

Background

- 2017 Montana had 368 Food and Beverage Manufacturers according to D&B.
- Almost all of them small.
- Claude Smith with 34 years food manufacturing experience.
- 34 years of HACCP.
- Quality and Operations background primarily.

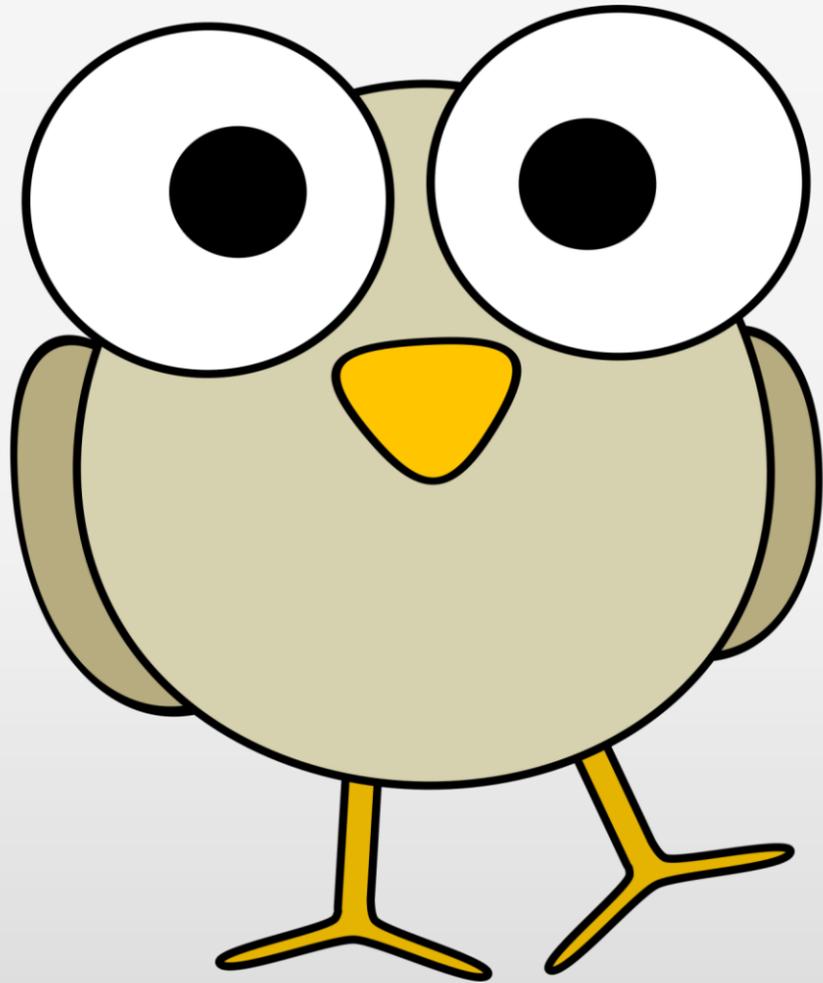
FOOD MANUFACTURING 101

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- Food manufacturing is a highly regulated industry.
- Food Safety being the primary goal.
 - One of the few industries where “losing a customer” might be more literal than you think.
- In 1902, the “Poison Squad” began eating Borax.
 - Then sulfuric acid, saltpeter, formaldehyde, etc.
 - How much of which food additives can you eat before symptoms appear?
- And Food Safety has moved forward ever since.

What is Food Manufacturing?



- **Manufacturing food that is sold or distributed to retailers.**
- In Montana, you will need a Wholesale Food license.
- Five Steps of Determination in Montana:
 - 1. DETERMINE WHETHER A LICENSE IS REQUIRED
 - 2. SUBMIT FOOD FACILITY PLAN
 - 3. SUBMIT FOOD PROCESSING PLAN AND LABELING EXAMPLES
 - 4. LICENSING PROCEDURE
 - 5. **FDA REGISTRATION**

FDA Registration



- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).
- Became effective on **December 12, 2003**.
- Facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States.
- Must renew such registrations every other year.
- There is no fee.
- Can be revoked if FDA suspects adulteration.

