Interaction of other FSMA Rules with the Produce Industry

Juan L. Silva

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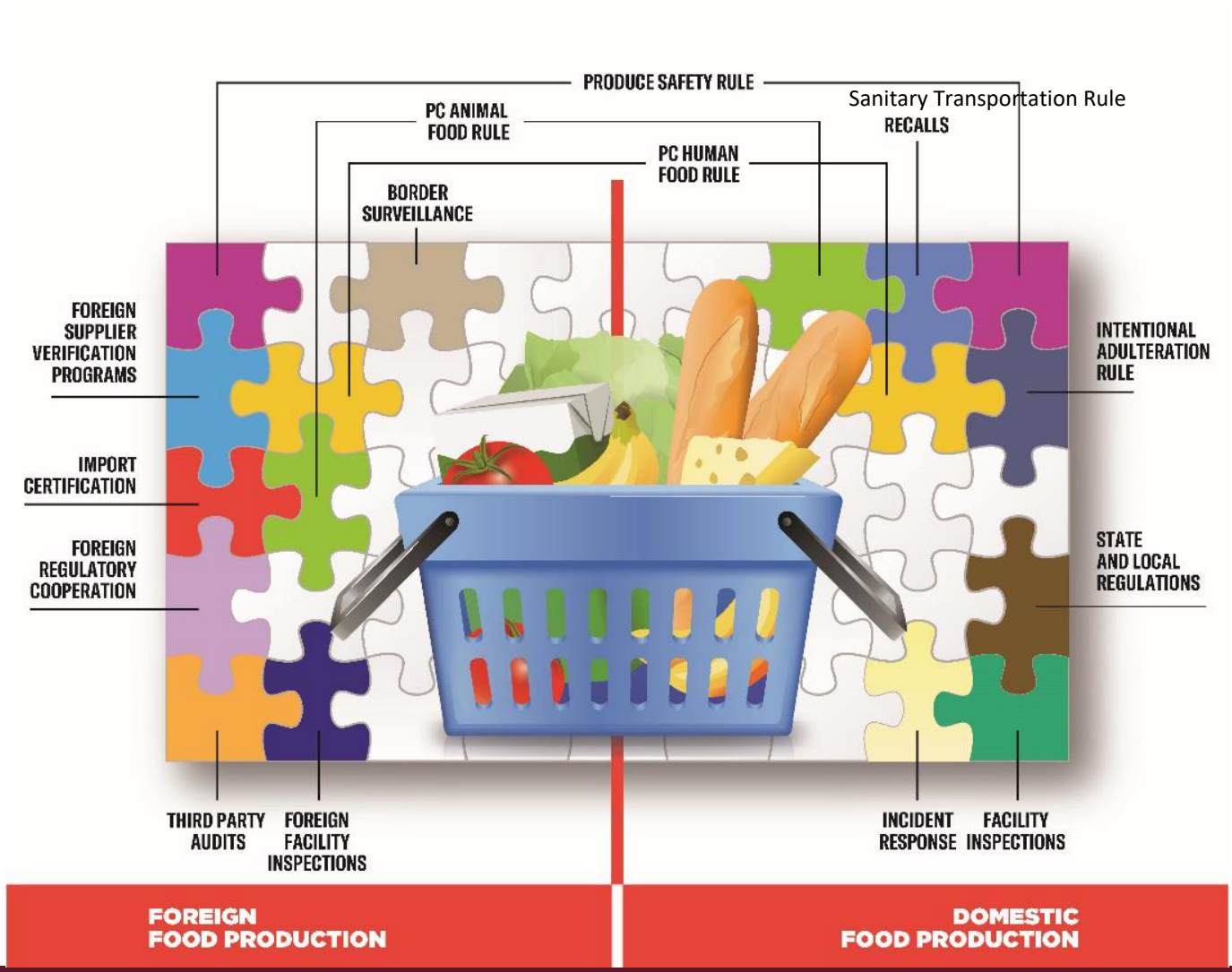
Thank you

North Central Region

Center for FSMA Training, Extension and Technical Assistance

Rules under FSMA

Foreign and Domestic Food Safety Oversight Activities (FDA, 2019)



FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Rule)- 21 CFR Parts 11 and 121

- With some exceptions listed below, this rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.
- This rule is designed to primarily cover large companies whose products reach many people, exempting smaller companies. There are 3,400 covered firms that operate 9,800 food facilities.
- *IA Qualified individual*

IA rule does NOT cover:

https://www.fda.gov/media/97788/download

This rule does not cover:

- Activities that fall within the definition of "farm" including mixed-type facilities - **It does not cover farms.**
- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact
- **On-farm** manufacturing, processing, packing, or holding (farm mixed-type facilities) by a small or very small business of certain foods identified as having low-risk production practices. The exemption applies if such activities are the only activities conducted by the business subject to the rule. These foods include certain types of eggs, and certain types of game meats.

