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To: Stephanie Barnes, Food Marketing Institute
From: Erik R. Lieberman
Date: September 25, 2015
Re: FSMA Final Preventive Control for Human Food Rule-Comparison with FMI Positions and Supplemental Proposed and Proposed Rules

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You asked us to draft a memorandum which evaluates how the U.S. Food and Drug Administration (FDA) ultimately decided in regard to FMI's positions on key issues related to the implementation of the preventive controls requirements of the Food Safety Modernization Act (FSMA).[1] The memo compares FMI's positions on key issues to FDA's in the Final, Supplemental Proposed and Proposed Preventive Controls for Human Food Rules.

Background

On September 17, 2015, the U.S. Food and Drug Administration (FDA) published the final rule on Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Final Rule).[2] On September 29, 2014, FDA published the Supplemental Proposed Preventive Controls for Human Food Rule ("Supplemental Rule").[3] The Supplemental Rule amended the original Proposed Preventive Controls Rule for Human Food Rule ("Proposed Rule")[4] which was published on January 16, 2013. FMI filed comments on the Proposed Rule and Supplemental Proposed Rule.

On issues of key importance to FMI members—including domestic supplier verification, the most significant matter impacting retailers and wholesalers in all of FSMA—FDA adopted the position advocated for by FMI of excluding distribution centers. This alone saved the industry billions of dollars in regulatory costs.

FDA also adopted the position advocated by FMI allowing for flexibility in terms of who can perform supplier verification activities. For FMI members who process raw materials and ingredients, this flexibility will afford them the ability to have other entities perform supplier verification on their behalf.

FDA agreed with FMI on virtually all of FMI's major points. Thanks to the advocacy of FMI, the retail industry has saved many billions in dollars of regulatory costs.

The following sections compare FMI's positions on key issues to FDA's in the Final, Supplemental Proposed and Proposed Preventive Controls for Human Food Rules.

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[1] Section 103, 21 USC 350g.
[2] 80 Fed. Reg. 55908 (September 17, 2015).
[3] 79 Fed. Reg. 58574 (September 29, 2014).
[4] 78 Fed. Reg. 3646 (January 16, 2013).

Analysis

Supplier Verification, Product Testing and Environmental Monitoring

Supplier verification: The supplier verification requirements in FSMA had the potential to have a larger impact on retailers and wholesalers than any other aspect of the law. FDA had considered requiring holding facilities like supermarket distribution centers to conduct supplier verification on the suppliers they source from in the U.S. FMI, in its comments to the Agency, strongly argued against supplier verification requirements for holding facilities due to the cost of the requirement and limited public health benefit. The Agency adopted FMI's position in the Final Rule and excluded holding facilities from supplier verification requirements. Supplier verification will however be required for raw materials and ingredients if the facility identifies a hazard controlled before the facility receives the raw material or ingredient and determines a preventive control is required. Supplier verification is also required by importers of foods under the Foreign Supplier Verification Program Rule (regardless of whether or not they are raw materials, ingredients or finished foods). For hazards where there is a reasonable probability of serious adverse health consequences or death to humans (SAHCODH) an annual onsite audit is required unless the facility can determine (and document) that other verification activities and/or less frequent auditing provide adequate assurances that hazards are controlled. Holding facilities such as warehouses and supermarket distribution centers will not be required to conduct supplier verification on the products they receive. Only facilities that further manufacture/process raw materials or ingredients are required to conduct supplier verification.

FMI, in comments on the Supplemental Proposed Rule, argued that FDA should not require verification activities in circumstances in which a food will not be sent to any facility that would be required to have preventive controls before reaching consumers. Rather, the Agency should provide for voluntary verification. FDA agreed with FMI on this matter in the Final Rule.

Domestic Supplier Verification			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
Supplier verification should not be required for holding facilities like distribution centers	N/A (FDA included "The Role of Supplier Approval and Verification" in the appendix of the rule, but it was not codified in regulatory language)	**Agree**: Supplier verification not required for distribution centers	**Agree**: Supplier verification not required for distribution centers
FDA should not require verification activities in circumstances in which a food will not be sent to any facility that would be	Not addressed	Sought comment on matter	**Agree**: Verification not required in circumstances in which a food will not be sent to

required to have preventive controls before reaching consumers. Rather, the Agency should provide for voluntary verification.			facility that would be required to have preventive controls. Voluntary verification allowed.

