THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

November 22, 2013

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food[1]

Docket No. FDA–2011–N–0920

Dear Sir or Madam:

On January 16, 2013, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a proposed rule entitled Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the "Proposed Rule"). The Proposed Rule amends the regulation for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMPs) and adds requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

[1] 78 Fed. Reg. 3646 (January 16, 2013).

FMI supported the enactment of the Food Safety Modernization Act (FSMA) including section 103 (21 USC 350g) which directs FDA to issue the Proposed Rule. We believe the regulations issued to implement section 103 of FSMA, if crafted in a manner consistent with the following comments will enhance public health and strengthen our nation's food safety regulatory system.

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Background

Categories of FMI Member Facilities Affected

FMI members own and operate a variety of food facilities required to be registered under section 415 of the FD&C Act. While retail stores themselves are not required to be registered, the distribution centers that service them are. Most chain food retailers and all wholesalers operate distribution centers. Recent statistics indicate that 193 different food retailers operate 224 distribution centers in the U.S.[2] Many chains operate multiple distribution centers and large retailers may have 10, 20 or more than 30.[3] In terms of wholesalers, 1,098 wholesale grocery companies operate 1,679

[2] 2013 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains (Database accessed on April 12, 2013).
[3] Id.

distribution centers in the U.S.[4] A number of FMI members also operate central dairy, deli and bakery facilities that are required to be registered under the FD&C Act. All of these facilities are subject to various requirements of the Proposed Rule. While certain FMI members own and operate a variety of types of food facilities, the vast majority of food facilities they own and operate are distribution centers.

Supermarket Distribution Center Operations

Supermarket distribution centers (hereinafter "supermarket distribution centers" or "distribution centers") are handling facilities and generally do not engage in processing or packing. The typical distribution center handles a wider variety of product categories than any other type of facility in the food industry. FMI highlighted this fact in comments filed previously with the Agency:

> FMI has reviewed FDA's draft Form 3797 (Draft Form) and in it the Agency provides a list of 27 types (plus a write in slot) of products the user of the form is to select from . . . the typical Supermarket Distribution center handles nearly all of the 27 products types listed in Draft Form.[5]

Distribution centers store packaged foods not exposed to the environment, refrigerated and frozen foods, USDA-regulated meat and meat products, eggs and produce in packaged and unpackaged form. The vast majority of food products handled by distribution centers are packaged foods not exposed to the environment. Where a distribution center holds unpackaged produce, it is virtually always in a confined space separated from the rest of the facility. Areas for the storage of produce generally have temperature and humidity controlled to preserve quality.

Produce in Supermarket Distribution Centers

Produce in distribution centers is essentially always in boxes or bins and generally does not come into direct contact with humans. In the Proposed Rule, FDA considers "not exposed to the environment" and "unexposed" to mean "that the food is in a form that prevents any direct human contact with the food." FDA, in the public meeting on the Proposed Rule in Washington D.C. on March 1, 2013, clarified that direct human contact means direct physical contact with the human body. For example, bags of baby carrots, iceberg lettuce heads wrapped in plastic, and strawberries in clamshells would meet the requirements to be unexposed packaged foods. Although the clamshells holding strawberries generally have vents, the vents are so small that human contact is prevented (i.e. a finger is much too large to be accommodated by the vent). FDA stated in the March 1 public meeting that produce in boxes with handholds or vents/holes large enough to accommodate a finger or hand would be considered exposed to the

[4] Id.
[5] FMI Comments to FDA on Voluntary Food Facility Registration Module, July 10, 2012.

environment. Only a small number of products within the typical distribution center would be considered to be exposed to the environment—less than one percent. These would nearly always be limited to produce items. FMI seeks clarification if the potential for direct human contact with the skin of a produce item not typically consumed (i.e. a watermelon, corn husk, coconut, banana) is considered direct human contact with the item. We do not believe that it should be considered direct human contact. FMI notes that FDA is contemplating similar issues in the Produce Safety Rule:

> For example, the QAR ranked certain produce commodities, such as bananas and coconuts, as lower risk for illness, in part because such commodities are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity. Should such commodities be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements?[6]

Holding of Produce is Characterized as a Low-Risk Activity in the Proposed Rule

Under §117.5(g)(6), FDA exempts from subpart C on-farm packing or holding of intact produce by small and very small businesses on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership on the basis that it is a "low-risk" holding activity. Packing and repacking of intact fruits and vegetables is similarly considered low-risk when performed by small and very small businesses and exempted from subpart C. FMI believes that just as packing and holding of intact produce is a low risk activity that is exempt from subpart C when conducted by certain small and very small businesses, it also is a low risk activity when conducted by larger businesses and similarly should be exempt.

FDA Should Exempt Supermarket Distribution Centers From Subpart C Requirements and Instead Require them to Have Written CGMPs

Distribution centers are low-risk facilities and requiring them to comply with Subpart C would impose very large costs ($23 million by FDA's estimate, $173 billion + by FMI's estimate if supplier verification is required) while not leading to enhancement of public health. Rather than requiring distribution centers to create and implement a written food safety plan, FMI proposes that FDA require distribution centers to create and implement written CGMPs instead.

CGMPs are essential in distribution centers. Prerequisite programs are the foundation of HACCP plans and have to be written and documented. The only control step in a distribution center is temperature control, which can be addressed through the modified requirements. The "preventive" part of food safety in distribution centers is in having

[6] 78 CFR 3528 (January 16, 2013).

strong CGMP programs and proper temperature controls in place for the type of products. While increasing the burdens imposed on retailers and wholesalers, requiring written CGMPs would be far less onerous than subjecting distribution centers to subpart C. We believe that requiring CGMPs to be written strikes the proper balance between costs and benefits in the Proposed Rule.

A Risk-Based Approach Should Not Prioritize Regulation at Distribution Centers

The driving principle in implementing FSMA is risk. FDA has stated that it is taking a risk-based approach in implementing the law and the title of 21 USC 350g incorporates the term ("risk-based" preventive controls). It follows that FDA should not prioritize regulation at warehouses or distribution centers because risks are very low. As FDA has stated in the Proposed Rule, the outcome of conducting a hazard analysis on the holding of non-TCS (time/temperature control for safety) unexposed packaged foods is that no hazards are reasonably likely to occur.

In many cases an item may be in a distribution center for a period of mere hours and there is minimal handling.

The holding of food at a distribution center is a low-risk activity and should not be the focus of preventive controls regulations.

A typical distribution center facility ships in excess of 545,000 cases of product every week and more than 47 million pounds of food every four weeks.[7] More than 600 million pounds of food is shipped out of the typical distribution center facility every year. The industry transports billions of pounds of food across the nation annually. The dearth of recalls related to holding activities at distribution centers is a testament to the effectiveness of industry practices as well as the low level of risk associated with such activities.

Congress Never Identified Food Safety Risks Associated with Holding Facilities During Consideration of FSMA

FMI conducted an exhaustive search of the legislative history of FSMA and nowhere in the record is there any indication that Congress identified holding facilities as being an area of concern in need of regulation.

The Preliminary Regulatory Impact Analysis Has Failed to Account for Regulation of Distribution Centers

The preliminary regulatory impact analysis for the Proposed Rule (PRIA) has failed to account for the fact that 1,903 supermarket distribution centers are subject to the

[7] Food Marketing Institute, Distribution Center Benchmarks 2007.

regulation. Supermarket distribution centers are classified under Standard Industrial Classification Code 5141. The PRIA did not contemplate that these facilities are subject to the regulation. Code 5141 is not included in Table 7 of the PRIA, which indicates the number of FDA-Regulated Food Facilities subject to the Proposed Rule partitioned by the 4 digit SIC Code. The PRIA excludes 1,903 warehouses from the calculation.

FDA Estimates Indicate that Exempting Distribution Centers From Subpart C Will Cut $23 Million in Regulatory Costs from the Proposed Rule

The PRIA estimates that the Proposed Rule imposes average annualized costs of $13,000 per facility for facilities subject to subpart C and $1,000 for facilities exempt from subpart C. Multiplying the difference between these two figures by the number of facilities regulated ($12,000 x 1,903) equals $22,836,000. Thus, exempting distribution centers will reduce the burden of the rule by $23 million. FMI, however, knows the savings would be significantly greater. This will significantly reduce the overall burdens of the Proposed Rule on the economy while having no significant impact on public health for reasons explained further in these comments.

