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Thomas M. Jones Biography

Thomas M. Jones is the Senior Director of Analytical Services in the Safe Food Alliance division of DFA. He has degrees in Microbiology from California State University, Fresno and the University of California at Berkeley. Mr. Jones has conducted research into the survival of pathogenic bacteria in dried foods and the effects of commodity fumigation on toxigenic molds. He has also lectured in many training seminars for the food industry on a variety of topics, including microbiology, sanitation, GMPs, HACCP and product recalls, and is a lead instructor for the Produce Safety Alliance Grower Training course.

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Farm Food Safety Plans: What Almond Growers Need to Know

Thomas Jones

June 7, 2018

- Compliance with FSMA Produce Safety Rule (PSR) will require training, testing and recordkeeping.
- The Food Safety Plan:
  - The farms' guide to minimizing crop contamination (pathogen focus-PSR).
  - Can include other GAP elements.
  - Includes policies, practices and procedures.
- PSR does not require a plan, but it is recommended.

CURRENT SITUATION FOR ALMONDS

- Almonds are covered by the PSR as “raw agricultural commodities”.
  - Subpart A, § 112.1 (b).
- Almonds are also eligible for an exemption, via a written disclosure.
  - Subpart A, § 112.2 (b).
- Plan emphasis differs for these two compliance options:
  - PSR Compliance ➡ pathogen reduction.
  - Exemption ➡ disclosure process.

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What would a Food Safety Plan Look Like Under the Produce Safety Rule?

KEY ELEMENTS OF THE PLAN

- Farm description.
  - Location, size, crops, food safety manager.
- Risk assessment.
  - Practices, farm environment.
- Practices to reduce risk.
  - SOPs, supporting documentation.
- Records that document practices.
  - Training, testing, monitoring, corrective actions.
- Supplier/buyer records.
- Recall/traceability.
  - Lot IDs, mock recalls.

FARM DESCRIPTION

- Legal description, address of farm location(s).
  - Maps of orchard/farm locations.
- Farm Policies
  - Food safety, disciplinary, visitors, etc.
- Total acreage and crops grown.
- Identity of Farm Food Safety manager.
  - Contact information.
  - Alternate contact/back-up.

- Evaluate operations, practices that contribute to or increase food safety risks.
- Previous history of land, adjacent land use.
- Risks can be biological, chemical and physical:
  - Biological (microbes like *Salmonella*).
  - Chemical (pesticides, aflatoxin, allergens).
  - Physical (stones, glass, metal).

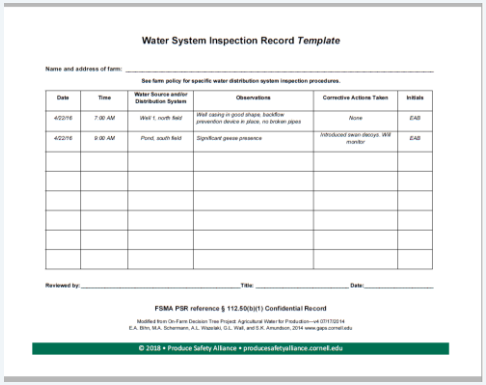
- Focus on the biggest risks first.
  - Most likely to occur/ happen often.
  - Can impact the entire crop
- Risks that have caused previous recalls or outbreaks.
  - What have we learned?
  - Example: stockpiling/aflatoxin control.
- Changes to farm production practices.
  - New equipment, people, suppliers, practices?

- The standard operating procedures (SOPs) for key farm activities:
  - Employee training, health/hygiene.
  - Fertilizer/soil amendments.
  - Wildlife/animal management.
  - Pest control, pesticide use.
  - Water monitoring/testing/treatment.
  - Sanitation (workers, harvest/delivery).
  - Stockpile management.

- This is a written procedure for completing a specific task in the food safety plan.
- Key elements:
  - Step-by-step instructions that allow someone to do the task correctly the first time.
  - Location/name of any supplies needed.
  - Timing & frequency of completing the task.
  - Recordkeeping that is required.

MONITORING

- Document practices, monitoring, corrective actions.
- Monitoring on a regular schedule:
  - Verifies that practices are being followed.
  - Signed/initialed and dated by person performing the activity.
  - Periodic review by their supervisor or responsible party.
- May be electronic or paper.
- Templates available.