Food Safety Programs

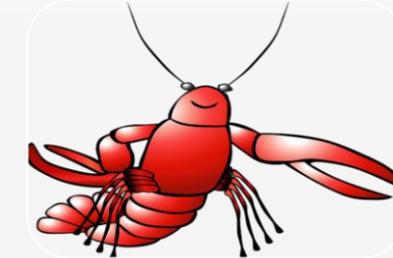
- Industry specific.



US Space program



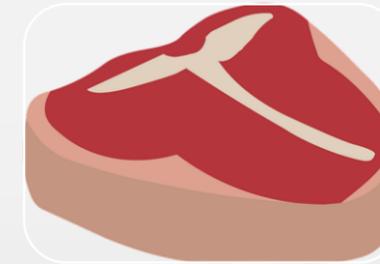
Low-acid canned food regs



FDA Seafood HACCP regs



FDA Juice HACCP regs



USDA HACCP regs



Codex HACCP Annex



NCIMS Dairy HACCP



*BUT
THE BIG
ONE.....*

FSMA

- The law created rules that created exemptions that created questions. Especially for small manufacturers.



The problem and challenge is real.

- Foodborne illness is a significant burden
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- Food supply more high-tech and complex
 - 15 percent of U.S. food supply is imported
 - More foods in the marketplace
 - New hazards in foods not previously seen

FSMA is a sweeping law for the FDA, with new and enhanced enforcement powers.

- It is a prohibited act to fail to meet the requirements.
- FDA will have **Administrative Compliance** tools such as;
 - Voluntary correction,
 - Administration detention,
 - Voluntary or mandatory recall,
 - Administrative suspension of facility registration.
- FDA will have **Judicial Enforcement** tools such as;
 - Seizure actions
 - Injunction action
 - Criminal prosecution.

The **key requirements** **target all** facilities that are required to register with the FDA.

***Some small manufacturers not aware of this requirement to register.

On October 10, 2003, FDA issued an interim final rule to implement amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

- Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that **manufacture, process, pack, or hold food for human or animal consumption in the U.S.** to register with FDA by December 12, 2003.
- FSMA mandates re-register every 2 years.

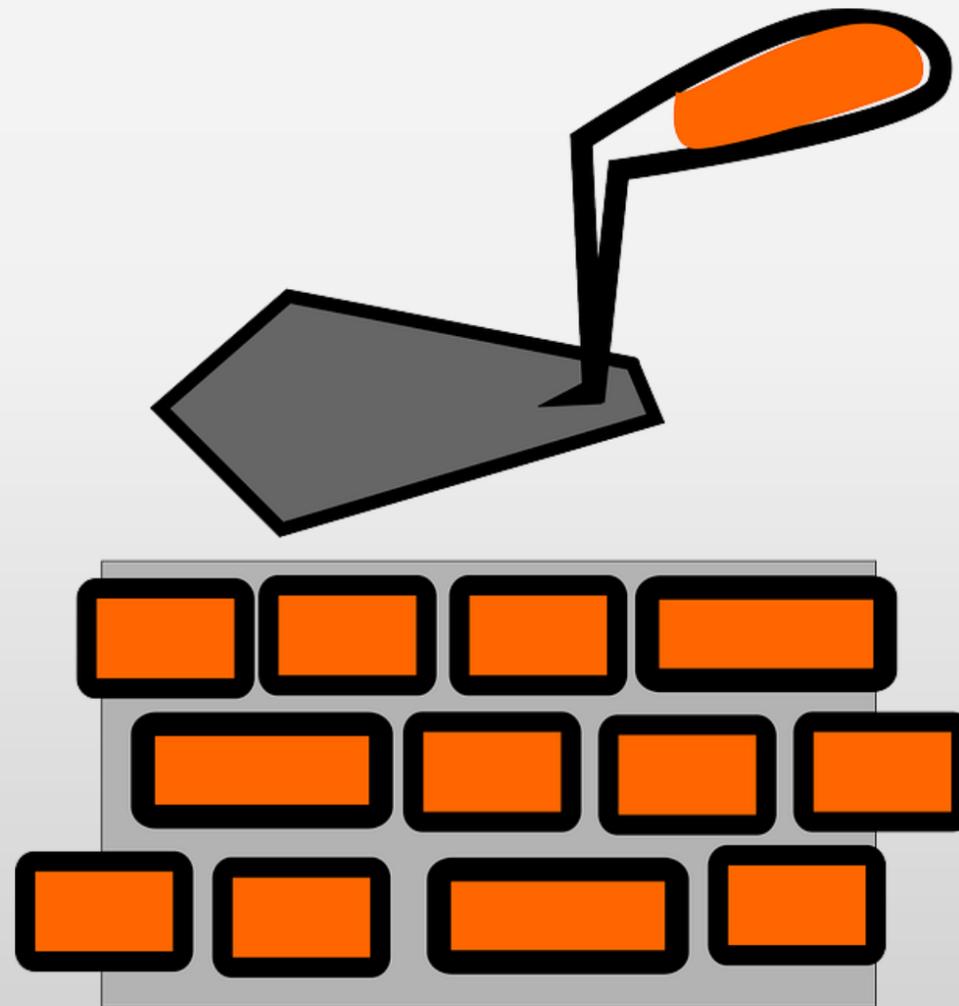
Who does not have to register?