Product testing: The Final Rule requires product testing as an activity for verification of implementation and effectiveness of preventive controls, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system. Facilities must have written testing procedures and corrective action procedures (relating to a positive test result for a pathogen or indicator organism). Product testing records must be maintained. FDA is not requiring that distribution centers conduct finished product testing. Instead, the Agency is providing flexibility for a facility to make risk-based decisions on when product testing is appropriate. FMI had opposed a requirement for distribution centers to conduct finished product testing and FDA agreed with this position. FMI also contended that product testing should be treated as a verification activity and FDA agreed.

Finished Product Testing			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
Finished product testing should not be required at the wholesale level	N/A (FDA included "The Role of Finished Product Testing" in the appendix of the rule, but was not codified in regulatory language)	**Agree**: Distribution centers and warehouses are not required to conduct finished product testing	**Agree**: Distribution centers and warehouses are not required to conduct finished product testing
The nature and extent of testing needs to be adapted to the particular circumstances of each facility and product	N/A	**Agree:** Product testing is required as appropriate to the facility, the food, and the nature of each hazard	**Agree:** Product testing is required as appropriate to the facility, the food, and the nature of each hazard
Testing should be considered a verification activity and not a control step	N/A	**Agree:** Product testing is treated as a verification activity	**Agree:** Product testing is treated as a verification activity

Environmental Monitoring: The Final Rule requires environmental monitoring as an activity for verification if contamination of a ready-to eat food with an environmental pathogen is a hazard requiring a preventive control. Written environmental monitoring procedures and corrective action procedures (for the presence of a pathogen or indicator organism) are required. Environmental testing records must be maintained. Environmental monitoring is not required for holding facilities such as

distribution centers. FMI had opposed mandatory environmental monitoring requirements from distribution centers. FDA adopted this position.

Environmental Monitoring			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
Environmental monitoring should not be required for warehouses and distribution centers	N/A (FDA included "The Role of Environmental Monitoring" in the appendix of the rule, but was not codified in regulatory language)	**Agree**: Distribution centers and warehouses are not required to conduct environmental monitoring	**Agree**: Distribution centers and warehouses are not required to conduct environmental monitoring
Environmental monitoring should be considered a verification activity and not a control step	N/A	**Agree:** Environmental monitoring is treated as a verification activity	**Agree:** Environmental monitoring is treated as a verification activity

Hazard Definitions

Hazard Requiring a Preventive Control: The term "hazard requiring a preventive control" replaces the term "significant hazard" in the Final Rule. The term "significant hazard" was used in the Supplemental Proposed Rule and replaced the term "hazard reasonably likely to occur" in the Proposed Rule to avoid the potential for misinterpretation that all necessary preventive controls must be established at critical control points. FMI supported eliminating the term "hazard reasonably likely to occur" in favor of "known or reasonably foreseeably hazards" to avoid confusion. FDA largely responded to FMI's concerns about confusion arising from the use of the term "hazard reasonably likely to occur." The Final Rule uses the term "known or reasonably foreseeable hazards." FMI contended that the rule should make clear that both likelihood and severity need to be considered in a scientific hazard analysis. FDA agreed. The hazard analysis in the Final Rule requires an evaluation of known or reasonably foreseeable hazards to assess the severity of a hazard if it were to occur and the probability of it occurring.

