New York State Association of Food Protection

Core Food Safety Modernization Act Rules for Dairy

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Four Proposed Rules Essentially Establish Food Safety For Dairy

- Preventive Controls for Human Food
- Foreign (and Domestic) Supplier Verification Program
- Sanitary Food Transportation
- Intentional Contamination

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Proposed Rule for Preventive Controls for Human Food

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Two Requirements

- Conduct Hazard Analysis and Establish Risk-Based Preventive Controls
  - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Follow Newly Updated Good Manufacturing Practices (GMPs)

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Who is Covered?

- Food facilities that are required to register with FDA - domestic and foreign
- Some exemptions and modified requirements are being proposed

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What Preventive Controls Are Required?

- Process controls (e.g. pasteurization)
- Food allergen controls
- Sanitation controls
- Recall plan

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Updated Good Manufacturing Practices (GMPs)

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Changes generally acceptable to regulated community

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Exemptions and Modified Requirements

- "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)

    OR
  - 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

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Exemptions and Modified Requirements

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

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Exemptions and Modified Requirements

- Warehouses that only store packaged foods that are not exposed to the environment
- Storage facilities such as grain elevators

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NMPF Requests to FDA:

- Exempt PMO facilities
- Do not mandate finished product pathogen testing
- Make the rule more like traditional HACCP
- Exempt warehouses
- Do not require food safety plans to be submitted to FDA - onsite review only

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Supplemental Proposal on the Way

- FDA has stated that it would issue a supplemental proposal to this rule which may be released this week. It will cover:
  - Finished Product Pathogen Testing
  - Environmental Monitoring
  - Domestic Supplier Verification

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Effective and Compliance Dates

- Effective date is 60 days after the final rule is published which is anticipated to be 8/30/15
- Compliance Dates
  - Very Small Businesses - three years
  - Small Businesses - two years
  - All others - one year

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Proposed Rule for Foreign Supplier Verification Programs (FSVPs)

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Key Points

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards
- The requirements provide flexibility based on the risk of the food
- Key principles generally acceptable to regulated community
- This rule likely mimics soon to be proposed domestic supplier verification requirements

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Overview of FSVP

- Importers would be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- The requirements vary based on:
  - Type of food product
  - Category of importer, such as very small
  - Nature of the hazard identified in the food
  - Who is to control the hazard

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Who Is Covered?

- An importer is a person in the U.S. who has purchased the food being offered for import
  - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee
  - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee.

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What Is Exempt?

- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Food imported for research and evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages
- Other

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FSVP Requirements

- In general, importers would need to conduct the following activities:
  - Compliance status review of foods and suppliers
  - Hazard analysis
  - Supplier verification activities
  - Corrective actions (if necessary)
  - Periodic reassessment of the FSVP
  - Importer identification at entry
  - Recordkeeping

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Control of Hazards

- The proposed requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur.
  - Supplier's supplier
  - Supplier
  - Importer
  - Importer's Customer

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Importer or Customer Controls Hazard

- If the importer will be controlling a hazard identified as reasonably likely to occur, the importer would be required to document, at least annually, that it has established and is following procedures that adequately control the hazard.

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Importer or Customer Controls Hazard (cont.)

- If the importer's customer will be controlling a hazard, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures that adequately control the hazard.

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Hazard Controlled by Foreign Supplier or Its Supplier

- FDA is proposing two options for supplier verification activities when:
  - The foreign supplier is to control a hazard or
  - The foreign supplier's supplier is controlling a hazard
- The options differ based on approach to hazards that can cause serious adverse health consequences or death to humans or animals (SAHCODHA)

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Option 1

- If the foreign supplier controls the hazard at its establishment and it is a SAHCODHA hazard, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier. Boots must be on the ground!

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Option 1 (cont'd)

- For non-SAHCODHA hazards and all hazards for which the foreign supplier verifies control by its supplier, importer would be required to choose a verification activity:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure

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Option 2

- For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records, or some other appropriate procedure.

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Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 10/31/15
- Compliance dates
  - Generally 18 months after publication; or
  - Six months after the importer's foreign supplier is required to comply with the new preventive controls or produce safety regulations.

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NMPF Requests to FDA:

- Eliminate complex hazard analysis, facilities should consider ingredient risk and supplier risk together
- Discourage over auditing
- Use Option #2
- Supplier audits should be confidential
- Extend compliance date by another year

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Proposed Rule for Sanitary Food Transportation

Overview

- **Appears to follow common transportation practices in use today**
  - Make sure transportation equipment and vehicles are designed and constructed in a manner that allows them to be kept clean
  - Make sure the equipment and vehicles are kept clean – check before loading
  - Shipper must keep carrier informed in writing about any safety issues and need for refrigeration
  - Temperature records must be created and maintained
  - Some training requirements which require documentation
- **FDA has proposed to waive application of this rule to "permitted" NCIMS activities as well as facilities subject to the Food Code**

