FSMA: Update on Preventive Control Rule

by
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- These two proposed rules are the first among five rules that would lay the cornerstone of a prevention-based, modern food safety system.

- These proposed rules work together to address hazards in the commodities FDA regulates and to address food safety both in domestically produced and imported foods.

- We expect to soon propose the Foreign Supplier Verification Program, Preventive Controls for Animal Food and Accredited Third Party Certification.

Human PC vs. Animal PC

- Very similar, both establish new sections in CFR
- Animal PC established cGMPs
- Human PC modifies some CGMPs
- Animal PC does not include allergens as a hazard
- Potential for different definitions of very small business

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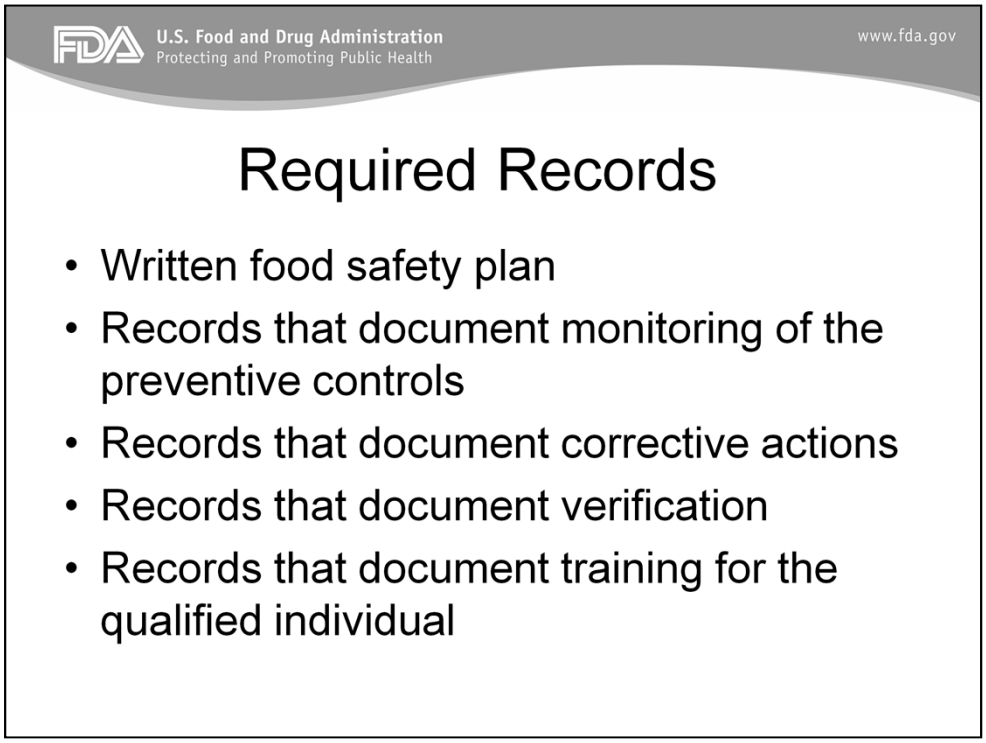
Current Good Manufacturing Practices Elements*

- Personnel.
- Plant and grounds.
- Sanitary operations.
- Sanitary facilities and controls.
- Equipment and utensils.
- Processes and controls.
- Warehousing and distribution.

Preventive Control Elements

Requirements for a food safety plan

- Hazard analysis.
- Preventive controls for hazards that are reasonably likely to occur.
- Plan must be written
- Recall plan for animal food in which there is a hazard that is reasonably likely to occur.
- Monitoring.
- Corrective action.
- Verification.
- Records required for preventive controls.
- Control for supplies



(4) Records that document verification, include as applicable, those related to:

(i) Validation,

(ii) Monitoring,

(iii) Corrective actions,

(iv) Calibration of process monitoring and verification instruments,

(v) Records review, and

(vi) Reanalysis;

Other Features of the Rule

- Updates definitions in 21 CFR Part 1
  - Clarifies the activities that are included in the definition of the term “facility”
  - This in turn clarifies activities that constitute on-farm manufacturing, processing, packing and holding of food
- Proposes definitions for a small and a very small business

