THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

December 15, 2014

Division of Dockets Management ()

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

Docket No. FDA–2011–N–0920

Dear Sir or Madam:

On September 29, 2014, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a supplemental proposed rule entitled Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the Supplemental Rule).[1] 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.

FMI appreciates the significant outreach conducted by the Agency and the transparency they have provided throughout the rulemaking process. FMI appreciates FDA's decision to issue the supplemental proposed rules and believes that they are more targeted, risk-based and practical for our members. We believe that regulations issued to implement section 103 of FSMA, if

[1] 79 Fed. Reg. 58525 (September 29, 2014).

crafted in a manner consistent with the following comments, will enhance public health and strengthen our nation's food safety regulatory system.

Table of Contents

Supplier Verification

In the 2013 proposed preventive control rule ("Proposed Rule"), FDA described the statutory framework of FSMA for supplier controls but did not propose requirements in the regulatory text. In the Supplemental Rule, FDA proposes to limit a supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw materials or ingredients. FDA defines a receiving facility as a facility that manufacturers/processes a raw material or ingredient that it receives from a supplier. A supplier is defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment; except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimus* nature. FMI agrees that a supplier program should be limited to these circumstances.

The Supplemental Rule states that a facility would not be required to establish a supplier program for food products that it only packs or distributes. FMI supports the decision to exclude holding facilities like warehouses and distribution centers from the supplier verification provisions and believes this will alleviate significant burdens for our members in addition to representing a more risk-based approach consistent with FSMA. Requiring supplier verification for every single product in a distribution would simply be unworkable and would impose billions of unnecessary costs on industry every year. FMI estimates that a domestic supplier verification program applied to holding facilities like distribution centers and warehouses would impose well over $100 billion in regulatory costs annually on the industry.[2]

FMI agrees 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 with very few corresponding public health benefits.[3]

Gaps in Supplier Controls

FDA is seeking comments regarding whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain (e.g. by Supplier A, a farm), and Point B in the supply chain is a facility

[2] The typical distribution center carries approximately 15,000 different SKUs of food. 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.
[3] FDA: FSMA Preventive Controls Proposed Rule (November 22, 2013)

(such as Warehouse B, Distributor B, or Packing Shed B) that only packs or holds food, but does not manufacture/process food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain, which also would not be required to have a supplier program (e.g. Retail Food Establishment C or Consumer C). For example, if Packing Shed B distributes produce it packs after receiving the produce from Farm A directly to retail facilities (which would not be subject to the requirements of the preventive controls rule), no supplier controls would be applied to Farm A. FDA requests comments on whether verification activities should be required in circumstances in which a RAC such as fresh produce will not be sent to any facilities that would be required to have preventive controls before reaching consumers.

FMI does not believe that FDA should 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; however, the Agency should consider providing for a voluntary verification system in such circumstances. FMI believes that food which has been subject to such voluntary supplier controls should not be considered a high-risk food pursuant to section 204(d)(2) of FSMA, and thus not subject to the additional recordkeeping requirements. For example, a packing shed could voluntarily comply with supplier controls in accordance with the Preventive Controls for Human Food Rule for a produce item generally designated as high-risk by FDA and a retailer that sources the produce item would not be required to comply with the additional recordkeeping requirements for high-risk foods pursuant to section 204(d)(2) as they apply to the retailer's distribution center. FSMA provides for a voluntary program (VQIP) whereby foods subject to a higher degree of supplier verification (e.g. an accredited audit) enjoy preferential regulatory treatment (expedited entry at the border). We believe that the creation of a voluntary supplier control program follows the same logic as VQIP and is similarly consistent with the risk-based approach the Agency has taken in implementing FSMA.

FSVP and Supplier Verification Alignment

FDA seeks comment on the manner and extent to which the FSVP and preventive controls supplier verification provisions should be aligned in the final rule. FMI believes that to the greatest extent possible the FSVP and preventive control supplier verification provisions should be aligned to avoid imposing duplicative requirements on entities that are subject to both the preventive controls and the FSVP regulations.

Records

In the Supplemental rule, FDA states that recordkeeping requirements would not require duplication of existing records if those records contain all required information and satisfy the recordkeeping requirements. FMI supports FDA's decision to avoid duplicative recordkeeping requirements and agrees that facilities should not be required to keep all information in one set of records.

Known or Reasonably Foreseeable Hazards; Use of the Term Significant Hazard

The hazard analysis in the Proposed Rule required evaluation of hazards that are "reasonably likely to occur." In the Supplemental Rule, FDA acknowledged that it might be confusing to use the phrase "hazards reasonably likely to occur" in both the Agency's HACCP regulations and the preventive controls regulation because the phrase has been used as the basis for determining hazards that need to be addressed in a HACCP plan at critical control points. In the Supplemental Rule, FDA requires facilities to consider hazards that are known or reasonably foreseeable in their risk analysis rather than hazards that are reasonably likely to occur. FMI supports the use of the phrase known or reasonably foreseeable hazards. FMI believes this will avoid the problem of confusing preventive control requirements with HACCP requirements.