Exempting Distribution Centers will Save Hundreds of Billions if Supplier Verification is Required in the Final Rule

If FDA decides to subject supermarket distribution centers to subpart C, and subpart C contains a requirement for supplier verification, more than $173 billion in regulatory costs would be imposed annually on the industry. The typical distribution center carries approximately 15,000 different stock keeping units (SKUs) of food.[8] More than 13,000 of these SKUs are FDA-regulated. The typical GFSI audit costs approximately $5,000. If supermarket distribution centers were required to conduct audits for each FDA-regulated food product they carry, it would impose costs on the economy of more than $123 billion (13,000 x $5,000 x 1,903=$123,695,000,000) each year (assuming annual audits are required). Supplier verification entails more than just audit costs: recordkeeping, testing, document review are all parts of it. These would entail a minimum of $2,000 for each item annually which would add an additional $49 billion to the annual costs of the regulation (13,000 x $2,000 x 1,903=$49,478,000,000). The combined total of these two figures exceeds $173 billion ($173,173,000,000). These costs would be devastating for the industry. Even assuming that retailers did not incur costs for audits, the costs associated with merely reviewing and maintaining the paperwork under a supplier verification program would exceed more than eight percent of total supermarket sales annually.[9]

[8] FMI 2007 Distribution Center Benchmarks Study.
[9] 2012 total supermarket sales were $602.609 billion.

FDA Has Authority to Exempt Supermarket Distribution Centers from Subpart C Pursuant to 21 USC 350g(n)(3)

Authority Under 21 USC 350g(n)(3)

21 USC 350g(n)(3) requires that the Proposed Rule be promulgated in such a manner as to "provide sufficient flexibility to be practicable for **all sizes and types of facilities** (emphasis added), including small businesses such as a small food processing facility co-located on a farm . . ."[10] Furthermore, FDA is required to "acknowledge differences in risk."[11]

The language of the statute is clear: Congress granted FDA authority to provide flexibility within the Proposed Rule for businesses of "all sizes and types," not just small businesses and to acknowledge differences in risk. FMI believes this language grants FDA authority to exempt distribution centers from subpart C because (1) distribution centers are very low risk facilities and (2) requiring distribution centers to comply with subpart C would not be practicable.

FDA Has Authority to Exempt The Holding of Packaged Foods in Supermarket Distribution Centers from Subpart C Pursuant to 21 USC 350g(m)

Authority Under 21 USC 350g(m)

Congress granted FDA authority to exempt or modify the requirements for compliance under 21 USC 350g(m) for facilities that are solely engaged in the production of food for animals other than man; facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing; and, facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment.

FDA has exercised the aforementioned authority in the Proposed Rule by exempting facilities solely engaged in the storage of packaged food that is not exposed to the environment from subpart C and establishing modified requirements for facilities solely engaged in the storage of packaged TCS food that is not exposed to the environment. FMI believes FDA should similarly exempt unexposed packaged food in holding facilities also storing unpackaged produce, as well as provide for modified requirements for unexposed packaged TCS foods in such facilities, for reasons stated later in this document.

[10] 21 USC 350g(n)(3)(A).
[11] 21 USC 350g(n)(3)(C).

Exempting the Storage of Packaged Foods Not Exposed to the Environment in Distribution Centers Pursuant to 21 USC 350g(m) from Subpart C is Consistent with the Intent of Congress and Text of FSMA

In addition to the authority granted to FDA in 21 USC 350g(m). Congress included several other exemptions to the Preventive Controls Rule to avoid duplicative burdens and limit the applicability of the regulation to small businesses. 21 USC 350g explicitly exempts facilities required to comply and in compliance with (1) The Seafood Hazard Analysis Critical Control Points (HACCP) Program; (2) The Juice HACCP Program; and, (3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards. 21 USC 350g also provides for modified requirements for qualified facilities (small businesses).

21 USC 350g(j)(1) states that section 350g:

> shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with . . . The Seafood Hazard Analysis and Critical Control Points Program . . .The Juice Hazard Analysis and Critical Control Points Program . . . The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards . . .

In analyzing the section 350g(j)(1), FDA determined it had three options: (1) Exempting all food manufactured, processed, packed or held by a facility from section 350g if the owner, operator, or agent in charge of the facility is required to comply with and is in compliance with Seafood or Juice HACCP; (2) Exempting an entire facility only if the owner, operator, or agent in charge of the facility is subject to and in compliance with Seafood and Juice HACCP with respect to all food manufactured, processed, packed, or held by the facility; and (3) Exempting those activities of a facility that are subject to Seafood and Juice HACCP, regardless of whether the facility manufactures, processes, packs or holds other food. FDA adopted the third option.

In rejecting the first option, FDA stated, ". . . there is no apparent reason to regulate the same type of food not subject to part 120 or 123 differently depending on whether the food is manufactured, processed, packed or held by a facility that manufactures, processes, packs or holds other food that is subject to part 120 or 123."[12] (3703). We support FDA's position on this issue.

We believe this same logic applies to the regulation of distribution centers under the Proposed Rule. Why regulate the same type of food (unexposed packaged foods not exposed to the environment) differently depending on what facility that food is stored in? In the instance of a distribution center, such food would be subject to subpart C merely because the distribution center holds one or more unpackaged produce items. FMI

[12] 78 Fed. Reg. 3703.

does not believe this makes sense or reflects the intent of section 350g and asks that the Agency exempt unexposed packaged items in such distribution centers from subpart C. Subjecting such items in distribution centers to subpart C would impose enormous unnecessary costs on the industry. If supplier verification is required as part of subpart C for distribution centers costs could exceed $173 billion annually.

If FDA Believes it Does Not Have Authority to Wholly Exempt Supermarket Distribution Centers Then it Should Exclude The Holding of Unexposed Packaged Foods in Distribution Centers from Subpart C

Subpart C Should Not Apply to the Holding of Packaged Foods in Distribution Centers

The vast majority of product handled by the distribution centers of FMI members is packaged food not exposed to the environment. If FDA does decide to not exclude distribution centers from subpart C, FMI believes that the requirements of subpart C of the Proposed Rule should apply in distribution center solely to those products that are exposed to the environment. The holding of all products by a distribution center that are packaged products not exposed to the environment or products subject to and compliant with (1) The Seafood Hazard Analysis Critical Control Points (HACCP) Program; (2) The Juice HACCP Program; and, (3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards should be exempted from the subpart C. Such an exemption would be consistent with FDA's logic in applying subpart C to facilities conducting activities involving both foods subject to Seafood HACCP and Juice HACCP and foods not subject to those HACCP requirements. For such facilities FDA decided to exempt those activities subject to Seafood HACCP and Juice HACCP from subpart C, while applying the subpart C to the other foods the facility is conducting activities with. FMI further believes that the modified requirements in §117.206 should apply to the holding of any unexposed TCS foods in distribution centers.

Distribution Centers are Already Subject to CGMP Requirements

In justifying its decision to exempt facilities engaged solely in the storage of unexposed, packaged food. FDA states:

> There are limited routes of contamination for unexposed packaged food in a facility that solely stores unexposed packaged food (e.g. packaged food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or it human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed part 117, subpart B…..would apply to the storage of unexposed packaged food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator or agent in charge of a facility to address these routes of contamination by

> applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C.[13]

Distribution centers are subject to the same CGMP requirements in the Proposed Rule referenced above as being adequate to prevent contamination of unexposed packaged foods. We believe there is no reason not to also exempt unexposed packaged foods in distribution centers from subpart C. Furthermore, the CGMP requirements apply to all foods in distribution centers, including exposed foods. The proposed CGMP requirements require that food must be stored under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container. These requirements are adequate to prevent the contamination of unexposed packaged foods as well as exposed foods in holding facilities like distribution centers.