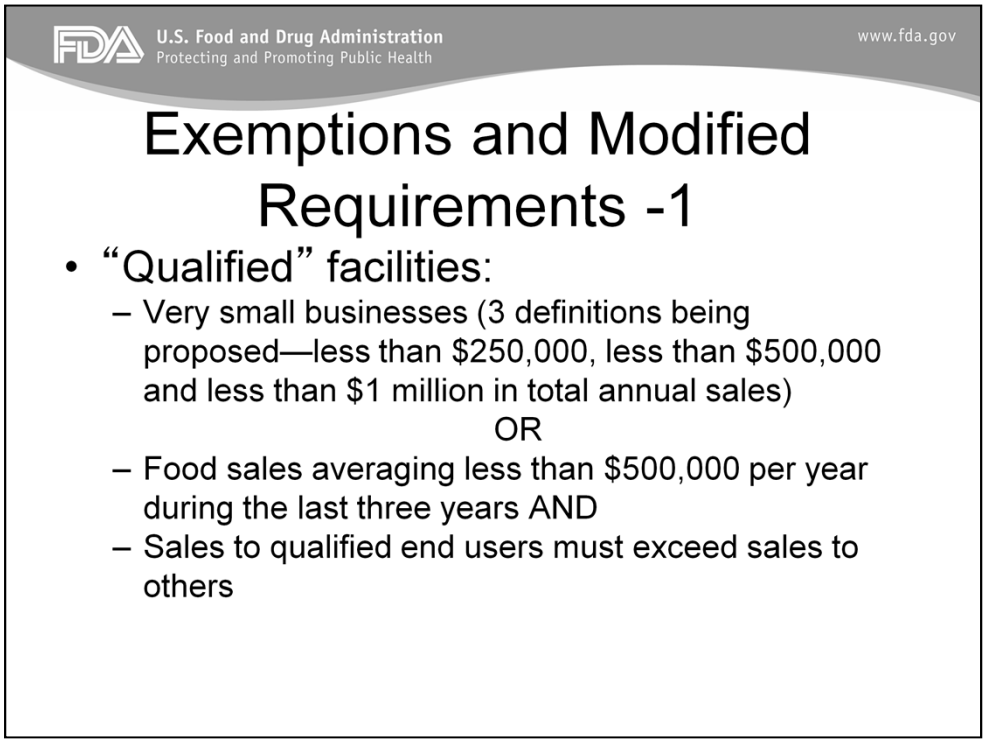
These were required by FSMA section 103

- Facilities that would be covered by the proposed rule are those that manufacture, process, pack or hold human food

- In general, facilities required to register with FDA under current regulations are covered.

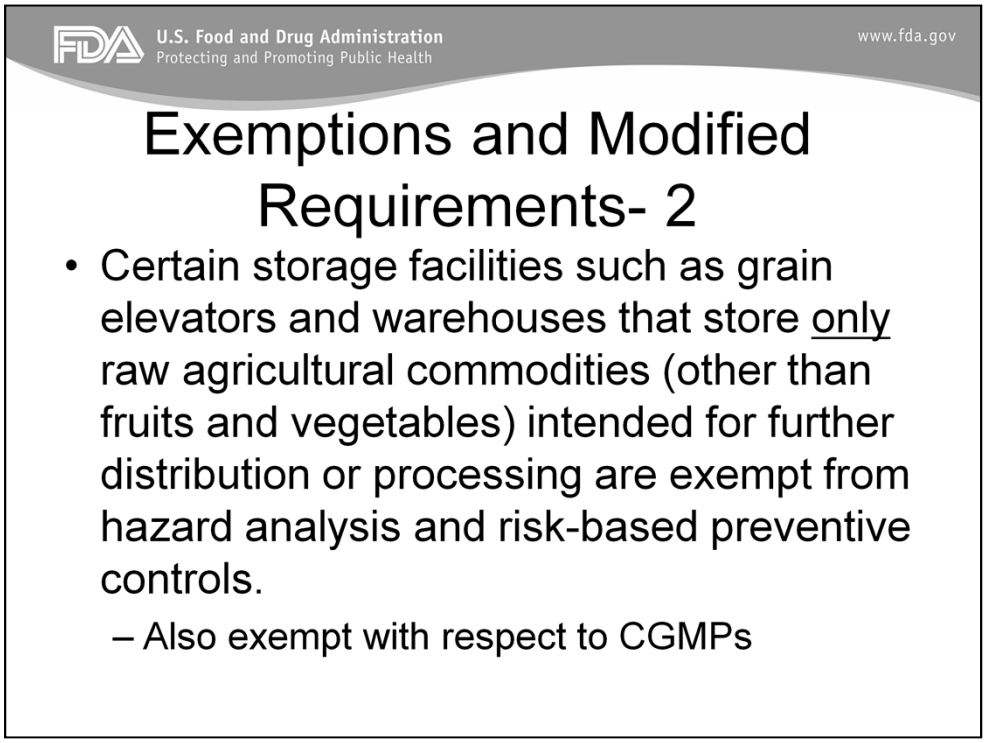
- The proposed rule would apply to domestic and imported food

- Some exemptions and modified requirements are being proposed.



