EAS CONSULTING GROUP

Dallas Love Airport

April 5, 2018

Specializing in FDA Regulatory Matters

Wine Institute
Sanitary Transportation Rule

Charles M. Breen, Independent Advisor
cbreen@easconsultinggroup.com

Sanitary Transportation of Food

The **rule** establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use **sanitary** practices to ensure the safety of that food. The requirements do not apply to **transportation** by ship or air because of limitations in the law. www.fda.gov

FDA provides common sense exceptions and exemptions.

Sanitary Transportation of Food
Exemptions

- Transportation activities performed by a farm.

- Transportation of food that is completely enclosed by a container

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Sanitary Transportation of Food Exemptions

- Transport of human food byproducts for use as animal food without further processing, and
- Transportation operations of less than $500,000 in average annual revenues, are both exempted.

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Sanitary Transportation of Food

- Bulk shipments by tanker
  - Shipper must prepare written specs for suitability of tankers
  - Shipper must inspect tanker and record results before loading
    - Purpose is to ensure prior load does not cause unsafe conditions for next load

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Sanitary Transportation of Food

- Bulk shipments by tanker
  - Shipper may request and carrier must answer in writing what the prior cargo was, and cleaning procedures used

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Sanitary Transportation of Food

https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf

- User friendly FDA Fact Sheet on Sanitary Transportation – see Page 3 for exemptions.

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Questions?

Specializing in FDA Regulatory Matters

Wine Institute

Produce Safety Rule and Letters of Assurance

Charles M. Breen, Independent Advisor

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Produce Safety Rule – Very Briefly

FDA: "The Produce Safety rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption."

Produce Safety Rule

Produce means any fruit or vegetable. . .. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. . ..

Produce Safety Rule

Major Control Requirements:

- Water Quality
- Biological Soil Amendments
- Domesticated and Wild Animals
- Worker Training and Health and Hygiene
- Equipment, Tools and Buildings
- Sprouts (special case)

Produce Safety Rule

Key Exemption:

- The rule does not apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

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"[U]nder certain conditions."

FDA recognizes that wine making does adequately reduce the presence of microorganisms of public health significance. Growing wine grapes does not require compliance with Produce Safety Rule if . . .

"[U]nder certain conditions."

- Grower TO winery:
  - You disclose in documents accompanying the produce **in accordance with the practice of trade**, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance"

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"[U]nder certain conditions."

- Grower FROM winery:
  - Annually obtain written assurances from the customer; and document compliance with required disclosures and written assurances' . . ..
- No, growers don't have to obtain assurance from winery, at least not yet.

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Written Assurances

- FDA has delayed enforcement of upstream written assurances to growers. Downstream assurance to customers must still be provided.
- Growers must provide a written statement that microbiological hazards have not been controlled.
- Your customers do not have to assure you they will control the hazards.

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Written Assurances

- FDA is reconsidering the whole "written assurances" question.
- Mar 15, 2018 FDA letter to Napa Valley Vintners and California Association of Winegrape Growers, said FDA is "exploring options to allow for exemption from the records requirement as part of the commercial processing exemption for certain commodities."

Written Assurances

- "Rulemaking will likely be necessary."
  - Translation: It will take time and enforcement will be postponed.

- FDA also to consider streamlining and reducing records requirements for firms with annual contracts.

Written Assurances

- What do winegrape growers who sell grapes do now?
- Best advice: Provide notice to customers that "Microbiological hazards have not been controlled."
- Very high chance that rubber stamp on invoice, B/L, other shipping document will be acceptable.
- Or pre-print on forms.

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Produce Safety Rule

https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf

User friendly FDA Fact Sheet on Produce Safety Rule – see Page 5 for processing exemption.

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Questions?

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Training Requirements

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Training Requirements

- Management is required to ensure that all employees who manufacture, process, pack, or hold food are qualified to perform their assigned duties.
- Every employee with food safety responsibilities must be a "qualified individual."

Training Requirements

- Supervisors must also be qualified to supervise food safety during processing, and practices of employees.

Training Requirements

- Education,
- Training, and/or
- Experience necessary to make clean and safe food.
- Any combination is OK.

Training Requirements

- Every employee with food safety responsibilities must be a "qualified individual."
- Includes seasonal, part-time, temporary, and contractors
- Be aware of contractor training needs if repairs must be made during processing season

Training Requirements

- Qualified means:
  - Having the necessary combination of education, training, and/or experience necessary to make clean and safe food.
  - Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.

Training Requirements

Very Briefly:

- Principles of Food Hygiene, briefly
  - Clean (enough) facility, equipment, utensils, and anything that touches or is touched by the food.
- Food safety,
  - Exclude pest, vermin, and contaminants. Control the process so it performs as desired.
- Importance of employee health and hygiene
  - Supervisors & employees know not to contact food when sick, proper handwashing as needed, clean work clothes

Training Advice

- Principles of Food Hygiene:
  - How to clean facility, equipment, utensils, and anything that touches or is touched by the food;
  - Proper use of cleaning and sanitizing chemicals, able to read, understand, and follow label instructions;
  - Use of proper cleaning tools;
  - Care in storage of hoses and cleaning equipment to prevent contamination; and
  - That everyone should always report anything that is not as clean as it should be.

Training Advice

- Food safety:
  - Train employees to recognize pests and vermin;
  - To keep screens and doors closed where appropriate;
  - Prevent contaminants from getting into food;
  - Monitor process so it performs as desired; and
  - Consistent hair/bread net use if chosen as a practice.

Training Advice

- Importance of employee health and hygiene
  - Train supervisors to notice if employees appear ill and assign to non-food contact work;
  - Post proper handwashing instructions, both what makes it necessary (such as after eating, drinking, smoking, toilet use) and how-to;
  - Clean work clothes must be worn;
  - Open wounds, sores, boils, lesions must be properly covered (use colored bandages);

Training Advice

Training Advice

Training Requirements

How to satisfy FDA:

- Documented training is usually easiest way.
- Can be very basic.
- Should be repeated each season.
- Refresher can be less detailed, or the same as initial training.
- Food safety and personal hygiene need roughly the same rigor as OSHA safety training.

(continued)

Training Requirements

How to satisfy FDA:

- Local food handler course may be a good starter model.
- Sign-in sheets OK, but print names in addition to signing.
- If just initials allowed, have a sheet with initials next to person's name.
- Be sure to document that supervisors also receive training and are qualified.

Questions?

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Wine Institute

Recordkeeping Requirements

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Recordkeeping Requirements

To be a **qualified individual,** all employees, temp workers, & visitors, must: **Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. (Paragraph (b)(2))**

Recordkeeping Requirements

- (d) **Records.** Records that document training required by paragraph (b)(2) of this section must be established and maintained.

Recordkeeping Requirements

- **§ 117.9 Records required for this subpart.**
- (a) Records that document training required by § 117.4(b)(2) must be established and maintained.
- (b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

Recordkeeping Requirements

- The requirements of subpart F:
  - Records must be original or true copies
  - Be accurate, indelible, and legible
  - Be created when training actually occurs
  - Be as detailed as necessary

Recordkeeping Requirements

- The requirements of subpart F:
  - Include name and location of facility
  - The dates of training
  - Signature or initials of trainers & those receiving training
- Electronic records for FSMA exempt from Part 11

Recordkeeping Requirements

- The requirements of subpart F:
  - Must be maintained at facility for two years, or
  - Be available within 24 hours upon FDA request
  - Must be made available to FDA for review and/or copying

Recordkeeping Requirements

- The requirements of subpart F:
  - Subject to disclosure requirements of FOIA
  - Use of existing records and recordkeeping systems allowed – if they satisfy the requirements listed above.

Recordkeeping Requirements

- Sanitary transport records:
  - Must be retained for 12 months following termination of the agreements with the carriers

Questions?

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Specializing in FDA Regulatory Matters

Wine Institute

How to Prepare for an FDA Inspection

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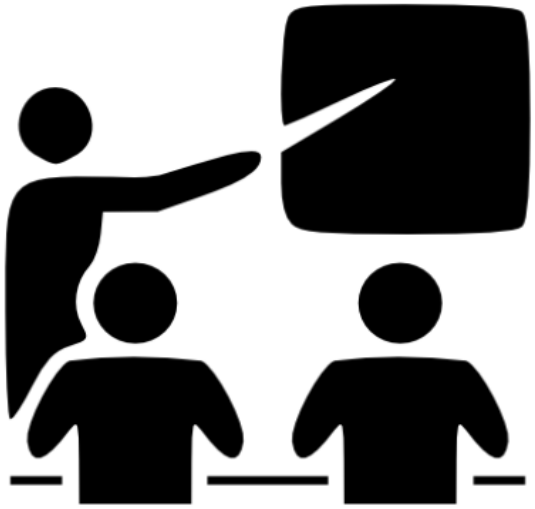
Prepare for FDA Inspection

- Prepare policies:
  - Photos, allow or not to allow, your choice
  - Identify who must accompany FDA, but be flexible
  - Visitor safety and GMP briefing (see Training Requirements)

Prepare for FDA Inspection

- Prepare Employee Training Materials
  - See "Training Requirements"
  - Include supervisors in training
  - Decide how you will document training



Prepare for FDA Inspection

- Prepare policies:
  - Understand what you must provide to FDA upon request:
    - Records including distribution, training, and documents that show GMP compliance, such as water testing (if applicable), excludes recipes and financial data
    - Keep copies of all records provided