Since the CGMPs are so essential in distribution centers, FMI recommends that the CGMP programs be written plans. With HACCP plans, prerequisite programs are the foundation of HACCP plans and have to be written and documented. The only control step in a distribution center is temperature control, which can be addressed through the modified requirements. The "preventive" part of food safety in distribution centers is in having strong CGMP programs and proper temperature controls in place for the type of products. In general, distribution centers have dry storage, refrigerated storage and frozen storage.

Most of the Requirements of Subpart C are Not Applicable to the Storage of Non-TCS Unexposed Packaged Food

FDA states in the Proposed Rule that:

> Many of the requirements that would be established in proposed subpart C would be directed to manufacturing, processing, and packing food and would not apply to the storage of unexposed packaged food that does not require time/temperature control for safety. This is the case for:
>
> Process controls
> Food allergen controls
> Sanitation controls
> Monitoring of process controls, food allergen controls, and sanitation controls
> Corrective actions
> Verification (including initial validation) of process controls; and
> A recall plan (recalls generally are initiated by the manufacturer, processor, or packer of the food).

[13] 78 Fed. Reg. 3713 (January 16, 2013). The exception is for facilities solely engaged in the storage of raw agricultural commodities and is not applicable to supermarket distribution centers.

FMI agrees with this conclusion and believes it illustrates the fact that subpart C is generally not applicable to the storage of unexposed packaged non-TCS foods. We therefore believe that these foods in distribution centers should be exempt from subpart C.

Most Subpart C Requirements are Not Applicable to the Storage of Unpackaged Produce

21 USC 350g(m) of FSMA states: "The Secretary may, by regulation, exempt or modify the requirements for compliance, under this section with respect to facilities that are solely engaged in the . . . storage of packaged foods that are not exposed to the environment." While FMI understands that FDA is seeking to define the term "packaged" for purposes of administering the authority granted to them in 21 USC 350g(m), we do not believe this analysis is relevant from a food safety perspective. The mere fact that some produce items may come into direct contact with humans (although this would be incidental contact in a distribution center setting) does not create a significant food safety risk, particularly because there are not prohibitions on direct human contact at the farm level.

In addition, the CGMP requirements mandate that any employee in a distribution center who is ill or appears to be ill where there is a reasonable probability of them contaminating food be excluded from any operations where contamination could be expected to occur. Furthermore, the CGMP requirements mandate that all persons working in direct contact with food must conform to certain hygienic practices to the extent necessary to protect against cross-contact and contamination of food.

All of these requirements are more than sufficient to ensure protection of public health in lieu of subpart C requirements, which again, are largely inapplicable to distribution center operations.

If FDA Believes it Does Not Have Authority to Wholly Exclude The Storage of Unexposed Packaged Foods Held in Supermarket Distribution Centers from Subpart C, Then The Agency Should Maintain its Position that No Hazards are Reasonably Likely to Occur in the Storage of Unexposed Packaged Non-TCS Foods and Thus Not Require Such Foods to be Subject to Preventive Controls

The Outcome of a Hazard Analysis for Storage of Unexposed Packaged Non-TCS Food is That There are no Hazards Reasonably Likely to Occur

FDA has concluded in the Proposed Rule that the outcome of a hazard analysis for storage of unexposed non-TCS packaged food is that there are no hazards reasonably likely to occur.[14] We agree with FDA's position and believe that because no hazards

[14] 78 Fed. Reg. 3713.

are reasonably likely to occur with non-TCS unexposed packaged foods, the holding of such foods should not be subject to the requirements of subpart C when stored in warehouses or distribution centers.

FDA has also concluded in the Proposed Rule in regard to packaged foods stored in a packaged food warehouse:

> . . . that there would be no need for the facility to establish and implement preventive controls, with corresponding monitoring, corrective actions, or verification (including validation), because there would be no hazards reasonably likely to occur to trigger such activities. We also tentative conclude that there would be no need for a qualified individual to conduct activities such as preparing the food safety plan, developing the hazard analysis; validating the preventive controls; reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions; or performing reanalysis of the food safety plan because the facility would not need to conduct these activities. Thus with the exception of the unexposed refrigerated packaged TCS food, we tentatively conclude that the food safety system that would be established in proposed subpart C is not needed to significantly minimize or prevent the occurrence of hazards that could affect unexposed packaged food at a facility solely engaged in the storage of such food.[15]

FMI agrees with this conclusion and believes the same logic applies to the holding of unexposed packaged foods in distribution centers. As FDA determined that the CGMPs are adequate to prevent contamination of unexposed packaged food in warehouse facilities, we believe there is no need for distribution centers to establish and implement preventive controls as no hazards are reasonably likely to occur. The holding of unexposed packaged foods stored in distribution centers should be excluded from the requirements of subpart C. The holding of unexposed packaged TCS foods in such facilities should be subject to the modified requirements of §117.206.

If FDA believes it does not have authority to wholly exclude unexposed packaged foods held in distribution centers from subpart C, then the Agency should maintain its position that no hazards are reasonably likely to occur in the storage of unexposed packaged non-TCS foods and not require such foods to be subject to preventive controls.

The Holding of Unexposed TCS Packaged Food in Distribution Centers Should be Subject to the Modified Requirements

FDA has exempted the holding of unexposed packaged TCS food in packaged food warehouses from subpart C (subject to the modified requirements in §117.206). FMI supports this position and believes that the holding of such items should similarly be exempted from subpart C in distribution centers and subject to the modified requirements.

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[15] Id.

FDA states that the principal hazard that would be identified in any hazard analysis for unexposed packaged food is the potential for the growth of, or toxin formation by, microorganisms of public health significance when an unexposed refrigerated packaged food requires time/temperature control for safety.[16]

The modified requirements under §117.206 would require:

- Establishing and implementing temperature controls;
- Monitoring the temperature controls;
- Taking corrective actions when there is a problem with the temperature controls;
- Verifying that temperature controls are consistently implemented; and
- Establishing and maintaining records documenting the monitoring, corrective actions, and verification.

FMI believes these requirements, combined with the CGMP requirements distribution centers are subject to are sufficient to protect public health in lieu of the subpart C requirements, which are generally inapplicable to packaged and unpackaged foods stored in distribution centers.

In addition, the requirements should be applied by temperature control area and not on a product-by-product basis due to the nature of distribution centers. For example, one plan should be adequate for the refrigerated storage area that houses TCS products and the same for frozen TCS products. It would be unrealistic and unnecessarily burdensome for distribution centers to perform a hazard analysis on each TCS product in the distribution center. In general, the hazards are the same for all TCS foods and the controls (temperature) are the same for all.

Applying Subpart C to Distribution Centers Would Impose Unnecessary Costs

The typical distribution center holds more than 13,000 FDA-regulated food items. Approximately one percent or less of these items are unpackaged and exposed to the environment. Section 117.130 requires owners/operators of facilities identify and evaluate known or reasonably foreseeable hazards, for each type of food manufactured, processed, packed or held at the facility to determine whether there are hazards that are reasonably likely to occur. Furthermore, FDA states:

> The written hazard analysis includes the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 117.130(a)(2) would not limit the requirement for a written hazard analysis to those circumstances where the owner,

[16] 78 Fed. Reg. 3712 (January 16, 2013).

> operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur.[17]

It would be very expensive and unnecessarily burdensome for a distribution center to individually review the more than 13,000 FDA-regulated unexposed packaged food items it holds and document in a written hazard analysis for each that no hazards are reasonably likely to occur. Similarly, it would be unnecessarily burdensome for a distribution center to individually review the thousands of unexposed packaged TCS items it carries and document in a written hazard analysis that the hazard for each item is the potential for the growth of, or toxin formation by, microorganisms of public health significance. Even if many of these items could be grouped into the same type of food, the burdens would still be very significant and costly. Additionally, if FDA were to require supplier verification for facilities like distribution centers, the costs imposed would exceed $170 billion annually for just that aspect of the rule alone. Packaged foods held in distribution centers should be exempt from subpart C.

Clarity on Grouping Different Food Types

Distribution centers carry more than 13,000 FDA-regulated food items. Federal HACCP regulations allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical. FDA states in the Proposed Rule that this type of grouping would be allowed under subpart C. FMI seeks greater clarity on how grouping could apply to products subject to subpart C in distribution centers. Having to conduct an individual hazard analysis for every FDA-regulated food item held in a distribution center and document it would be unnecessarily burdensome and unworkable.