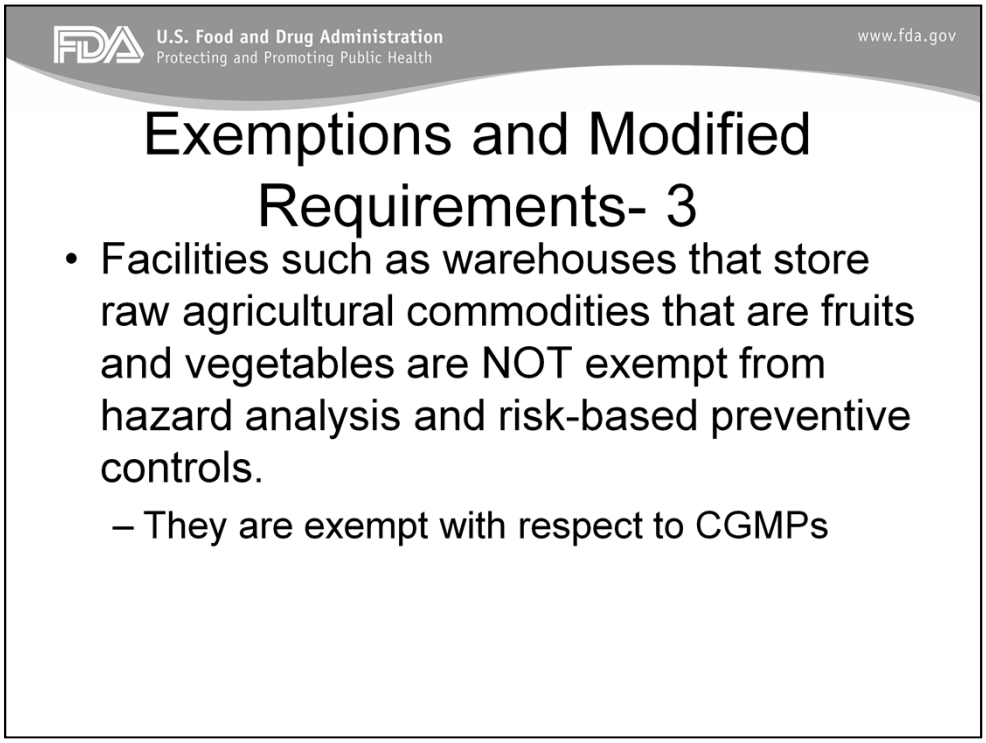
- A number of exemptions and modified requirements are being proposed:

- "Qualified" facilities:
  - Very small businesses (3 definitions being proposed—less than $250,000, less than $500,000 and less than $1 million in total annual sales)
  - Food sales averaging less than $500,000 per year during the last three years AND
  - Sales to qualified end users must exceed sales to others.
    - Qualified end users are consumers (in any location), and restaurants and retail food establishments in the same state or within 275 miles of the facility that purchase the food for sale directly to consumers.



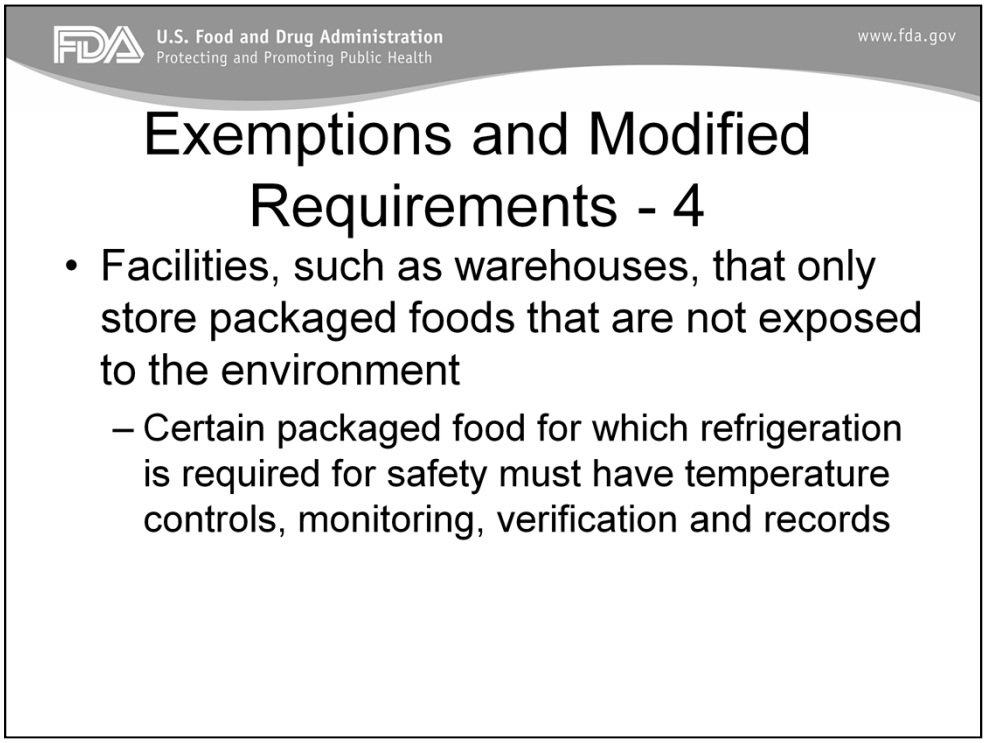
Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.