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NCIMS Waiver

- **As currently proposed:**
  - **Most likely in response to ANPR comments IDFA filed in 2010**
  - **Appears to apply to incoming and outgoing products to PMO facilities**
  - **Despite proposed language shipping non-Grade A in conjunction will not destroy waiver**

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Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 3/31/16
- Compliance dates:
  - One year for general businesses
  - Two years for small businesses

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NMPF Requests to FDA:

- Make clear the PMO waiver applies to incoming and outgoing finished products
- Make clear that shipping non-Grade A products does not jeopardize waiver
- Make a determination that finished ice cream transportation is outside the scope of the rule

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Proposed Rule for Intentional Contamination/Focused Mitigation Strategies

Overview

- Scope is potential acts of terrorism that could cause massive public harm and economic disruption
  - Excludes disgruntled employees, economic adulteration
  - Excludes Economically Motivated Adulteration
- Uses a HACCP framework, with different terminology

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Who is Covered?

- Food facilities that are required to register with FDA - domestic and foreign
  - Includes many facilities exempt from preventive controls requirements:
    - Juice & Seafood HACCP
    - Low-acid canned food
    - Dietary supplements
  - Does not include farms (except dairy farms), restaurants, retailers, food contact substance manufacturers

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Exemptions

- Proposed exemptions:
  - All food storage activities except liquid storage
  - Packing, re-packing, or labeling activities (immediate food container remains intact)
  - Activities subject to the produce rule
  - Animal food facilities
  - Certain alcoholic beverage facilities
  - Qualified facilities (i.e., very small businesses with less than $10 million in annual sales)

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Key Terms and Phrases

- Actionable process steps (nodes)
- Focused mitigation strategies (countermeasures)

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Key Principles

- Prevention of acts intended to cause widespread public health harm
- Considers vulnerabilities and risks related to intentional adulteration
- Risk-based and flexible

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Summary of Requirements

- Written food defense plan, including
  - Actionable process steps
  - Focused mitigation strategies
  - Monitoring
  - Corrective actions
  - Verification
- Training

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Summary of Requirements

- Identification of actionable process steps using "key activity types" or a vulnerability assessment
  - Determination of the presence of "key activity types" similar to a hazard analysis
  - Actionable process steps similar to critical control points
- Identification and implementation of focused mitigation strategies
  - Focused mitigation strategies similar to preventive controls

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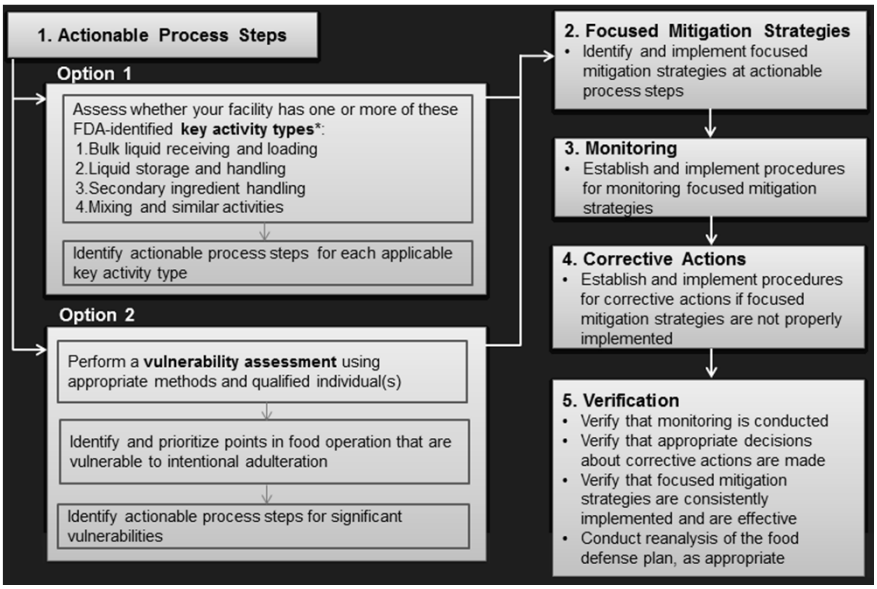
Proposed Requirements



*FDA identified these key activity types using findings of vulnerability assessments of over 50 food products and processes. These activity types commonly rank high in vulnerability based on various factors, including the ability to physically access the food or process and the potential to adulterate a sufficient quantity of product in order to cause massive public health harm.