Prepare for FDA Inspection

- Prepare policies:
  - Understand what you must provide to FDA upon request:
    - Access to all food and food related areas,
    - Give truthful answers – never lie
    - Much better to admit ignorance than make something up

Prepare for FDA Inspection

- Before processing season begins:
  - Facility walk-through with copy of GMPs in hand
  - Ask yourself would you like what you see if you were a buyer or consumer
  - Make a punch list for needed actions

Punch List

Room / Location	Trade	Item to check	Work needed	Completed?
		KITCHEN		
Kitchen	Appliance	Garbage disposal working properly		
Kitchen	Appliance	Stove has gas/power & turns on		
Kitchen	Appliance	Oven has gas/power & turns on		
Kitchen	Appliance	Range hood working properly		
Kitchen	Appliance	Refrigerator is cold & working properly		
Kitchen	Appliance	Dishwasher is connected to water & working properly		
Kitchen	Carpentry	Cabinets are aligned and level		
Kitchen	Carpentry	Cabinet doors and drawers open and close smoothly		
Kitchen	Carpentry	Drawer pulls and knobs are level and centered		
Kitchen	Carpentry	Windows/doors open & close properly		
Kitchen	Carpentry	Sink(s) installed properly with no dents		
Kitchen	Plumbing	Water is flowing well at faucets with hot and cold water		
Kitchen	Plumbing	Faucet handles and pull out faucet heads working smoothly		

Prepare for FDA Inspection

- Prioritize and schedule repairs
- Complete before processing begins or ASAP
- Review existing start-up practices with GMPs in hand

Prepare for FDA Inspection

- When the FDA Investigator Arrives:
  - Examine credentials
    - Name
    - Expiry date
  - If no business card(s) offered, write down name(s)

Prepare for FDA Inspection

- Plan to accompany Investigator
- Answer questions, or get answers ASAP, & ask your own questions
- Know, or have someone available who knows what cleaning chemical are used and how to prepare them
- Know what is added to process in addition to grapes

Prepare for FDA Inspection

- When the FDA Investigator Arrives:
  - Ask the purpose of the inspection
    - Routine surveillance
    - Complaint follow-up
    - For cause (very rare)
      - May want to alert your attorney if "for cause"

Prepare for FDA Inspection

- When the FDA Investigator Ends Inspection:
  - List of Objectionable Conditions (if any) will be provided
  - Plan on responding in writing within 15 working days, sooner is better
  - Discuss any remaining questions

Questions?

EAS CONSULTING GROUP

Specializing in FDA Regulatory Matters

Wine Institute

What Happens When FDA Inspects?

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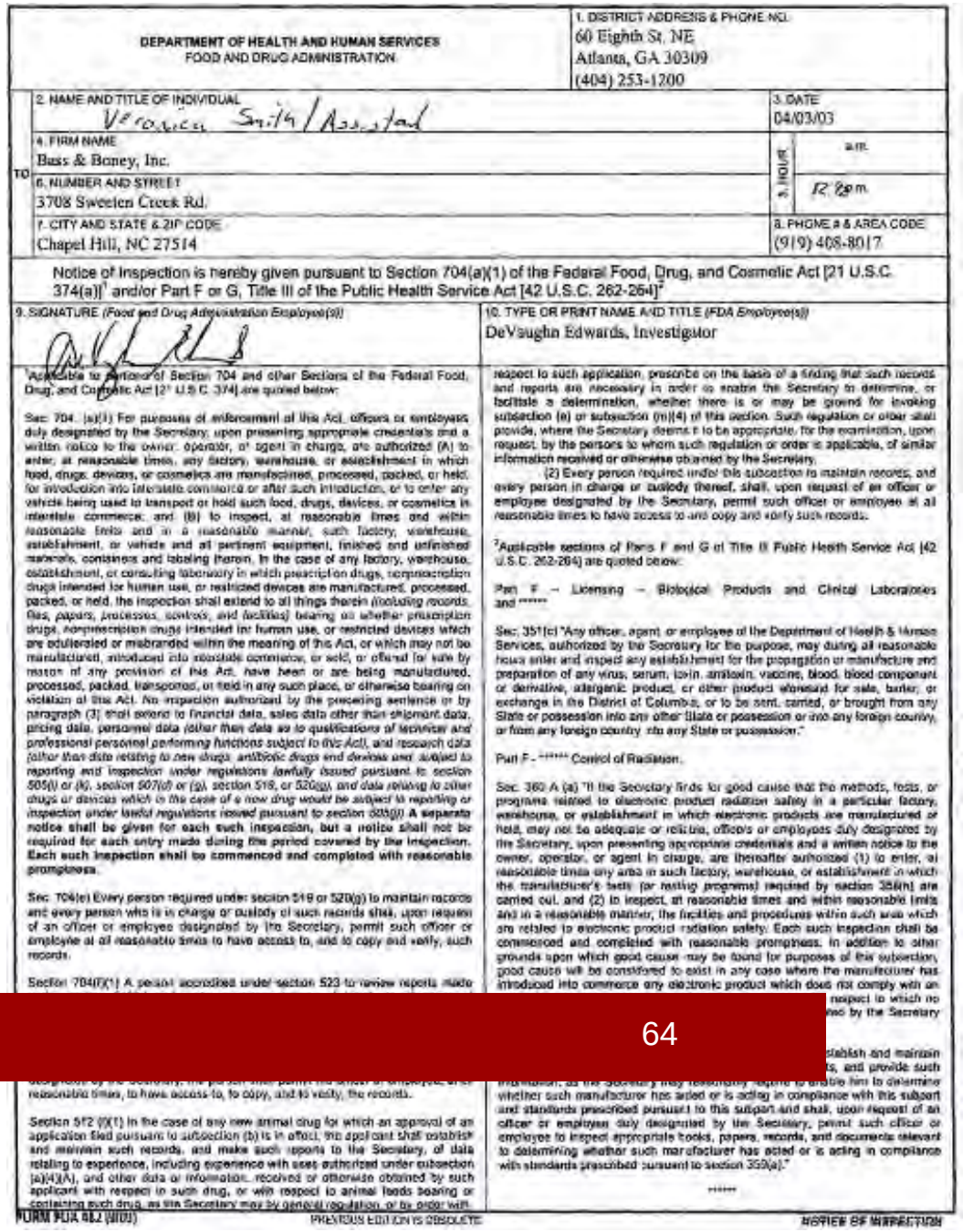
When FDA Inspects

- Almost always unannounced
- Will present credentials
- Will issue Notice of Inspection, FDA Form 482 to "owner, operator, or agent in charge," i.e., the most responsible person present

FDA Form 482 Notice of Inspection



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
60 Eighth St. NE
Atlanta, GA 30309
(404) 253-1200

TO

2. NAME AND TITLE OF INDIVIDUAL
Veronica Smith / Assistant

3. DATE
04/03/03

4. FIRM NAME
Bass & Boney, Inc.

5. HOUR
a.m.
12 p.m.

6. NUMBER AND STREET
3708 Sweeten Creek Rd.

7. CITY AND STATE & ZIP CODE
Chapel Hill, NC 27514

8. PHONE # & AREA CODE
(919) 408-8017

Notice of inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
DeVaughn Edwards, Investigator

[1]Applicable to portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)) **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

Section 704(f)(1) A person accredited under section 523 to review reports made [illegible] reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (i)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2]Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and ******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product whenever for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ****** Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an [illegible] respect to which no [illegible] by the Secretary [illegible] establish and maintain [illegible], and provide such [illegible] information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

FORM FDA 482 (9/73) PREVIOUS EDITION IS OBSOLETE NOTICE OF INSPECTION

When FDA Inspects

- "At a reasonable time, and in a reasonable manner" FD&C Act
  - **Reasonable time** means anytime business is open or processing
  - **Reasonable manner** means mutual respect for each parties responsibilities

When FDA Inspects

- FDA Investigations Manual
  - "It is your responsibility to conduct all inspections at reasonable times and within reasonable limits and in a reasonable manner. Proceed with diplomacy, tact and persuasiveness."

When FDA Inspects

Raw Materials

- Presence of rodents, insects, birds, as sources of contamination.
- Storage facilities clean, dry, well ventilated.

When FDA Inspects

Raw Materials

- Tests made on incoming raw materials,
  - results of tests,
  - acceptance criteria for filth, mold, chemical contaminants, pesticides, aflatoxin, bacterial load, deterioration, etc.

Raw Materials

- What happens to rejected raw materials and reason for rejection.
- Are food and color additives permitted and used at allowable levels.

When FDA Inspects

Raw Materials

- Check use of rodenticide and insecticides
  - permitted for use,
  - used properly, and
  - do not become contaminants.
- Check solutions, detergents, adequacy of rinsing operation, and removal of soil borne bacteria.

When FDA Inspects

Processing

- Evaluate sorting and inspection to eliminate unsuitable raw materials.
- Observe product manufacturing operations:
  - Mixing times, and
  - Times and temperatures in the process.
- Are appropriate procedures followed?

When FDA Inspects

Processing

- Prepare a flow diagram if this will assist in evaluating the firm.
- Check equipment as to suitability:
  - for its intended use,
  - type of contact surface, and
  - possible cleaning problems because of equipment construction, etc.