Use of the Term "Significant Hazard"			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
The term "hazard reasonably likely to occur" should be eliminated to avoid confusion	Used the term "hazard reasonably likely to occur"	**Agree**: The term "hazard reasonably likely to occur" is eliminated to avoid confusion. It is replaced with the	**Agree**: The term "hazard reasonably likely to occur" is eliminated to avoid confusion. It is replaced with the

		term "significant hazard"	term "hazard requiring a preventive control"
Likelihood and severity need to be considered in a hazard analysis	Must evaluate identified hazards to determine if they are reasonably likely to occur including an assessment of the severity of the illness or injury if the hazard were to occur	**Agree:** Hazard analysis requires an evaluation of known or reasonably foreseeable hazards to assess severity and probability	**Agree:** Hazard analysis requires an evaluation of known or reasonably foreseeable hazards to assess severity and probability

Classification of Radiological Hazards: FMI called for radiological hazards to be considered as a subcategory of chemical hazards, rather than a separate category. FDA agreed with this position in the Final Rule.

Classification of Radiological Hazards			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
Radiological hazards should be considered as a subcategory of chemical hazards, rather than a separate category of hazard	Radiological hazards are a separate category of hazards from chemical hazards	**Agree**: Radiological hazards are considered a subcategory of chemical hazards, rather than a separate category of hazard	**Agree**: Radiological hazards are considered a subcategory of chemical hazards, rather than a separate category of hazard

Definition of Farm

Revision to the definition of farm: The definition of farm is expanded in the Final Rule to allow farms that pack and hold raw agricultural commodities of other farms and dry/dehydrate raw agricultural commodities (RACs) to be exempt from the Final Rule (and instead be subject to the Produce Safety Rule (if applicable)). Previously, if a farm conducted such activities it would be required to register as a food facility. As such it would have been subject to the Final Rule. FMI opposed the expansion of the definition of farm to include the activities of drying/dehydrating RACs.

Definition of the Term "Farm"			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
The definition of farm should not be expanded to	Drying/dehydrating herbs constitutes	**Disagree**: The definition of farm	**Disagree**: The definition of farm

allow farms that dry/dehydrate herbs to be exempt from the rule	manufacturing/processing and thus subjects a farm to the Proposed Rule	is expanded to allow farms that dry/dehydrate herbs to be exempt from the rule	is expanded to allow farms that dry/dehydrate herbs to be exempt from the rule
None	The definition of farm does not provide for the on-farm packing and holding of raw agricultural commodities regardless of ownership of the RACs (i.e. a farm can pack a separately-owned farm's produce). Subject to rule.	The definition of farm provides for the on-farm packing and holding of raw agricultural commodities regardless of ownership of the RACs (i.e. a farm can pack a separately-owned farm's produce). Not subject to rule.	The definition of farm provides for the on-farm packing and holding of raw agricultural commodities regardless of ownership of the RACs (i.e. a farm can pack a separately-owned farm's produce). Not subject to rule.

Applicability of Preventive Controls Requirements to Grocery Distribution Centers

The Final Rule does not exempt holding facilities such as grocery distribution centers from Subpart C, which requires facilities to have a written food safety plan, conduct a hazard analysis, and identify and implement preventive controls for hazards among other things. Grocery distribution centers are generally subject to Subpart C, because they hold unpackaged produce. FDA stated in the Final Rule that a grocery distribution center may determine whether any preventive controls are necessary for unexposed non-refrigerated packaged foods, and that the less stringent modified requirements under Subpart D may be appropriate for the unexposed, refrigerated, packaged TCS foods it holds. Facilities that solely engage in the storage of unexposed packaged food are not subject to the preventive controls or supplier verification requirements. Facilities that solely engage in the storage of unexposed packaged foods, some of which are TCS foods, are exempt from Subpart C, but subject to modified requirements under Subpart D for the TCS foods.

Regulation of Grocery Distribution Centers			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
Grocery distribution centers should be exempt from Subpart C, or FDA should exempt the holding	Grocery distribution centers are covered under Subpart C because they generally hold unpackaged produce,	**Disagree**: Grocery distribution centers are covered under Subpart C because	**Disagree:** Grocery distribution centers are covered under Subpart C because

of unexposed packaged foods in distribution centers from Subpart C	no separate exemption for the holding of unexposed packaged foods in distribution centers contemplated	they generally hold unpackaged produce, no separate exemption for the holding of unexposed packaged foods in distribution centers	they generally hold unpackaged produce, no separate exemption for the holding of unexposed packaged foods in distribution centers

Alignment with FSVP Requirements; Supplier Verification Flexibility

The Final Rule addresses redundancy in the application of supplier verification requirements. FMI had contended that for imported foods, the only verification that should be required is the one conducted by the entity that is the importer under the FSVP Rule. FMI stated that once a food is imported by an importer in a 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. FDA largely agreed with FMI's comments in the Final Rule. Duplicate verification activities are not required by receiving facilities that are importers and in compliance with the FSVP Rule. In addition, any entity may perform supplier verification activities for a facility. The facility is not required to perform the activities.