FMI proposes that the requirements should be applied by temperature control area and not on a product-by-product basis. For example, one plan should be adequate for the refrigerated storage area that houses TCS products and the same for frozen TCS products. It would be unrealistic and unnecessarily burdensome for distribution centers to perform a hazard analysis on each TCS product in the distribution center. The hazards are the same for all and the controls (temperature) are the same for all.

Indeed Congress required FDA in Sec. 103 to “acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.”

Summary of FMI Positions

To summarize FMI’s positions:

[17] 78 Fed. Reg. 3733 (January 16, 2013).

Types of storage in Distribution Centers

1. Dry
2. Refrigerated
    - **a.** TCS
    - **b.** Non-TCS
3. Frozen
    - **a.** TCS
    - **b.** Non-TCS

The holding of 1 should be exempt from subpart C, the holding of 2b, and 3b should be subject to the modified requirements.

Part II Supplier Verification and Testing

FDA has indicated it intends to require domestic supplier verification in the final version of the Proposed Rule. In comments made by Agency officials at the September 2013 public meeting on the Foreign Supplier Verification Program (FSVP) and Accreditation of Third Party Auditors rules it was stated that the domestic supplier verification program will look very similar to the FSVP Proposed Rule. In addition, in the preamble to this Proposed Rule, the Agency says:

> FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent so we do not impose duplicative or unjustified requirements under those two regulations . . . Likewise, FDA is aware that there is great interest from our trading partners on, among other things, the potential overlap between the supplier verification requirements in preventive controls and in FSVP. FDA believes that the approach to harmonization between supplier verification and FSVP described above would adequately address this and comports with our obligations under the World Trade Organization (WTO) trade agreements, including adherence to the principles of the Sanitary and Phytosanitary (SPS) Agreement. In enacting FSMA, Congress explicitly recognized the importance of compliance with international agreements by providing in section 404 of FSMA that "[n]othing in [FSMA] shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.[18]

FMI has closely examined the FSVP rule and offers these comments under the assumption that domestic supplier verification will closely parallel the FSVP requirements. **FMI believes however that the public should be afforded an opportunity to comment on the regulatory text of any domestic supplier verification requirement before it is issued in a final regulation.**

[18] 78 Fed. Reg. 3767.

The Public Should be Afforded an Opportunity to Comment on the Regulatory Text of any Domestic Supplier Verification Requirement Before it is Issued in Final Form

A domestic supplier verification requirement would impose very significant impacts on many points in the supply chain. While FDA has addressed certain aspects of such a requirement in the preamble to the Proposed Rule, no regulatory text was published to give the public an opportunity to comment on it. FMI believes that the Agency should publish the proposed regulatory text for any domestic supplier verification requirement so the public may be afforded an opportunity to comment on it. The preamble to the Proposed Rule merely cites that FDA "intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805."[19] This does not provide the public with sufficient information to provide meaningful comment. We believe the Agency should release the regulatory text of any and all supplier verification requirements as proposals before they are finalized. Because of the broad impact of such a requirement, it is necessary to see the precise manner in which the text of subpart C is changed by such a provision.

Alignment with FSVP

For imported foods, the only verification that should be required is the one conducted by the entity that is the importer under FSVP. Foods imported by an importer who is in compliance with FSVP should not have to again be verified by the customer of the importer. Supplier verification under the Proposed Rule should not extend to foreign product imported in compliance with FSVP. Once a food is imported by an importer in manner which complies with the FSVP Rule, it should not be required to be verified again by the customer of such importer or at any other point down the supply chain.

Holding Facilities Like Distribution Centers Should Not Be Required to Conduct Supplier Verification

FDA requests comment on who a supplier verification program should apply to, namely whether an approval and verification program should apply to all facilities that manufacture, process, pack or hold food, or be limited (such as to facilities that manufacture or process food)? FMI believes that supplier approval and verification should be limited to facilities that manufacture and process food. Requiring holding facilities like distribution centers to conduct such activities would result in hundreds of billions of dollars in unnecessary costs and many duplicative audits.

A domestic supplier verification program applied to distribution centers would impose over $173 billion in regulatory costs annually on the industry. The typical distribution

[19] Id.

center carries approximately 15,000 different SKUs of food.[20] More than 13,000 of these SKUs are FDA-regulated. The typical GFSI audit costs approximately $5,000. If distribution centers were required to conduct audits for each FDA-regulated food product they carry, it would impose costs on the economy of more than $123 billion (13,000 x $5,000 x 1,903=$123,695,000,000) each year (assuming annual audits are required). Supplier verification entails more than just audit costs, recordkeeping, testing, document review are all parts of it. These would entail a minimum of $2,000 for each item annually. This would add an additional $49 billion to the annual costs of the regulation (13,000 x $2,000 x 1,903=$49,478,000,000). The combined total of these two figures exceeds $173 billion ($173,173,000,000). These costs would be devastating for the industry. Even assuming that retailers did not incur costs for audits, the costs associated with merely reviewing and maintaining the paperwork under a supplier verification program would exceed more than eight percent of total supermarket sales annually.[21] Requiring distribution centers to conduct verification for all of their suppliers would impose a devastating burden on the supermarket industry. While the supermarket industry would face many of these costs, with average annual profit margins of less than one percent, many of these costs would be passed on to consumers resulting in very significant price increases at the register. FDA should not require holding facilities like distribution centers to conduct supplier verification on their domestic suppliers.

A Domestic Supplier Verification Program for Holding Facilities and Would Impose Unnecessary and Redundant Burdens

Distribution centers receive consumer-ready foods. Under a domestic supplier program, for the processed foods distribution centers receive, the food manufacturer would be required to verify the practices of ingredients coming from domestic suppliers (ingredients from the foreign suppliers would be verified by the importer pursuant to FSVP). All of the ingredients would thus already be verified. The manufacturing of the food would be in a facility subject to the direct jurisdiction of the Food and Drug Administration and required to comply with the Preventive Controls Rule. Requiring an audit to ensure compliance with the Preventive Controls Rule would be an unnecessary additional layer of burden because the facility would already be required to comply and subject to the direct jurisdiction of the FDA. The distribution center would be verifying the verifier who is under direct FDA jurisdiction. This is in contrast to FSVP where the importer is verifying farms and facilities not subject to direct FDA jurisdiction.

FDA states:

> The development of a supplier approval and verification program can be part of a preventive approach. Because many facilities acting as suppliers procure their raw

[20] FMI 2007 Distribution Center Benchmarks Study.
[21] 2012 total supermarket sales were $602.609 billion.

> materials from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient.[22]

FMI does not believe FDA should implement a mandatory domestic supplier verification regime for holding facilities. The Preventive Controls Rule itself should establish a regulatory structure sufficient to ensure public health without requiring additional verification by retailers and wholesalers. Currently some retailers use supplier verification for certain categories of products based on risk. The existing system is working well in our view and a one-size-fits-all FDA-mandated approach to supplier verification would be inconsistent with a risk-based approach and would impose unnecessary costs.

Imposing Domestic Supplier Verification Requirements on Holding Facilities is Inconsistent with FSMA

Congress explicitly prohibited FDA in the Preventive Controls Rule from requiring a facility to hire a third party to audit preventive controls. "The regulations . . . shall . . . not require a facility to hire a consultant or other third party to identify, implement, certify or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party."[23] By virtue of the fact the typical distribution center handles more than 13,000 SKUs of FDA-regulated food, such a facility would effectively have to rely on third party auditors to conduct verification activities. It would simply be unfeasible for a facility to use its own employees to conduct audits. As such, a domestic supplier verification requirement for holding facilities like distribution centers would be inconsistent with FSMA.

The Role of Finished Product Testing as a Verification Measure in a Food Safety System

FDA states in the Proposed Rule that "Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing."[24] FMI agrees with this comment and believes it is particularly relevant to the retail and wholesale environment. Finished product testing at the retail level does not serve the public health interest as products are already at the point of purchase. Finished product testing at the wholesale level would be greatly burdensome and not confer a significant public health benefit.