Water System Inspection Record *Template*

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.

Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	7:30 AM	Well 1, north field	Well casing in good shape, backflow prevention device in place, no broken pipes	None	EAB
4/22/16	9:00 AM	Pond, south field	Significant geese presence	Introduced swan decoys. Will monitor	EAB

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.50(b)(1) Confidential Record

Modified from On-Farm Decision Tree Project: Agricultural Water for Production—v4 07/17/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and E.R. Amundson, 2014 www.gaps.cornell.edu

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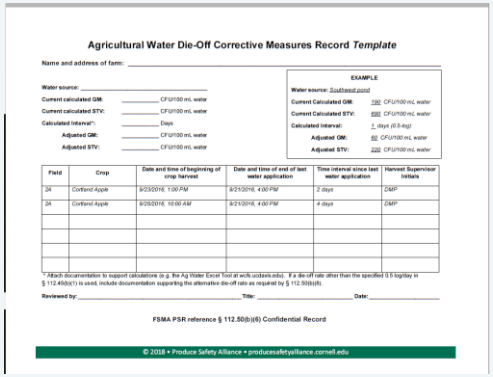
CORRECTIVE ACTIONS

- Purpose of monitoring is to catch problems *before* they impact food safety.
- Plan for possible scenarios. Ex:
  - Portable toilets not clean/stocked.
  - High *E. coli* counts on water.
- Must confirm that corrective measures solved the problem.
  - Toilets restocked.
  - *E. coli* issue resolved.
- Document the process.



Agricultural Water Die-Off Corrective Measures Record *Template*

Name and address of farm: _____

Water source: _____

Current calculated GM: _____ CFU/100 mL water

Current calculated STV: _____ CFU/100 mL water

Calculated Interval*: _____ Days

Adjusted GM: _____ CFU/100 mL water

Adjusted STV: _____ CFU/100 mL water

EXAMPLE

Water source: Southwest pond

Current Calculated GM: 190 CFU/100 mL water

Current Calculated STV: 690 CFU/100 mL water

Calculated Interval: 7 days (0.5 log)

Adjusted GM: 60 CFU/100 mL water

Adjusted STV: 220 CFU/100 mL water

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	Cortland Apple	9/23/2016, 1:00 PM	9/21/2016, 4:00 PM	2 days	DMP
2A	Cortland Apple	9/25/2016, 10:00 AM	9/21/2016, 4:00 PM	4 days	DMP

* Attach documentation to support calculations (e.g. the Ag Water Excel Tool at wcfs.ucdavis.edu). If a die-off rate other than the specified 0.5 log/day in § 112.450(c)(1) is used, include documentation supporting the alternative die-off rate as required by § 112.50(b)(6).

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.50(b)(6) Confidential Record

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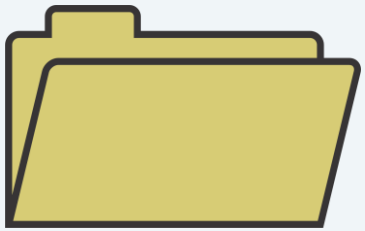
- Includes documentation of practices, monitoring and corrective actions.
- Should be made as convenient as possible;
  - Build into normal routines.
  - Needed supplies should be readily accessible.
  - Frequent enough to get the job done.
- Use the information!
  - Look for trends, outliers.
  - Investigate and fix the problem.

- The PSR has some specific requirements for recordkeeping (§ 112.161 (a-b)).
  - Records supporting exemption status (§ 112.2) or qualified exemption (§ 112.7).
  - Personnel training (§ 112.30,§ 112.22).
  - Water monitoring/testing/treatment (§ 112.50 (b)).
  - Biological soil amendments (§ 112.60(b)).
  - Equipment cleaning/sanitation (§ 112.140(b)(2)).

- Storage of records, allowable record types and off-site storage (PSR Subpart O).
- Must be original records, true copies or electronic records (§ 112.165).
- Must be kept for at least 2 years (§112.164).



- Must be made available to FDA within 24 hours of request (§122.166).
  - Records obtained are subject to 21 CFR part 20 (Public Information/FOIA).

