



New Rules for Food and Produce

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Outline

- Compare 21 CFR Parts 112 for produce and 117 cGMPs for processed food – what rule does your operation fall under?
- Trade impact of these new rules – Pacific region



Where Does Your Operation Fall Under FSMA?

- Do you make “processed food” (Part 117) or
- Do you make a “raw agricultural product” that is commonly eaten raw? (Part 112)
- Are you a “farm” or a “processor?”
- Manufacturing/processing now includes **packing, and holding**



Major Changes Under FSMA for Processors

- Definition of food
- Qualified facility
- Preventive controls qualified individual – each facility
- Processors must take **condition of facility** into account as part of hazard analysis (this will determine whether product is high risk)
- Control programs for **allergens** (allergen cross contact)
- Control programs for **undesirable** (not just pathogenic) microorganisms, radiological hazards, unapproved additives, color additives, economic adulteration for **processed food**
- **Preventive controls based food safety plan – verification and monitoring**
- Compliance larger operations is Sept 2016, <500 employees 2017



Major Changes Under FSMA for Producers of Raw Agricultural Products

- Must **have plan for controlling microbes of public health significance** – know and document who in the value chain controls a hazard if it is not you
- Must have trained people with their training documented
- Environmental testing– agricultural water safety
- Safety of water for harvesting and other uses
- Process and microbial specifications for biological soil amendments
- **Records** – lots of records
- Compliance for larger operations (>\$500K/yr) is 2017



It's the Water

- Water quality profile for surface water - initial survey
- 20 tests for generic *E. coli* over first 2 to 4 years to establish microbial water quality profile
- Ground water test annually
- If not able to meet water quality criteria – permitted to show “die off” at a certain rate between last irrigation period and harvest or between harvest and end of storage



Our Familiar Definition of Food

- The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. 21 USC §321(f)



Food

- §1.227 **Food**
- §1.227 (2) Examples of food include: **fruits, vegetables**, fish, dairy products, eggs, **raw agricultural commodities for use as food or as components of food, animal feed** (including pet food), food and feed ingredients, food and feed additives, **dietary supplements and dietary ingredients** infant formula, beverages (including **alcoholic beverages** and bottled water), **live food animals**, bakery goods, snack food, candy and canned foods.



Are You a Farm or a Manufacturer?

- Farm – primary, secondary, mixed
- Manufacturer/processor, hold, pack



Farm – Primary Production

- §1.227 **Farm** means
- §1.227 (1) **primary production farm** is an operation **under one management in one general (location)** but not necessarily contiguous physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.



Farm – Primary Production

- The term “farm” includes operations that, in addition to these activities:
- §1.227 (1) (i) **pack or hold raw agricultural commodities;**



Farm – Primary Production – Can Process Food but Can't Sell it Without Additional Regulation

- §1.227 (1) (ii) **pack or hold processed food**, provided that all processed food use in such activities is either consumed on that farm or another farm under the same management,



Farm – Primary Production – Dried Fruit or Minimal Processing OK

- §1.227 (1)(iii) manufacture/process food, provided that:
- §1.227 (1)(iii) (A) all food used in such activities is consumed on that farm or another farm under the same management; or
- §1.227 (1)(iii) (B) any manufacturing/processing of food that is not consumed on that farm or another farm under the same management that consists **only of**:
- §1.227 (1)(iii) (B) (1) involves drying/dehydrating a raw agricultural commodity to create a distinct commodity (such as drying/dehydrating grapes to produce **raisins**, and **packaging and labeling** such commodities, without additional manufacturing processing (an example of additional manufacturing/processing is **slicing**);



Farm – Primary Production- CA ok

- §1.227 (1)(iii) (B) (2) treatment to **manipulate the ripening** of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
- §1.227 (1)(iii) (B) (3) **packaging and labeling** raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation; or



Farm – Secondary Activities Farm

- §1.227 **Farm** means (2) **Secondary activities farm**. A secondary activities farm is an operation, **not located on a primary production farm, devoted to harvesting** (such as hulling or shelling), packing, and/or **holding of raw** agricultural commodities, provided that the primary production farms(s) that grows, harvests and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.
- A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in §1.227 (1)(ii) and (iii) of this definition.



