Section 103: Hazard Analysis and Risk-Based Preventive Controls (completely new requirement at 21 USCA 418)

Overview:
This section of the Food Safety Modernization Act (FSMA) requires certain regulated food facilities to assume a more proactive role in preventing food-borne illness. This provision requires regulated facilities to conduct an extensive hazard analysis of their operations, implement and monitor preventive controls that will reduce identified risks, maintain records of the effectiveness of these controls, and adjust the controls as necessary to protect the food supply. The facilities are also required to create a written plan that documents and describes how they will address these requirements. However, there are several types of facilities that are exempt from these requirements or subject to modified safety measures.

Section 103 applies to both food for humans and food for animals. This primer will only address the impact on facilities that produce human food.

Effective Date of Provision:
Congress intended for this provision to be self-executing. As a result, the requirements of this section were effective July 2012 and some in the food industry expressed concern regarding accountability for the requirements of this provision without the guidance of FDA regulations that were mandated by FSMA. In response to the concerns expressed regarding the enforcement of this provision, Deputy Commissioner for Foods, Michael Taylor, issued a letter indicating that the FDA would exercise enforcement discretion and will not enforce Section 103’s requirements until after the regulations have been promulgated.

However, the Center for Food Safety and the Center for Environmental Health filed a lawsuit on August 29, 2012 alleging the FDA had violated FSMA and the Administrative Procedures Act by failing to issue regulations by their statutory deadlines. The plaintiffs sought injunctive relief that would require the FDA to issue the regulations subject to a court-ordered deadline. At issue in the law suit were seven sets of regulations, which included regulations for the following topics: (1) preventive controls for human food (2) preventive controls for animal food (3) the foreign supplier verification program (4) produce safety standards (5) accreditation of third party auditors (6) sanitary transportation of food and feed; and (7) intentional contamination.

During the lawsuit, the proposed regulations required under this section (103) were published for public comment on January 16, 2013. The proposed regulations, which do not yet carry the weight of law, were met by a flood of public apprehension. The FDA faces the daunting task of addressing the outpouring of concern generated by these proposed regulations; it could have been several years before final regulations emerged. However, the parties to the Center for Food Safety lawsuit, recognizing the complexity of this situation, have reached a consent decree that establishes new deadlines for each of the seven contested sets of final regulations. The consent decree established August 30, 2015 as the deadline for the final preventive control regulations.
While the final regulations have not been adopted, the proposed regulations provide for an effective date of 60 days after the publication of the final rule. They also propose a range of compliance dates depending on the size of the business. A "small business" that employs less than 500 people has two years from the publication of the final rule. A "very small business" has three years from the publication of the final rule to comply with the modified requirements of a qualified facility which are discussed below. The regulations propose three options for the definition of very small business: a business with less than $500,000, $750,000, or $1,000,000 in total annual food sales, adjusted for inflation. Finally, all other businesses have one year from the publication of the final rule to reach compliance.

Relevance to State and Local Authorities:
An understanding of this section is critical because it creates substantial new requirements for regulated food facilities. In addition, the requirements outlined in this section will affect the duties of states that conduct facility inspections for the FDA. The FDA will require that facility inspections evaluate whether hazard analysis and preventive control plans are being implemented correctly and effectively.

Explanation of Statutory Provision and Potential Impacts

What are the hazard analysis and preventive control requirements?
This section of FSMA requires that facilities develop a written food safety plan that addresses a variety of factors. These factors are explored in greater detail in the proposed regulations. Each food safety plan must include the following:

1. Hazard Analysis: Facilities must identify and evaluate known or reasonably foreseeable hazards that could affect the food manufactured, processed, packed or held at their site. In identifying hazards, the facility should search for "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives." The analysis should include threats that are naturally occurring, unintentionally introduced, or intentionally introduced, such as acts of terrorism. The regulations propose that the hazard evaluation must consider the effect of the following factors on the finished food product:
   a. the formulation of the food;
   b. the condition, function, and design of the facility and equipment;
   c. raw materials and ingredients;
   d. transportation practices;
   e. manufacturing/processing procedures;
   f. packaging activities and labeling activities;
   g. storage and distribution;
   h. intended and reasonably foreseeable uses;
   i. sanitation, including employee hygiene; and
   j. any other relevant factors.

The hazard evaluation must be in writing as part of the food safety plan.