When FDA Inspects

Processing

- Determine if water used is:
  - from an approved source, or
  - if from the firm's own well, how often it is tested to determine its quality.
- Evaluate usage levels of food and color additives. **(Formulation is not the same as recipe. CMB)**

When FDA Inspects

Processing

- Determine equipment cleaning and sanitizing procedures:
  - check effectiveness of procedures.
- Evaluate product packaging operations for possible routes of contamination.
- Report the key to the firm's lot coding system.

When FDA Inspects

Sanitation

- Verify adequacy of:
  - Equipment and plant cleanup,
  - Storage of cleaned portable equipment and utensils, and
  - Sanitizing solutions used.
- Determine adequacy of plumbing, i.e.; cross connections, waste disposal, etc.

When FDA Inspects

Sanitation

- Examine processing system for insects, filth, and potential adulterants, such as lubricating materials.
- Evaluate employee practices which could contribute filth or bacteria to the finished product.

When FDA Inspects

Quality Control

- What finished product tests are performed for:
  - Filth,
  - Bacteria, etc.
- Evaluate the results of these tests. **(Does not include sensory and quality tests. CMB)**

When FDA Inspects

Economics and Labeling (rarely done in wineries)

- Audit firm's net weight and fill of container practices.
- **(If asked about labels, winery may need to explain to Investigator that labeling approval is a TTB responsibility. CMB)**

When FDA Inspects

Consumer Complaints

- Review the firm's complaint file covering a reasonable period, i.e., past year, since last EI, etc.
- Tabulate the complaints versus the annual production of each product involved.

When FDA Inspects

- If, in the opinion of the Investigator, deviations from regulations were seen, a written list of observation will be issued to the most responsible person present.

When FDA Inspects

- FDA Form 483

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
	FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO:

FIRM NAME	STREET ADDRESS
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM I (WE) OBSERVED:

EAS CONSULTING GROUP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	04/12/2012 - 04/20/2012
	FEI NUMBER 3004348077

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Douglas N. Braden, Plant Manager

FIRM NAME	STREET ADDRESS
Diamond Pet Food Processors of SC, LLC	Hwy 321 & Wood Trail Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gaston, SC 29053	Pet Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, no microbiological analysis is conducted or there is no assurance that incoming animal fat will not introduce pathogens into their production and cause contamination of finished product. Also, the firm's current sampling procedure for animal digest does preclude potential for adulteration after sampling and during storage in warehouse. On 4/13/12, an employee was observed touching in-line fat filter and oil with bare hands.

OBSERVATION 2

Failure to provide hand washing and hand sanitizing facilities at each location in the plant where needed.

Specifically, there are no facilities for hand washing or hand sanitizing in the production areas where there is direct contact with exposed finished feed/food.

OBSERVATION 3

Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

Specifically, paddles in conveyor (South or Middle conveyor leading to the screeners going to packaging) were observed to have gouges and cuts, which exhibited feed residues. The damage to the paddles may allow for harborage areas for microorganisms and are difficult to clean and sanitize.

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	T. Linda Stewart, Investigator Dellarese L. Herbert, Investigator Alphonso A. Haupt, Investigator Hristu B. Chepa, Investigator Kenny R. Robinson, Investigator	04/20/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 1 OF 2 PAGES

When FDA Inspects

- After the inspection ends:
  - Investigator will write a report
  - Report will be reviewed by a Supervisor, possibly a Compliance Officer, for classification
  - Final classification will guide further FDA actions

When FDA Inspects

- Classification and actions:
  - NAI, no action indicated
    - Routine reinspection, might be five years later
  - VAI, voluntary action indicated
    - 483 was issued, may reinspect sooner than five years, or not
    - Untitled letter possible

When FDA Inspects

- Classification and actions:
  - OAI, official action indicated
  - Things have to be **bad**, usually more than once, for an OAI classification
    - Warning Letter
    - Facility registration suspension
    - Seizure, injunction, prosecution

Questions?

EAS CONSULTING GROUP

Specializing in FDA Regulatory Matters

Wine Institute
FDA Winery Observations

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FDA Winery Observations

- Observations 2010 – 2017
- Wineries cited located in:

– California	- New York
– Kansas	- Pennsylvania
– Maryland	- Texas
– Missouri	- Washington

FDA Winery Observations

- Most frequently cited:
  - Failure to provide adequate screening or other protection against pests.
  - Effective measures are not being taken to exclude pests from the processing areas.

FDA Winery Observations

- Cited more than once:
  - Plumbing constitutes a source of contamination to equipment and utensils.
  - Failure to maintain physical facilities in repair sufficient to prevent food from becoming adulterated.

FDA Winery Observations

- Cited more than once:
  - Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.
  - Failure to provide safety-type lighting fixtures suspended over exposed food.

FDA Winery Observations

- Cited more than once:
  - The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and kept in good repair.
  - The plant is not constructed in such a manner as to allow floors to be maintained in good condition.

FDA Winery Observations

- Cited more than once:
  - Failure to clean as frequently as necessary to protect against contamination of food.
  - Failure to manufacture and package foods under conditions and controls necessary to minimize contamination.

FDA Winery Observations

- Other citations:
  - Failure to use water which is safe and of adequate sanitary quality in food and on food-contact surfaces.
  - Lack of backflow protection from piping systems that discharge waste water.

FDA Winery Observations

- Other citations:
  - Failure to handle and maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

FDA Winery Observations

- Other citations:
  - Failure to provide hand washing facilities at each location in the plant where needed.
  - Failure to provide sufficient space for placement of equipment and storage of materials as necessary for the maintenance of sanitary operations and the production of safe food.

FDA Winery Observations

- Other citations:
  - Failure to properly store equipment and remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

FDA Winery Observations

- Other citations:
  - Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms and foreign substances.
  - Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination.

FDA Winery Observations

- Other citations:
  - Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food.


Delta

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - Be sure you understand what the Investigator saw and why it is a violation before ending discussion with Investigator.
  - If still in doubt, consider asking Wine Institute for advice.

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - Send a written reply. (**Not required. CMB)**
  - Be prompt. FDA allows 15 business days.
  - Start by saying you understand and desire to comply with FDA regulations.
  - Either use same sequence as 483, or address most significant items first.

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - Describe how each item will be (or was) corrected.
  - Provide a timeline for each correction, note those already completed.

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - Don't find fault or blame, FDA does not care.
  - Briefly explain why conditions were not discovered and corrected before inspection.

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - Attach reference documents, such as modified SOPs to address 483 items.
  - Describe changes in employees or in their responsibilities.

FDA Winery Observations

- What to do if you receive a FDA Form 483:
  - You can and should appeal in writing to FDA if a 483 item is wrong.
  - Make sure you comply with all GMPs whether or not noted on 483.
  - Be aware the 483 (properly redacted) is releasable under FOIA.

Questions?

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Thank You

MODEL GOOD MANUFACTURING PRACTICES (GMP) MANUAL FOR WINERIES – 2018

Wine Institute
425 Market St., Ste. 1000
San Francisco, CA 94105

Table of Contents

SECTION 1: INTRODUCTION

This manual provides compliance advice on the current Good Manufacturing Practices (GMP) regulations found in the US Code of Federal Regulations (CFR) under Title 21, Part 117, subparts A and B, and enforced by the US Food and Drug Administration (FDA). These are operational requirements for all food manufacturers and apply to wineries crushing grapes and other fruit, storing, transporting and/or fermenting the juice, and food-packaging wine for commercial, institutional, or consumer consumption.

This manual does not include California government requirements, nor those enforced by the US Alcohol and Tobacco Tax and Trade Bureau (TTB). Processing unfermented juice beverages is not addressed in this manual. FDA Juice HACCP Regulations (21 CFR 120) contains specific requirements for juice in addition to those found in 21 CFR 117, subpart B.

There is some overlap in the GMPs. When overlap occurs, it is a signal that FDA considers the items important enough to break out into details to ensure the safety of food.

The advice given here is intended to be adapted and implemented by individual wineries to meet their specific kinds of operations and facilities.

A written GMP compliance program is strongly advised, but apart from some specific tasks that must be documented (identified within the manual), is not mandatory under FDA regulations.

1.1 HOW TO USE THIS MANUAL

Each of the sections explain the purpose of the GMP, individual elements of each GMP written program, and an explanation of what the winery must do to accomplish the scope and tasks to be completed for each written model program. It is the preference of the winery as to which format they would like to include in their written food safety and operational program. Either format can also be easily modified to fit the needs of an individual winery and its unique operations.

1.2 REGULATORY FRAMEWORK

This manual is intended to provide recommendations for wineries of any size on how to build, and if desired, create a written GMP compliance program that meets the requirements of FDA's revised GMP. Each part of the Manual provides additional detail on how wineries can comply with each section of the revised regulations.

21 CFR Part subpart A – Definitions and Qualifications
- 117.3 Definition of *Qualified Individual*
- 117.4 Qualifications of Individuals Who Manufacture, Process, Prepare, or Pack Food

21 CFR Part 117 subpart B – Current Good Manufacturing Practice (cGMPs)

117.10 Personnel
117.20 Winery and grounds
117.35 Sanitary operations
117.37 Sanitary facilities and controls
117.40 Equipment and utensils
117.80 Processes and controls
117.93 Warehousing and distribution
21 CFR 121.5 Food Defense
21 CFR 507.12 By-products for Animal Food

1.3 DISCLAIMER

This GMP manual is intended to assist wineries with meeting the applicable food safety laws and regulations enforced by the US Food & Drug Administration (FDA). There is no intent or representation by Wine Institute that implementing all of advice in this Manual is an implied or overt guarantee that the winery will be in full compliance with all FDA laws and regulations. It is the responsibility of the winery operators to know what is needed and to be in compliance with the GMP requirements.