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[22] 78 Fed. Reg. 3668 (January 16, 2013).
[23] Sec. 103(n)(3)(D).
[24] 78 Fed. Reg. 3667 (January 16, 2013).

Testing Should Not be Considered a Control Step

Testing should be treated by the Proposed Rule as a verification activity depending on the hazard analysis and not a control step. The nature and extent of testing needs to be adapted to the particular circumstances of each facility and product. In general, each kind of testing has its own role and purpose. Environmental testing is usually the most beneficial type of testing to verify if sanitation and other preventive controls are working effectively. Testing of incoming raw materials also has a role, particularly if the ingredients are not subject to a "kill step" at the manufacturing level. Finished product testing is only a beneficial verification activity in limited circumstances and requirements should not be mandated. Testing decisions should be based on the hazard analysis and level of control the facility has for those hazards. FDA should afford the public an opportunity to comment on codified text related to this topic before a final rule is issued.

Environmental Monitoring is Unnecessary for Warehouses and Distribution Centers and Should Not be Required

FDA states that they believe the environmental testing can form an important component of a modern food safety system; however, the Agency says they believe the role and need for these measures varies depending on the types of products and activities of the facility.

FMI believes environmental monitoring in the warehouse/distribution center context is not necessary because the emphasis is on prevention of contamination and strong CGMPs. FMI is not aware of any outbreaks linked to microbiological hazards introduced in a distribution center setting. Environmental pathogens in warehouses and distribution centers are not generally hazards that are reasonably likely to occur. Effectively all foods in distribution centers are in boxes, bins or sealed packages not exposed to the environment and do not come into contact with surfaces in the distribution center. The risk is simply not there to justify the very significant burden environmental testing requirements would impose on distribution centers.

Standards Should be Based on the Latest Research and be In Guidance Documents Rather than Written into Regulations

FMI strongly believes that all standards should be based on the latest scientific research available and for that reason they should be in guidance documents and not the regulation itself. This premise applies scientific standards, analytical methods, indicator organisms, and pathogens of concern. If FDA requires any of these in the final rule, FMI recommends that FDA refer to guidance where the appropriate technical and scientific standards can be made available to the industry and changed with advances in science.

Part III Food Facility Profile/Plan Submission and Consumer Complaints

Submission of a Facility Profile to FDA

FDA seeks comment on whether to require submission to the Agency of a subset of the information that would be in a food safety plan should be mandatory. The Agency notes that it had previously announced an opportunity for public comment on the proposed collection of such information on a voluntary basis. FMI previously expressed concerns with this voluntary food facility profile information collection in comments filed on July 10, 2012 on the information collection request (ICR) published by the Agency in May 2012. FMI does not believe that submission of a facility profile should be mandatory.

As part of the required food facility registration process, FDA proposes to require the submission of additional food facility profile information. According to the Agency, food facility profile information will assist FDA in determining whether a firm is high-risk or non-high-risk. The Agency states that the profile information will assist them in determining the frequency at which the firm will be inspected.

The information FDA proposes to collect includes:

> (1) The facility type (e.g. manufacturer/processor, repacker/packer, or warehouse/holding facility) and contact information;
>
> (2) The products, and hazards (e.g., biological, physical, chemical) and preventive controls measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures (e.g. seafood and juice), or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive controls measures; and
>
> (3) Other facility information such as food safety training, facility size, operational schedule, and number of employees.

The Paperwork Reduction Act (PRA) applies to the Proposed Rule. Indeed Congress explicitly directed FDA to comply with the PRA in crafting the Proposed Rule.[25] FMI thus provides comments in light of PRA requirements:

> (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

[25] 21 USC 350g(n)(3)(B).

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validation of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of technology.

Paperwork Reduction Act Analysis on Facility Profile Submission

1. Is the Proposed Collection of Information Necessary for the Proper Performance of FDA's Functions? Will the Information have Practical Utility?

FMI believes that certain information FDA has proposed to collect will have practical utility, while other information the Agency seeks to collect will not.

A. Information with Practical Utility

FMI believes that certain information will have practical utility in that it will facilitate FDA's inspection process. This information includes:

(1) Facility type;

(2) For processing facilities, products handled by the facility OR for holding facilities, the types of storage (i.e. refrigerated, frozen, dry storage); and

It is essential for FDA to make the distinction between processing facilities and holding facilities like distribution centers. FMI has reviewed FDA's draft Form 3797 (Draft Form) and in it the Agency provides a list of 27 types (plus a write-in slot) of products the user of the form is to select from. As discussed later in these comments, the typical distribution center handles nearly all of the 27 products types listed in Draft Form and should not be considered high-risk on the basis of merely handling a variety of items. FMI believes that distribution centers should generally be considered low-risk. These facilities only handle products; they do not process or pack them. FDA's existing Food Facility Registration Module contemplates the difference between processing and handling facilities and FMI believes the Draft Form should contemplate this fact as well. Distribution centers should not be required to identify individual product categories. We believe information on the types of storage maintained by a distribution center is more useful to the Agency. If a user identifies a food facility as a holding facility, the Draft

Form should automatically skip questions related to processing and inquire only on issues relevant to warehousing.

(3) Facility size based on areas where food is handled.

It is important for FDA to consider that facilities such as distribution centers may have truck washing and maintenance operations and tractor/trailer parking areas on-site. Assessing the size of a facility based on areas where food is handled rather than total area will provide the Agency with a more useful metric in preparing for inspections.

The previous information will provide FDA with the tools it needs to more effectively conduct inspections and notify facilities that might be affected by accidental or deliberate contamination of the food supply. The information will allow the Agency to better predict how long an inspection could take, the number of inspectors to send, and whether inspectors with particular expertise are needed.

B. Information Without Practical Utility

A number of the data points FDA seeks to collect will not provide the Agency with useful information and impose a very significant—and unnecessary—paperwork burden on the industry.

Hazards and Preventive Controls

FMI believes that the information on hazards and preventive controls FDA seeks to collect lacks practical utility, will not serve to facilitate the inspection process, and will be extremely burdensome for food retailers to submit. The Draft Form provides a list of 27 types (plus a write in slot) of products the user of the form is to select from. For each product, the user is asked to identify potential hazard(s) from a list of 46 options, and select preventive controls implemented for each hazard from a list of 20 options. Many types of products will have multiple hazards and multiple controls.

Of the 27 products listed, the typical distribution center will carry well over 20 of them. It is conceivable that one product category will have multiple potential hazards identified with multiple controls for each hazard. The form does not specify that hazards required to be identified are only hazards controlled by the facility submitting the form. If distribution centers are required to enter hazards the facility does not control (hazards are not reasonably likely to occur for the storage of non-TCS unexposed packaged food), completing the hazards and controls section for a distribution center using the Draft Form will likely require hundreds of entries. We believe this information will be of little practical utility to the Agency while imposing tens of hours of paperwork burdens for each facility. Furthermore, all of this information is generally available to inspectors

when they conduct inspections. Requesting it to be disclosed in advance places a redundant paperwork burden on the supermarket industry.

FMI is concerned not only about the paperwork burden, but that the hazard and preventive control information could be misinterpreted. Risks can be managed effectively using different controls. FDA should not view differences in the controls applied in various facilities as an indication that one facility has better practices than another and thus should have a different risk profile.

As an alternative, the Agency could consider asking in the form of yes/no questions as to whether a facility has one or more hazard analyses and HACCP plans available for review.

Number of Employees

FMI does not believe that information on the number of employees at a facility has practical utility to the Agency. The number of employees at distribution centers fluctuates regularly. In addition, processes at distribution centers are becoming increasingly automated. Information submitted on facility size is more relevant to assisting the Agency in preparing for inspections.

Operational Schedules

Information on operational schedules should be limited only to the question FDA proposes in the Draft Form: whether a facility operates on a seasonal or year-round schedule. Any more detailed information may present the Agency with an inaccurate picture as operating schedules may change regularly. As such, this information would be of little practical utility to FDA.