****More confusion here.*

1. FARMS
2. RETAIL FOOD ESTABLISHMENTS
3. RESTAURANTS
4. NON-PROFIT FOOD FACILITIES
5. FISHING VESSELS
6. FACILITIES EXCLUSIVELY UNDER USDA REGULATION
7. SOME FOREIGN FACILITIES

Reference - (21 CFR 1.226)

There are seven Foundational Rules in place.
Most small manufacturers will have to comply with one or two.



THEY ARE:

1. Preventive Controls for Human Food
2. Preventive Controls for Animal Food
3. Produce Safety
4. Foreign Supplier Verification
5. Third Party Certification
6. Food Defense (adulteration)
7. Sanitary Transport

Rule #1

The rule sets requirements for a written Food Safety Plan that includes:

1. HAZARD ANALYSIS
2. PREVENTIVE CONTROLS for those hazards
3. MANAGEMENT of those hazards (which means MONITORING)
4. Taking CORRECTIVE ACTIONS when necessary
5. and VERIFYING those controls are working.
6. Each facility must have a Qualified Individual preparing, signing, and verifying the Food Safety Plan.
7. Must be trained and certified as a PCQI.



Rule #1

The definition of a 'farm' is clarified to cover two types of farm operations.

Farms are NOT subject to the Preventive Controls rule.



Rule #1

There is a **Primary Production Farm** defined and a **Secondary Activities Farm** defined. Primary Production Farm is an operation under one management in one general but not necessarily contiguous location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

Rule #1

A Secondary Activities Farm is an operation NOT located on the Primary Production Farm that is devoted to harvesting, packing and/or holding RAC. It must be **owned** by the Primary Production Farm that supplies the majority of the RAC harvested, packed, or held by the Secondary Activities Farm.

**Please note that any Farm operation conducting activities on produce are still bound by the Produce Safety Rule.*

Rule #1

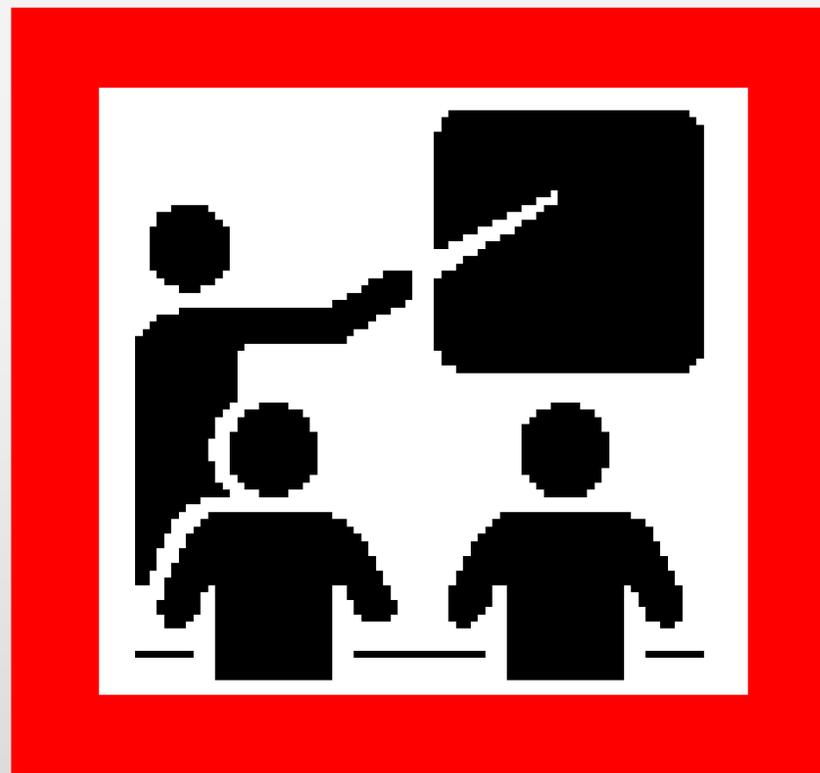
The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control.



eed.