2. Preventive Controls: The facility’s hazard analysis will guide the identification and implementation of prevention controls to assure that the identified risks are significantly minimized or prevented and that the facility’s food will not be adulterated. The proposed regulations require that these preventive controls include, when appropriate for the facility, the following elements:
   a. Process controls that address the procedures and practices performed on the food.
   b. Food allergen controls that prevent cross-contact of foods during storage and use. These controls must also ensure that the finished food is properly labeled.
   c. Sanitation controls that address (1) the cleanliness of food contact surfaces and (2) prevent contamination of food based on unsanitary contact with personnel, objects, food packaging, food contact surfaces, and raw products.
   d. A recall plan that identifies the specific procedures and personnel required to (1) notify the direct consignees of the food being recalled; (2) notify the public when needed to protect the public health; (3) verify that the recall is effectively carried out; and (4) dispose of the recalled food.
   e. Any other control necessary to significantly minimize or prevent the identified hazards.
   f. The parameters associated with the control of a hazard, i.e., heat processing, acidifying, irradiating, and refrigerating food. The food safety plan must also identify the value range for any biological, chemical, physical, or radiological parameter that will minimize or prevent the identified hazard. For example, if the plan identifies heat processing as
These preventive controls must be documented in writing as part of the food safety plan.\textsuperscript{32}

3. \textbf{Monitoring}: Each food safety plan must include written procedures for monitoring the effectiveness of preventive controls.\textsuperscript{33}

4. \textbf{Corrective Actions}: Facilities must establish written procedures to address improperly implemented or ineffective preventive controls.\textsuperscript{34} These procedures must address how to (1) reduce the chance that implementation failure will reoccur; (2) evaluate all affected food for safety; and (3) prevent the affected food from entering commerce, if the facility operator cannot ensure the food is safe.\textsuperscript{35} The proposed regulations require documentation of all corrective actions.\textsuperscript{36}

5. \textbf{Verification}: The owner, operator, or agent in charge of a facility must verify that the preventive controls are adequate to control identified hazards.\textsuperscript{37} The proposed regulations require that a qualified individual (see the discussion of qualified individuals below) performs or supervises this verification prior to the implementation of the food safety plan, when necessary during the first 6 weeks of food production, and whenever reanalysis of the plan indicates the need.\textsuperscript{38} This verification requires the collection of scientific and technical data relevant to the effectiveness of the preventive controls.\textsuperscript{39} The owner, operator, or agent in charge must also verify that monitoring is occurring and that appropriate decisions are being made regarding corrective actions.\textsuperscript{40} They must also verify that the preventive controls are effectively minimizing or preventing identified hazards.\textsuperscript{41} The proposed regulations require that this verification include calibration of process monitoring instruments and verification instruments, as well as the review of monitoring and calibration by a qualified individual within specific timeframes.\textsuperscript{42}

FSMA’s verification requirement also calls for periodic reanalysis of the food safety plan to ensure it remains relevant to raw materials, conditions and processes in the facility, and new threats.\textsuperscript{43} Reanalysis must occur at least every three years or whenever there are significant changes at the facility that create a reasonable probability for a new hazard or a significant increase in the probability of an identified hazard\textsuperscript{44}. The FSMA also states that the FDA may require reanalysis in response to new hazards and developments in scientific understanding.\textsuperscript{45} The proposed rules attempt to codify this requirement by requiring reanalysis whenever new information develops regarding potential hazards.\textsuperscript{46} The regulations also propose mandatory reanalysis when (1) a preventive control is implemented incorrectly and there is no corrective action addressing it in the food safety plan and (2) a preventive control is ineffective.\textsuperscript{47}

6. \textbf{Record Keeping}: The facility must establish and maintain specific records related to the monitoring of the preventive controls, corrective actions, verification\textsuperscript{48}, and potentially the training of qualified individuals.\textsuperscript{49} These records must be maintained for at least 2 years.\textsuperscript{50}

Are facilities required to submit their food safety plans to the FDA?

Facilities are not required to submit their food safety plans to the FDA prior to an inspection.\textsuperscript{51} However, the proposed regulations request public comment on a “facility profile” requirement.\textsuperscript{52} This profile would contain select information from the food safety plan, i.e., facility type, products, identified hazards, preventive controls established, and facility size.\textsuperscript{53} The FDA envisions facilities submitting their profiles at the “same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration.”\textsuperscript{54} They believe that the profile would help the agency better target inspection resources and improve on-site inspections, without flooding the agency with food safety plans that vary greatly in content and format.\textsuperscript{55}

What does the defined term “qualified individual” mean?

The proposed regulations require that a qualified individual must perform or oversee (1) the preparation of the food safety plan, (2) validation of preventive controls, (3) review of records for implementation and effectiveness of preventive controls, and (4) reanalysis of the food safety plan.\textsuperscript{56} To become a qualified individual requires completion of FDA recognized training in development and application of risk based controls or job experience that provides comparable knowledge.\textsuperscript{57} The qualified individual does not need to be an employee of the facility.\textsuperscript{58}

Which facilities are required to comply with the statutory provisions and its related regulations?