2. The Accuracy of FDA's Estimate of the Burden of the Proposed Collection of Information

FDA has Grossly Underestimated the Burden

In the ICR, FDA estimates that submitting a new domestic food facility profile will take only 15 minutes. FMI believes this grossly underestimates the amount of time retailers will need to respond to the form. As discussed earlier, the typical distribution center carries 26 of the 27 product categories listed in the Draft Form. Providing detail on the potential hazards and preventive controls implemented for each product will take retailers a total of 20-30 or more hours per facility. Most chain retailers have multiple facilities. A national retailer will easily have a dozen or more distribution centers. The largest food retailers will have several dozen. It is conceivable that hundreds of hazard and preventive control entries will be required to be made for each distribution center to

respond to the Draft Form if such facilities are required to input information on hazards they do not control. The typical distribution center carries more than 13,000 different SKUs of FDA-regulated food.[26] Completing the form itself will require several hours due to all of the entries. Compiling the information for each facility will take 20-30 hours. Under the Paperwork Reduction Act, FDA is required to consider not only the time it takes to complete the form, but also the time it takes to compile the information.[27] FDA must revise its estimate of the burden imposed by the ICR.

3. Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected

As discussed previously, FMI believes that FDA's proposal to collect hazard and preventive control information will not provide the Agency with clear, useful or relevant information. To enhance the quality, utility and clarity, the Agency should eliminate the collection of hazard and preventive controls information. FMI also believes that the question on the number of employees in the Draft Form should be eliminated for the reasons discussed previously.

4. Ways to Minimize the Burden of the Collection of Information on Respondents

Distribution Centers Should Generally be Considered Low-Risk

While distribution centers handle a wide range of products, the vast majority of these products are enclosed in packaging and no processing occurs within the facility. FDA should contemplate this fact and generally consider distribution centers to be in a low-risk category. Focusing FDA resources on distribution centers at the expense of inspecting other categories of facilities would only serve to diminish the effectiveness of the Agency's efforts to strengthen food safety regulation and be inconsistent with the objectives of FSMA. Generally classifying distribution centers as low-risk will minimize the burden of the ICR on the supermarket industry.

Information on Preventive Controls

FMI has concerns regarding FDA's proposal to collect information on hazards and preventive control measures implemented at each facility. The Draft Form directs users to select from lists of hazards categorized as biological, chemical and physical, as well as lists of process controls. As discussed previously, completing this section would impose a burden on industry of 20-30 hours or more per facility. FMI does not believe the Agency should request this documentation as it would impose an enormous paperwork burden on retailers without being of practical utility to FDA. This information

[26] FMI 2007 Distribution Center Benchmarks Study.
[27] 5 CFR Part 1320.

is currently available to the Agency upon inspection. Furthermore, the Agency enjoys expanded authority to access records under FSMA. Various controls can be effective in managing risk and the Agency should not be making risk assessments on the basis of this information. Eliminating this section of the Draft Form would minimize the burden of the ICR.

Supplemental Information on Preventive Controls, Food Safety and Food Defense Training

FMI seeks clarification that the Agency only intends to have users identify hazards and preventive controls from the lists provided on the Draft Form and not request the vast records of HACCP plans, standard operating procedures (SOPs) and prerequisite programs (PRPs) of facilities pursuant to the ICR. Similarly, FMI seeks clarification on the level of detail FDA intends to request regarding food safety and food defense training. Records on HACCP plans, SOPs and PRPs are vast and retailers have reams of materials related to food safety and food defense training. Requiring such information to be submitted to FDA would be extremely burdensome while providing the Agency with information that has little or no practical utility. This information is available to the Agency upon inspection. In the Draft Form, the Agency poses food safety and food defense training questions in simply a yes/no format. We believe the inquiry should remain in that format or be stricken entirely. FMI does not believe any of the above mentioned supplemental information should be requested by the Agency in conjunction with this ICR or any in the future as it would impose an enormous paperwork burden on retailers; be very cumbersome to submit; and provide the Agency with little useful information.

Allowing Partially Completed Forms to be Submitted

While some facilities may wish to respond to all inquiries FDA is proposing to collect information on, others may wish to only respond to certain questions. FMI believes that facilities that wish to voluntarily submit the information FDA is seeking to collect pursuant to the ICR be able to selectively respond to the fields they wish to rather than being required to complete the form in its entirely, or not fill it out at all. Permitting a partially completed form to be submitted is likely to increase the number of responses received by FDA and would ease the burden associated with the ICR. FDA should not penalize firms in any way for submitting partially completed forms. Users should also be able to save the data they have entered into the system before submitting it to the Agency.

Education and Outreach

FMI encourages the Agency to conduct education and outreach in regards to the ICR and the overall registration process. Providing clear and concise educational materials,

hosting webinars and participating in industry events would make the transition to the new system easier for industry.

Confidentiality

FMI seeks clarification from FDA as to how information submitted pursuant to the ICR will be maintained confidentially and also whether the Agency intends to share such information with other entities, including governmental entities at the federal, state and local level. If the Agency does seek to share information with other entities, FMI seeks clarification as to which types of entities and the manner in which the information will be shared, including steps taken to ensure the security of such data. FMI believes that such information should be shared solely for the purposes of food safety related inspections and notifying facilities that might be affected by a deliberate or accidental contamination of the food supply. FMI believes information obtained in connection with the ICR should be treated as confidential and be protected from disclosure under the Freedom of Information Act.

Quantitative Information Format

It will be less burdensome if the reregistration module allows quantitative information to be submitted in ranges rather than requiring submission of an exact number.

Obligation to Update Information

The number of employees at a facility and types of products handled may vary over the course of one or two years. If a facility chooses to provide information on a voluntary basis and begins handling a new type of product, or significantly changes the number of employees before it is due to reregister with the Agency, would it be obligated to update the information? FMI strongly believes information should only be required to be updated in conjunction with the compulsory biennial mandatory registration schedule. Food facilities should not be penalized for failing to update information provided on a voluntary basis pursuant to the ICR. Requiring updates only in conjunction with the mandatory biennial registration process would ease the burden of the ICR.

Eliminating Redundant Disclosures

On June 22, 2012, Cass Sunstein, the Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget, sent a memorandum to the heads of executive departments and agencies regarding reducing reporting and paperwork burdens. The memo directed agencies to “take meaningful steps to reduce paperwork and reporting burdens on the American people” by, among other things, “Eliminating redundant or unnecessary collections.”

The ICR does contain redundant collections. Namely, the existing Food Facility Registration Module requests information on facility type and products handled while the ICR seeks the same information.[28] FMI believes the Agency should minimize redundancies to the greatest extent possible and use the information it already has. As such, the Agency should not be requesting information on facility type, products handled and, if it decides to as we recommend, types of storage, through this ICR. All of these data points are already collected by the existing Food Facility Registration Module.

Submission of Food Safety Plan to FDA

FDA should not require electronic submission of food safety plans. Food safety plans are most appropriately reviewed by FDA during on-site facility inspection, with the support of people familiar with the system who can answer questions and show an inspector relevant equipment, operations and procedures. Plans are of limited utility outside of the plant context and there would be significant challenges in providing updates to FDA. We agree with FDA that submission of food safety plans should not be required.

Review of Complaints

FDA is seeking comment on whether and how a facility's review of complaints, including complaints from consumers, customers or other parties, should be required as a component of its activities to verify that its preventive controls are adequately minimizing the occurrence of hazards.

Grocery retailers receive tens of thousands of complaints from consumers each year. Most complaints relate to product quality rather than safety. Retailers proactively deal with such complaints. Complaints are generally managed at the retail level, and not at distribution centers. FMI questions the utility providing this information to FDA and notes that systems exist currently, like the Reportable Food Registry. FMI seeks greater clarification as to what constitutes a valid complaint. Investigation of complaints should only be required under the Proposed Rule for complaints potentially related to hazards controlled by the facility receiving them.

Part IV GFSI Schemes and the Proposed Rule

Compatibility with GFSI Benchmarked Schemes

FMI believes that FDA should structure the Proposed Rule, as well as other requirements of FSMA, in such a manner that contemplates the existing Global Food

[28] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/ucm073706.htm#section1

Safety Initiative (GFSI) benchmarked schemes, such as FMI's Safe Quality Food Institute. The GFSI system was developed by the global food industry to improve food safety. It has been in place for over a decade and exceeds most governmental standards for food safety. Tens of thousands of food facilities and farms currently adhere to such standards and requiring them to redo existing preventive control plans and processes that are consistent with FSMA standards would impose needless costs and burdens. FDA should seek to craft regulations to maximize compatibility with existing GFSI benchmarked standards. Existing GFSI scheme-complaint food safety plans should not have to be completely rewritten solely for purposes of complying with the Proposed Rule.