Rule #1

Current Good Manufacturing Practices (CGMPs) are updated and clarified. Some of the previously nonbinding provisions, such as education and training, are now binding.



Rule #1

Lastly, a staggered schedule of compliance dates with this Preventive Controls for Human Food rule has been established based on business size.

- For the largest businesses, they had to be in compliance within one year.
- Small businesses with fewer than 500 Full Time Equivalent Employees had two years.
- Very Small Businesses (with sales less than \$1 million per year in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale) are ***EXEMPT**.

** But most or all food distributors are requiring a Preventive Controls Plan of their suppliers regardless. So the exemption is essentially meaningless.*

Rule #1

Who's Exempt from this Rule?

1. USDA inspected facilities.
2. Those subject to FSMA Produce Safety Rules.
3. Those subject to seafood and juice HACCP rules.
4. Certain microbiological aspects of low-acid and acidified canned foods.
5. Dietary supplement makers in compliance with pertinent cGMP's.
6. Certain "Qualified" facilities.
7. Activities within the "Farm" definition conducted on site.
8. A large number of "food/process" combinations.

- 6. "Qualified Facilities"
 1. A Very Small Business as defined with annual sales of human food less than \$1,000,000. –BUT–
- General provisions,
- Current Good Manufacturing Practices,
- Modified requirements that apply to a qualified facilities*,
- Certain recordkeeping requirements, and
- Withdrawal of modified requirements that apply to qualified facilities.
- *(2)(i) An attestation that you have identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; **or**
- *(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

Breweries and Distilleries

**** This gets asked a lot.*

- Must register with FDA so technically are bound by FSMA.
 - FDA considers their products “food”.
- But jurisdiction is handled by TTB.
- So will not be bound by Preventive Controls.
 - Current situation is more inspections from FDA, TTB, and State.
 - Any TTB knowledge of adulterated beer WILL result in FDA inspection.
 - Still must follow cGMP’s. CFR 117
 - Some Preventive Controls for Animal Food requirements.

Rule #2

Preventive Controls for Animal Food.



- Facility will have to follow newly issued Current Good Manufacturing Practices.
- Processors (such as breweries and distilleries) that are already following human cGMP's are in compliance so long as they are only supplying a by-product and the by-product is properly labelled in an appropriate container.
- Any further processing (pelletizing, drying, etc.) of by-products will require cGMP program and Preventive Controls..
- Preventive Controls and a written Food Safety Plan are required.
 - Hazard Analysis.
 - Preventive Controls.
 - Monitoring and Verification of the PC's.
 - Recall Plan.

Rule # 2

Exemptions



FARMS ARE EXEMPT

- An operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.
 - Allows farms to pack or hold raw agricultural commodities (food in its raw or natural state) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

Rule #3

PRODUCE SAFETY

- Science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.
- **Reminder:** 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.



Rule # 3

Key Requirements



Key Requirements in following 6 Areas

1. Agricultural Water
 1. Requirements for Quality and Testing.
2. Biological Soil Amendments
 1. Raw Manure.
 2. Stabilized Compost.
3. Sprouts
4. Domesticated and Wild Animals.
5. Worker Training and Health and Hygiene.
6. Equipment, Tools, and Buildings.

Rule #3

Exemptions

EXEMPTIONS

1. Produce that is not a Raw Agricultural Commodity.
2. Produce that is rarely consumed raw.
 1. 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.
3. Food Grains.
4. Produce used for on-farm consumption only.
5. Very small Farms.
 1. average annual value of produce sold during the previous three-year period of \$25,000 or less



Rule #3

Yet more Exemptions



MORE EXEMPTIONS

- Produce that receives adequate commercial processing.