Sanitary Transportation Rule (ST)

https://www.fda.gov/media/104455/download

- With some exceptions, the final rule applies to shippers, receivers, loaders, and carriers who transport food in the United States by motor or rail vehicle, whether the food is offered for / or enters interstate commerce.
- Transportation of food that is completely enclosed by a container except when it requires temperature control for safety is covered

ST Rule does NOT cover:

- Transportation **activities performed by a farm**

- Transportation of human food byproducts for use as animal food without further processing

Preventive Controls for Human Foods, PCHF Rule- 21CFR117

- This rule, in general, covers establishments that are registered under section 415 of the Federal Food, Drug, and Cosmetic Act that engage in food (human) food processing activities.
- *PCQI HF Qualified individual*

□ Baking; □ Boiling; □ Bottling;

□ Canning; □ Cooking; □ Cooling;

□ Cutting; □ Distilling; • *Drying/ dehydrating raw agricultural commodities to create a distinct commodity;*

□ Evaporating; □ Eviscerating; □ Extracting juice;

□ Formulating; □ Freezing; □ Grinding;

□ Homogenizing; □ Irradiating; □ Labeling;

□ Milling; □ Mixing; □ Packaging (MAP…);

□ Pasteurizing; □ Peeling; □ Rendering;

□ Treating to manipulate ripening;

□ Trimming; □ Washing, □ Waxing.

Mixed-type facilities- PCHF

- An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered.
- 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 require the establishment to be registered.

Low-risk manufacture / process / pack / hold activities for "very small businesses"

https://www.fda.gov/media/100921/download

- Establishment averaging <$1 million in total food sales in the 3 preceding years (2017-2019)
- The facility has to register under § 405 FD&C Code
- Conducts "low-risk" activities for certain products

1. Boiling: Gums; Latexes; Resins.
2. Chopping, coring, cutting, peeling, pitting, shredding, and slicing
3. Coating
4. Drying/dehydrating
5. Extracting: herb oils
6. Freezing
7. Grinding/cracking/crushing/milling
8. Labeling
9. Making
10. Mixing
11. Pasteurizing: Honey
12. Roasting and toasting: peanuts
13. Salting: seeds
14. Sifting

Mixed Type Facilities cGMPs: 21CFR107B or 21CFR112…

- Packing operations that do not qualify as "farms" but are only packing and holding produce can elect to either comply with CGMPs or comply with the relevant Produce Rule requirements (Subparts K, L, etc.)

Preventive Controls for Animal Foods, PCAF Rule- 21CFR507

- Businesses that manufacture, process, pack, or hold food for consumption by animals in the United States are covered.
- Feed mills, animal feed and pet food manufacturers and processors, and holding facilities.
- Manufacturing and processing: making food from one or more ingredients or chemically or physically modifying food ingredients to create new products.
- *PCQI AF Qualified individual*

Exemptions from Preventive Controls for Animal Foods Rule

- **Farms** that only grow crops used for animal food are not covered under this regulation.
- Feed mills that are part of fully vertically integrated **farming operations** (i.e., where the farm, its animals, and the feed mill are all together under one management) are not subject to the rule.
- Retail establishments that sell animal feed or pet food directly to consumers and home-based producers of pet foods are also not subject to this federal regulation, although they may be covered under local and state regulations.

Exemptions from Preventive Controls for Animal Foods Rule

- Mixed type facilities both **grow crops for animals and conduct animal food processing and manufacturing activities**.
- Only to facilities with **less than 500 full-time employees** or with previous **3-year average annual feed sales plus the value of the inventory less than $2,500,000 and** only if **all of animals** that consume all of the feed are **at the same location and under the same ownership** or management.
- To obtain the exemption, all products and processes must be in the **low risk category** as determined by FDA.