We are reestablishing the “RAC exemption” in existing CGMPs (21 CFR 110.19(a))

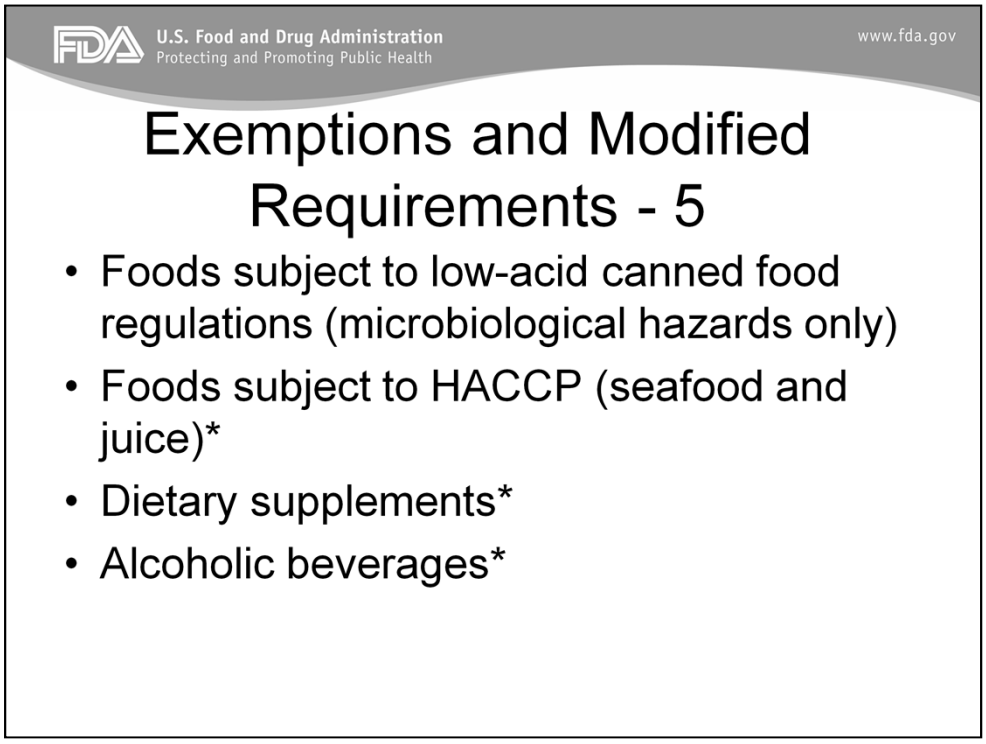


- FSMA provided FDA with authority to exempt or modify requirements for storage of RACS but specifically excluded storage of fruits and vegetables intended for further distribution or processing.

- The exemption with respect to CGMPs is the current RAC exemption.



- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment, are exempt from the requirements for hazard analysis and risk-based preventive controls, except:
    - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records



- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages
- The types of businesses listed would be exempt from food safety plan requirements but are not exempt from GMP requirements

- Farm-related exemptions also are being proposed. They are:

- Activities within the definition of "farm," including farm activities that are covered by the proposed produce rule, and

- Certain low-risk manufacturing/processing activities conducted by small/very small businesses on farms for specific foods

Grain Elevators and Exemptions

- Are grain elevators exempt from cGMPs
  - It depends but likely yes
- Are grain elevators exempt from preventive controls (Part C)
  - It depends but likely no (as proposed)
  - Holding definition is key
- Are farms or mixed facilities that hold their own grain exempt
  - Yes and they can also sift and fumigate

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Holding

- **Holding** means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a RAC, 201(r) FFDCA into a processed food as defined in 201(gg) FFDCA

Manufacturing/processing

- Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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Might you be small or very small?