Alignment with FSVP Requirements; Supplier Verification Flexibility			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
If an imported product has already been verified by an importer in compliance with FSVP, a redundant verification under the Preventive Controls Rule should not be required	N/A (FDA included "The Role of Supplier Approval and Verification" in the appendix of the rule, but was not codified in regulatory language)	**Partially Agree**: Importers who are subject to and in compliance with the Preventive Controls Rules are deemed to be in compliance with the FSVP Rule (this position was in the FSVP Rule)	**Partially Agree**: Importers who are subject to and in compliance with the Preventive Controls Rules are deemed to be in compliance with the FSVP Rule (this position was in the FSVP Rule). Any entity may perform supplier verification activities on behalf of a facility

GFSI Schemes

The Final Rule does not explicitly recognize Global Food Safety Initiative (GFSI) schemes as being sufficient to meet all compliance requirements. Indeed FDA states that "We have no plans to endorse certification under GFSI."[5] FDA does however say that "we expect that many existing (GFSI) plans will only need minor supplementation to fully comply . . ."[6] The Agency also stated that: "We agree that a supplier's certification to a GFSI scheme that considers FDA food safety regulations can be a consideration in the determination of the type and frequency of verification activity conducted."[7] FDA noted that "GFSI schemes that consider FDA food safety regulations and include a review of the supplier's written HACCP plan. . . and its implementation. . . are likely to satisfy the requirements for an onsite audit."[8] FDA also noted that the GFSI provisions for auditor competency are consistent with the Agency's definition of qualified auditor.[9] FMI contended in comments to FDA that the Agency should make the rule compatible to the greatest extent possible with existing GFSI schemes.

Compatibility with GFSI Schemes			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
FDA should make the rule compatible to the greatest extent possible with existing GFSI schemes	GFSI (and SQF) cited in "The Role of Supplier Approval and Verification" in the appendix of the rule.	Not addressed	**Partially Agree**: FDA did not recognize or endorse GFSI schemes; however, the Agency stated they could be used to meet onsite audit requirements if they consider FDA food safety regulations. FDA noted that GFSI provisions for auditor competency are consistent with the rule.

[5] P. 56054
[6] P. 56024
[7] P. 56104
[8] P. 56115
[9] *Id.*

Additional Issues

The below table covers additional issues FMI submitted comment on:

Additional Issues			
FMI Position	**FDA Position in Proposed Rule**	**FDA Position in Supplemental Proposed Rule**	**FDA Position in Final Rule**
FDA should not require submission of food safety plans or detailed facility profiles (containing information on products, hazards, food safety training etc.) to FDA	Requested comment on issue, did not address in regulatory text	Did not address	**Agree**: Submission of facility profile not required. FDA will explore other mechanisms
Investigation of consumer complaints should be limited	No regulatory provision for reviewing complaints	**Agree:** No requirement to review complaints as a verification activity	**Agree:** No requirement for review of complaints as a verification activity. Review of complaints is more likely to be useful in providing feedback for continuous improvement.
Exempt records from compliance with Part 11	Electronic records must be kept in accordance with Part 11	Not addressed	**Agree:** Electronic records are exempt from the requirements of Part 11
Facilities that are subject to and in compliance with the Pasteurized Milk Ordinance (PMO) should be exempted from the Rule	Not exempt	Not addressed	**Partially Agree:** Extended compliance date to Sept. 17, 2018 for Subparts C and G with aim that PMO will be changed by then to meet requirements of rule