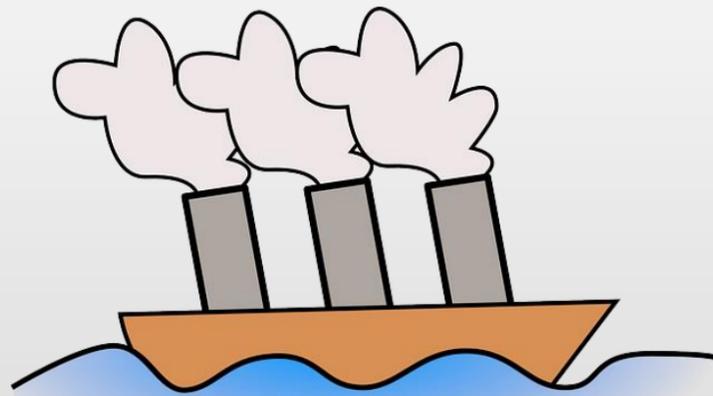
QUALIFIED EXEMPTIONS

- Farms that have food sales averaging less than \$500,000 per year during the previous three years **AND** sales to *qualified* end-users must exceed sales to all others combined during the previous three years. (*qualified= consumer, restaurant, or nearby retailer.*)
- Still some requirements though.
- Qualified Exemption can be withdrawn.
- Withdrawn Exemption may be reinstated.
- May be able to request a VARIANCE.

Rule #4

FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

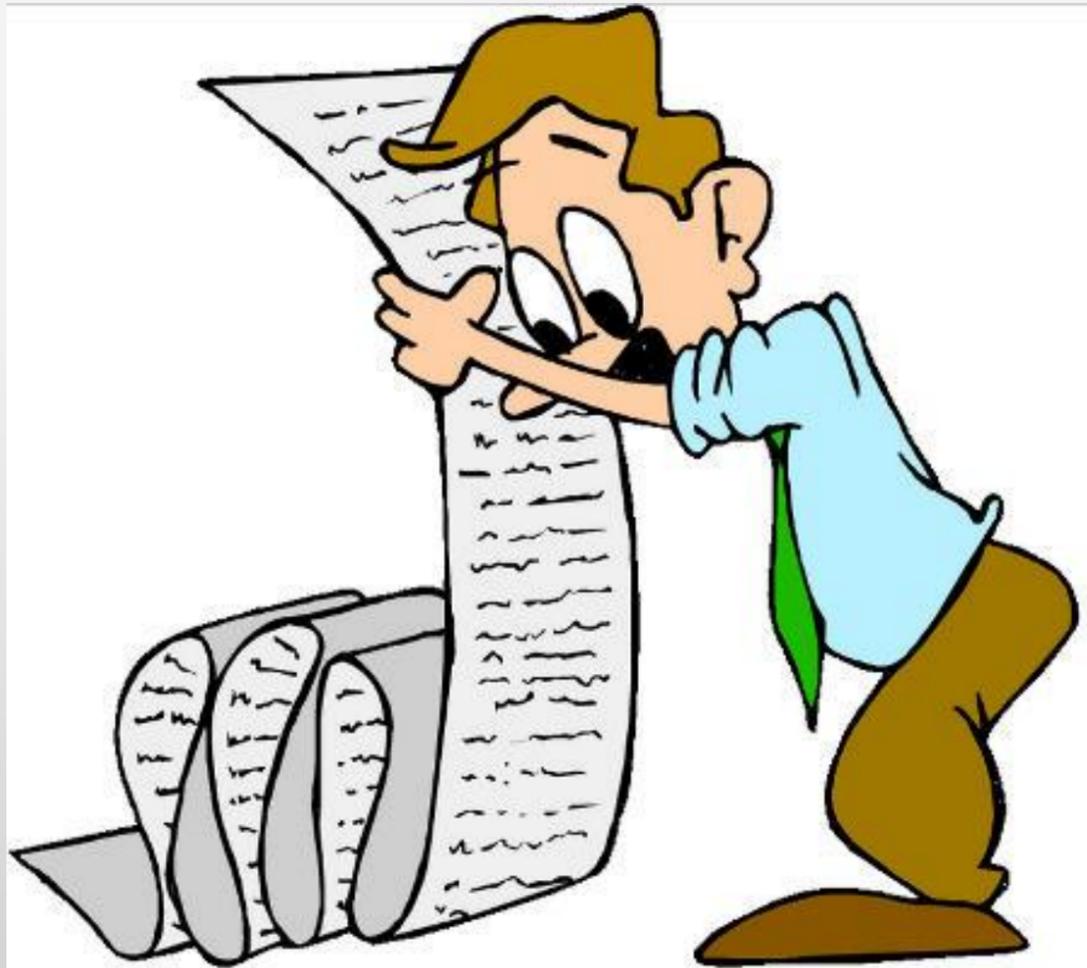
Huge impact on small
manufacturers.