Generally, any foreign or domestic facility required to register with the FDA under section 102 of FSMA (21 U.S.C.A. § 350d) is required to comply with the hazard analysis and preventive control requirements of this section.\textsuperscript{59} This requirement mandates that any facility,
domestic or foreign, which is engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States must register with the FDA. Farms; restaurants; other retail food establishments, e.g., grocery stores, convenience stores, and vending machines; nonprofit food establishments in which the food is prepared for or served directly to the consumer; certain fishing vessels; and facilities regulated exclusively by the U.S. Department of Agriculture (meat, poultry, and egg product facilities) are exempt from the registration requirements of this section.

**Are there facilities that are exempt from the hazard analysis and preventive control requirements?**

FSMA exempts two general categories of facilities from the requirements of this section. First, FSMA exempts facilities that are already regulated by the Seafood Hazard Analysis Critical Control Points Program, the Juice Hazard Analysis Critical Control Points Program, or the Thermally Processed Low-Acid Foods Packaged in Hermetically sealed Containers standards. Second, FSMA exempts facilities that are subject to the new standards for produce safety required by section 105 of the Act. However, FSMA also provides the Secretary of DHHS with the authority to exempt from or modify the requirements for additional types of facilities. The proposed regulations issued on January 16, 2013 put forth several additional exemptions. The proposed exemptions include the following:

1. facilities that store packaged foods that are not exposed to the environment and do not require refrigeration;
2. facilities that store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing;
3. facilities that produce dietary supplements;
4. certain alcohol related facilities;
5. certain low-risk manufacturing, processing, packing, and holding activities that are conducted by small and very small businesses on farms for specific types of foods; and
6. farms.

**What are qualified facilities?**

Qualified facilities are subject to a modified hazard analysis requirement. To be designated as a qualified facility, the entity, its subsidiaries and affiliates, must either

1. meet the very small business standard (see the “Effective Date” section on page 1 for the proposed standards), or
2. have very limited sales that are restricted to its local area. To qualify for this designation, the majority of the facility’s sales must be made to qualified end-users, which are defined as the consumers of the food, restaurants, or retail food establishments that are located in the same state or within 275 miles of the facility. The restaurants and retail food establishments must also purchase the food for sale directly to consumers. Finally, the average monetary value of sales for this type of facility may not exceed $500,000 over the three preceding years.

**What are the modified requirements for qualified facilities?**

Although exempt from the standard hazard analysis requirements of this section, qualified facilities must still submit documentation that proves they are a qualified facility. They must also provide documentation that either (1) demonstrates that the facility has conducted a hazard analysis and is implementing and monitoring preventive controls or (2) verifies that the facility is in compliance with state and local food safety laws.

Qualified facilities that chose to submit documentation proving compliance with state and local food safety laws are required to provide consumers the following information:

1. For any food that is required to be labeled under the Federal Food Drug and Cosmetic Act, the facility must prominently and conspicuously include the name and business address of the facility where the food was manufactured on the label.
2. For any food that is not required to be labeled under the Federal Food Drug and Cosmetic Act, the facility must prominently and conspicuously display the name and business address of the facility where the food was manufactured or processed at the point of purchase. If the food is made available through the internet, then this information must be provided by an electronic notice.

It is important to note that FSMA states that federal regulation of qualified facilities does not preempt “state, local, county, or other non-Federal law regarding the safe production of food.” As a result qualified facilities are subject to the existing—or new—regulations of state and local authorities.
Can a qualified facility lose its exemption?
A qualified facility can lose this exemption if it is directly linked to a foodborne illness outbreak or the FDA determines such action is "necessary to protect the public health and prevent or mitigate a foodborne illness outbreak." The proposed regulations describe the potential due process protections available to facilities faced with the loss of their qualified facility status.

1. **Notice:** First, the FDA must provide the facility with a written order to withdraw the exemption. The order must contain specific information, e.g., the name, address, and location of the facility at issue; date of the order; a brief, general statement of the reasons for the order; a statement indicating that the facility must comply with the hazard analysis and risk-based preventive controls, i.e., develop the standard written plan, within 60 days of the date of the order; information on the informal hearing process for an appeal of the order; and contact information for the FDA district office and the name of the FDA District Director in whose district the facility is located.

2. **Appeal:** Second, once the order is received the facility can choose to comply with the order or they can submit a written appeal to the FDA District Director for their district. The appeal must be made within ten days of the date of the order. It must address with particular facts and supporting documents the food safety issues contained in the order. In addition, the facility may make a written request for an informal hearing as part of the appeal.