- Food Sector Report (ref 32)
  - Estimate 4461 pet food and animal feed firms
    - 4439 met definition of small business (<500)
    - Produce 86.9% of manufactured pet food and animal feed based on sales
  - Very small business
    - <$250,000 = 3 and 0.003% of sales (0.5%)
    - <$500,000 = 3 and 0.003% of sales (1%)
    - <$1M = 619 and 1.71% of sales (2%)

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Seeking Comments

- Should the following be required
  - Environmental testing
  - Produce testing
  - Supplier verification progam
- Should grain elevators be exempt
  - Is holding correctly/adequately defined
  - Is processing correctly/adequately defined
  - What is the cost of including grain elevators

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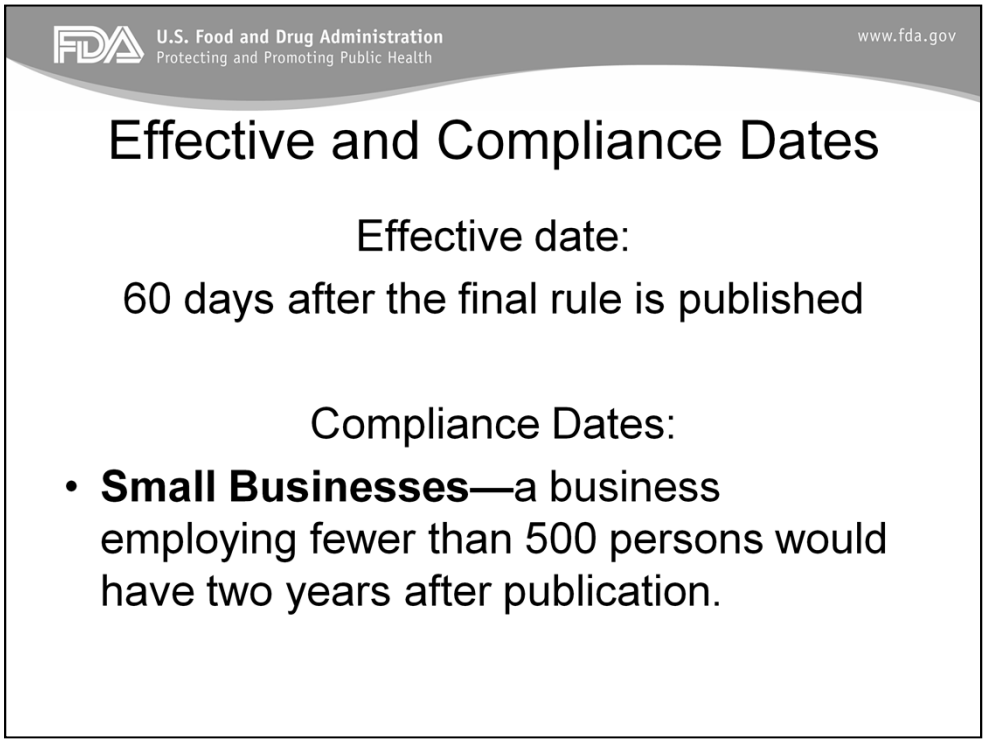
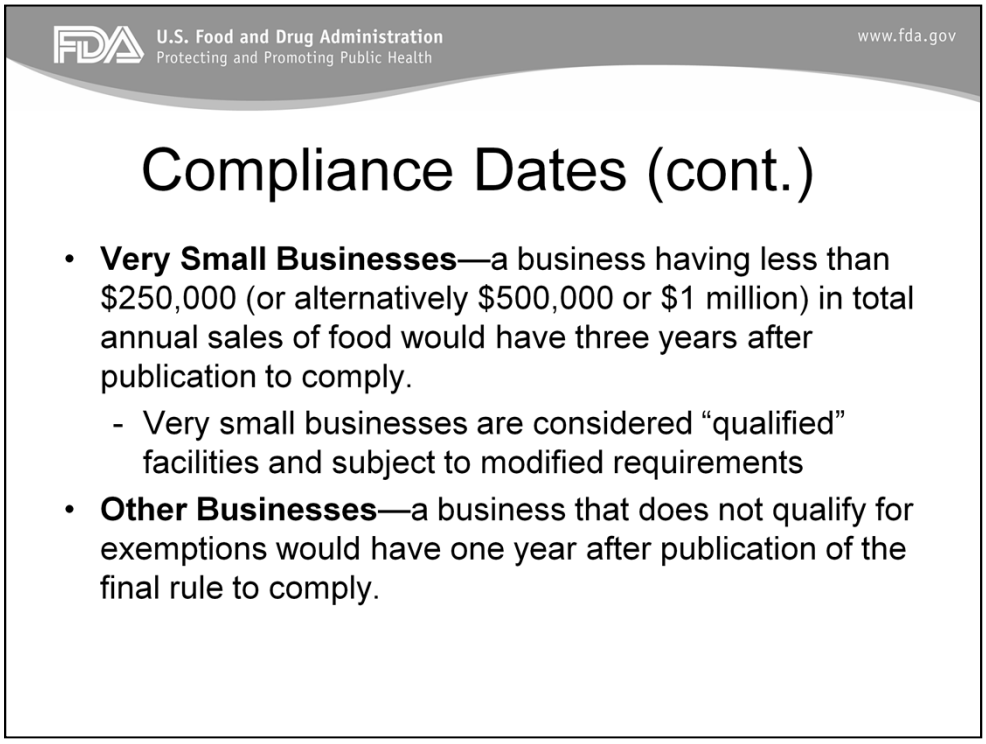