Mixed-type Facility – Must be Registered

- §1.227 **Mixed-type facility** means an establishment that engages in both activities that are exempt from registration (**e.g. farming**) under § 415 of the Federal Food Drug and Cosmetic Act and activities that require the establishment to be registered (**e.g. processing**)
- An example of such a facility is a “farm mixed-type facility” which is an establishment that is a farm, but also conducts activities outside the farm definition that requires the establishment to be registered



Farm – Processing Exclusions

- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.



Harvesting

- §1.227 **Harvesting** applies to farms and farm mixed-type facilities and means activities that are **traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as foods.**



Harvesting

- Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by **drying/dehydrating a raw agricultural commodity without additional manufacturing or processing on a farm.**
- Harvesting does not include activities that transforms a raw agricultural commodity into a processed food as defined in § 201 (gg) of the Federal Food, Drug and Cosmetic Act.



Harvesting - Examples

Cooling

Filtering

Hulling

Shelling

Threshing

Washing

Field coring

Gathering

Removing stems and husks

Sifting

Trimming of outer leaves



Holding

- §1.227 **Holding** means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that foods, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities **when the drying/dehydrating does not create a distinct commodity** (such as drying/dehydrating hay or alfalfa)).



Holding

- Holding also includes activities **performed as a practical necessity** for the distribution of that foods (such as blending of the same raw agricultural commodity and breaking down pallets), **but does not include activities that transform the raw agricultural commodity into a processed food** as defined in § 201 (gg) of the Federal Food Drug and Cosmetic Act.
- Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators and liquid storage tanks.



Manufacturing/processing

- **§1.227 Manufacturing/processing** means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.



Manufacturing/Processing - Examples

- Examples of Manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, **cutting**, distilling, **drying/dehydrating raw agricultural commodities to create a distinct commodity** (such as drying dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, **labeling**, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, **peeling**, rendering, **treating to manipulate ripening**, **trimming**, **washing or waxing**.



Manufacturer

§ 1.276 (b)(9) Definition of (9) **manufacturer** is changed to mean the last facility, as that word is defined in § 1.227, that manufactured /processed the food.

A facility is considered the last facility even if the food undergoes further manufacturing/ processing that consists of adding labeling or any similar activity of a *de minimis* nature.



Ready-to-eat food

- § 117.3 Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards



Produce

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs



Produce - Fruit

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 - Vegetable

A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro)



Grains Are Not Produce

Food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion).

Examples of food grains include 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).



Dietary Ingredient

- A **dietary ingredient** is a vitamin; a mineral; an **herb or other botanical**; an amino acid; a dietary substance for use by man to **supplement the diet by increasing total dietary intake**; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients. (See section 201(ff)(1) of the FD&C Act (21 U.S.C 321(ff)(1)).)



Produce Safety Rule – “Covered Produce”

- 21 § 112.1 Raw agricultural commodity (RAC) grown domestically or imported.



Covered Activity

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm”



Covered Produce – A List

Almonds, apples, apricots, apriums, artichokes – globe, Asian pears, avocados, babacos , bananas, Belgian endive, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (bok choy, mustard, and Napa), cantaloupes carambolas, carrots cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel- Florence, garlic, genip, gooseberries, grapes, green beans, guavas,



Covered Produce – A List

herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and



More Covered Products

- (2) Mixes of intact fruits and vegetables (such as fruit baskets).



What is Not Covered Produce

Produce that is **rarely consumed raw**, specifically the produce **on the following exhaustive list**: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; **beets, garden (roots and tops)**; beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; **corn, sweet; cranberries; dates; dill** (seeds and weed); eggplants; **figs; ginger; hazelnuts; horseradish**; lentils; okra; peanuts; **pecans; peppermint; potatoes**; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.



