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# PSR and PC Rule Implementation & Enforcement

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# General Tips for Inspections

- Be polite
- Know your rights

# PSR

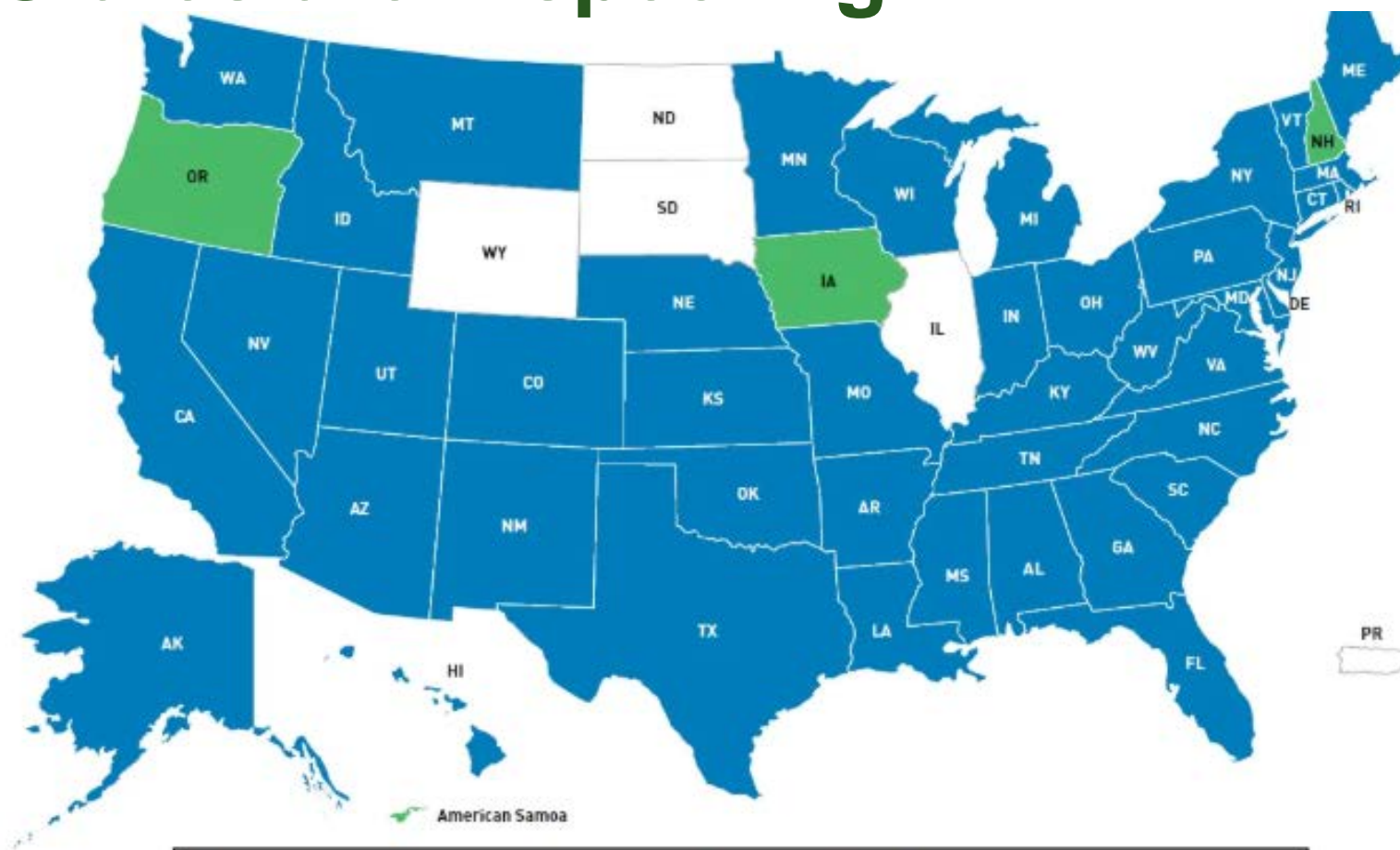
- Brand new regulation
  - New for farms
  - New for FDA
- “Educate before and during regulation”

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# OFRR



# States are Inspecting



**Green** Competition A includes Infrastructure, Education, Technical Assistance, and Inventory Program.  
**Blue** Competition A/B includes Competition A components AND an Inspection, Compliance and Enforcement Program.