Exemptions from Preventive Controls for Animal Foods Rule

- Low risk products include roughage like alfalfa meal or pulp, plant protein meal, grain by-products such as bran, flour, middlings, and brewer's or distiller's grain, oilseed products, molasses, animal protein meal, milk products including casein or lactalbumin, animal tissue products, vitamins, minerals, concentrates, and processing aids.
- Processes that are considered low risk include chopping or shredding hay, cracking or shelling grain, crushing, grinding, rolling, or milling grain, making silage or haylage, and labeling or packaging certain products.

Exemptions from Preventive Controls for Animal Foods Rule

- Facilities that meet the requirements for this exemption are not required to comply with the Preventive Controls or the Supply-Chain Program section.
- However, **compliance with GMPs is required (Subpart B)**

- Personnel
- Plant and grounds
- Sanitation
- Water supply and plumbing
- Equipment and utensils
- Plant operations
- Holding and distribution
- Holding and distribution of human food by-products for use as animal food

https://feedmilling.ces.ncsu.edu/2019/09/self-audit-checklist-for-animal-food-current-good-

Exemptions from Preventive Controls for Animal Foods Rule- Hold & Storage

- **Facilities that only store packaged animal food that does not require time and temperature controls to prevent or minimize the growth of pathogens,** such as refrigeration. cGMPs apply
- Facilities that only store packaged animal food that does require time and temperature controls to keep it safe are required to implement a plan to meet temperature controls that includes monitoring, corrective actions, verification, and implementation records. GMPs must be followed.
- Facilities where only raw agricultural commodities are stored are eligible for this type of exemption. These are businesses that solely engage in holding or transporting raw agricultural commodities, hulling, shelling, drying, packing, and holding nuts and hulls, or the ginning of cotton. Businesses under this exemption do not have to comply with GMPs, conduct a hazard analysis and implement preventive controls or supply chain controls.

Foreign Supplier Verification Programs Rule

- The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.
- For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States.
- Includes produce

FSVP- Who is the supplier?