SECTION 2: GMP NARRATIVE MODELS

2.1 Qualified individual – 117.3 and 117.4

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Management is responsible for assuring that every individual, including part-time and temporary employees who have assigned tasks in producing, storing, and transporting food are qualified to perform their assigned tasks. Every individual with food responsibilities must receive basic training in the principles of food and personal hygiene, and food safety. The basic principles include the importance of employee health and personal hygiene. For example, employees with real or apparent illness, open sores or wounds must not be assigned duties that might permit contamination of food. Employees must also receive basic training in personal hygiene, such as wearing clean garments and proper hand washing, as appropriate to the food, the facility and the individual's assigned duties.

For every individual with assigned food duties, make a record of training, including supervisors. A training record can be a sign-in sheet for a presentation on basic principles, with additional material for more specialized training. The material presented must be in a language understood by the individual being trained.

2.2 Personnel - 117.10

Employee, Supervisor, Visitor & Contractor Personnel Hygiene

General hygiene training is required for all processing staff, visitors or contractors that will be close to or come into contact with any area in which food, food-contact surfaces, or food, food-packaging is exposed, such as incoming fruit storage and processing, crushed fruit storage, fruit juice storage, fermentation, and bottling/food-packaging. The degree of personal hygiene training required is that which is appropriate to the operations where persons are. For example, cleanliness of hands and garments is more important where fruit, juice or other food is exposed than in areas where there is no exposed food, such as warehouses of finished wine.

"Food-contact surface" is discussed further below in 2.4, Sanitary Operations.

If a manager or supervisor sees an employee or other person that appears to have an illness, open wound, boils, sores, or infected wounds, or another apparent source of pathogen contamination, that person must not be assigned work in any operation that might result in food, food-contact surfaces, or food-packaging becoming contaminated until the condition is corrected. Personnel must be instructed to report health conditions to their supervisors.

Open or infected wounds, and boils that are adequately covered (*e.g.* by an impermeable cover) is an acceptable corrective measure.

Personal cleanliness and clean clothes - appropriate to assigned duties - must be maintained during operations when food is exposed. Storing of outerwear, other clothing unsuitable for a given operation, or other personal belongings must be stored in areas other than where food is exposed or where equipment or utensils are washed. If employee lockers are provided, management is responsible for assuring they do not become a source of contamination. One means to assure lockers are in good order is for management to make periodic inspections for trash, food residue, or pests to be sure they do not become a source of contamination.

Visitors entering any area in which food, food-contact surfaces, or food-packaging is exposed must not contribute to contamination. Visitors must wear appropriate outer garments as decided upon by management. If hair restraints or other measures are used by employees, visitors must be similarly garbed to the extent necessary to protect against allergen cross-contact and against contamination of food before entering processing areas. There will be few areas, if any, in a winery that require these measures. It is management's responsibility to decide what is needed for a given area.

Hand washing is necessary for all individuals who will be in contact with food, food-contact surfaces, or food-packaging. Hands must be washed immediately after using restrooms, eating, drinking, or smoking, and immediately after hands have become soiled or contaminated, before

resuming work that includes contacting food, food-contact surfaces[1], or food-packaging materials[2].

Hand washing stations supplying warm potable water must be conveniently located near processing areas. Signs saying hands must be washed should be posted next to hand washing stations. Proper hand washing techniques may be an appropriate topic for employee training. Hand sanitizer stations may be placed near processing lines, but are not a substitute for hand washing. Sanitizers are not as effective in removing microorganisms as proper hand washing.

Anyone entering areas where food, food-contact surfaces, or food-packaging is exposed must not get so close that they may contribute to contamination of exposed food, food-contact surfaces, or food-packaging.

Unsecured jewelry, including earrings, watches, rings, neck chains, bracelets, and exposed piercings, that cannot be adequately sanitized when food is manipulated by hand, must be removed or covered. If covered, the covering must be sanitary and prevent anything from entering the food, food-contact surfaces, and food-packaging. Medical alert bracelets on the wrist or ankle and wedding bands without any attachments are allowed as long as they do not appear to present a risk of contaminating the raw materials, ingredients, food-packaging or finished wine. Winery management may choose to prohibit wearing false nails where food is exposed as a measure to prevent them from contaminating food.

If gloves are used in contact with food, food-contact surfaces, and food-packaging, they must be kept intact and sanitary.

The use of hair and beard nets when working in any area in which food, food-contact surfaces, or food-packaging is exposed, such as raw materials, ingredients, food-packaging and wine

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[1] *FDA defines Food-contact surfaces as 'those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.' In addition to those items onto which food is intentionally placed, overhead objects that may drip or allow objects to fall onto food are considered food-contact surfaces.*

If the surface is not one for which food-contact "ordinarily occurs during the normal course of operations," and is not overhead and likely to allow something to drop, then it is not a food-contact surface. Exteriors of tanks, equipment that is below or apart from actual food-contact, and which does not offer a probable means to contaminate food, are not food-contact surfaces.

[2] *FDA does not define "food packaging" in Part 117. With regard to wineries, the term is understood by FDA to mean the interior surface of containers and closures that is or will be in contact with wine. These surfaces, and the area in which exposed food-contact surfaces of packaging are held, must be kept clean and not contribute to contamination of the finished food.*

processing areas is recommended, but not required. Management is responsible for assuring finished products are not contaminated.

Eating food, chewing gum, drinking beverages, or using tobacco of any kind must not be allowed in any area where food, food-contact surfaces, and food-packaging is exposed.

2.3 Winery and Grounds 117.20

Grounds

The grounds about a winery that are under the control of the winery must be properly kept and maintained, and, whenever they are applicable, must include:

- Properly storing equipment, removing litter, waste and trash, and cutting weeds or grass within the immediate vicinity of the plant if they might otherwise become an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- Adequately draining areas if they that might otherwise contribute to food contamination by seepage, foot-borne or vehicle-borne filth, or providing a breeding place for pests.
- If there is on-site waste treatment and disposal, the systems must be operated in an adequate manner so that they do not become a source of contamination in areas where food is exposed.
- If the plant grounds are bordered by grounds not under the operator's control and not well maintained, management must take whatever steps are needed, such as trapping, extermination, or other means to exclude pests, dirt, and filth from the winery property that may otherwise become a source of food contamination.

It is up to management to decide what is appropriate. For example, driveways, lanes and areas serving vehicles should be paved, graded, drained and free from pools of standing water. If paving is not practical, dust control measures should be used during processing when food, food-contact surfaces, and packaging is exposed.

Waste material must be stored in suitable covered containers that prevent the waste material from attracting pests. For example, dumpsters and outside storage areas should be located on smooth, non-absorbent surfaces, and have lids that are kept closed except when trash is being added or removed.

Outdoor areas for the unloading and/or crushing of grapes, fruit, or other raw materials should be constructed of smooth concrete or equally impervious material, properly sloped to drain, or equipped with trapped drains of sufficient size to prevent the buildup of liquids.

Unused equipment and pallets should be organized and stored only in designated areas that are maintained so pests are not provided harborage.

If the winery property is bordered by grounds not under the winery's control and not properly maintained as described above, extra care must be exercised inside winery property to exclude pests, dirt, and filth that may be a source of food contamination. The extra steps may include inspection, pest extermination, or other means to prevent food contamination.

Plant Construction and Design

The winery buildings must be suitable in size, construction, and design to permit maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The facility must provide adequate space for placing of equipment and storage of materials to allow ready access for maintenance, sanitary operations, and the production of safe food. There should be enough space to allow for the segregated storage of ingredients containing allergens (any ingredient containing proteins from eggs, dairy, peanuts, tree nuts, wheat, seafood, shell fish, or soybeans), lubricants, and toxic chemicals.

Drips or condensate from fixtures, ducts and pipes must not be allowed to contaminate food, food-contact surfaces, or food-packaging materials. Aisles or working spaces between equipment and walls should be unobstructed and of adequate width to permit employees to perform their duties without risking contamination of food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

Walls, floors and ceilings must be adequately constructed and maintained. In food, food-contact surfaces, and food-packaging areas, the walls, floors, and ceilings should be light-colored, easily cleanable and constructed of material providing a smooth, impervious, cleanable surface. If concrete is used for floors or walls, its surface should be sealed with a clear or light-colored epoxy-based resin. Paint may be used on walls, but extra care must be taken to ensure peeling or mold growth does not occur.

Where necessary ("necessary" means when there are insects or other pests that might enter), doors, windows, roof openings and other openings that might allow the entry of pests should be self-closing, screened if required for interior ventilation, and kept closed at all times when not needed to be open to allow passage. All openings to the outer air where food is exposed must be effectively protected against entry by pests using one or a combination of the following:

a. Screens.
b. Effective electric screen panels.
c. Fans or air curtains which provide sufficient air velocity to prevent the entrance of insects.
d. Properly constructed and maintained flaps where it is impractical to use self-closing doors or air curtains.