# Inspection Form 4056



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**FDA**

## PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department *(if acting under commission with FDA)*

DISTRICT OFFICE ADDRESS

DISTRICT OFFICE PHONE NUMBER

DATE(S) OF INSPECTION

FEI NUMBER

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
*(Most responsible individual present)* TO:

FARM NAME *(include business name, if different)*

OWNER/OPERATOR

FARM MAILING ADDRESS

FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS *(e.g., location identifiers such as GPS coordinates)*

23. § 112.114: Disposition of dropped covered produce

Observation       Corrective action taken

Description:

[Redacted description area]

24. § 112.115: Measures related to packaging covered produce

Observation       Corrective action taken

Description:

[Redacted description area]

25. § 112.116: Measures related to food-packing (including food-packaging) material

Observation       Corrective action taken

Description:

[Redacted description area]

**Equipment, Tools, Buildings, and Sanitation (21 CFR Part 112, Subpart L)**

26. § 112.123: Equipment and tools

Observation       Corrective action taken

Description:

[Redacted description area]

27. § 112.124: Instruments and controls used to measure, regulate, or record

Observation       Corrective action taken

# Produce Safety Rule

- **Agricultural water** that contacts produce (irrigation, crop chemicals, washing) or food contact surfaces (including hands)
- **Domesticated and wild animals** and their excreta that may come into contact with produce
- **Biological soil amendment of animal origin (manure)** that may reasonably come into contact with produce
- **Health and hygiene of workers** that contact produce (harvesters, sorters, packers)
- **Equipment, tools, buildings and sanitation** (tools, utensils, containers, equipment)
- **Growing, harvesting, packing, and holding activities** that may reasonably be a source of contamination



# Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, *current* Subpart E

*“all agricultural water must be safe and of adequate sanitary quality for its intended use”* (§ 112.41)

- water that is intended to, or is likely to, contact the **harvestable portion** of **covered produce** or food-contact surfaces (§ 112.3(c))
- Requirements on inspection/maintenance of ag water sources and systems, microbial quality, and record-keeping
  - Microbial limits are specified
  - Specifies generic *E. coli* as the indicator organism

# Delay of Ag Water Compliance

- “The extension is designed to provide additional time to ensure the FDA applies the best thinking to **clarify standards** for **pre-harvest microbial water quality** and to *continue working closely with produce farmers on sensible approaches* to protect consumers”
  - March 15, 2019 Statement from former-Commissioner Gottlieb  
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633586.htm>
- FDA needs time to compile and interpret the science
  - Opportunity for industry to provide input and support
- Rulemaking required if updates made to the standards

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# Harmonized Ag Water Working Group

- Initiated in 2018 to mitigate varying interpretations on how to conduct a risk assessment
- Basic risk assessment 'decision tree' based on:
  - Crop use
  - Water source
  - Water delivery system
  - Application method
- Detailed hazard mitigation table

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# Agricultural Water: What to do?

- Do the right thing!
- Ag water is out of scope for an inspection
- “Produced or held under insanitary conditions” still applies

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# Domesticated & Wild Animals

- *Not* exclusively about animal exclusion
- How to identify & react to evidence of intrusion



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# PSR Record Requirements

- The name and location of the farm
- Actual values and observations obtained during monitoring
- An adequate description of covered produce, if applicable to the record (e.g. the commodity name, or the specific variety or brand name of a commodity, and any lot number or other identifier)

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# A Good Record

- The location of a growing area or other area, if applicable to the record (e.g. a specific field or packing shed)
- The date and time of the activity documented
- Records must also be created at the time an activity is performed or observed
- Be accurate, legible, indelible, dated, and signed or initialed by the person who performed the activity.

# Required Records

- Exemptions (e.g. commercial processing)
- Training
  - Date of training, topics covered, and the names of persons trained
  - Required training topics are outlined in § 112.22
  - Training records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made



# Required Records, Cont.

- Biological Soil Amendments of Animal Origin
  - From a 3<sup>rd</sup>, party, annually document that: •
    - The process used to treat the biological soil amendment of animal origin is a scientifically valid process that was carried out with appropriate process monitoring
    - The biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

# Required Records, Cont.

- Cleaning & Sanitizing
  - Keep a record of the date and method of cleaning and sanitizing equipment used in covered harvesting, packing, or holding activities
  - This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made.

