U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Food

FSMA Domestic Facility Risk Categorization (FY 2012)

More on Inspection & Compliance [1]

Background

Section 201 of the FDA Food Safety Modernization Act (FSMA), "Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry," created section 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which mandates inspection frequency, based on risk, for domestic food facilities. The section specifies that the inventory of food facilities be limited to those required to register under section 415 of the FD&C Act (BT Registration). It mandates inspection frequencies based on a facility being identified as high-risk (HR) or non-high-risk (NHR). HR facilities must be inspected at least once in the first 5 years following enactment of FSMA and then once every 3 years thereafter. NHR facilities must be inspected at least once in the first 7 years following enactment and then once every 5 years thereafter. These inspection frequencies are minimums and some firms may be inspected on a more frequent basis.

Current Status

The total inventory of domestic facilities is estimated at 82,300. The FDA inventory for HR and NHR facilities is estimated at 22,325 and 60,000, respectively. The goal is to complete the HR inventory in a 3-year cycle (FY 2011-13) and the NHR in a 7-year cycle (FY 2011-17). For FY 2012, approximately 7,400 HR and 8,600 NHR facilities are planned for inspections. FDA plans to inspect HR facilities every 3 years although the new legislation provides an initial frequency mandate of inspecting each HR facility once in a 5-year period. Changes to the process will be minimized in the FY 2013 cycle to allow for incorporation of multi-year workplanning in the field.

- Challenges with the current BT registration data and pending changes to the registration requirements based on Section 102 of FSMA led to the decision to use the inventory of food facilities from the agency's Official Establishment Inventory (OEI) database for the FY 2012-13 cycle.
- The current decision-making method for determining HR and NHR risk facilities is described below and is likely to evolve for the FY 2014 planning cycle as better data are available and other "risk defining" sections of FSMA continue to progress.

How does FDA identify a high-risk (HR) facility?

The agency is utilizing a decision-making process based on the risk factors identified in section 421(a)(1) of the FD&C Act, which are:

1. The known safety risks of the food manufactured, processed, packed, or held at the facility;
2. The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards;
3. The rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls;
4. Whether the food manufactured, processed, packed or held at the facility meets the criteria for priority under section 801(h)(1) of the FD&C Act, which relates to the prioritization to detect intentional adulteration in food offered for import into the U.S.;
5. Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) (concerning imported food) or 806 (voluntary qualified importer program) of the FD&C Act, as appropriate;
6. Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

For the FY 2011-13 planning cycle for domestic facilities, the decision-making process is based primarily on the first two factors listed, as well as certain additional criteria identified as part of the sixth factor. There are not data available at this time to characterize the third factor for all industry types. It will be incorporated as the Preventive Controls regulation and the data collection develop. The fourth factor applies only to foreign facilities. While the fifth factor may apply to some domestic facilities, the relevant certification programs have not yet been established.

Two additional factors that have been identified pursuant to the sixth item are: establishment type / type of activity conducted at the facility (manufacturer/processor, repacker/packer, etc.) and years since last inspection.

Table 1. Primary FSMA Factors for FY 2011-13

FSMA Risk Factors	Data Elements
Known safety risks of the food	• Class 1 Recalls, • Outbreaks
Compliance history of a facility	Inspection Classifications • Facilities with significant violations (OAI)[1] • Facilities with a history of non-compliance (VAI $\geq$3)[2]
Facility's hazard analysis and risk-based preventive controls	Limited data.
Priority under section 801(h)(1)	Not applicable to domestic facilities.
Certifications for imported food	Programs not yet established.

Any other criteria deemed necessary	• Type of activity (establishment type), • Years since last inspection.

The method utilized is through a software program that assesses the characteristics of each facility in the agency's inventory. SAS® software provides data access, analysis, and reporting from the agency's internal data systems. The current model is best depicted with a decision tree as shown in Diagram 1 resulting in facilities being categorized as HR or NHR.

Identification of HR facilities is based on the known safety risks of foods at the industry-wide level and compliance history, which is firm specific.

- The "known safety risks" of food are based on broad, industry-level food commodity categories, e.g., bakery, leafy vegetables, spices. If a facility manufactures food commodity categories associated with foodborne outbreaks AND class I recalls, then they are placed in the HR facility category. If a facility manufactures food commodities associated with foodborne outbreaks OR class I recalls and they have not been inspected within the previous five fiscal years, then they are placed in the HR facility category.
- The facility-specific factor of "compliance history" is based on inspection results for a facility from the previous five fiscal years. Facilities with a history of non-compliance with food safety requirements (a history of three or more VAI within the five year time period) and those with food safety violations of regulatory significance (one or more OAI in the five year time period) are placed in the HR facility category.

Will this approach be updated?