Lighting, including skylights, located over wine/food preparation facilities and washing areas must be shielded, coated or otherwise shatter-resistant. Hand-washing areas, dressing and locker rooms, toilet facilities, and in all areas where wine is being processed, manufactured, processed, packed, or held, and where equipment or utensils are cleaned need adequate lighting.

To the extent possible, wiring and plumbing should be not be located where condensate and accumulated dust might fall in food, or onto food-contact surfaces, and food-packaging.

FDA recommends, but does not require, that all equipment and pallets of material be stored 18 inches away from any wall to allow for access for cleaning, placing of pest control devices if necessary, and to clean the equipment. What FDA does require is that storage conditions and practices not contribute to contamination.

Ventilation should be controlled to minimize dust, odors and vapors (including steam and noxious fumes) in areas where there might be allergen cross-contact, or that might contaminate food. Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces. Restrooms should have exhaust fans that vent directly outside of the winery.

Utensil and equipment wash sinks with two or three compartments are recommended, but not required. If used, they should be large enough to accommodate the complete immersion of equipment and utensils. Each sink should be supplied with hot and cold potable running water that can reach the compartments. Employees should be instructed that these utensil and equipment sinks are not for hand-washing.

Whether or not compartmented sinks are used, equipment and utensils must be properly cleaned. Cleaning and sanitizing of utensils and equipment must be done in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

At least one service sink with a floor drain should be provided for the cleaning of mops and for the disposal of mop water or similar liquid wastes. Back-siphon preventers or vacuum breaks are not explicitly required by regulation, but their absence may be cited as an objectionable condition.

2.4 Sanitary Operations 117.35

General Maintenance

Buildings, fixtures, and other physical facilities of the winery must be maintained in a clean and sanitary condition, and as repaired and as clean as is necessary to prevent adulteration. To FDA, “adequate repair” means the roof is not leaking, there are not holes in walls, or major cracks in

floors or walls. The purpose of the regulation is for the structure to be sufficiently repaired and cleaned to prevent adulteration. It does not mean that structures must be in perfect condition, but must, at all times when processing occurs, be in good enough condition to not contribute contamination or adulteration.

> *Recommended but not required: Depending upon the size and complexity of the winery operation, it may be appropriate to establish a written maintenance program. Doing so will contribute to the safety of ingredients, food-packaging, in-process product and packaged wine.*
>
> *If a maintenance program is written, it should include a schedule for examination and routine replacement of expendable items (such as air filters), and when needed, work orders for repair or replacement of durable equipment:*
>
> a. *Lighting as needed in all areas of the winery.*
> b. *Air filter maintenance and replacement schedule.*
> c. *Interior and exterior doors and windows are periodically checked to ensure they are tight and solid to prevent entry of pests and unauthorized visitors.*
> d. *Hand washing stations.*
> e. *Water and wastewater plumbing.*
> f. *Electrical circuit breakers, switches and general wiring.*
> g. *Water and wastewater treatment equipment.*

Even if no written schedule is prepared, equipment must be clean and sanitary upon start-up. If processing equipment becomes contaminated while in use, then processing needs to stop to allow for cleaning of the equipment. At the end of processing, equipment should be cleaned, as necessary for storage.

Winemaking operations should include routine procedures for:

a. Examining equipment and utensils before each day's production for possible sources of contamination, including condensate and pests, by the operator.
b. Examining utensils and food-contact surfaces (including equipment) that have come in contact with the floor, waste, or other insanitary objects.[3]
c. Responding to food or wine processing equipment becoming contaminated.[4]
d. Storing all equipment in a manner to protect against contamination of the product at the end of the processing day, or conclusion of an operating cycle, in such a manner that it will not contribute to contamination later in production.
e. Sanitizing all utensils, spoons, spatulas, containers, etc. before start-up, at the end of each

[3] *Contaminated food or wine processing equipment must be cleaned, sanitized, and inspected before restarting production.*

[4] *If food or wine processing equipment is contaminated in any form of waste or floor splashing during production, the operator must immediately stop production. The section affected must be cleaned, sanitized, and then inspected before resuming production.*

production batch, and after a thorough cleaning.

Substances Used in Cleaning and Sanitizing, Storage of Toxic Materials

Cleaning compounds and sanitizing agents used for cleaning and sanitizing must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification. Use of EPA approved cleaning and sanitizing agents is satisfactory to meet this requirement.

Only the following toxic materials may be used or stored in a facility where food is processed or exposed:

a. Those required to maintain clean and sanitary conditions;
b. Those necessary for use in laboratory testing procedures;
c. Those necessary for winery and equipment maintenance and operation, such as lubricants; and
d. Those necessary for use in the winery's operations.

Chemicals for cleaning and sanitizing food-contact surfaces should be segregated from non-food grade or other toxic chemicals.

Toxic cleaning compounds, sanitizing agents, and pesticides must be identified, held, and stored in a manner that avoids contamination of food, food-contact surfaces, or food-packaging materials. A caged storage area or locker with limited access by authorized employees is one way to manage and control use.

> *Recommended but not required: A master list of all chemicals used in the winery should be maintained and updated as needed, but at least annually. No new chemicals are allowed in the winery unless reviewed by winery management and added to the master list*.

All staff authorized to handle hazardous chemicals are to be trained on the proper use, labeling, and storage of hazardous chemicals as part of their annual GMP training as individuals qualified to perform these tasks.

Pest Control

When good housekeeping practices, door and window closures and/or screens, and routine cleaning are insufficient to prevent pest entry, then consider the use of more aggressive measures, such as sticky boards and insect-attracting UV light and/or pheromone traps inside the winery and the use of baited rodent traps outside the winery. Do not allow pesticide use to contaminate food, food-contact surfaces, or food-packaging. Be sure to comply with California

state licensing requirements for pesticide application and use.

Pest control starts with preventing pest entry. External doors, including overhead dock doors in areas where food is exposed, as well as pedestrian or truck access should be constructed and maintained to minimize the entry of dust, vermin and insects by at least one or a combination of the following methods:

- A self-closing device.
- Effective air curtains.
- A fly-proof screen.
- A fly-proof annex.
- Adequate sealing around trucks in docking areas.
- Electric insect control devices, pheromone or other traps and baits that are strategically located so they do attract insect to areas where food, food-contact surfaces, and exposed food-packaging material are present.

If using pest control stations, it is suggested they be checked once every two weeks and a record made of the general amount and specific type of pests caught. A site map that has the identification, location, and type of all sticky boards, interior insect and exterior bait stations and traps plotted on a facility diagram is helpful.

> *Recommended but not required: If pests are noticed as a problem, a trend analysis should be developed, plotting all of the individual pest control reports on a monthly basis to direct attention to any areas that consistently have pests. It helps to compare against the same month from the prior 2 years to determine if increased pest activity is normal or if a pattern of pest activity is not following the prior patterns for the same month the prior 2 years. Records of this monitoring activity should be maintained for review by designated staff and for future reference.*

In the event of ongoing pest problems that the existing system does not to appear to address, it is important to respond quickly with additional control measures, such as traps, etc. Be sure the building is in good repair. It may be necessary to hire a professional pest control service if the winery does not have one already under contract.

Share the results of the pest control program with staff. All employees should be encouraged and trained to observe and immediately report any pests in the winery.

Note: Pest control chemicals are toxic substances and must be stored so they will not contaminate food, food-contact-surfaces, and food-packaging. Storing pest control chemicals in a secured area separate from other chemicals used by the winery is advised.

> *Recommended but not required: Winery management should conduct a quarterly review of the winery layout and structure to ensure that pest activity is not observed internally or externally.*

Cleaning, Sanitation and Storage of Food-Contact Surfaces

All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. All food-contact surfaces must be properly cleaned and sanitized. A written cleaning plan is not required, but clean equipment is required.

Recommended but not required: If appropriate, a written Master Sanitation Schedule that identifies all winemaking equipment and utensils can be useful. General procedures and frequencies for the cleaning, sanitizing and proper storage between uses should be included.

All food-contact surfaces, utensils, and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of food or unintended allergen cross-contact.

IMPORTANT: Overhead surfaces that may drip or shed onto exposed food-contact surfaces are also considered food-contact by FDA.

Recommended but not required: Review existing procedures and consider if building a Master Sanitation Schedule is appropriate. If so, begin by first establishing a list of all winery fruit, juice and wine processing equipment and utensils.

For each piece of equipment and utensil:

a. *Identify the specific cleaning chemical(s), sanitizing chemical, minimum concentration, minimum cleaning and sanitizing solution temperature, and a reference to the Standard Operating Procedure (SOP) for details on the cleaning and sanitizing of each piece of equipment and utensil.*

b. *Identify if the cleaning will be Clean-In-Place (CIP), Clean-Out-of-Place (COP), or manually cleaned.*

c. *Identify the type of record that will capture the details of the CIP, COP and/or manual cleaning.*

d. *Describe the methods used to prepare cleaning solutions. Confirm the correct concentration of cleaning and sanitizing chemicals and check at least once per week.*

After cleaning, all equipment must be stored in a manner to protect against contamination of the product contact surfaces. At the close of an operating season, equipment should be cleaned before storage, and covered or protected from contamination by pests. If covering is not practical, then pre-production cleaning must ensure no contamination remains before using the

equipment.