3. **Hearing:** Third, an informal hearing is not guaranteed. The presiding officer, an FDA official senior to an FDA district director, may reject the request, if the official determines that "no genuine or substantial issue of material fact" has been raised in the appeal. If the request for an informal hearing is granted, the hearing must be held within 10 calendar days of the appeal's filing or at a time agreed to by the facility and the FDA. This hearing must be conducted as a regulatory hearing in accordance with 21 C.F.R. pt. 16. The FDA must issue a decision within 10 calendar days of the hearing. If the request for a hearing is rejected, the FDA must issue a final decision on the appeal within 10 calendar days of the date the appeal was filed. If the presiding officer confirms a withdrawal order, it can be appealed to a federal district court.

What are the penalties for failing to comply with this section of FSMA?
Failure to comply with the provisions of this section is a violation of the Food Drug and Cosmetics Act and may result in an injunction, prison time, and/or fines. Currently, a violation of this provision can result in up to a year in prison and/or a $1,000 fine. However, if the violation was committed with the intent to defraud or mislead, or was committed after the conviction for a separate violation of the act, the penalty is increased to up to 3 years in prison and/or a $10,000 fine.

What are the potential economic impacts of Section 103 and the proposed regulations?
The FDA estimates that nearly 1 million foodborne illnesses each year are attributed to food subject to these proposed regulations. The economic value of preventing these illnesses is calculated at $2 billion a year. These proposed regulations would apply to an estimated 206,800 facilities: 97,600 domestic facilities and 109,200 foreign facilities. The proposed rule has an estimated first year industry cost of $701 million and an annualized industry cost of $472 million.

What concerns have been expressed regarding the proposed regulations?
The FDA has received over eight thousand public comments regarding the proposed regulations. To help understand the breadth of issues facing these regulations, a sampling of concerns is provided below.

1. **The definition of very small business for qualified facility exemptions:** There are two opposing schools of thought on this topic. First, some community groups argue that it should be narrowly defined as a business with less than $250,000 in total annual sales. These groups argue that this provides the greatest public health benefit by requiring the greatest number of facilities to comply with the standards of this section. They also point out that defining it at the $500,000 or $1 million dollar level would be ineffective to negate the second type of qualified facility exemption. A qualified facility may be either (1) a very small business or (2) a business with limited annual sales of less than $500,000 provided a majority of its sales are made directly to qualified end-users. Since this provision makes clear that these are two separate categories, "it stands to reason that the two categories would be defined differently and would represent different levels of annual sales." So a definition of "very small business" as having annual sales less than $500,000 or $1 million would totally negate the geographic restrictions of the second category of qualified facilities. Other organizations argue that setting the level at $250,000 would unfairly burden small business with unnecessary compliance cost that could put them out of business and discourage the development of new businesses. In fact, the U.S. Chamber of Commerce has suggested at setting the income level as high as $25 million. Some groups advocate for further protection of small business interests by measuring a qualified facilities income generated by regulated food products, rather than all food products.
2. **Submission of food safety plans**: Some groups advocate for the submission of food safety plans for the highest risk food products. This review could provide the FDA with insight into how facilities are interpreting the regulations. Also by targeting the highest risk products it would help the FDA allocate its finite amount of resources in manner to maximize public health benefit. It would also allow the FDA to identify problem areas that could guide its inspection plans.

3. **Clarification of retail food establishment definition**: Retail food establishments are exempt from the requirements of section 103 and its regulations. In the regulations, a retail food establishment is defined as “an establishment that sells food products directly to consumers as its primary function.” A retail food establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. The regulations specifically identify grocery stores, convenience stores, and vending machines as retail food establishments. Even though they appear to be included in the general definition provided by the regulations, some organization are advocating that the regulations specifically identify roadside farm stands, farmer’s markets, and community supported agricultural programs as retail food establishment.

4. **Required Testing**: As discussed above, the proposed regulations require facility operators to verify that preventive controls “are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs.” One organization argues that product testing is so essential in preventing foodborne illness that it should be required as part of the verification process in appropriate circumstances, rather than optional.

5. **Benefit and Cost Analysis**: The accuracy of the FDA’s Preliminary Regulatory Impact Analysis (PRIA) has been challenged by several groups. The U.S. Chamber of Commerce argues that the “FDA’s economic cost benefit analysis of the economic impact of the proposed rule is inaccurate and incomplete. It is not based on the best data that was within the power of the FDA to obtain. FDA should undertake further research, surveys, pilot tests, and experiments to improve source data on which its economic impact analysis is based.” Some organizations argue that it underestimates the costs and over estimates the benefits. Other organizations argue the inverse. For example the PEW Charitable trust referred to the PRIA as “a deeply flawed tool for evaluating and crafting regulatory policies….It systematically overestimates the costs of regulation while leaving out benefits that are not easily monetized.” Pew Charitable trust provides an extensive analysis of the PRIA in support of their assertion.

