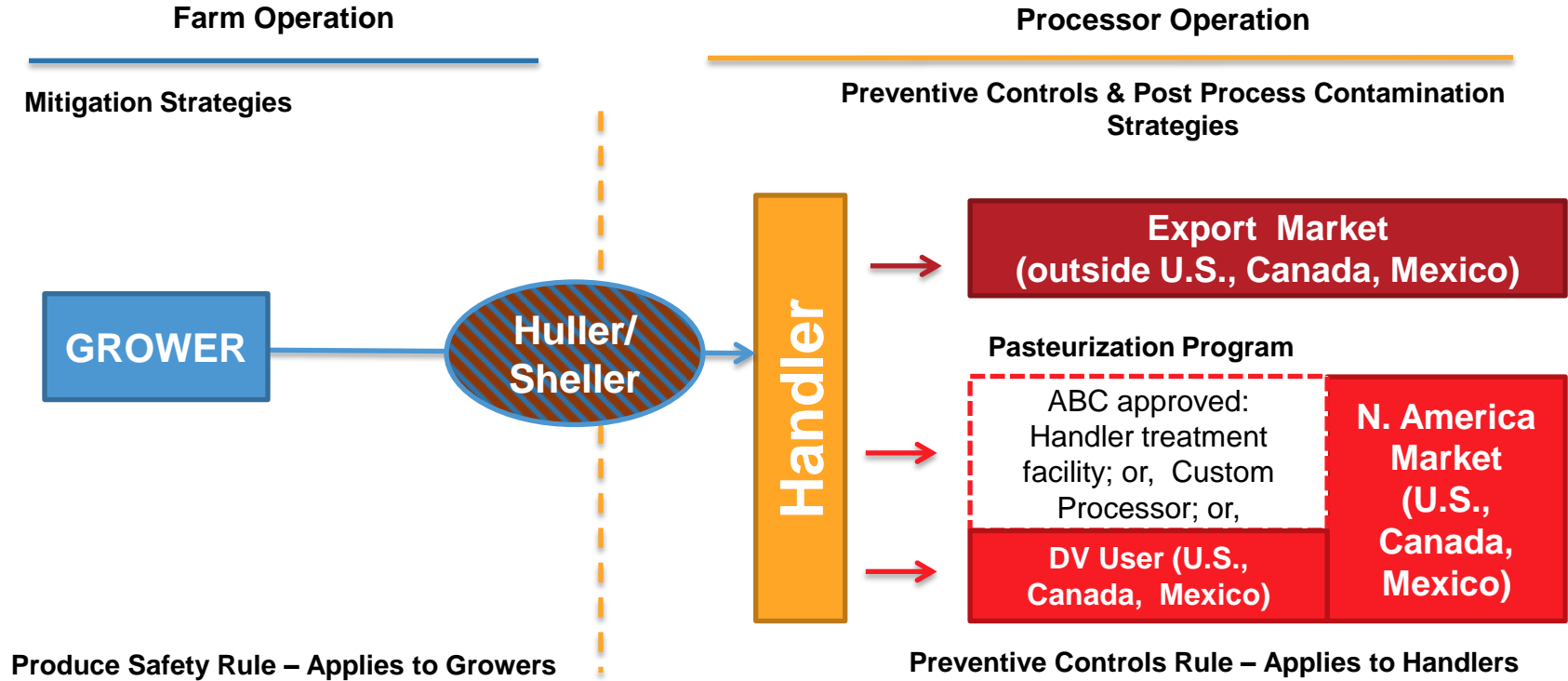


# Almond Food Safety & FSMA – Food Safety Plans

The Road Forward

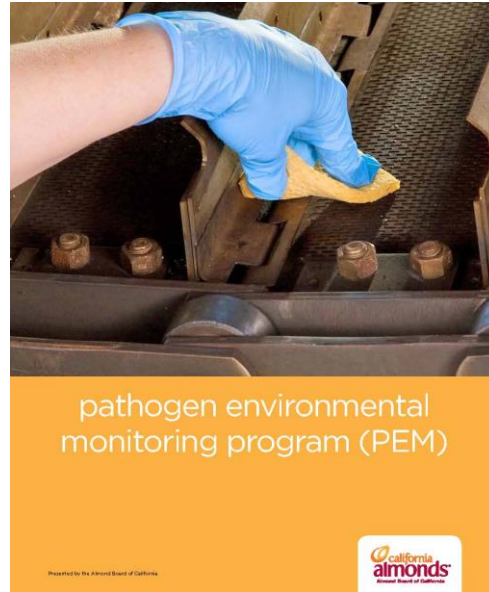


# Food Safety Plans – Let's not reinvent the wheel



# Food Safety Plans - Addressing all Hazards

- Biological hazards
  - Micro including environmental pathogens during production
- Chemical hazards
  - e.g. aflatoxin
- Physical hazards



## Fitting our pasteurization program into the FSMA Food Safety Plan Model

| FSMA Food Safety Plan                         | ABC Pasteurization   |
|---|--|
| Written Hazard Analysis                       | ABC Salmonella Survey and Risk Assessments                                 |
| Implement Preventive Controls (PC's)          | 170+validated processes  |
| Supplier Program                              | Not necessary if hazard controlled after receipt of material or ingredient |
| Monitoring Procedures for PC's                | Defined for pasteurization processes                                       |
| Corrective Action Procedures                  | Defined for pasteurization processes                                       |
| Verification / Validation Procedures for PC's | Defined for pasteurization processes                                       |
| Records                                       | Defined for pasteurization processes                                       |



# The Road Forward

- Develop food safety plan tools and guidance
  - Templates addressing multiple hazards
  - Recordation guidance and templates
  - Revised environmental monitoring guidance
- Review regulatory audit requirements
  - Identify synergies with current audit/verification activities
  - Engage regulators in dialogue to explore use of third party auditors
- Outreach with Industry for Food Safety Plan development



# Questions and Discussion