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FDA's Proposed Rule to Protect Against Intentional Food Adulteration—What Industry Needs to Know

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Overview of the Proposed Rule

- Published in the Federal Register on December 24, 2013
- Required by the FDA Food Safety Modernization Act ("FSMA")
- Would apply to major U.S. and international food processors and handlers
- Goal of the Rule: to prevent acts on the food supply intended to cause large-scale public harm
- Would require largest food facilities to have a written food defense plan that addresses significant vulnerabilities in a food operation

FSMA- Brief Background

- Signed into law on Jan. 4, 2011 (Pub. L. 111–353)
- Enables FDA to better protect public health by helping to ensure the safety and security of the food supply
- Provides Agency with enforcement authorities to:
  - Achieve higher rates of compliance with prevention- and risk-based safety standards, and
  - Better respond to and contain problems when they occur

Who Would Be Covered by the Rule?

- U.S. and international facilities that manufacture, process, pack, or hold food
- Entities required to register as food facilities under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Who Would Be Exempt from the Rule's Coverage?

- Farms
- Other food facilities that are not required to register under section 415 of the FD&C Act
- "Qualified facilities"

Qualified Facilities

- The Rule defines a qualified facility as:
  - A very small business (a business that has less than $10 million in total annual sales of food, adjusted for inflation), but such a facility may be required to provide to FDA documentation relied on to demonstrate that the business is very small, **or**
  - A facility whose average annual monetary value of food sold directly to qualified end users during the preceding three years exceeds that sold to all other purchasers **and** whose average annual value of all food sold during that three-year period is less than $500,000

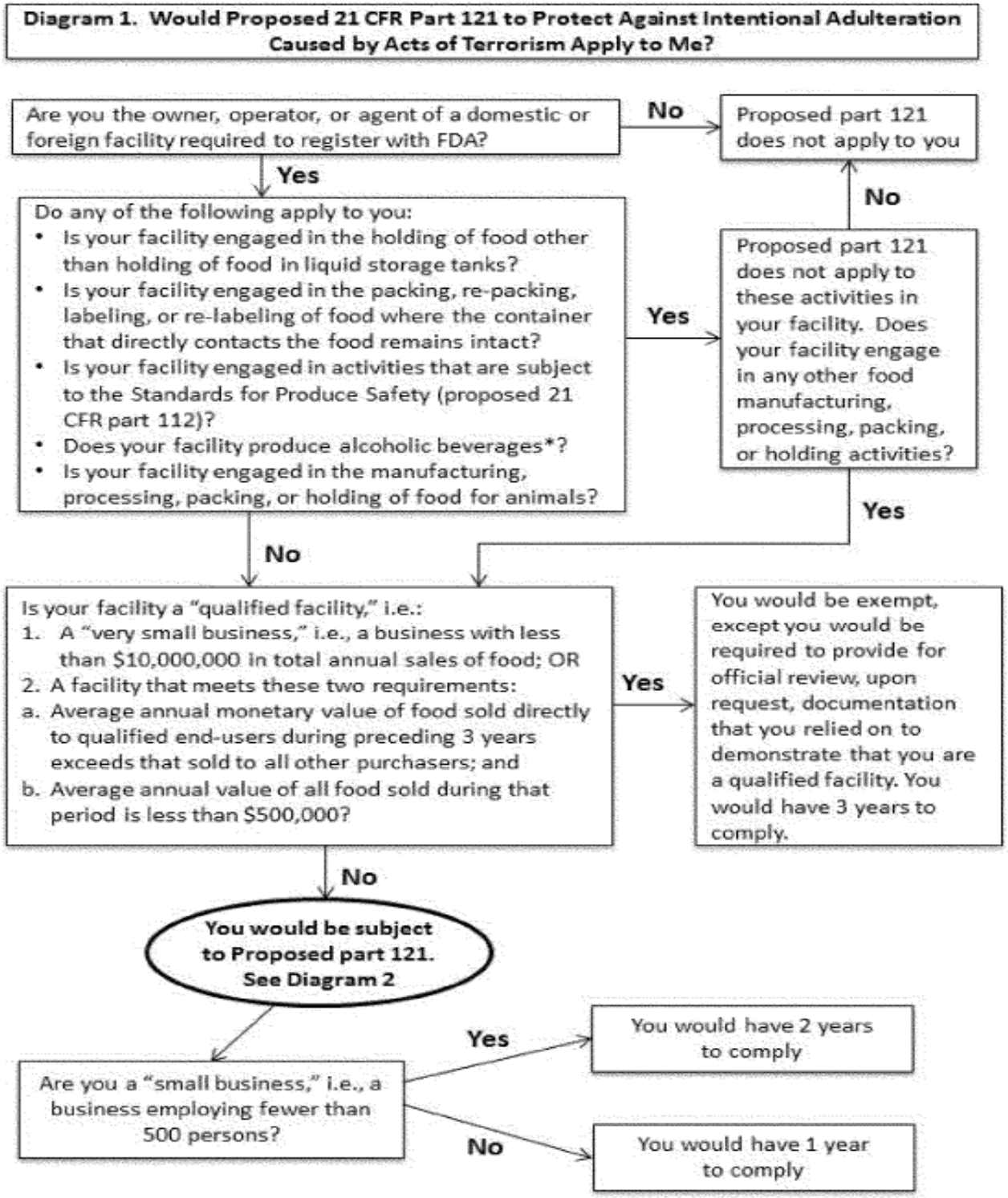
Activities That Would Be Exempt from the Rule's Coverage