FMI owns the Safe Quality Food Institute (SQF). SQF is a GFSI benchmarked scheme SQF has the broadest scopes of recognition of any GFSI scheme and its reach truly extends from farm to fork.

SQF has conducted a gap analysis between its requirements, and the requirements of the Proposed Rule. In most categories, SQF equaled or exceeded the requirements of the Proposed Rule. GFSI programs like SQF have greatly enhanced food safety practices both in the U.S. and around the world. Firms have dedicated very significant resources in improving systems to meet SQF standards.

Congress directed FDA in crafting the Preventive Controls Rule to ". . . ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date."[29] We believe this requires FDA to make the Proposed Rule compatible to the greatest extent possible with existing GFSI schemes.

Part V Preventive Controls Issues

Remote Access of Records

Proposed § 117.320 does not explicitly require a facility to send records to the Agency rather than making the record available for review at a facility's place of business. FDA is requesting comment on whether proposed § 117.320 should be modified to explicitly address this circumstance and if so, whether FDA should require that the records be submitted electronically. FMI does not believe that FDA should require records to be submitted electronically, and seeks information on the statutory authority the Agency is relying on in requiring electronic submission of records.

[29] Sec. 418(n)(5).

Public Disclosure of Records

Proposed § 117.325 would establish that all records required by proposed part 117 are subject to the disclosure requirements under part 20. FDA's regulations in 21 CFR part 20 govern FDA's disclosures of confidential information, including treatment of commercial confidential information and trade secret information. FDA's general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under the Proposed Rule. FMI emphasizes the importance of securely maintaining commercial confidential information and trade secret information.

Applying Part 11 to Part 117 Records

We believe that FDA should exempt part 117 records from compliance with part 11. Part 11 would mean for many businesses that recordkeeping systems would have to be redesigned and recreated. As such, FDA should not subject records required to be kept under part 117 to part 11.

Requirement to Store Records Onsite

Proposed §117.315(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after six months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of a request for official review. The food safety plan would be required to remain onsite. FMI believes that onsite storage of records should not be required so long as they can be provided to the Agency within a reasonable period of time. Records should be able to be kept in the location where they are created, which may be at corporate headquarters. FMI does support FDA's position that electronic records are considered to be onsite if they are accessible from an onsite location.

FMI supports FDA's position that provides that if the plant or facility is closed for a prolonged period, records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

Distinguishing Between Critical Control Points and Preventive Controls

FDA notes that:

> Although the approach in section 418 and this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls. Under proposed s. 117.135(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the

> facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility. . .[30]

FMI agrees that not all preventive controls need to be constructed as critical control points. It is important that FDA remain cognizant of this distinction throughout the rulemaking process.

Farm Mixed-Type Facilities

FMI supports FDA's position in the Proposed Rule that unless an exemption from section 418 of the FD&C Act applies, a facility that is required to register under section 415 of the FD&C Act should be subject to section 418 with respect to all its activities that trigger the section 415 registration regulations, but not with respect to its activities that would not trigger the section 415 registration regulations.

Drying a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities to Create a Distinct Commodity

FDA previously maintained the position that the drying of herbs on the farm was not considered a manufacturing activity. In the Proposed Rule, FDA changes this position and now would consider this activity manufacturing subject to FSMA Preventive Controls requirements. FMI supports FDA's position that drying of herbs is a manufacturing activity subject to Preventive Controls requirements.

Qualitative Risk Assessment of On-Farm Activities Outside of Farm Definition

FMI previously filed comments on the Quantitative Risk Assessment, which are attached as Exhibit A.

Recalls

Should there be a requirement for a mock recall as a verification activity in the Proposed Rule?

Yes, however, mock recalls should only be required for facilities initiating recalls, not registered facilities as recall receivers, such as distribution centers. Retail companies execute multiple recalls each week and adding the requirement to perform a mock recall would be an unnecessary burden on the retail industry.

[30] 78 Fed. Reg. 3660 (January 16, 2013).

Food Safety Plans

Should validation of a food safety plan occur prior to implementation of the plan, or when necessary during the first six weeks of production? Is six weeks enough time to implement any additional preventive controls?

Validation of a food safety plan should occur during the first six weeks of production or longer when necessary so long as the timeframe is reasonable.

Calibration

FMI agrees with FDA that setting a specific frequency for review of calibration records is not warranted.

Radiological Hazards Should be Considered a Subcategory of Chemical Hazards

Classifying radiological hazards as a subcategory of chemical hazards would simplify the hazard analysis for FMI members. FDA has considered radionuclides as chemical hazards previously,[31] and we believe that they should continue to do so for purposes of the Proposed Rule.

Responsibility For Product in Transit

The Proposed Rule requires the mandatory hazard analysis to evaluate transportation practices on the safety of the finished food for the intended consumer.[32] The food facility then has an obligation to identify and implement preventive controls to minimize or prevent the hazards identified in the analysis. FMI seeks clarity regarding the preventive controls obligations related to the transportation practices. FMI does not believe that a food facility receiving product should bear responsibility for preventing or minimizing hazards for foods that are not being transported under its custody. FMI is aware that the Sanitary Food Transportation Act (SFTA) implementation will likely impose such requirements on transporters.

FMI believes the following excerpt from the preamble to the seafood HACCP is relevant to the Proposed Rule:

> When processors accept raw materials for processing, especially from vessels, they assume some responsibility for the condition of the incoming materials, regardless of how others are regulated. This is true under both general commercial law and the laws administered by FDA. Carriers likewise have responsibilities. If a carrier fails to exercise such controls as are necessary, food that it carries may be rendered adulterated and the owner of the product, i.e., the processor, could suffer product loss. …..While these regulations exempt carriers and harvest vessels from direct

[31] http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/default.htm
[32] §117.130(c)(3)(iv).

> coverage, experience with the application of a mandatory HACCP program may, at some later date, cause the Agency to reconsider its approach…….

FMI believes SFTA requires FDA to reconsider the approach in the Seafood HACCP Rule of exempting carriers from direct regulatory coverage.

FDA states in the Proposed Rule: "We do not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur."[33] FMI seeks greater detail as to how FDA believes facilities must consider transportation practices following the implementation of SFTA regulations.

PRIA Does Not Contemplate Displaying Signs of Qualified Facilities at Retail

The Proposed Rule requires Qualified Facilities that do not submit documentation to FDA that demonstrates that the owner, operator or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls and is monitoring the performance of such controls, to notify consumers as to the name and complete business address of the facility. If the product requires a label, this information must be stated on the label. If the product does not require a label, this information must be displayed at the point of purchase on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice in the case of internet sales.

Retailers will incur costs in creating and maintaining such signage, and the PRIA failed to consider these costs.

FMI also seeks clarity over where the regulatory obligation lies for such products once they are offered for sale at retail. The Proposed Rule does not regulate retail stores as section 103 of FSMA applies only to food facilities, retail stores are not food facilities.

FMI believes that if a small producer has a program that meets basic food safety standards, the labeling requirement at retail should be waived. GFSI certified suppliers should be exempt from the labeling requirement.

Validation

FMI believes that validation should be addressed separately from verification. Validation should not be required for each individual control, but rather it should be permissible to validate combinations or systems of controls. Ninety days should be provided to conduct validation, which is consistent with FSIS's draft guidance on this issue.

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[33] 78 Fed. Reg. 3737 (January 16, 2013).

FMI has concerns related to the requirement that the validation of preventive controls include collecting and evaluating scientific and technical information, or conducting studies when such information is not available or is insufficient. FDA cites examples of such scientific and technical information as being scientific publications, government documents, predictive mathematical models, and technical information from equipment manufacturers and trade associations. FMI seeks clarity as to how the Agency expects such materials to be maintained.