Products Exempt from Produce Safety Rule – Destined for Further Processing

The produce receives **commercial processing** that **adequately reduces the presence of microorganisms of public health significance.**

Examples of commercial processing are thermal processing (juice and acidified foods), treating with **a validated process** to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products - AND



Products Exempt from Produce Safety Rule - Destined for Further Processing

(2) You must **disclose in documents accompanying the produce**, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;”
AND



Products Exempt from Produce Safety Rule - Destined for Further Processing

(3) You must either:

- (i) **Annually obtain written assurance**, subject from the customer **that performs the commercial processing** that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or
- (ii) Annually obtain written assurance from ***your customer*** **that an entity in the distribution chain subsequent to the customer will perform commercial processing** and that the customer:



Products Exempt from Produce Safety Rule - Destined for Further Processing

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”;
and



Products Exempt from Produce Safety Rule - Destined for Further Processing

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing , and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and



General Requirements Produce Safety

§ 112.11 What general requirements for produce safety?

You must take **appropriate measures to minimize the risk** of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to **provide reasonable assurances that the produce is not adulterated.**



General Requirements for Processed Food

- Sanitation
- Good Manufacturing Practices
- Hazard Analysis and Risk Based Preventive Controls Plan
 - Validation, Verification
- Defect Action Levels
- Supply Chain Management
- Recall Program
- Worker Training
- Audits



Known or Reasonably Foreseeable Hazard

- § 117.3 Known or reasonably foreseeable hazard means a **biological, chemical** (including radiological), or **physical** hazard that is known to be, or has the potential to be, associated with the facility or the food.
- § 112 Known or reasonably foreseeable hazard means a **biological** hazard that is known to be, or has the potential to be, associated with the farm or the food.



Microorganism – Same Definition for Produce and Processed Food

- § 117.3 Microorganism means yeast, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.
- The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.



Environmental Pathogens – Processed Food and Covered Produce

- § 117.3 Environmental pathogen means a pathogen capable of **surviving and persisting within the manufacturing, processing, packing, or holding environment** such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella* spp. but not spores of pathogenic sporeforming bacteria
- § 112 Includes specified testing for *E coli* 0157:H7, *Salmonella* spp., *Listeria monocytogenes*.



Environmental Monitoring Processed Food

- §117.165(b)(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:
- §117.165(b) (3) (i) be scientifically valid;
- §117.165(b) (3) (ii) identify the test microorganism(s);
- §117.165(b) (3) (iii) identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;
- §117.165(b) (4) (iv) identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
- §117.165(b) (4) (v) identify the test(s) conducted including the analytical method(s) used;
- §117.165(b) (4) (vi) identify the laboratory conducting the testing; and
- §117.165(b) (4) (vii) include the corrective action procedures required by §117.150(a)(1)



Preventive Controls – Processed Food

- § 117.3 Preventive controls means those risk-based, **reasonably appropriate procedures**, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ **to significantly minimize or prevent the hazard** identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.



Control Programs – Covered Produce

- Water quality monitoring
- Worker hygiene
- Animal control
- Buildings
- Equipment, tools, instruments
- Safety of biological soil amendments
- Monitoring and records programs; verification of effectiveness of control programs



117.4 Qualifications of individuals who manufacture, process, pack, or hold food.

- § § 117.4 (a) Applicability.
- § 117.4 (a) (1) The management of an establishment must ensure that all individual who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.
- § 117.4 (a)(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F or G of this part are qualified to perform their assigned duties.



Individuals Must Have Training in Food Safety to Perform Job

- § 117.4 (b) Qualifications all individuals engaged in the manufacture, process, pack, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary or seasonal personnel) or in the supervision thereof must:
- § 117.4 (b) (1) be a qualified individual as that term is defined in § 117.3 –i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold **clean and safe** as appropriate to the individual's assigned duties; and
- § 117.4 (b) (2) 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



Preventive Controls Qualified Individual

- § 117.3 Preventive controls qualified individual means a qualified individual who has **successfully completed training** in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system



Produce – Personnel Training

- § 112.22(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.