- Key Requirements in following Areas:
 1. Scope.
 2. Hazard Analysis.
 3. Evaluation of Food Risk and Supplier Performance.
 4. Supplier Verification.
 5. Corrective Actions.
 6. Exemptions and Modified Standards.

Rule #4

SCOPE



- Who is covered?
 - *the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry*
- What is an FSVP?
 - *It is a program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.*
 - Basically, it's a Preventive Controls Plan.
 - Required of each food and each Supplier.

Rule #4

Exemptions and Modified Standards



- Requirements for dietary supplements vary, depending on whether the material is a finished product or an ingredient/component.
 - If you are compliant with the currently required dietary supplement CGMP's you are exempt from most of FSVP.
 - Or if an importer has a customer who must comply with the dietary supplement CGMP's and can obtain written assurance.
 - Importers of other dietary supplements, including finished products, would be required to comply with most of the standard FSVP requirements (except the hazard analysis requirement), but their verification activities would focus on compliance with the dietary supplement CGMP regulations.
- Modified FSVP requirements are established for very small importers and importers of food from certain small suppliers.
 - very small importer is consistent with the definition of very small business in the preventive controls rules: a sales ceiling of \$1 million for human food and \$2.5 million for animal food
- There are other exemptions including certain categories of foods.

Rule #5

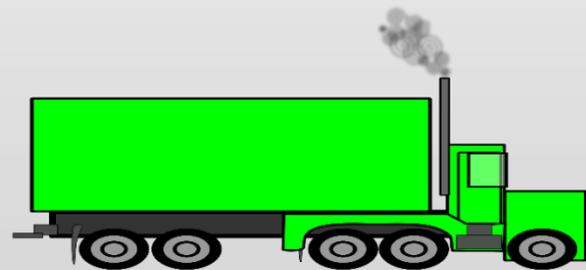
Accreditation of Third Party
Certification Bodies to Conduct
Food Safety Audits and Issue
Certifications

*****We don't care about this today.**

- **Key Requirements in following Areas:**
 1. **Scope.**
 2. **Requirements for Recognized Accreditation Bodies.**
 3. **Requirements for Third Party Certification Bodies.**
 4. **Related FDA Actions.**
 5. **Exemptions.**

Rule #6

SANITARY TRANSPORT OF HUMAN AND ANIMAL FOOD



1. The rule covers:

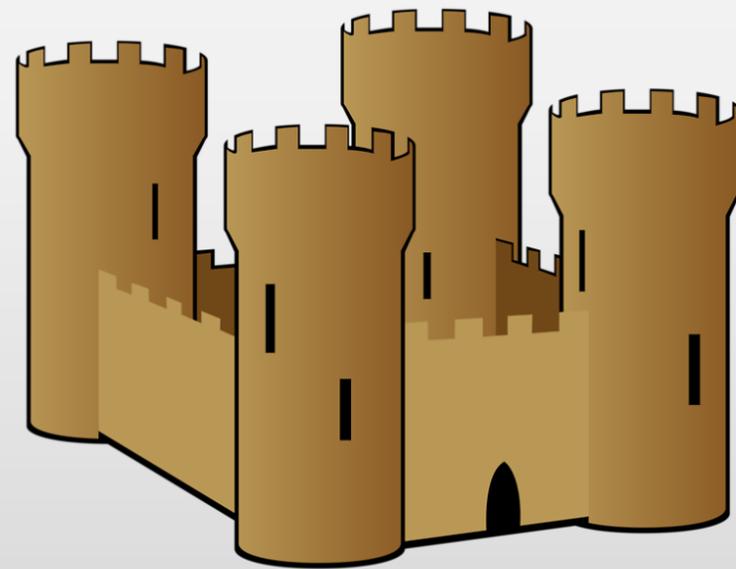
- Shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, regardless if shipment is interstate.
- Shippers in other countries if the food is to be consumed in the US. Air and rail included for them.
- Food shipped to export until the food reaches the port.