Pilot Plants and Test Kitchens

Developing a full food safety plan is cumbersome and restrictive for pilot plants and test kitchens. FMI believes this should not be a requirement for such facilities.

Pasteurized Milk Ordinance

FMI believes that facilities that are subject to and in compliance with the Grade "A" Pasteurized Milk Ordinance (PMO) should be exempted from the Proposed Rule and retailers and others sourcing from such facilities should not be required to conduct supplier verification activities related to them other than confirming they are subject to and in compliance with the PMO. Indeed, FDA states in the Proposed Rule that "The PMO HACCP Appendix essentially includes the same requirements as described in the HACCP regulation for juice . . ."[34] In addition, Congress directed FDA to contemplate exempting such facilities:

> In promulgating the regulations under paragraph (1)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the FDA Food Safety Modernization Act, including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date.[35]

Part VI Definitions

Definition of Facility

FMI supports FDA's definition under § 117.3 to define facility to incorporate the statutory definition under section 418 of the FD&C Act.

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[34] 78 Fed. Reg. 3743 (January 16, 2013).
[35] 21 USC 350g(n)(5).

Definition of Owner, Operator or Agent in Charge

FDA requests comment on whether it would be appropriate to revise the Proposed Rule to replace the terms "owner, operator, or agent in charge" with pronouns such as you or your. FMI does not believe this would simplify the presentation of the regulations because it is less precise and does not support such a change.

Definition of Manufacturing/Processing

FMI believes that chopping should be included in the definition of manufacturing/processing.

Definition of Food Allergen

FMI supports the definition of "food allergen" in the Proposed Rule. FDA defines the term as a major food allergen as defined in section 201(qq) of the FD&C Act.

Definition of Environmental Pathogen

FDA is proposing to define the term "environmental pathogen" to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing or holding environment. FDA states that examples of environmental pathogens include *Salmonella* spp. and *Listeria monocytogenes.*

FMI agrees with the definition but notes that the examples might change with time. Flexibility is needed in the regulation to address emerging pathogens. Flexibility can be achieved by issuing guidance on certain matters so they can reflect the latest advances in science.

Use and Definition of the Term Hazard Reasonably Likely to Occur

FMI seeks greater clarity on the definition of hazard reasonably likely to occur. Preventive controls apply to a broader array of food processes than simply CCPs. 21 USC 350g(c) states that: "The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any . . ." Preventive controls not only apply to CCPs, but other food processes. The term "reasonably likely to occur" is used in the Seafood and Juice HACCP regulations[36] which requires the HACCP plan to ". . .list the food safety hazards that are reasonably likely to occur," and list the critical control points and critical limits among other things.

FMI is concerned that using the same lexicon for hazards in the Proposed Rule as in the Seafood and Juice HACCP regulations will create confusion. We believe instead

[36] 21 CFR 123.6, 21 CFR 120.7.

that the definition contained in the Proposed Rule should be distinguished from the two as preventive controls apply to a universe of food processes beyond just CCPs. We believe that FDA should consider replacing the term "Hazard Reasonably Likely to Occur" with "Known or Reasonably Foreseeable Hazards," which is consistent with 21 USC 350g(b).

It is important that the Proposed Rule provide that both likelihood and severity need to be considered in a scientific hazard analysis, consistent with international standards. For example, as outlined in Codex HACCP guidelines, the selection and management of controls requires consideration of two important elements: severity and probability. By considering both severity and probability (or likelihood), facilities are able to successfully evaluate the significance of potential hazards on a case-by-case basis, determine the appropriate control measures, and decide how such measures need to be managed. Significantly, it is very common to consider the contributions of prerequisite programs—many of which FDA will likely want to regulate as preventive controls—in deciding a hazard is not reasonably foreseeable. This approach encourages strong food safety programs and aligns with FSIS precedent.

FDA states that specific pathogens would be considered to be a hazard that is reasonably likely to occur for raw materials and ingredients that have been documented to be contaminated with such pathogens, as well as for ingredients with similar characteristics (because such contamination might be expected in ingredients that are produced in a similar manner). We seek clarity as to what the Agency means by "documented." If there has been merely one incident under exceptional circumstances, it may not be appropriate to consider such hazard as a hazard reasonably likely to occur.

FMI also seeks more information regarding FDA's statement that although label information, such as cooking instructions, may be a factor to consider, a hazard may be reasonably likely to occur even with such label information.

Part VII CGMPs

Food Allergens/Cross-Contact

FDA should clarify that cross-contact is not a form of contamination, that the Agency is not imposing a zero tolerance standard for allergen management, (consistent with the rule on allergen thresholds), and that the necessary allergen controls are driven by the hazard analysis.

Training

Requirements for education and training should provide flexibility for companies to determine the scope and frequency of such training based on the facility, the types of products, and the job responsibilities of the employee. Training should also be widely available and open to a number of training providers to not be cost prohibitive.

Packaging

FDA should clarify that food packaging material refers to the food-contact portion of the packaging material.

Part VIII Conclusion

FMI appreciates the opportunity to comment on this important matter and we look forward to continuing to work with the Agency in the implementation of FSMA. We believe that supermarket distribution facilities should generally be exempt from subpart C and instead require them to have written CGMPs. Please contact me at elieberman@fmi.org or 202-810-4044 if you have any questions.

Sincerely,

Erik R. Lieberman
Regulatory Counsel

Attachment A

February 15, 2013

Submitted Electronically

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration,
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. FDA–2012-N-1258

RE: Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on the "Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm." We commend FDA for completing a risk assessment to support decisions made during the rulemaking process.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

The FDA qualitative risk assessment models risk from certain activity/food combinations conducted at small farm mixed-type facilities. Modeling these activities is a challenge due to the lack of specific small farm consumption data and other model inputs and known and unknown variability, such as infectious dose of pathogen/toxin and extrinsic and intrinsic growth conditions. The FDA risk assessment employs a definition of a low risk activity/food combination as: 1) has inherent controls, such as a low A_w for boiling honey; or an activity that

Attachment A

2) is not likely to introduce or increase potential of a Serious Adverse Health Consequence or Death (SAHCOD) hazard; or 3) an activity that doesn't minimize or prevent a SAHCOD hazard.

When performing a quantitative risk assessment, it is important to estimate the dose of a substance ingested, while comparing that dose to a level of human health concern. For instance, one would estimate the quantity of food consumed and multiply that by the concentration of the substance in that food, yielding consumer exposure to the ingested substance. Then, the exposure would be compared to a dose-response value that characterizes the presence/absence of an adverse human health effect at different levels of consumption of that substance. A simple quantitative risk assessment model, excluding growth conditions, might include sampling farm mixed type facility cracked peanuts (activity/food combination shown to be a low risk activity on Table 17) in order to develop a distribution of salmonella levels in peanuts that could be used in conjunction with quantity/frequency data from a dietary study in order to determine a distribution of consumer exposure. A dose-response value, generated from a determination of the level of salmonella that does/doesn't cause an adverse human health effect could be developed as a reference to compare to the distribution of consumer exposure.

While the standard for risk assessments is quantitative, FDA instead conducted a qualitative risk assessment. The risk assessment acknowledges a lack of exposure calculation data, which includes food consumption data, levels of contamination in the foods, as well as dose-response data necessary to do a risk characterization. We are concerned that the conclusions drawn regarding risk categories, and exemptions made based on this qualitative risk assessment do not quantitatively account for consumer risk from consumption of activity/food products.

The FDA qualitative risk assessment combined certain activity/food combinations in order to assess whether or not each one should be deemed low risk and excluded from additional food safety oversight of FSMA. Additionally, these activity/food combinations should be subjected to a more robust quantitative risk assessment, such as described above, before assessing risk and assigning exclusions or exemptions from food safety regulations.

We encourage FDA to continue to update this risk assessment and input more data into the model as it becomes available. We also encourage FDA to utilize this risk assessment as a dynamic tool for determining the risk of foods and on farm activities when enough data is available to perform a quantitative risk assessment.

FMI appreciates the opportunity to comment on this draft risk assessment and we look forward to working with FDA on the implementation of FSMA.

Sincerely,

Attachment A

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Josh M. Katz, PhD
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