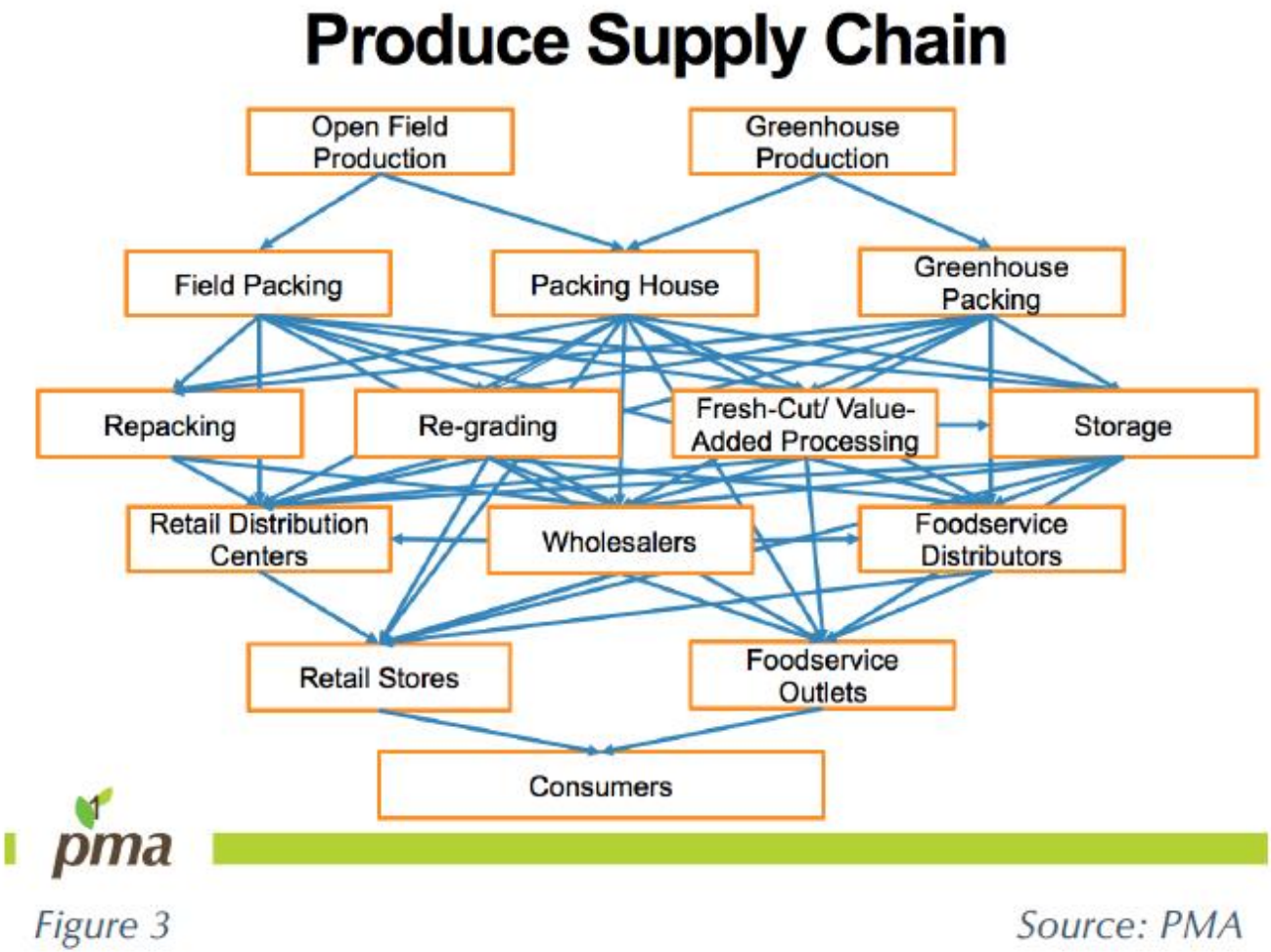


Figure 3

Source: PMA

Foreign Supplier Verification Programs Rule – Produce Safety

- Verify that their foreign supplier is following the Produce Safety rule,
- U.S. importers of produce are required to develop, maintain, and follow an FSVP for each type of food they import including:
  - Conducting a hazard analysis for known or reasonably foreseeable chemical and physical hazards. (Note: **No hazard analysis of biological hazards is necessary** as those hazards are covered through **compliance with the Produce Safety rule**),
  - Evaluating and approving each foreign supplier,
  - Determining what foreign supplier verification activities are necessary and appropriate as well as their frequency,
  - Taking corrective actions based on verification activities, and
  - Reevaluating their FSVP whenever they become aware of a food safety problem and at least every three years.
  - Identifying the FSVP importer at entry.
- Documenting all of the above, keeping adequate records, and making those records available to FDA upon request.

FSVP- Who conducts verification activities?