Start-up Tasks for Food-contact Surfaces:

Utensils and food-contact surfaces (including equipment) that have come in contact with the floor, waste or other insanitary objects need to be cleaned, sanitized, and inspected before resuming operations.

If winemaking equipment becomes contaminated by any form of waste or floor splashing during operational activities, the winemaker must immediately stop operations. The section affected must be cleaned, sanitized, and then inspected before resuming operations.

Sanitation of Non-Food-Contact Surfaces

Non-food-contact surfaces of equipment used in processing must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

2.5 Sanitary Facilities and Controls: 117.37

Water Supply

Each winery must have adequate sanitary facilities and accommodations including water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and trash disposal.

Water in wineries for washing of the grape and fruit stock, cleaning and sanitizing product contact and non-product contact surfaces (equipment and utensils), floors, walls, windows, hand washing, and drinking needs to be potable, with the source meeting US EPA Safe Drinking Water and State of California standards. If using a municipal water supply, then no further testing is required.

If individual water supplies (wells or non-municipal sources) and water supply systems for use in food processing and cleaning, need repair or have otherwise become contaminated, they must be disinfected before being returned to use.

Samples of individual water supplies (wells or non-municipal sources) should be taken upon the initial approval of the physical structure, after every six (6) months of use, and when any repair or alteration of the water supply system has been made. Since wineries seldom operate year-round, water testing from non-municipal sources should be performed at the beginning of each processing season. A winery's water sampling and testing should include analysis for total bacterial count and a coliform count.

Plumbing

All plumbing piping, fixtures, and drainage needs to meet the locally enforced sanitary plumbing code. There must be no cross-connection between the safe water supply and any unsafe or questionable water supply. Backflow preventers must be installed when there is the possibility of backflow occurring.

The piping within a facility must be designed to carry adequate quantities of water to locations where it is needed throughout the facility.

Drains must properly carry sewage and liquid disposable waste from the facility. There must be adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. If floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor, the floor should be sloped toward drains near the center of processing areas. Drains should not be located beneath equipment.

Sewage disposal

Sewage must be transported outside the facility by an adequate sewage system, or disposed of by other adequate means. Local water quality ordnances can specify what means are adequate.

Toilet facilities

Each winery must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials. It is expected but not explicitly required that doors to toilet facilities not open directly into areas where food is exposed, and should be self-closing. Doors to toilet facilities that do open directly to where food is exposed are likely to be cited by an FDA Investigator as an objectionable condition.

Hand-washing facilities

Each winery must provide hand-washing facilities that will ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. FDA does not specify what temperatures are suitable, only that it must not be so hot or cold that it will discourage proper handwashing.

Note: Some inspectors may say the regulations require hand washing water to be within a specific temperature range. If so, the regulation is not an FDA regulation for food processing. GMPs for food processing do not include a temperature specification for hand washing.

Convenient means located in or near areas where there is exposed food, food-contact surfaces, or food-packaging surfaces. Hand washing sinks are required in toilet facilities, and should be in lunch/break rooms. If not in lunch/break rooms, employees must be instructed to wash hands following eating, drinking, or smoking. Hand washing sinks are not required in areas where there is no exposed food, food-contact surfaces, and food-packaging.

Rubbish and offal disposal

Rubbish and any offal must be removed, stored, and disposed of in a manner that minimizes the development of odor, minimizes the potential for the waste to attract, harbor, or become a breeding place for pests. Disposal must not cause contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces in proximity to exposed food or food-contact surfaces.

2.6 Equipment and Utensils 117.40

Design and Material

All facility equipment and utensils used in manufacturing, processing, packing, or holding food must be designed and made of suitably durable and cleanable material. The workmanship must be adequately cleanable, and must be adequately maintained to avoid allergen cross-contact and contamination. Repairs must also be suitable and adequately cleanable. Equipment surfaces should be smooth and free from cracks and crevices.

Maintenance priority should be given to items identified posing a risk to food safety, with special attention given to any non-conformities, violations, or objectionable conditions identified by the State of California, FDA, Alcohol and Tobacco Tax and Trade Bureau (TTB), private third-party auditors and/or internal corporate audits. FDA expects food processors to know what needs to be done in their facility, and to promptly correct any condition that is putting food at risk.

Equipment should be made of material that is undamaged by the food being processed, easily cleaned, sanitized, and maintained in good condition. Wooden equipment and utensils, other than aging barrels, is discouraged because wood is a porous material and cannot be completely cleaned.

Seams

In particular, seams and welding repairs must be smooth, continuous, and not become a site where debris, dirt, or product residue will accumulate.

Non-food-contact equipment

Equipment in areas where food is manufactured, processed, packed, or held and that does not come into contact with food, must also be kept in a clean and sanitary condition.

Floor-mounted equipment, unless easily moveable, should be sealed to the floor or elevated to provide distance between the floor and equipment to allow for cleaning underneath.

Recommended but not required: If necessary for efficient operations, the winery maintenance manager should establish an equipment maintenance schedule for processing equipment, and review and repair all items that need periodic attention. If used, this preventive maintenance schedule should address:

a. *Annual or semi-annual review (depending on processing schedules) of all processing equipment and utensils.*
b. *Lubrication schedule (using only food-grade non-allergenic lubricants) for all processing equipment.*
c. *Bearing schedule to check wear and lubrication.*
d. *Valve schedule to check valve operation.*
e. *A review of the causes for disruptions after breakdowns or unplanned line shutdowns occur*.

In the event of an equipment failure during production hours, the crushed fruit, juice or wine should be protected from contamination while remaining in place, removed and stored for later processing, or discarded. If the juice is to be made into wine, then its further processing will minimize or eliminate risks from microbial contamination.

Following repair, food-contact surfaces of the repaired processing equipment should be thoroughly cleaned and sanitized prior to being used for winemaking.

Equipment in areas where wine, juice, food additives, or food-packaging that does not come into contact with food or packaging must be cleanable and kept in a clean and sanitary condition.

Instruments and Controls

If temperature control is needed to prevent a pathogen hazard or decomposition, each freezer and cold storage compartment must be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device that accurately shows the temperature within the compartment. This requirement for temperature monitoring applies only when a food safety or decomposition risk may exist when temperature is not within a set range.

Instruments and controls are used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions to control or prevent the growth of undesirable microorganisms in food, must be accurate, precise, and adequately maintained, and adequate in number for their intended uses. Proper pH, below 4.6, is important to protect wine from

pathogen contamination.

Compressed Air Systems

Compressed air or other gases (excluding commercially packaged gases such as carbon dioxide, nitrogen, and others) intentionally introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives. If the compressed air will be sprayed on any winemaking equipment, utensils, food-packaging or on the juice or wine itself using compressed air from an on-site compressor, then it should have an oil filter, moisture collector, and a particulate filter prior to use.

2.7 Processes and controls 117.80

General

All operations in the manufacturing, processing, packing, and holding of wine (including receiving, inspecting, transporting, and segregating) must be done using adequate sanitation principles.

For example:

- Product contact surfaces of equipment and utensils should be inspected and identified as clean prior to use.
- Hoses, and in particular, the ends, should be stored off the floor and flushed with potable water before use.
- Debris, unnecessary equipment, and other items not needed in a particular operation should be stored in other areas of the winery.

Appropriate quality control operations must be used to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. An appropriate degree of quality control for wine is to be sure that the final product is fit for consumption. Routine monitoring of the winemaking process is sufficient to meet the intent of this regulation.

Overall sanitation of the winery must be under the supervision of one or more competent individuals assigned the responsibility to maintain sanitation in the facility. Competence can be demonstrated by experience, training, education, or a combination of these.

FDA is evaluating whether allergens used in winemaking need to be declared on the wine label. At present, March 2018, there is no such requirement. If that changes, TTB and FDA will coordinate what label changes might be needed. Until that happens, there are no required changes in the use or labeling of allergens in winemaking.

If any non-alcoholic foods are made in the winery, the winery should maintain a list of all

allergens known to be received, stored, processed, packaged/bottled and/or shipped to customers.

The Big Eight allergens of concern to FDA are:

1. Milk
2. Eggs
3. Fish
4. Crustacean shellfish (e.g., crab, lobster, shrimp)
5. Tree nuts (e.g., almonds, walnuts, pecans)
6. Peanuts
7. Wheat
8. Soybeans

If any allergens are used, they should only be stored in a segregated area of the warehouse, with each different allergen stored in a manner that it will not cross-contact another allergen.

The facility management must exercise care to ensure that processing operations and procedures do not allow allergen cross-contact.

If a non-wine food contains known allergens and other non-wine food is made at the same winery that do not contain allergens, or contains different allergens, management is required to ensure there is no unintentional allergen cross-contact. If food with allergens is processed, packaged or bottled on the same processing equipment as food without allergens, then it is strongly recommended that an allergen processing matrix, including a cleaning schedule, be established, to minimize unintentional allergen cross contact.

Inspect lubricants for possible use of an oil derived from an allergen, such as soy or peanuts. Check with the lubricant manufacturer and determine if the lubricant is highly refined, which is effective in removing allergens.

In the event of an unintentional cross-contact between fruit, crushed fruit, juice, other ingredients, or food-packaging/bottles exposed to an allergen(s), the labeling on the finished non-alcoholic food must either indicate the allergen is present or the food must be discarded.[5]

Simply put, management is responsible for not allowing contamination from any source.

