THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

June 30, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2013-N-1425

Re: Proposed Rule on Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Dear Sir or Madam:

On December 24, 2013, the Food and Drug Administration (FDA or the Agency) published in the *Federal Register* a proposed rule entitled Focused Mitigation Strategies to Protect Food Against Intentional Adulteration ("Proposed Rule").[1] The Proposed Rule requires domestic and foreign facilities that are required to register under the Federal Food, Drug and Cosmetic Act (FD&C Act) to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. The Proposed Rule is being issued to implement the Food Safety Modernization Act (FSMA).

The Food Marketing Institute (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 and for information regarding the FMI foundation, visit www.fmifoundation.org.

[1] 78 Fed. Reg. 78014 (December 24, 2013).

FMI appreciates the opportunity to comment on this important matter.

Summary of Key Points

1. **FMI Commends FDA on the Risk Based Approach of the Proposed Rule**
2. **FMI strongly supports the exclusion of holding activities from the scope of the Proposed Rule**
3. **Greater clarity is needed regarding the distinction between acts of terrorism and acts of disgruntled employees**
4. **Greater clarity is needed as to the interplay of the Proposed Rule and Accreditation of Third-Party Auditors Rule**

Introduction

The Proposed Rule is being issued to implement sec. 420 of the FD&C Act (sec. 106 of FSMA) which states:

> Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations to protect against the intentional adulteration of food subject to this Act. Such regulations shall--
> (1) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food; and
> (2) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate.
> (c) Applicability.--Regulations promulgated under subsection (b) shall apply only to food for which there is a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (a), that could cause serious adverse health consequences or death to humans or animals and shall include those foods--
> (1) for which the Secretary has identified clear vulnerabilities (including short shelf-life or susceptibility to intentional contamination at critical control points); and
> (2) in bulk or batch form, prior to being packaged for the final consumer.

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, food manufacturing facilities and 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 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. 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. Distribution centers are holding facilities that generally will not be within the scope of the Proposed Rule. The vast majority of products held within distribution centers are packaged foods. Central dairy, deli and bakery facilities operated by retail companies generally fall within the scope of the Proposed Rule.

Key Issues

FMI Commends FDA on the Risk Based Approach of the Proposed Rule

The driving principle in implementing FSMA is risk. This Proposed Rule takes a risk-based approach into consideration looking at facility size, key activities, and vulnerabilities. Distribution centers are low-risk and FMI applauds the Agency for recognizing that activities performed during the holding of food do not fall within any of the four key activity types. The required actions proposed are based on risk and sound science and are consistent with approach required under FSMA. FMI encourages the Agency to craft any final rules under FSMA in a similar, risk-based manner.

FMI strongly supports the exclusion of holding activities from the scope of the Proposed Rule

Most registered food facilities operated by food retailers are holding facilities and thus will not be subject to the Proposed Rule. FMI strongly supports the position of the Agency in excluding holding activities from the scope of the Proposed Rule and believes it is consistent with the risk-based approach that is the foundation of FSMA. The risk of mass casualties from intentional adulteration caused by acts of terrorism at holding facilities is low. Firstly, intentionally adulterating finished, packaged foods, or produce in a facility on a large scale without detection would be very difficult, as in most circumstances products would have to be adulterated on an item-by-item basis.

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

Secondly, the impact of the attack would in most circumstances be limited by the number of items the perpetrators could adulterate on such item-by-item basis.

Excluding holding facilities from the scope of the Proposed Rule provides significant regulatory relief to the supermarket industry and substantially lowers the overall cost of the regulation on the economy. The Preliminary Regulatory Impact Analysis the Agency has conducted on the Proposed Rule estimates compliance costs per facility at $37,600 annualized based on a discount rate of 7%. By excluding holding facilities from the scope of the Proposed Rule, FDA has saved the supermarket industry $71,552,800 in annual compliance costs based on the Agency's estimate. In reality, we believe the savings could be even larger. FMI strongly supports the Agency's decision to exclude the holding of food from the scope of the Proposed Rule.

Greater clarity is needed regarding the distinction between acts of terrorism and acts of disgruntled employees

FDA states in the Proposed Rule that:

> While the goals and outcomes of acts of disgruntled employees, consumers or competitors can overlap with acts of terrorism, generally, the distinction has to do with differences in scale. Disgruntled employees are generally understood to be interested primarily in attacking the reputation of the company and otherwise have little interest in public health harm. On the other hand, terrorist organizations are generally understood to be interested in maximizing public health harm . . ."[5]

The Agency states that these acts are not considered high risk because they are not intended to cause widespread, significant public health harm.[6]

FMI seeks further clarification as to what constitutes "widespread, significant public harm" and how the Proposed Rule applies to acts of employees intending to cause widespread, significant public health harm. We urge the Agency to provide greater clarity in distinguishing between acts of terrorism and acts of disgruntled employees, particularly in circumstances where the act of the disgruntled employee is intended to cause a degree of public harm.