Preventive Controls Qualified Individual

- §117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.
- §117.180(a) One or more preventive controls qualified individuals must do or oversee the following:
 - §117.180 (a)(1) Preparation of the food safety plan (§117.126 (a)(2));
 - §117.180 (a)(2) Validation of the preventive controls (§117.160 (c) (5));
 - §117.180(a)(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable foods;
 - §117.180(a)(4) Determination that validation is not required (§117.160 (c) (5));
 - §117.180 (a)(5) Review of records (§117.165(a)(4));
 - §117.180(a)(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;
 - §117.180(a)(7) Reanalysis of the food safety plan (§117.170(d));
 - §117.180(a)(8) Determination that reanalysis can be completed, and additional preventive controls validated; as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food safety plan



Qualifications and Training for Personnel Who Handle (Contact) Covered Produce or Food Contact Surfaces

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, **as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.**

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the **supervision** thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.



Training Under Produce Safety Rule

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

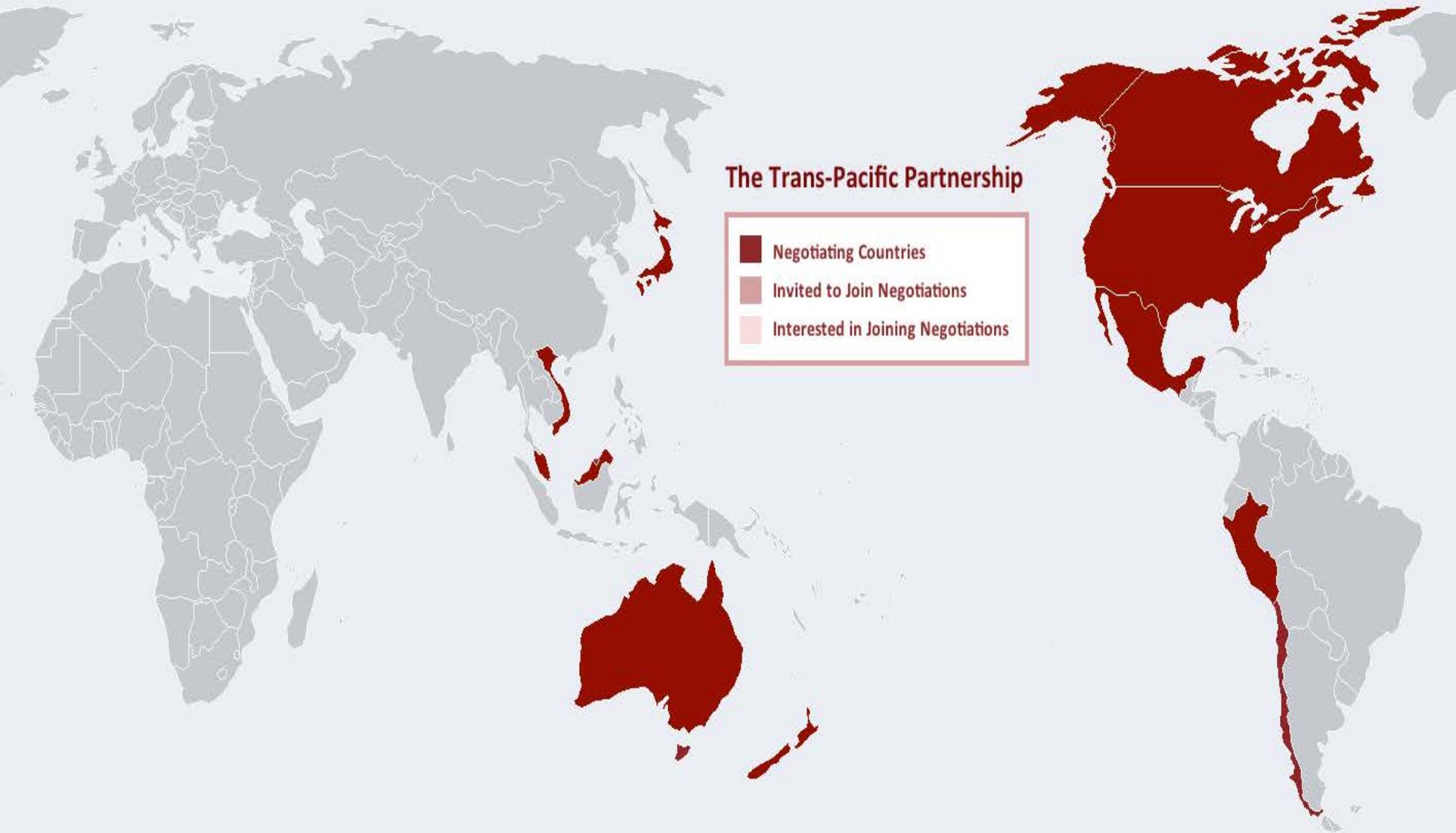
(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.