Modifications and adjustments to allocate resources will be addressed in FY 2014 or as needed. Some changes are anticipated when the following issues have been resolved:

- Modifications to the registration system (Section 415 of the FD&C Act) that could potentially improve the quality of data for identifying domestic facilities as HR.
- Policies, procedures, and data collection for reviewing and evaluating a facility's hazard analysis and risk-based preventive controls.
- Deliberative discussions towards addressing the definition and consistency of "risk" and "known safety risks" as those terms are used throughout FSMA.

What additional considerations might affect the frequency of inspections?

FDA may inspect facilities more often than the frequency mandate as a result of emerging public health information, follow-up to violative inspections and/or samples, any other triggers.

The FDA inventory and identification of HR and NHR food facilities is dynamic and subject to change. For example, new facilities enter the market, existing facilities go out of business, definitions of high-risk food/facility evolve, and a facility's compliance history may change.

How is the FSMA inspection frequency mandate for high-risk food facilities associated with the agency's annual performance goal metric "number of high-risk food inspections"?

The performance goal metric has historically been a fixed target, a numerical value designated during budgetary planning discussions. This performance goal target did not align with the FSMA high-risk facility inspection frequency mandate. The performance goal has recently been changed to align with the FSMA high-risk frequency mandate.

What datasets are used to determine the risk category for facilities?

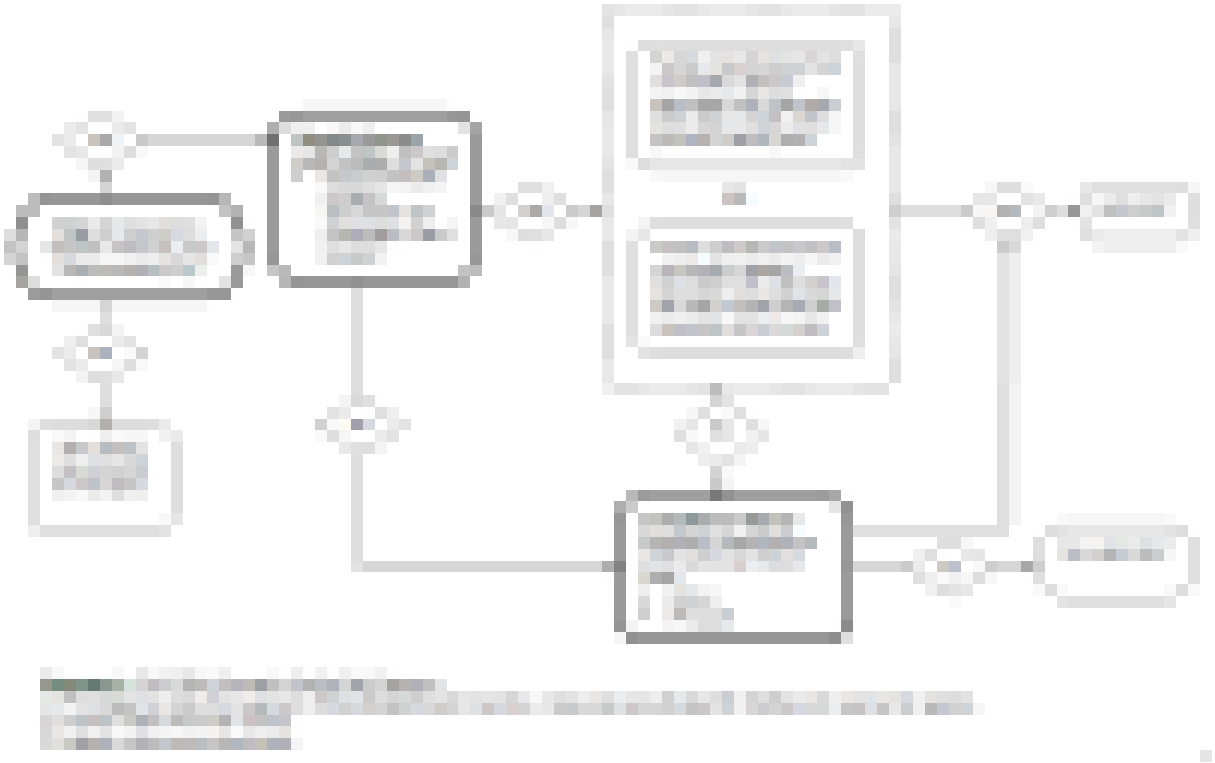
Most of the datasets used to determine HR facilities are internal to FDA. A data-driven approach to identifying facilities and available resources is highly dependent on reliable and accurate data. Efforts are continuously being made to improve the quality of data to assist with risk-based decision-making for operational activities.