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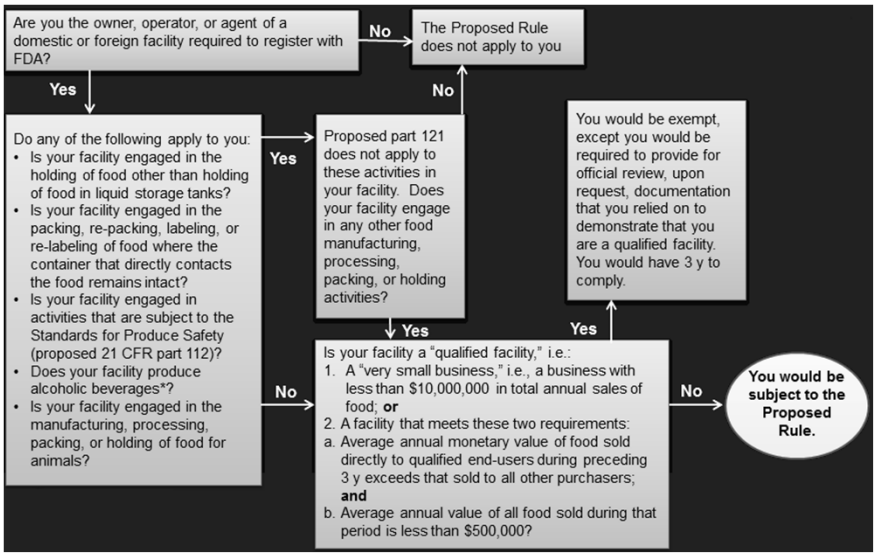
Proposed Coverage



*See proposed 121.5(e) for specific conditions

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Food Defense Plan Requirements

- Each facility would need to prepare a written food defense plan to:
  - Determine the steps in their process where food defense measures are needed to address significant vulnerabilities (i.e., *actionable process steps*)
  - Identify and implement *focused mitigation strategies* to significantly minimize and prevent these significant vulnerabilities
  - Engage in *monitoring, corrective actions,* and *verification* of the focused mitigation activities

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Key Takeaways

- HACCP framework reflects FDA's desire for consistency with food safety plans
- Rather than identify foods at high risk of intentional adulteration by food type, focus is on certain activities in food manufacturing
- FDA is NOT proposing to require broad mitigation strategies – those general, facility-wide mitigation measures (e.g., fences, guards, security cameras)

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Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 5/31/16
- Compliance dates:
  - Three year for very small businesses (<10M)
  - Two years for small businesses
  - One year for all others

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NMPF Requests to FDA:

- Keep plans basic
- Achieve compliance with FDA's software tool
- Allow plans to escalate in the event a credible threat materializes
- Keep plans confidential
- FDA should develop its communication plan based on the Food Facility Registration system

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Food Defense on Dairy Farms

- Dairy farms are the only farms subject to this rule
- FDA is uncertain as to whether to regulate them or exempt them
- The authority and potential mandate to regulate farms came from Congress in Section 106 of FSMA
- But, section 106 mandates that the regulation only apply to "food for which there is a high risk of intentional contamination"

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Food Defense on Dairy Farms

- The Global Terrorism Database (GTB) covers terrorist incidents from1970 to 2012
- Of the 113,000 incidents in the GTB, only 13 involved targeting food or water facilities
- There were 265 incidents that involved food or water at non-food manufacturing facilities
- There have been 3 global terrorist incidents involving dairy farms

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Food Defense on Dairy Farms

- On December 5,1979, The Popular Revolutionary Bloc (PRB) attacked a dairy farm in El Salvador with pistols and took hostages
- On May 18,1987, unknown assailants attacked a dairy farm in Zimbabwe with automatic weapons and killed 1 person
- On November 11, 2007, the al-Aqsa Martyrs Brigades fired 3 rockets into Israel; one of which hit a dairy farm and killed 6 cows

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Food Defense on Dairy Farms

- In order for a there to be a high risk, there must be an adversary with the intent and capability to carry out an attack and the target must be vulnerable
- In my informed opinion, I do not believe there are adversaries out there today with an intention to carry out an attack involving a US dairy farm
- Further, contamination at a dairy farm is vastly more complex than authorities have surmised

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Food Defense on Dairy Farms

In 2004, the US Department of Transportation proposed numerous terrorism mitigation strategies for use on dairy farms and dairy processing facilities, the two funniest recommendations were:

- Having dairy farms use unmanned aerial vehicles (UAV aka drones) to surveil large open tracks of land
- Having IDFA and NMPF train farm personnel in food defense and then have those two organizations levy a security tax to ensure compliance

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Food Defense on Dairy Farms

- FDA food defense personnel have frequently raised the issue of locking the milk house to prevent contamination
- FDA's Milk Safety Branch personnel and state authorities do not think that makes sense
- NMPF does not believe farms represent a high risk therefore they should not be regulated under this rule

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Food Defense Bottom Line

- FDA will likely re-propose this rule next spring
- NMPF will pressure FDA to keep dairy farms out of the rule
- NMPF will advocate that the use of FDA's Food Defense Plan Builder software tool should for the most part constitute/indicate compliance with the rule for processing facilities

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Registration Reminder

- FSMA requires food facilities that manufacture, process or hold food to register.
- Every two years in even numbered years those facilities must re-register or renew.
- The re-registration period is from October 1st through December 31st
- Failure to re-register is a prohibited act.

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Questions?

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