Greater clarity is needed as to the interplay of the Proposed Rule Accreditation of Third-Party Auditors Rule

[5] 78 Fed. Reg. 78027.
[6] 78 Fed. Reg. 78017.

FDA is clear that the Proposed Rule applies to both foreign and domestic facilities that are required to register with the Agency pursuant to section 415 of the FD&C Act. The Agency has not addressed however whether or not auditors accredited pursuant to section 808 of the FD&C Act will be required to audit foreign facilities for compliance with the Proposed Rule. The Proposed Accreditation of Third-Party Auditors Rule (Proposed Third-Party Auditor Rule) requires that audits:

> . . . be sufficiently rigorous to allow the accredited auditor/certification body to determine whether the entity is in compliance with the FD&C Act at the time of audit; and for a regulatory audit, whether the entity would be likely to remain in compliance with the applicable requirements of the FD&C Act for at least 12 months following the audit. . .[7]

On its face, the Proposed Third-Party Auditor Rule does appear to require that foreign facilities be audited for compliance with the Proposed Rule as the Proposed Rule is being issued to implement the FD&C Act. FMI seeks confirmation from FDA as to this point.

Responses to FDA's Specific Requests for Comment in the Proposed Rule

Exclusion of Holding Facilities from the Proposed Rule

FMI strongly supports FDA's exclusion of holding facilities from the scope of the Proposed Rule as stated previously in these comments.

Appropriateness of a HACCP-Type System to Ensure Focused Mitigation Strategies are Consistently Applied

FMI agrees with the Agency that a HACCP-type system can be effective to ensure that the focused mitigation strategies contemplated by the Proposed Rule are properly developed and consistently applied. In general, the food industry is familiar with HACCP systems and making this aspect of the Proposed Rule consistent with a HACCP approach will ease compliance for the industry for the reasons outlined previously in these comments. The Agency's recent introduction of the Food Defense Plan Builder provides helpful tools for the industry to develop their food defense strategies.

[7] 78 Fed. Reg. 45833 (July 29, 2013).

From which entities would implementation of measures to protect against intentional adulteration derive the greatest benefit to public health protection?

FMI strongly agrees with the Agency that regulation of holding facilities is not warranted. FMI does not believe that regulation of holding facilities under the Proposed Rule would result in a significant vulnerability. We do recognize the Agency should balance the impact of new food defense training requirements and new recordkeeping requirements that could pose an adverse financial impact to the industry.

Regulation of Economically Motivated Adulteration

FDA has decided that economically motivated adulteration is best addressed in the Preventive Controls Rule for Human Food and Preventive Controls Rule for Animal Food (collectively the Preventive Controls Rules) where economically motivated adulteration is "reasonably likely to occur" as opposed to the Proposed Rule. Under this approach, facilities subject to section 418 of the FD&C Act would be expected to implement controls against economically motivated adulteration under circumstances where there has been a pattern of such adulteration in the past, even though the past occurrences may not be associated with the specific supplier or the specific food product but the pattern suggests a potential for intentional adulteration. This marks a change in the position of the Agency. In the proposed Preventive Controls Rules, the Agency had taken the position that economically motivated adulteration was best addressed in the Food Defense Rule. The Agency notes that before it decides to finalize provisions on economically motivated adulteration in the Preventive Controls Rules, it will provide new language and an analysis of costs associated with the provisions and seek comment. FMI appreciates the Agency providing an opportunity for public comment on these revised provisions.

FDA has tentatively concluded that a hazard analysis-type approach is better suited to address economically motivated adulteration than the vulnerability assessment-type approach the Agency has employed in the Proposed Rule.

FMI agrees that a hazard analysis-type approach is more appropriate for addressing economically motivated adulteration than the vulnerability assessment-type approach in the Proposed Rule. We believe that a requirement to conduct vulnerability assessments for economically motivated adulteration would pose greater burdens on industry than a requirement to conduct a hazard analysis. As the Agency notes, predictive tools such as CARVER+Shock are not currently configured to assess the risk

of economically motivated adulteration, nor have extensive vulnerability assessments for economically motivated adulteration in food products been conducted by FDA or others. The industry is familiar in conducting risk assessments of the supply chain that take into consideration not only food safety aspects, but also nonfood safety factors, such as environmental conditions (e.g. tsunamis or droughts) and nationalities of political unrest as identified by the State Department's Bureau of Consular Affairs.

We appreciate the opportunity to comment on this important regulation. Please contact us if you have any questions.

Sincerely,

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