Raw Materials and Other Ingredients

This section is primarily directed toward wine additives, fining agents, and any non-wine foods made at a facility.

Contents of partially used bins, lugs, totes, other types of containers or bags of other ingredients,

[5] This applies to products other than alcohol that may also be manufactured at the facility.

or food-packaging should be closed or covered, with the lot identifier visible, and properly stored if not completely used. In addition, partial bins, lugs, totes, other types of containers or bags should be emptied as soon as possible.

If food has become contaminated, it must be rejected, or if appropriate, treated or processed to eliminate the contamination. For example, if a batch has been contaminated with lubricating grease, it is adulterated. The winery may decide to discard or divert it to some use other than for human consumption.

If a spill occurs, juice or wine spillage should be cleaned up immediately using procedures appropriate to the location of the spillage.

Note: FDA does not require monitoring of the volumes of wine produced. TTB regulations on monitoring wine volume loss must be followed.

Piping and tank outlets need to be capped or covered when not in use, and cleaned and ready for use. Covers for juice storage and/or fermentation tanks containing juice or wine need to be kept closed while still allowing venting at times when being open is not a necessity for operations.

All raw materials, ingredients, food-packaging, in-process product and finished product other than wine need to be stored off the floor on pallets, barrels, slip-sheets or racks in their designated area (dry or cold storage areas). TTB requirements for storing wine must be followed.

Pallets need to be kept in good repair or discarded. When not in use, pallets should be stored in protected areas to protect them from accumulating bird droppings, attracting pests, or become a pest harborage area.

Outer surfaces of ingredient containers shall be clean before moving to a processing area.

Incoming loads and shipments should be inspected by adequately trained staff prior to unloading to ensure that the goods do not appear to be contaminated.

Incoming material that is accepted and not intended for immediate processing should be stored in pre-designated areas of the winery, appropriate to the storage needs of the material received. This usually means areas that are clean, dry and protected from the outside environment, pests, and contamination.

Manufacturing Operations

Winemaking operations must be conducted and managed in a manner that minimizes the potential for the packaged wine to be contaminated. Equipment, utensils, and food containers must be adequately maintained with appropriate cleaning and sanitizing practices, as necessary. If needed for thorough cleaning, equipment must be taken apart.

Unintentional allergen cross-contact must be avoided.

2.8 Warehousing and Distribution 117.93

The storage environment of the packaged wine, although protected by the bottle, plastic pouch or other types of food-packaging, needs to be clean and sanitary. If the winery uses the same storage area for the packaged wine as is used for ingredients and food-packaging, the packaged wine should be segregated to dedicated areas of the common storage area.

Trailers and railcars should be inspected prior to loading for shipment. If problems are noted that make the container unsuitable, it should be rejected and the owner or operator of the conveyance notified.

2.9 Food Defense 121.5

Wineries are exempt under 21 CFR 121.5(e) from the requirements of the rule on Mitigation Strategies to Prevent Intentional Adulteration, commonly known as the Food Defense Rule. Prudence dictates that measures recommended for food defense may be easily applied in wineries at low cost. Provisions to protect against theft are also useful in deterring attempts at intentional adulteration.

Fences, lights, locks, limited and controlled visitor access, all contribute to food defense. The cost of modest video surveillance is much less costly than it was only a few of years ago. If video surveillance is used, the monitoring should be focused on bulk vessels, whether for fermentation, storage, or aging. The probability of intentional adulteration after final packaging in retail containers is low.

2.10 By-Products Diverted to Animal Food 507.12

By-products of winemaking, such as seeds, stems, and pomace, without any further processing by the winery, may be directed to animal food. The by-products must be held under conditions that will protect against contamination by:

- Holding in appropriate containers and equipment, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
- Holding in a way to protect against contamination from sources such as trash; and
- During holding, identifying the human food by-products as intended for use as animal food.

The by-products must be labeled to identify the by-product by the common or usual name, either on the container or accompanying the shipment as human food by-products for use as animal food. Accompanying documents includes bills of sale or lading, invoices, and receipts.

If the winery is responsible for transporting the human food by-product, or arranges with another party to transport the human food by-products, then the shipping containers (*e.g.* totes, drums, and tubs) and bulk vehicles must be examined prior to use to protect against contamination from the container or vehicle.

Additional Resources

1. **Part 117 subpart B, the GMPs**
    a. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117&showFR=1&subpartNode=21:2.0.1.1.16.2
2. **Produce Safety Rule Fact Sheet**
    a. https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf
3. **Sanitary Transportation Rule Fact Sheet**
    a. https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf
4. **Copies of FDA Inspection Forms (FDA 482 Notice of Inspection & FDA 483 List of Objectionable Conditions)**
    a. https://www.fda.gov/downloads/iceci/inspections/iom/ucm127428.pdf
    b. https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm500328.pdf

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2017]
[CITE: 21CFR117]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 117 CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart B--Current Good Manufacturing Practice

Sec. 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.

If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

Sec. 117.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and

operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

Sec. 117.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

Sec. 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

Sec. 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

Sec. 117.80 Processes and controls.

(a) *General.* (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving,

inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) *Raw materials and other ingredients.* (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen

cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) *Manufacturing operations.* (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for

preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

Sec. 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Sec. 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for

use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

[80 FR 56337, Sept. 17, 2015]

Sec. 117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at*http://www.fda.gov/pchfrule* and at*http://www.fda.gov* .

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.
Source: 80 FR 56145, Sept. 17, 2015, unless otherwise noted.

KEY REQUIREMENTS:
Final Rule on Sanitary Transportation of Human and Animal Food

The FDA Food Safety Modernization Act (FSMA) rule on Sanitary Transportation of Human and Animal Food is now final, advancing FDA's efforts to protect foods from farm to table by keeping them safe from contamination during transportation. The earliest compliance dates for some firms begin one year after publication of the final rule in the Federal Register.

This rule is one of seven foundational rules proposed since January 2013 to create a modern, risk-based framework for food safety. The goal of this rule is to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food.

The rule builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (SFTA). Because of illness outbreaks resulting from human and animal food contaminated during transportation, and incidents and reports of unsanitary transportation practices, there have long been concerns about the need for regulations to ensure that foods are being transported in a safe manner.

The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food. The requirements do not apply to transportation by ship or air because of limitations in the law.

Specifically, the FSMA rule establishes requirements for vehicles and transportation equipment, transportation operations, records, training and waivers.

WHO IS COVERED?

- With some exceptions (listed below), the final rule applies to shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. It also applies to:
  - persons, e.g., shippers, in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the United States.
- The rule does not apply to exporters who ship food through the United States (for example, from Canada to Mexico) by motor or rail vehicle if the food does not enter U.S. distribution.
- Companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border.

KEY REQUIREMENTS

Specifically, the rule would establish requirements for:

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
- **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
- **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.
- **Records:** Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.

WAIVERS

The Sanitary Food Transportation Act allows the agency to waive the requirements of this FSMA rule if it determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health.

The FDA announced in the proposed rule that it intended to publish waivers for two groups of people/businesses (see below). The agency intends to publish these waivers in the Federal Register prior to the date firms are required to comply with this rule.

The FDA also received comments asking for a waiver for transportation operations for molluscan shellfish for entities that hold valid state permits under the National Shellfish Sanitation Program. The agency continues to review comments on this request, and will issue a determination in the near future.

The agency intends to publish waivers for:

- Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety program. This waiver only applies when Grade A milk and milk products—those produced under certain sanitary conditions—are being transported. FDA acknowledges that controls for such transportation operations already exist under the NCIMS program, with State enforcement and FDA oversight.
- Food establishments holding valid permits issued by a relevant regulatory authority, such as a state or tribal agency, when engaged as receivers, shippers and carriers in operations in which food is relinquished to customers after being transported from the establishment. Examples of such establishments include restaurants, supermarkets, and home grocery delivery operations. FDA acknowledges that controls for such transportation operations already exist under the Retail Food Program, with state, territorial, tribal and local enforcement and FDA oversight.

COMPLIANCE DATES

Recognizing that businesses, especially small businesses may need more time to comply with the requirements, the compliance dates are adjusted accordingly.

- **Small Businesses—**businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts would have to comply two years after the publication of the final rule.
- **Other Businesses—**a business that is not small and is not otherwise excluded from coverage would have to comply one year after the publication of the final rule.

ASSISTANCE TO INDUSTRY

- The FDA FSMA Food Safety Technical Assistance Network is already operational to provide a central source of information to support industry understanding and implementation of FSMA. Questions submitted online or by mail will be answered by information specialists or subject matter experts.
- The FDA plans to develop an online course that would meet the training requirements for this rule. The agency anticipates this course will be available before the first compliance dates go into effect.
- The agency will also issue guidance to assist industry in complying with the final rule.

KEY CHANGES FROM THE PROPOSED RULE

The proposed rule opened for public comment on February 5, 2014. The FDA made changes throughout the rule in response to public comments, as it has for the other FSMA rules that have become final in the last seven months. The agency's goal is protecting public health while making each rule as feasible for companies as possible.

- In keeping with the overarching food safety goal of FSMA, this rule now solely focuses on practices that create safety risks, rather than on those that affect its quality but don't necessarily make it dangerous to consume.
  - There are provisions in the Federal Food, Drug, and Cosmetic (FD&C) Act that cover spoilage and other forms of adulteration, including during transportation.