- Compliance dates for the preventive controls rule also are staggered depending on facility size

Small businesses

- Small businesses, defined as employing fewer than 500 persons and not qualifying for an exemption, would have two years after publication



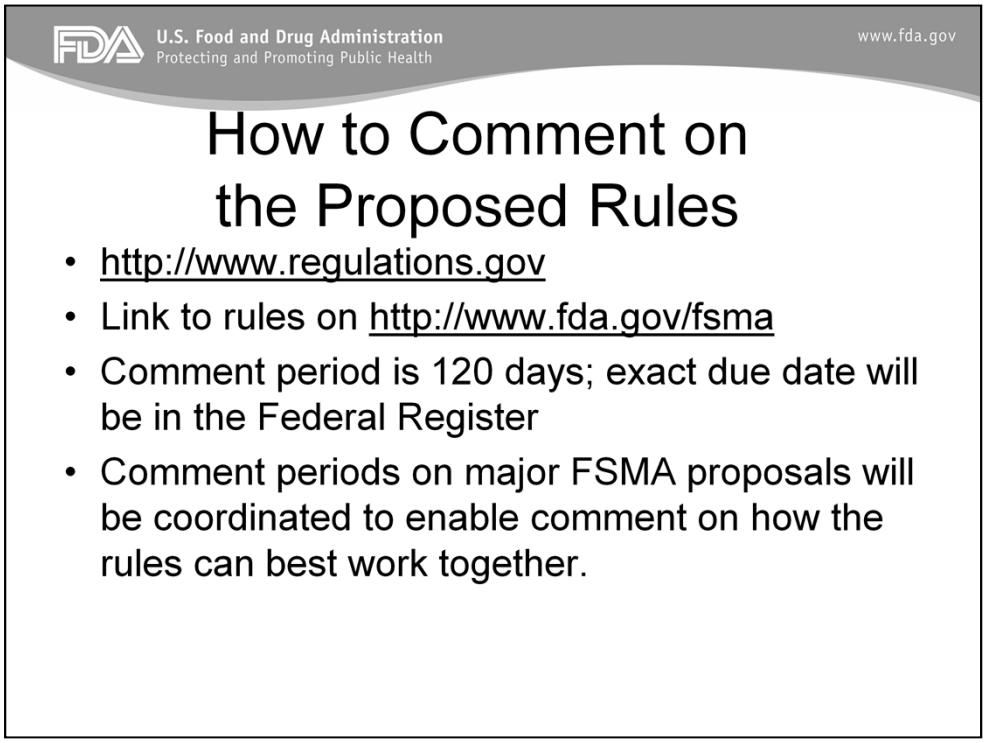
Very small businesses

- Very Small Businesses—Three options are being proposed for the definition of a very small business: less than $250,000, less than $500,000 or less than $1,000,000 in total annual sales of food, adjusted for inflation. Very small businesses would have three years after publication of the final rule to comply.

- Very small businesses are considered "qualified facilities" and subject to modified requirements for preventive controls.