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# Current Guidance- Oct 2018

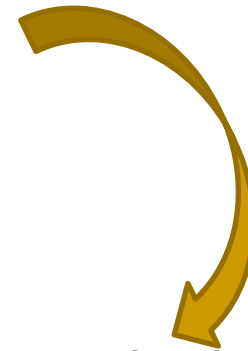
Standards for the Growing, Harvesting,  
Packing, and Holding of Produce for Human  
Consumption: Guidance for Industry

## *Draft Guidance*

**This guidance is being distributed for comment purposes only.**

# Preventive Controls

- Updates cGMPs for human food (110 -> 117)
  - Cull/ animal feed
- Requires a food safety plan
  - Hazard analysis
    - \*evaluate\* *Listeria* in RTE foods
  - Preventive controls
    - Process PC (HACCP CCPs)
    - Allergen PC (not for animals)
    - Sanitation PC (verify through env. monitoring)
    - Supply chain program



# Training: NOT required (but expected)

  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## CERTIFICATE OF TRAINING

is awarded to

### Jennifer McEntire

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:  
**Lead Instructor Training for FSPCA Preventive Controls for Human Food**  
delivered by Lead Instructor  
Warren Stone  
completed on  
12/10/2015

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials

 IFSH | INSTITUTE FOR  
FOOD SAFETY  
AND HEALTH

 ifpti | INTERNATIONAL  
FOOD PROTECTION  
TRAINING INSTITUTE

 AFDO

# Hazard Analysis

*Draft-Not for Implementation*

Table 1H: Information that you should consider for potential ingredient or other food-related biological hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	<i>Cyclospora</i>	Example Products
Fresh Cut	1	Fresh cut vegetables	Refrigerated		X <sup>1</sup>				X	X	X	X	X	X			Leafy Greens (Single and Mixed Greens), Shredded Carrots, Avocado Chunks, Leafy green salad blends, Diced Onions, Cut Tomatoes, Sliced Mushrooms
Fresh Cut	2	Fresh cut fruits	Refrigerated						X	X	X	X					Mixed Fruit Salad; Packaged Single Fruits, Cut Melon, Apple Slices, Cut Pineapple, Cut Mango

<https://www.fda.gov/media/99581/download>

# Process PCs for Produce

- Wash water
  - Limiting cross contamination
    - Validation study
  - Demonstrating control of your system (monitoring, verification)
- Time/temperature control *for safety*
  - Ties into Sanitary Transportation Rule

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# Sanitation PC

- Is citrus “ready to eat”?
- Potential contamination from Listeria or Salmonella?



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# Ask Trevor for More Details

Based on the test results, the FDA found the overall prevalence of *Listeria monocytogenes* in the avocado pulp samples to be 0.24 percent and in the avocado skin samples to be 17.73 percent. The report addresses these findings in its various sections and aggregates the discussion of them in a dedicated appendix, in addition to providing breakdowns as described above.

FDA found some of the *Listeria monocytogenes* strains isolated from both skin and pulp samples to be highly related to *Listeria monocytogenes* strains found in ill persons.

- Do's and Don'ts of a swabathon
- <https://www.unitedfresh.org/content/uploads/2017/03/FDA-Swabathon-Discussion-Group-Summary-Feb-2017.pdf>
- Duplicate swabs?
- Do you hold product?
- Do you keep producing on that line after sanitation?

# Supply Chain Preventive Control

- “receiving facilities”
- Steps
  - Written hazard analysis
  - Evaluate suppliers
  - Approve suppliers
  - Ongoing verification
  - Corrective actions
  - Reanalysis
- Inspection is of records only
- (same as FSVP- inspection can be email only)

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# Preventive Controls (cont)

- Oversight and management of preventive controls
  - Monitoring
  - Corrective actions and corrections
  - Verification
- Recall plan

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# Inspection Tips

- Have management present for opening and especially closing meetings
- Have 2 people accompany the inspector
  - One who speaks (and is trained!)
  - One who takes notes
- Correct issues you see before they are pointed out to you

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# Questions?

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