The Supplemental Rule requires facilities to analyze the known or reasonably foreseeable hazards in a food, based on experience, illness data, scientific reports, and other information, to determine whether they are "significant hazards." A "significant hazard" is defined as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections, corrective actions, verification, and records) as appropriate to the food, the facility, and the control. FMI supports the use of the term "significant hazard."

In the Supplemental Rule, FDA has defined a known or reasonably foreseeable hazard as a potential biological, chemical (including radiological), or physical hazard that is known to, or has the potential to be, associated with a food or the facility in which it is manufactured/processed. FDA states that the hazard analysis would need to include an evaluation of both the severity and probability of the hazard. FDA describes probability as meaning the likelihood the hazard would occur in the absence of preventive controls. FMI agrees that the hazard analysis should include

an evaluation of known or reasonably foreseeable hazards to assess severity of a hazard if it were to occur and the probability of it occurring.

Product Testing

In the Supplemental Rule, FDA proposes that all verification activities, including product testing, be conducted "as appropriate to the facility, the food and the nature of the preventive control." FDA indicates in the corrective action provisions that ready-to-eat foods (RTE) would be appropriate candidates for product testing, by requiring, as appropriate, corrective action procedures to address the presence of a pathogen or indicator organism in a RTE food detected as a result of product testing.

FMI agrees that facilities should have the flexibility to make risk-based decisions on when product testing would be appropriate. FMI agrees that the terminology "product testing" rather than "finished product testing," is more consistent with FSMA terminology and agree with the Agency that finished product testing requirements should not be mandated. Finished product testing is a beneficial verification activity in very limited circumstances and testing decisions should be based on the hazard analysis and level of control the facility has for those hazards.

FMI does not believe that distribution centers should be required to conduct finished product testing. Finished product testing at the retail level does not serve the public health interest as products are already at the point of purchase. Similarly, finished product testing at the wholesale level would be greatly burdensome and does not confer a significant public health benefit. FMI supports flexibility for product testing and believes the nature and extent of testing needs to be adapted to the particular circumstances of each facility and product.

Environmental Monitoring

In the Supplemental Rule, FDA states that environmental monitoring would be conducted as a verification activity "as appropriate to the facility, the food and the nature of the preventive control." The supplemental proposal provides for such testing if "contamination of a ready-to-eat food with an environmental pathogen is a significant hazard."

FMI agrees that environmental testing can form an important component of a modern food safety system; however, we believe that the role and need for these measures varies depending on the types of products and activities of the facility. FMI urges the Agency to maintain flexibility for environmental monitoring while recognizing the limited benefit in the context of warehouses and distribution centers. FMI believes that environmental testing is more beneficial than product testing in most circumstances. Environmental monitoring does not make sense for warehouses

and distribution centers as it would have little to no positive impact on public health. FMI believes environmental monitoring in the warehouse/distribution center context is not necessary because the emphasis is on prevention of contamination and strong CGMPs. Additionally, environmental pathogens in warehouses and distribution centers would generally not be considered a significant hazard.

FMI does not believe that environmental monitoring requirements would be necessary for distribution centers and warehouses. The minimal risk of environmental contamination in distribution centers clearly does not justify the massive costs such a requirement would import of food retailers and wholesalers.

Radiological Hazards

In the Proposed Rule, radiological hazards were included among the types of hazards (biological, chemical and physical) that facilities must consider in their hazard analyses. Radiological hazards were in a separate category from chemical hazards in the Proposed Rule. In the Supplemental Rule, radiological hazards are a subcategory of chemical hazards. Treating radiological hazards as a separate category, rather than a subcategory, would be inconsistent with Codex and global HACCP standards. FMI supports FDA in taking the position that radiological hazards are a subcategory of chemical hazards. We believe that classifying radiological hazards as a subcategory of chemical hazards will simplify the hazard analysis for FMI members.

Definition of Farm

In the Supplemental Rules, FDA expands the definition of farms to those farms that pack and hold raw agricultural commodities of other farms and dry/dehydrate raw agricultural commodities (RACs) to be exempt from the rule (and instead be subject to the Produce Safety Rule (if applicable)). FMI does not believe the definition of farms should be expanded to include the activities of drying/dehydrating RACs. FMI believes that drying of RACs would be a manufacturing activity subject to Preventive Controls requirements.

Standards should be in Guidance Documents

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.

FMI Urges the Agency to Issue Additional Supplemental Rules

FMI appreciates FDA's decision to issue the Supplemental Rules and believes that they are more targeted, risk-based and practical for our members. While we understand that the Agency is under tight deadlines, FMI believes that the public should similarly be afforded an opportunity to comment on potential revisions to the Sanitary Transportation of Human and Animal Food Proposed Rule and the Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications; Proposed Rule.

We appreciate your consideration of these comments. Please do not hesitate to contact me at sbarnes@fmi.org or (202) 220-0614 if you have any questions.

Sincerely,

Stephanie Barnes

Stephanie K. Barnes

Regulatory Counsel