- Must be able to identify a lot in order to do traceability.
- A lot is a distinct, limited portion of a crop.
- Example: the loads delivered to the H/S from a specific orchard:

Grower_____ _____Field _____Variety_____

Buyer_____ Field Load #_____ Final Load: Yes / No

Trailer #_____ _____ SPLIT LOADS MUST HAVE TWO SEPARATE FIELD TAGS
Front Back

Carrier	Truck Lic.
Driver Signature	Date

Field Tag Example

- Goal is to be able to trace your crop “one step forward” and “one step back”:
  - Huller/sheller, handler (forward).
  - Orchard (back).
    - Inputs (amendments, sprays).
    - Contracted services (labor, harvest, trucking).
- Traceability exercise (mock recall):
  - Contact buyer and document lot status (in stock, sold or processed).
  - Trace back through your own records.
  - Ideal goal is 2 hours to get all of the information!

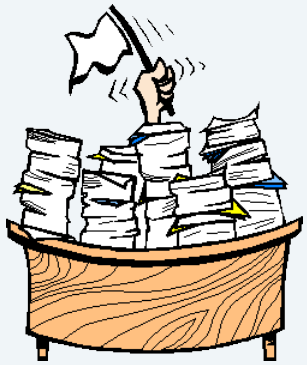
- Document the results of the traceability exercise.
  - If there are issues identified, correct them.
  - Repeat exercise to confirm the fix.
- Crisis management plan is a good idea.
  - Key contacts (farm/family contacts, legal consul, industry groups like ABC).
  - Designated spokesperson.
  - Plan ahead for a crisis!

WHAT ABOUT THE PSR EXEMPTION?

- Growers pursuing the exemption "must disclose in documents accompanying the produce, in accordance with the trade, that the food is 'not processed to adequately reduce the presence of microorganisms of public health significance;'"

  –*Subpart A General Provisions, §112.2 (b)(2)*

- This simplifies the elements of a Farm Food Safety Plan.



Grower Exemption Option

The exemption is available to all almond growers as well as huller/shellers and brownskin almond facilities falling under the primary or secondary farm definition – Only requires written disclosure

The “Written Disclosure” Statement

Almonds are not processed to adequately reduce the presence of microorganisms of public health significance

Grower (Farm) Exemption Steps for Utilizing Commercial Processing Exemption

- Almond Farms (Primary or Secondary) must provide written disclosure to huller/sheller and handler
  - Disclosure should be made from grower to huller/sheller to handler

Written Disclosure Statement:

Almonds are not processed to adequately reduce the presence of microorganisms of public health significance

FDA has acknowledged that this is an appropriate disclosure statement for almonds

- Disclosure may be made in documents accompanying the product including:
  - Grower / Field Tags; Delivery Statements; Bills of Lading, Shipping Manifests; Contracts
  - Other means which are specific to grower lots, provided on behalf of the grower to the huller/sheller and the handler

- As long as the grower (farm) has provided the written assurance to the huller/sheller and the handler, they have satisfied the exemption requirement, and no further Produce Safety Rule Compliance is required
  - FDA may come back some years down the road with requirements for the grower to obtain written assurance from the Handler that they are treating for pathogen reduction

Grower Exemption Plan Summary

- Growers and Huller / Shellers should put together an "Exemption Plan Summary"
  - Not required but a good idea!
  - Could prove useful if an inspector shows up

- Describes the farm operation
  - Location
  - Manager
  - Size
  - Huller / Sheller(s) and Handler(s) used
- Cites the specific statue for the exemption
  - § 112.2 (b) (1); § 112.2 (b) (2)
  - References FDA Enforcement Discretion Notification (January 4, 2018) for written assurances
    - https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm590646.htm
    - https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM591242.pdf

- Describes how farm is making the written disclosure

ENFORCEMENT DISCRETION FOR CERTAIN FSMA PROVISIONS

At this time, FDA does not intend to enforce certain provisions in four regulations implementing FSMA.

Which provisions and why?

The FDA has announced that it does not intend to enforce certain provisions in four of the rules that implement the FDA Food Safety Modernization Act (FSMA). The enforcement discretion covers certain entities or activities covered by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal food rules (PC Human Food and PC Animal Food or CGMP & PC rules), Foreign Supplier Verification Programs rule (FSVP), and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety rule).