Other businesses

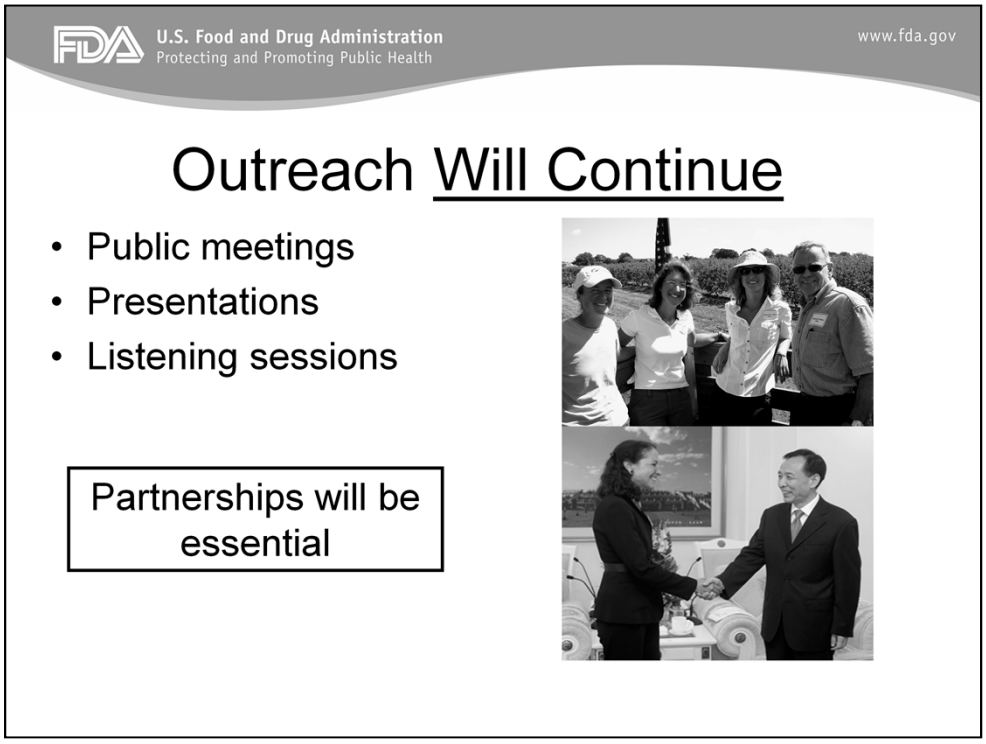
- Other Businesses—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.



▪We encourage comments on the proposed rule from a wide variety of stakeholders.

▪The proposed and final rules and supporting documents will be filed in FDA's official docket on http://www.regulations.gov and also can be accessed at www.fda.gov/fsma.

▪ The comment period is 120 days and the exact date will be set in the Federal Register. However, we plan to coordinate the comment periods on the major FSMA proposals as fully as possible to enable public comment on how the rules can best work together to create an integrated and effective food safety system.