- The holding of food, except the holding of food in liquid storage tanks
- The packing, repacking, labeling, or relabeling of food, where the container that directly contacts the food remains intact
- Activities that fall within the definition of "farm"
- Manufacturing, processing, packing, or holding of food for animals

Which Types of Intentional Adulteration Would the Proposed Rule Cover?

- **YES**: Acts intended to cause massive public health harm, including acts of terrorism
- **NO**: Acts of disgruntled employees, consumers, or competitors intended to attack the reputation of a company, and not to cause public harm
- **NO**: Economically motivated adulteration intended to obtain economic gain, and not to cause public harm
  - *See* 78 Fed. Reg. 78017
  - Can the goals and outcomes of acts of disgruntled employees, consumers, or competitors overlap with acts of terrorism?

Proposed Rule Applicability Flowchart



http://www.gpo.gov/fdsys/pkg/FR-2013-12-24/pdf/2013-30373.pdf

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Risk-Based Approach

- Rule targets what FDA considers to be the most vulnerable elements of the food processing and handling chain
  - Specific food categories not the Agency's focus
- Identification of "key activities" that are most vulnerable to intentional adulteration
  - Protecting against intentional adulteration requires a shift in perspective from what is considered adequate for traditional food safety (*i.e.*, not addressed by traditional HACCP or other food safety systems)

Key Activities Most Vulnerable to Intentional Adulteration

- Bulk liquid receiving and loading
- Liquid storage and handling
- Secondary ingredient handling
  - The step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient
- Mixing and similar activities

What the Rule Would Require of Nonexempt Entities

- Review production systems to determine if engaged in any of the key activity types (or complete vulnerability assessments)
- Identify actionable process steps (*i.e.*, points, steps, or procedures in a food process that will require focused mitigation strategies to reduce the risk of intentional adulteration)
- Complete written food defense plan

Food Defense Plan- Required Elements

- Actionable process steps
- Focused mitigation strategies
- Monitoring
- Corrective actions
- Verification
- Training
- Recordkeeping

Food Defense Plan- Elements Explained

- Actionable process steps
  - Identify any actionable process steps
    - Using key activity types or own facility-specific vulnerability assessment
  - Presence of one or more of key activity types at a process step indicates a significant vulnerability to intentional adulteration aimed at large-scale public harm

Food Defense Plan- Elements Explained

- Focused Mitigation Strategies
  - Identify and implement focused mitigation strategies at each actionable process step
  - Provides assurance that the significant vulnerability at each step will be significantly minimized or prevented and that food manufactured, processed, packed, or held by the facility will not be adulterated

Food Defense Plan- Elements Explained

- Monitoring
  - Facilities would need to establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies
- Corrective Actions
  - To be used if focused mitigation strategies are not properly implemented

Food Defense Plan- Elements Explained

- Verification
  - Would ensure that:
    - Monitoring is being conducted and appropriate decisions about corrective actions are being made
    - Focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing any significant vulnerabilities
  - Rule would require periodic reanalysis of the food defense plan every three years or under certain conditions