Foodborne Outbreaks: CFSAN epidemiologists track and monitor FDA-regulated products possibly associated with outbreaks and illnesses.

Recalls: The Agency assigns a numerical designation (I, II, III) to product recalls to indicate the relative degree of health hazard. Class I Recalls are of primary concern because there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Inspection Results: Field staff enter inspection classifications in FDA's Field Accomplishments and Compliance Tracking System (FACTS), an agency-wide computer based program for the entry and monitoring of work performed in the field (including state contract work). These classifications are used to determine the compliance history of a facility.

FSMA Domestic Facility Risk Category Determination Process FY12 (text version)



Text Version

Step 1: Determine if facility is required to register under Sec 415 Requirements. (*FY12 based on data from agency's Official Establishment Invenotry. Resources are allocated for facilities not required to register.)*
If no, Section 421 (a) requirements do not apply.
If yes, move to step 2.

Step 2: Determine if the facility packs, processes or holds a commodity that has been identified with known food safety risks. Know food safety risks are currently considered to be food commodities that are associated with Outbreaks and Class 1 Recalls.
If yes, move to step 2a.
If no, move to Step 3 Compliance History.

Step 2a: Determine if the facility is a manufacturer of a food commodity category associated with outbreaks AND class I recalls within previous 5 fiscal years. Or alternatively, a manufacturer or a food commodity category associated with outbreaks OR class I recalls and NOT inspected within the previous 5 years.
If yes, the facility is considered to be a High-Risk facility and will be inspected a minimum of once within a 3-year cycle.
If no proceed to Step 3 Compliance History.

Step 3: Consider the compliance history of a facility. Determine if a facility has received an inspection classification of "Official Action Indicated" (OAI) in the previous 5 fiscal years. Or alternatively, three (3) inspections classified as "Voluntary Action Indicated" (VAI) in the previous 5 fiscal years.
If yes, the facility is considered to be a High-Risk facility and will be inspected a minimum of once within a 3-year cycle.
If no, the facility is considered to be a Non-High Risk facility and will be inspected a minimum of once within a 7-year period.

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[1] OAI is an FDA inspection classification of “Official Action Indicated.”
[2] VAI is an FDA inspection classification of “Voluntary Action Indicated.”

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

An Invitation to Join the Food Safety Preventive Controls Alliance Working Group

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public-private alliance established in late 2011 by a grant from the U.S. Food and Drug Administration to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH). The mission of the Alliance is to support safe food production by developing and delivering educational programs that assist the food industry in complying with the preventive controls regulations that will be promulgated in response to the Food Safety Modernization Act (FMSA). The Alliance currently consists of executive and steering committees, and specific subcommittees and working groups are now being formed.

FSPCA invites subject matter experts from the food industry, trade associations, regulatory agencies and academia to participate and collaborate in the creation of a national preventive controls training curriculum.

Five initial working groups have been created by the Alliance:

- Hazard Identification and Preventive Controls Curriculum Development
- Food Categories and Representative Processing
- Allergen Management and Control
- Sanitation, Current Good Manufacturing Practices and Environmental Monitoring
- Supply Chain and Ingredient Management

Each working group will have a specific agenda, assignments, tasks and activities to fulfill the mission of the Alliance and will be guided by a liaison from the FSPCA Steering Committee in accomplishing its objectives and tasks. Working Group tasks and communications will be accomplished primarily through electronic document exchange, webinars and telephone conference calls.

If you are interested in serving on any of the FSPCA working groups, please fill in the form below and mail, FAX, or email it to:

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6502 South Archer Rd., Bedford Park, IL 60501-1957
(Fax) 708.563.8263
(Email) FSPCA@iit.edu

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA WORKING GROUP PARTICIPATION FORM

Name (Last, First,): Occupation/Title: Company/Affiliation:
E-Mail: Phone: FAX:
Mailing address:
Working Group* Interest (select all that apply): ☐ Hazard Identification and Preventive Controls Core Curriculum Development ☐ Food Categories and Representative Processing (e.g., minimally processed/RTE, low moisture/low water activity foods, baked goods, cut fruit, animal/pet food) ☐ Allergen Management and Control ☐ Sanitation, Current Good Manufacturing Practices and Environmental Monitoring ☐ Supply Chain and Ingredient Management * Additional working groups may be added by FSPCA's Steering Committee as necessary.
Describe your occupational experience relative to food safety preventive controls:
How long have you been engaged in this activity?
List education and any relevant specialized experience:
List applicable education and training programs that you have developed, conducted or implemented:
List other technical affiliations and/or leadership experiences that would benefit you in your role as a member of a working group:
Would you/your company/organization be willing to share any existing training material/content for possible use for FSPCA training? Proper acknowledgement and source attribution will be made.