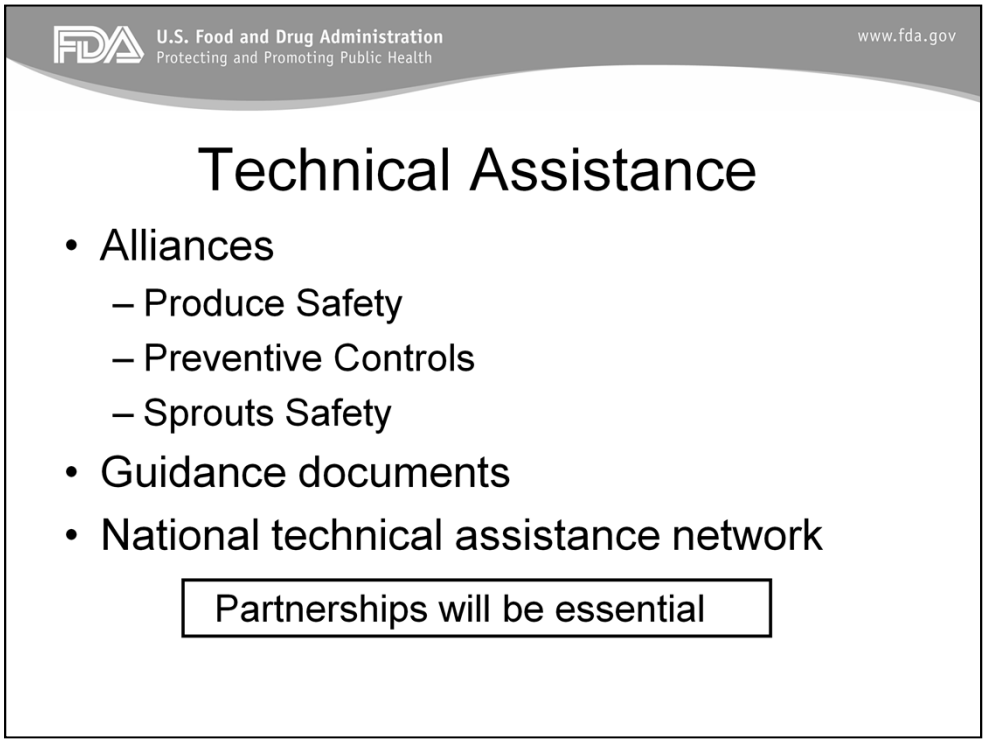


Outreach

• FDA conducted extensive outreach before the proposed rules were issued and that outreach will continue

•We will work closely with our government partners at the state and federal levels and with stakeholders.

• We will hold public meetings across the country, give presentations and hold listening sessions to explain the proposed rules and get comments.



Technical assistance

• Will help farms comply with produce safety requirements and facilities comply with the preventive control requirements once the final rules are issued.

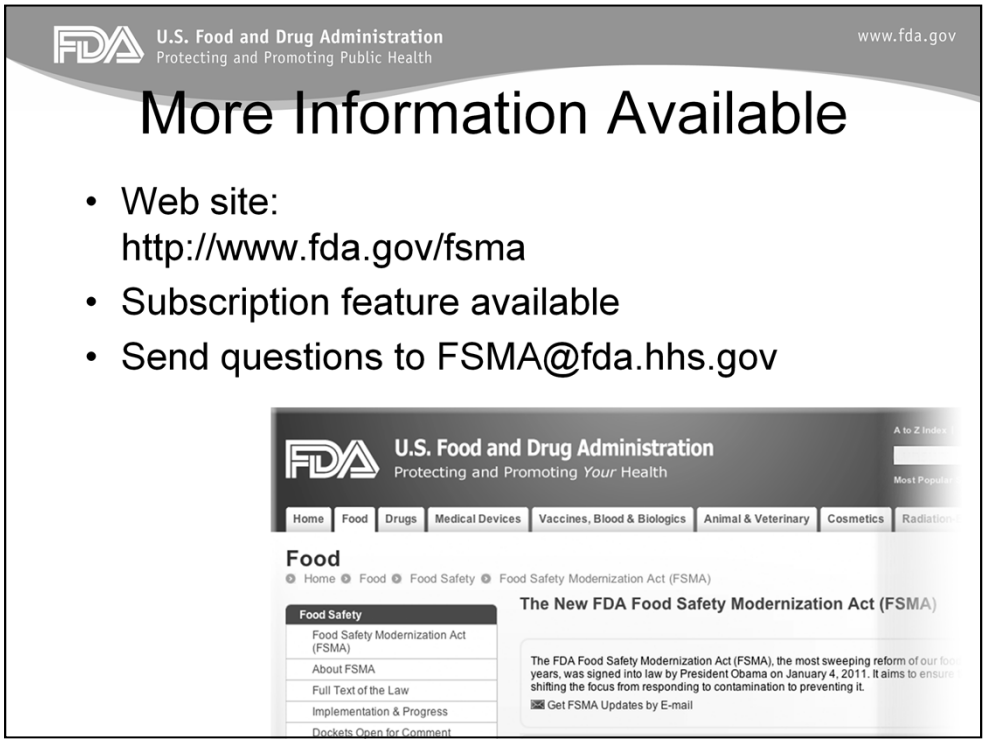
• We are working with stakeholders through three public-private partnerships known as alliances.

• The alliances are developing training materials and will disseminate information to industry, particularly small and very small businesses.

- The Produce Safety Alliance was established in partnership with Cornell University
- The Food Safety Preventive Controls and Sprouts Safety Alliances were established in partnership with the Illinois Institute of Technology

•FDA also intends to issue a number of guidance documents to help industry comply with requirements.

•A national network to provide technical assistance is under development.



- The FSMA web site, at fda.gov/fsma, has a number of materials on the proposed rules that you can download.
    - They also are available in several languages.

- We have a subscription feature to get the latest news

- Stakeholders can send questions to FSMA@fda.hhs.gov.
    - We will continue to update the frequently-asked-questions on our web site.

- I hope this overview has been helpful and we look forward to continuing our discussions on the rules during the comment period.

Thank You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