FSMA and Impact on Trade



Transpacific Partnership Member Countries



Importance of Pacific Trade

- Roughly 20% percent of U.S. farm income comes from agricultural exports
- Foreign taxes on our agricultural exports are often very high, much higher than foreign taxes on other exports.
- TPP will open foreign markets to U.S. food and agriculture, providing new and commercially meaningful market access and advancing regulations that are transparent and based on science.



PNW Agriculture Export Markets

IDAHO	OREGON	WASHINGTON
Wheat	Wheat	Fruits/nuts
Dairy	Fruits/nuts	Vegetables
Vegetables	Vegetables	Wheat
Beef/veal	Dairy	Dairy
Feed	Beef/veal	Beef/veal
JOBS: 18,200	15,900	34,100
VALUE: 2.4B	2.1B	4.55B



TPP Provisions That Should Help US Producers

- Support the roughly \$70 billion in U.S. food and agricultural exports to the TPP partners
- Safeguarding the strong food safety regulatory system we already have in the United States:
- New obligations that promote science-based and transparent regulation should lead to improvements in the food safety and animal and plant health regulatory systems of other TPP countries
- The provisions requiring documented, objective, scientific evidence better align other countries' regulatory systems with U.S. safety and regulatory systems



TTP Provisions – Tariffs, Subsidies and Transparency

- **Eliminates tariffs on the majority of U.S. exports of food and agricultural products.** E.g., agricultural tariff rates average 19% in Japan and 16% in Vietnam. Some products have **peak tariffs of over 300%** or more.
- **New and commercially meaningful market access** through significant tariff reductions or preferential tariff rate quotas .
- Requires TPP countries to **eliminate all agricultural export subsidies.**
- **Discourages countries from imposing export restrictions** on food and agricultural products to protect domestic market from world market shifts.
- WTO to **improve transparency on agricultural export state trading enterprises;** agree on rules preventing special governmental financing or trade restrictions on exports that distort trade.



TTP Provisions – Food Safety

- Ensures food safety, animal health, and plant health **measures are developed and implemented transparently and in a science-based manner** based on risk, as we do in the United States.



TTP – Provision for Foreign Food Safety Audits

- TPP commitments permit an importing country to conduct an audit of an exporting country's food safety regulatory system to determine whether the exported food meets the importing country's requirements.
- U.S. can use systems audits to enhance confidence in the safety of imported food, minimizing need for inspections by multiple foreign countries of tens of thousands of U.S. food processing plants.
- TPP provides a new consultative mechanism for seeking quick resolution of measures related to U.S. food and agricultural exports, which will allow regulatory agencies to ensure that these issues are resolved based on safety and science.



Summary

- Many new requirements for produce and processed food
- Compliance deadlines are coming up fast
- We have training programs and technical assistance to help you with compliance
- Predict that similar regulations will be adopted across Pacific region