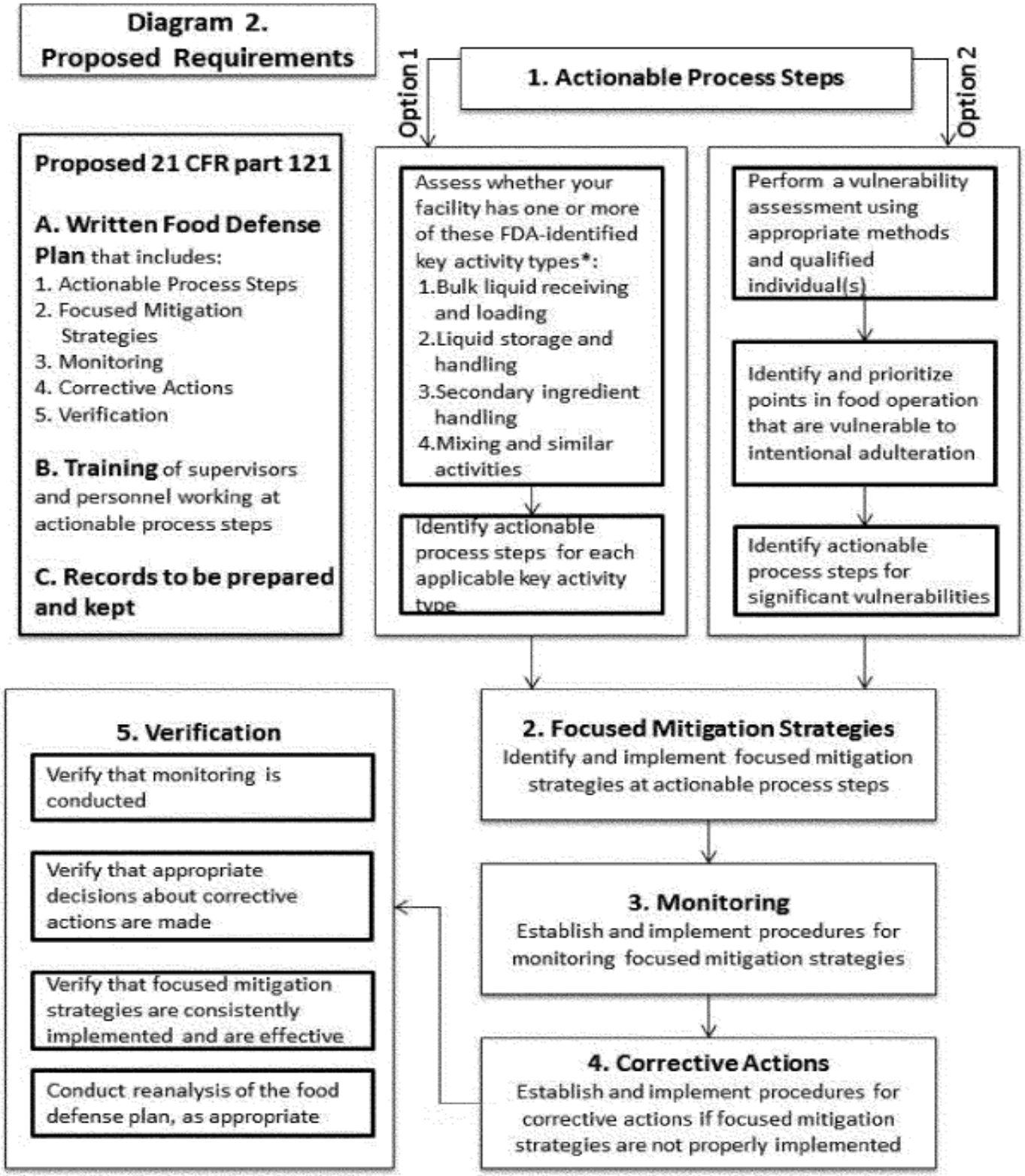
Food Defense Plan- Elements Explained

- Training
  - Personnel and supervisors assigned to the actionable process steps would be trained in:
    - Food defense awareness
    - Responsibilities for implementing focused mitigation strategies

Food Defense Plan- Elements Explained

- Recordkeeping
  - Facilities would be required to establish and maintain certain records:
    - Written food defense plans
    - Records documenting monitoring, verification activities, and corrective actions
    - Documentation related to training of personnel

Proposed Rule Requirements Flowchart



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Compliance Dates

- Rule contains staggered compliance dates, based on business size:
  - Very Small Businesses: A business that has less than $10 million in total annual sales of food would have to comply within three years after the publication of the Rule
  - Small Businesses: A business employing fewer than 500 persons would have to comply two years after the publication of the Rule
  - Other Businesses: A business that is not small or very small and does not qualify for exemptions would have to comply one year after the publication of the Rule

Public Comment on the Proposed Rule

- The Agency encourages the public to submit comments on the Proposed Rule
- Identify comments by Docket No. FDA–2013–N–1425 and/or Regulatory Information Number (RIN) 0910–AG63
- Deadline to submit comments: March 31, 2014

Thank You!

Questions?