- The definition of "transportation operations" has been changed to exclude:
  - Transport of foods completely enclosed by a container (except for food that requires temperature control). The original proposal specified that the enclosed foods must be shelf-stable (safely stored at room temperature in a sealed container).
  - All transportation activities performed by a farm. Under the proposed rule, only the transportation of foods that are raw agricultural commodities would have been excluded.
    - The diversity of farms and their transportation operations make it difficult to develop regulations that would be broadly suitable. Instead, the FDA is considering providing guidance on good farm transportation practices.
    - Farms are still subject, however, to FD&C Act's provisions that prohibit the holding of food under insanitary conditions.
  - Transport of human food byproducts for use as animal food without further processing, i.e., those sold directly to farmers to be fed to livestock. These do not include byproducts that are transported to facilities to be manufactured into feed or pet food.
  - Transport of food contact substances, which include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging.
  - Transport of live food animals, except for molluscan shellfish (such as oysters, clams, mussels and scallops). The original proposal excluded all live food animals, including molluscan shellfish.

- Another change is particularly important to rail carriers. Commenters raised concerns that rail operators often do not own, prepare or operate equipment, e.g, refrigeration units, in the railcars they transport, and do not have the ability to ensure that certain requirements such as temperature control and sanitary conditions, are met. The shipper or loader, and not the rail carrier, has generally assumed responsibilities, such as inspecting a railcar, to ensure that it is suitable. Shippers will continue to hold primary responsibility for sanitary conditions of transport under this rule unless the carrier has entered into a written agreement with the shipper to assume this responsibility.
  - By contrast, motor carriers generally own their vehicles and are directly involved with sanitation during transportation operations.

- "Loaders" have been added as a covered party. A loader is a person who physically loads food onto a motor or rail vehicle.
  - Before loading a food not completely enclosed by a container, the loader must determine that the transportation equipment is in appropriate sanitary condition.
  - Before loading a food requiring temperature control, the loader must determine that each mechanically refrigerated cold storage compartment is adequately prepared for refrigerated transportation, including precooling, if necessary.

- The final rule clarifies that the intended use of the vehicle or equipment (e.g., transporting animal feed versus human food) and the production stage of the food being transported (e.g., raw materials versus finished products) are relevant in determining the applicable sanitary transportation requirements.

- Requirements for the use of a temperature indicating or recording device during transport have been replaced with a more flexible approach. The shipper and carrier can agree to a temperature monitoring mechanism for foods that require temperature control for safety.
  - The original proposal specified that a compartment must be equipped with a thermometer, temperature measuring device, or temperature recording device.

- The agency agreed with commenters that there are a number of effective ways for ensuring temperature control that parties subject to this rule should be able to use.
- The agency also agreed with commenters that carriers need to demonstrate they maintained requested temperature conditions only upon request, rather than as a requirement for every shipment, as previously proposed.

- Primary responsibility for determining appropriate transportation operations now rests with the shipper, who may rely on contractual agreements to assign some of these responsibilities to other parties.
  - Shippers must develop and implement written procedures to ensure that equipment and vehicles are in appropriate sanitary condition.
  - Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make food unsafe.
  - And shippers of food that require temperature control for safety must also develop and implement written procedures to ensure that food is transported under adequate temperature control.

- If a covered person or company at any point in the transportation chain becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe, that food must not be sold or distributed until a determination of safety is made.

EXEMPT FROM THE RULE

- Shippers, receivers, or carriers engaged in food transportation operations that have less than $500,000 in average annual revenue
- Transportation activities performed by a farm
- Transportation of food that is transshipped through the United States to another country
- Transportation of food that is imported for future export and that is neither consumed or distributed in the United States
- Transportation of compressed food gases (e.g. carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products), and food contact substances
- Transportation of human food byproducts transported for use as animal food without further processing
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety
- Transportation of live food animals, except molluscan shellfish

MORE INFORMATION

Visit http://www.regulations.gov/

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

KEY REQUIREMENTS:
Final Rule on Produce Safety

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see "Compliance Dates" below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of "farm" and related terms were revised in the final Preventive Controls for Human Food rule, and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

Below are summaries of some key requirements, compliance dates, and other information.

1. AGRICULTURAL WATER:

- **Water quality:** The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
  - No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.
  - The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic *E.coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E.coli* in 100 mL of water.
    - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
    - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.

- The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.
- These criteria account for variability in the data and allow for occasional high readings of generic *E.coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.
- These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.

- If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
  - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
  - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
  - Treating the water.

■ **Testing:** The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).

- In testing untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the "microbial water quality profile") and determine if the water meets the required microbial quality criteria.
  - After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.
  - The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
  - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.
  - The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.
  - If the four initial sample results meet the no detectable generic E. coli criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.
- There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements

established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements.

2. BIOLOGICAL SOIL AMENDMENTS:

- **Raw Manure:** The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)
  - At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
  - The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered prdouce after application.

- **Stabilized Compost:** Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. SPROUTS

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.
  - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of Listeria monocytogenes associated with sprouts in the United States.

- Requirements specific to sprouts include, for example:
  - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
  - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
  - Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*.
  - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.

- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.

4. DOMESTICATED AND WILD ANIMALS

- The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.
  - At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
  - In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.

- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.

- As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. WORKER TRAINING AND HEALTH AND HYGIENE

- Requirements for health and hygiene include:
  - Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
  - Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
  - Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.

- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.

- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. EQUIPMENT, TOOLS AND BUILDINGS

- The rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities.
  - Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

EXEMPTIONS

The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)

- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets

(roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint;potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce that is used for personal or on-farm consumption.
- Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less.

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
  - The farm must have food sales averaging less than $500,000 per year during the previous three years; and
  - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn as follows:
  - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
  - If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.
- Before FDA issues an order to withdraw a qualified exemption, the agency:
  - May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
  - Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.
- A withdrawn exemption may be reinstated if (as applicable):
  - The FDA determines that the outbreak was not directly linked to the farm, and/or
  - The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

VARIANCES

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variances to those

requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.

- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.
- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

COMPLIANCE DATES

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period: four years.
- Small businesses, those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period: three years.
- All other farms: two years.
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020.
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule.
- For all other modified requirements:
  - Very small businesses, four years after the effective date of the final rule.
  - Small businesses, three years after the effective date of the final rule.

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

ENVIRONMENTAL IMPACT STATEMENT

The FDA has also released the Final Environmental Impact Statement (EIS), which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.

- The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant environmental impacts. The provisions of the final rule represent FDA's preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency's preferred alternatives are those that the FDA believes best fulfill the agency's statutory mission and responsibility, giving consideration to economic, environmental, technical and other factors.

- A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.

- As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.

- The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.

ASSISTANCE TO INDUSTRY

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance

- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.

- The FDA is developing a comprehensive training strategy that includes collaboration with:
  - The Produce Safety Alliance;
  - The Sprout Safety Alliance;
  - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
  - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).

- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.

- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

MORE INFORMATION

Visit http://www.regulations.gov/

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO. 1431 Harbor Bay Parkway Alameda, CA 94502 (510)337-6700

TO	2. NAME AND TITLE OF INDIVIDUAL	3. DATE
	Helen E. Castro, President	07/28/13
	4. FIRM NAME ABC Bread Company	5. HOUR: 7:30 a.m. / p.m.
	6. NUMBER AND STREET 579 Main Street	
	7. CITY AND STATE & ZIP CODE Richmond, CA 94805	8. PHONE NO. & AREA CODE (510)123-4567

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Sidney H. Rogers	Sidney H. Rogers, Investigator

[1] **Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:**

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

PSC Publishing Services (301) 443-6740 EF

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave. SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404 Industry Information: www.fda.gov/oc/industry	03/14/2016 - 03/17/2016
	FEI NUMBER 3005098811

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Emily J. Camp, Director of Quality Assurance

FIRM NAME	STREET ADDRESS
CRF Frozen Foods, LLC	1825 N. Commercial Ave.
CITY, STATE AND ZIP CODE Pasco, WA 99301-9533	TYPE OF ESTABLISHMENT INSPECTED Vegetable Processor

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED

OBSERVATION 1:

The materials and workmanship of equipment and utensils does not allow proper cleaning and maintenance.

Specifically,

1. On 03/14/16, we observed a white, plastic shovel with chips and cracks near the scoop end. This shovel was stored near the production line and is used for food contact.

2. On 03/14/16, we observed blue tape being used as a temporary fix to a cracked metal plate located above the (b) (4) for consumer pack line (b) (4). During this inspection, product designated for export was being repacked on this line.

3. On 03/16/16, we observed chipping, cracking, and missing pieces of plastic in the following areas of the onion line, which, during the inspection, was producing organic whole peel onions, Lot code: 6495600000100, 03/16/16.

a) The clear plastic shield separating the (b) (4) was found ripped in the middle and broken and cracked on both edges.

b) The plastic conveyor belt located between the (b) (4) (b) (4) had pieces of plastic missing from at least five of the legs. The legs come into direct contact with the onions.

c) Utility knives used to hand slice undesired pieces off of the onions have etched initials directly on the blades, leaving a rough surface.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jessica B Clark Beau R. Lamb Nichole A Broadhacker	Jessica B. Clark, Investigator Beau R. Lamb, Investigator Nichole A. Broadhacker, Investigator	03/17/16 03/17/16 03/17/16

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."