2. Not covered:

- Canada to Mexico via US or vice-versa.
- Companies with less than \$500,000 in average annual revenue.
- Farms, compressed gases and food contact materials, human food by-products intended for animal food as is, live food except molluscan shellfish.
- AND, food completely enclosed by a container, except for temperature controlled food.

Rule #7

FOOD DEFENSE



1. Intention is to prevent acts that could cause wide-scale harm.
 - Economic adulteration is addressed in Preventive Controls.
2. Must have average sales above **\$10,000,000** annually for the preceding three years.
3. **So probably not relevant to small manufacturers.**

Implementation Schedule

Final Rule	Date Issued	Compliance Date Large Business*	Compliance Date Small Business**	Compliance Date Very Small Business***
CGMP and Preventive Controls for Human Food	Sept. 17, 2015	Sept. 19, 2016 [†]	Sept. 18, 2017 [†]	Sept. 17, 2018
CGMP and Preventive Controls for Animal Food	Sept. 17, 2015	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs) [†]	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs) [†]	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)
Produce Safety	Nov. 27, 2015	Jan. 26, 2018 [‡]	Jan. 26, 2019 [‡]	Jan. 26, 2020 [‡]
Foreign Supplier Verification Program	Nov. 27, 2015	May 27, 2017 [§]	Not applicable	Not applicable
Third Party Accreditation and Certification	Nov. 27, 2015	Requirements go into effect after FDA publishes Model Accreditation Standards		
Sanitary Transportation of Human and Animal Food	April 6, 2016	April 6, 2017	April 6, 2018	Not applicable
Food Defense/Intentional Adulteration	May 27, 2016	July 26, 2019	July 26, 2020	July 26, 2021

*** Large Business Definitions: *All Rules*** – Business that does not meet the definitions for “small business” or “very small business”

**** Small Business Definitions:**

- *CGMP and Preventive Control Rules for Human and Animal Food* – Business with less than 500 full-time equivalent employees
 - *Produce Safety* – Business with more than \$250,000 but no more than \$500,000 in average annual produce sales
- *Sanitary Transportation* – Business, other than a motor carrier 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
 - *Food Defense/Intentional Adulteration* – Business with less than 500 full-time equivalent employees

***** Very Small Business Definitions:**

- *Preventive Controls Human Food* – Business with less than \$1 million in annual human food sales plus market value of human food not sold;
- *Preventive Controls for Animal Food* – Business with less than \$2.5 million in animal food sales plus market value of animal food not sold;
 - *Produce Safety* – Business those with more than \$25,000 but no more than \$250,000 in average annual produce sales
 - *Food Defense/Intentional Adulteration* – Business averaging less than \$10,000,000 in annual human food sales plus market value of human food not sold

† **Supply Chain Program Compliance: *Human Food*** – Later of: 1) six months after supplier is required to comply with the applicable rule; or 2)

March 17, 2017 (large business) or Sept. 18, 2017 (small business); *Animal Food* – Later of: 1) six months after supplier is required to comply with the applicable rule; or 2) Sept. 18, 2017 (large business) or Sept. 17, 2018 (small business)

‡ **Produce farms** have an additional two years to comply with certain water-related requirements. Separate compliance dates applicable to sprouts.

§ **All importers** are to comply with FSVP requirements 18 months after the final rule or six months after their foreign suppliers’ reach their FSMA compliance deadlines, whichever is later. “Very small importers” (importers with average annual sales of less than \$1 million for human food and \$2.5 million for animal food plus market value of human food or animal food not sold) and “importers of food from very small foreign suppliers” are subject to modified requirements.

RESOURCE CONSIDERATIONS

- Practical knowledge and experience is essential.
- Huge variety of technologies, processes, risks in food manufacturing.
- Small manufacturers' questions will be practical, not theoretical.
- Have practical answers.
- Guidance comes from FDA. They are the pace-setter.
 - Stay informed of latest changes/updates.
- But, academic input will be needed for process validations.