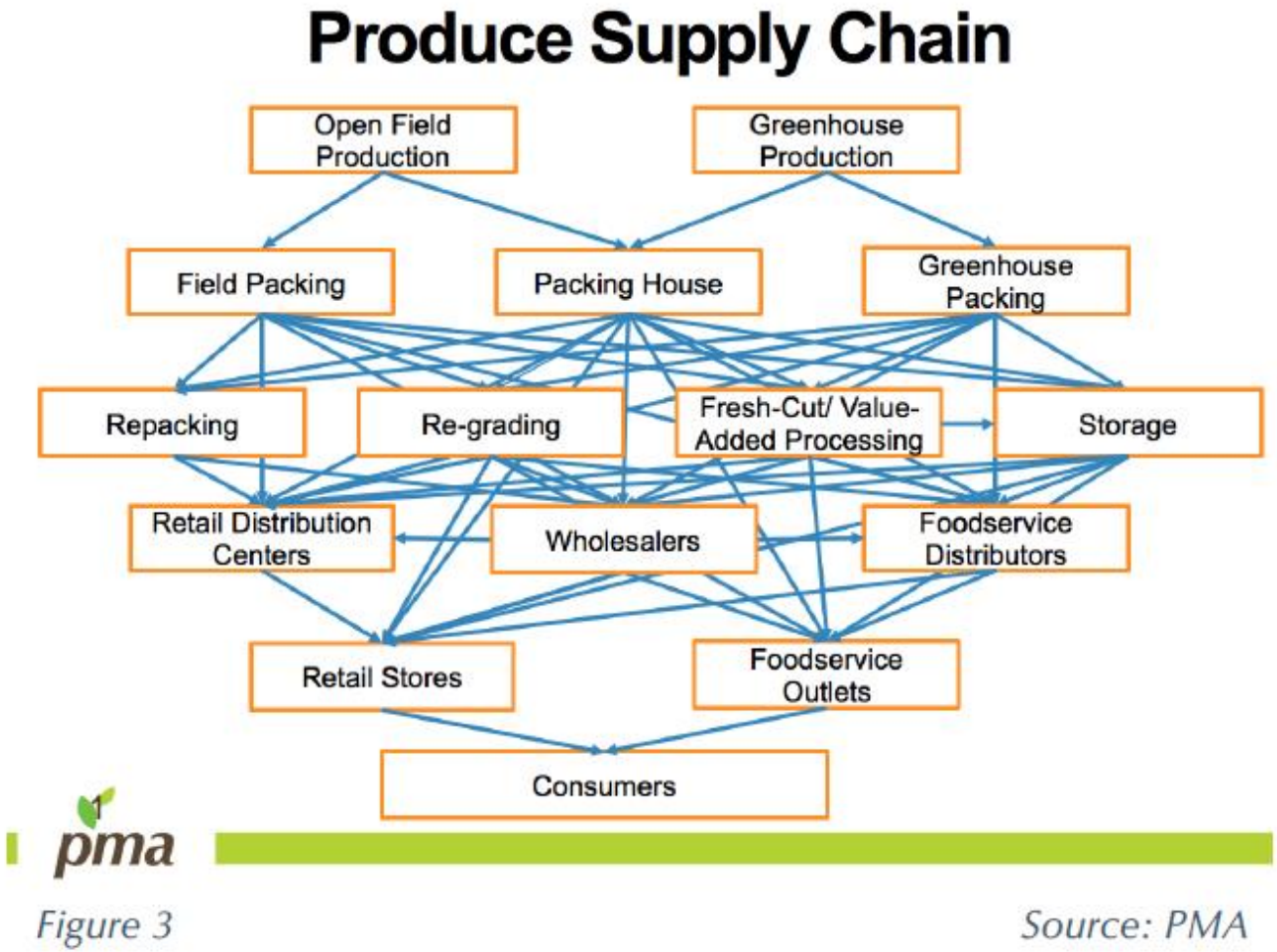


Figure 3 *Source: PMA*

FSVP- Evaluation & Approval

- FSVP importers must evaluate each foreign supplier's performance, including:
  - Processes and procedures for ensuring food safety, and
  - Its history of compliance with food safety requirements.
- FSVP importers must approve each foreign supplier and have written procedures to ensure use of approved foreign suppliers only.
  - May use an unapproved supplier on a temporary basis if necessary.

FSVP- Who conducts verification activities?

- Before importing, FSVP importers of produce must:
  - Select and conduct one or more appropriate verification activities.
- FSVP Importers must determine frequency of verification activities based on food risk and supplier evaluations.
- *FSVP Qualified individual*

Accreditation of Third Parties - Laboratory Accreditation for Analyses of Foods- Proposed § 1.1107

- Would require that food testing by an accredited lab (under the Third party accreditation rule) whenever food testing is conducted by or on behalf of an owner or consignee in any of the following five circumstances:
- (1) In response to explicit testing requirements (in the FD&C Act or implementing regulations) that address an identified or suspected food safety;
- (2) as required by FDA in a food testing order (issued under § 1.1108 of this rule);
- (3) to address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the FD&C Act (21 U.S.C. 350l) prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the FD&C Act (21 U.S.C. 350d) submitted after an order suspending the registration of a food facility, or as part evidence submitted for an appeal of an administrative detention order under section 304 (h)(4)(A) of the FD&C Act (21 U.S.C. 334(h)(4)(A));
- (4) in support of admission of an article of food under section 801(a) of the FD&C Act; and
- (5) to support removal from an import alert through successful consecutive testing.

FSMA


THE FOOD SAFETY MODERNIZATION ACT AND WOOD PALLETS
SOLUS GROUP
YOUR MATERIAL HANDLING DEPOT
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THANK YOU!
Stay Safe!

Juan L. Silva
jls46@msstate.edu