While this enforcement policy is in place, FDA will consider the most effective and practical approaches to address issues that have been raised since the FSMA rules became final and provide long-term certainty for stakeholders.

1. CERTAIN FACILITIES CONDUCTING FARM-RELATED ACTIVITIES THAT ARE SUBJECT TO THE PREVENTIVE CONTROLS REQUIREMENTS.

Farms are exempt from the preventive controls and CGMP requirements in the CGMP & PC rules. Produce farms are typically covered by the Produce Safety rule, unless an exemption applies. The enforcement policy applies to certain facilities conducting farm-related activities. Some of these facilities also conduct activities not within the farm definition even if conducted on farms (e.g., coloring RACs).

FARM-RELATED ACTIVITIES: These are activities within the definition of "farm" if performed on farms. These activities include growing and harvesting crops and some manufacturing/processing activities: drying/dehydrating raw agricultural commodities (RACs) to create a distinct commodity, treating RACs to manipulate ripening, and packaging and labeling RACs.

RAW AGRICULTURAL COMMODITY: RACs are a food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled form. Grains and eggs are examples of non-produce RACs.

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Grower Exemption Plan Summary – Freedom Farms

Farm Operation Description

Farm Location(s): 1 Ranger Way, Modesto, CA 95354

Farm Manager: Guy Safety

Farm Description: Freedom farms operates a single 100-acre almond orchard in Stanislaus County; Freedom Farms utilizes one contract Huller / Sheller (Victory Shelling) and one Handler (Leatherneck Nut Co.)

Exemption Basis

Exemption Regulatory Basis:

Freedom Farms is utilizing the Commercial Processing Exemption specified under § 112.2 (b) (1) of the Produce Safety Rule. As such Freedom Farms is only subject to specified disclosure requirements.

- Freedom Farms is fully complying with the disclosure requirements as specified in § 112.2 (b) (2)
- Based on the January 4, 2018 FDA Notification of Enforcement Discretion no written assurances are required
    - https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm590646.htm
    - https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM591242.pdf

Written Disclosure Process

Freedom Farms Written Disclosure Summary:

1. Freedom Farms utilizes field tags that accompany each load of almonds from the orchard to the huller sheller.
    a. Field tags are printed with the following disclosure statement: Almonds are not processed to adequately reduce the presence of microorganisms of public health significance
2. At the Huller/Sheller, a manifest is generated for each outgoing load of hulled and shelled nuts.
    a. The manifest is printed with the disclosure statement shown above.
    b. The manifest accompanies the product from the huller/sheller to the handler facility
3. Freedom Farms also provides the above disclosure on all contracts with Leatherneck Nut Co.

- A Food Safety Plan under the exemption requires fewer procedures and records.
  - Remove pathogen control elements:
    - FSMA water testing, composting records, etc.
- A more limited Plan that *includes* the Exemption Plan is still a good idea…
  - Good Agricultural Practices are important:
    - Aflatoxin control, pesticide use & worker training.

- A written plan is great tool for organizing your food safety efforts.
- This gives you a road map to follow and a way to document your progress.
- Being organized will make your efforts more efficient…and is essential in a crisis!
- Keep the plan as simple as possible.
  - Write what you do, not what you *hope* to do!
- Make sure it is a living document.
  - Make sure it is working (self-audits, mock recalls).
  - Update it as necessary.

REFERENCES

- Produce Safety Alliance:
  - Grower training information: https://producesafetyalliance.cornell.edu/training/grower-training-courses
  - Resources. https://producesafetyalliance.cornell.edu/resources/general-resource-listing
- Additional sources of information:
  - ABC Good Agricultural Practices Guide. http://www.almonds.com/sites/default/files/gap-quick-start-guide_1.pdf
  - UC Small Farm Program Food Safety. http://sfp.ucdavis.edu/food_safety/
  - Colorado State University. http://farmtotable.colostate.edu/grow-files/2012-ColoradoFarmPlanFillableForm.pdf
  - Penn State University. https://extension.psu.edu/template-harmonized-food-safety-plan

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Thank you

Questions?