### Additional Resources
1. [FSMA Facts: FSMA Proposed Rule for Preventive Controls for Human Food](#)
2. [Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risked-Based Preventive Controls for Human Food](#)

### SUPPORTERS

[Robert Wood Johnson Foundation](#)

The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation with direction and technical assistance by the Public Health Law Center at William Mitchell College of Law.

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1 21 U.S.C. § 350g (a-i).
2 21 U.S.C. § 350g (i).
5 Letter from Michael Taylor, Deputy Commissioner for Foods, FDA, to Jimmy McCarthy, President and CEO, Snack Food Association (June 18, 2012) available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm310083.htm
7 Id.
8 Id. at *2-4-6
11 Id.
14 Id.
15 Id.
17 See Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed.Reg.3646, 3671(Jan. 16, 2013) (discussing the review of plans during inspections); see also 78 Fed. Reg. 3646, 3810-11(to be codified at 21 C.F.R. pt. 117.315) (requiring that the food safety plan be retained at the facility to facilitate inspection of the plan.)
19 Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3805-3808 (Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 117.126, .130,.135, .137,.140, .145,.150,.155,.175)(proposing specific details for each of the required elements.)
20 21 U.S.C.A. § 350g(b).
21 Id.
22 Id.
23 Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3806 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.130(c)).
24 21 U.S.C.A. § 350g (c).


Id.


21 U.S.C. § 350g(d).

21 U.S.C. § 350g(e).

Id.

21 U.S.C. § 350g(e).

Id.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3807 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.145(c)).

21 U.S.C. § 350g(e).

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3807 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.150(a)).

Id.

21 U.S.C. § 350g(e).

Id.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3807 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.150(d)).

21 U.S.C. § 350g(f)

21 U.S.C. § 350g(i).

Id.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3807 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.150(i)).

Id.

21 U.S.C. § 350g(g)


21 U.S.C. § 350g(g)

See Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3671 (Jan. 16, 2013) (stating that the FDA will not require submission of the plans in the agency's response to public comment).


Id.

Id.

Id.


Id.

Id.

Id.

21 U.S.C. § 350g (a, h); see also 21 U.S.C.A. § 350g(o) (defining the term facility to mean operations subject to registration under 21 U.S.C.A. § 350d.)


See 21 C.F.R. § 1.227(b)(11) (providing an detailed definition of "retail food establishment.")
21 U.S.C. § 350d (c)(1) and 21 C.F.R. §1.226, 1227.

21 U.S.C. § 350g(j)

21 U.S.C. § 350g(k)

21 U.S.C. § 350g(m)

See Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3802 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.7) (exempting these facilities from the hazard analysis and risk based preventative controls requirements); but see Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed Reg. 3773-3775 (January 16, 2013) (to be codified at 21 C.F.R. pt. 117.206) (creating modified requirements for facilities that store packaged foods that are not exposed to the environment but require refrigeration).


Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3802 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.5(e)).

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3801-02 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.5(i)).

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3800-01 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117.5(g)).


See 21 U.S.C. § 350g(l)(4)(B) (defining the term “qualified end-use”).

Id.


Id.


Id.

Id.

Id.


Id.


See 21 U.S.C. § 331(uu) (making failure to comply with this section a violation of the Food Drug and Cosmetic Act); see also 21 U.S.C. § 332 (providing jurisdiction to federal district courts to issue injunctions to restrain violations of the Food Drug and Cosmetic Act); see also 21 U.S.C. § 333 (discussing prison time and fines for violations of the Food Drug and Cosmetic Act.)


21 U.S.C. § 350g(l)

See e.g. Chamber of Commerce, Comments on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 4 (Nov. 15, 2013) available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0701

See C.F.R. § 1.227(b)(11) (providing detailed definition of “retail food establishment.”)

See C.F.R. § 1.227(b)(11)


21 U.S.C. §350g(l)(4)

See e.g., Kraft Foods Group, Inc., Comments on Preliminary Regulatory Impact Analysis: Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food, 3 (Nov. 22, 2103)(stating “Our internal assessment suggests the PRIA does not adequately
account for many of the likely costs that would be triggered by the proposed rule. *) available at http://www.regulations.gov/#/documentDetail;D=FDA-2011-N-0920-1307
