THE VOICE OF FOOD RETAIL
Feeding Families Enriching Lives

March 31, 2014

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 Food for Animals[1]

Docket No. FDA–2011–N–0922

Dear Sir or Madam:

On October 29, 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 Food for Animals (the "Proposed Rule"). The Proposed Rule would establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. The Proposed Rule would also require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals. The Proposed Rule is being issued pursuant to the Food Safety Modernization Act (FSMA). 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 supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 103 of FSMA, if crafted in a manner

[1] 78 Fed. Reg. 64736 (October 29, 2013).

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

FMI members face impacts from the Proposed Rule in the following ways:

1. Food retailers place significant amounts of human food waste into the animal food supply chain.
2. Food wholesalers and self-distributing retailers hold packaged animal food in their distribution facilities.

These comments will address both of these impacts from the Proposed Rule.

I. Food Waste

The Proposed Rule and Food Waste

Food retailers and wholesalers divert significant amounts of human food waste into the animal food supply chain. According to the BSR Analysis of U.S. Food Waste Among Food Manufacturers, Retailers and Wholesalers, retailers and wholesalers in the U.S. divert 154,000,000 pounds of food waste into the animal food supply chain every year.[2] While most food waste is generated at the retail level, and thus exempt from the Proposed Rule, other waste is generated by manufacturing and processing facilities owned and operated by retailers.

Diversion of food waste into the animal food supply chain not only makes good business sense, it also helps food retailers and wholesalers meet their sustainability goals. If the Proposed Rule imposes significant new regulatory requirements on this practice, food retailers and wholesalers will be forced to dispose of human food waste in landfills, at a significant direct cost to them. An end to this practice would also impose very significant environmental costs including wasting landfill space, and increased greenhouse gas emissions. Reducing the availability of animal food ingredients would drive up costs for animal food manufacturers leading to higher prices for animal food users. These higher costs are likely to be passed down the supply chain to consumers in the form of higher prices at retail.

Applicability of Rule to Food Retailers and Wholesalers

FDA discusses in the preamble of the Proposed Rule that the regulation applies to human food waste generated by human food facilities that is used or sold as animal food.

[2] BSR Analysis of U.S. Food Waste Among Food Manufacturers, Retailers and Wholesalers, Prepared for the Food Waste Reduction Alliance, April 2013.

> Proposed §507.1(d) would apply to facilities that manufacture, process, pack or hold animal food and human food. The agency wanted to address the instances where a facility may handle both human and animal food in some form, to make it clear which proposed rule would apply for that facility manufacturing, processing, packing, or holding these foods. In addition, in some facilities, "waste" from human food production, such as by-products that may not be edible for humans, or lack nutritional value for humans, are used or sold for animal food. Many species of animals have different digestive systems and nutritional requirements than humans, this allowing for this use. For the human food manufactured, processed, packed, or held, the facility would need to comply with proposed part 117 (proposed rule for preventive controls for human food (78 FR 3646)). . . For the animal food manufactured, processed, packed or held, the facility may choose to comply with either proposed part 507 subparts B and C as applicable or proposed part 117 subparts B and C as applicable, so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food including nutrient imbalances. "Food" used in proposed part 117 would be read to include "animal food" when the facility is applying proposed part 117 to the animal food. For example, human food waste that is used for animal food would be treated as "food" for the purposes of its animal food use and as waste for the purposes of its role in human food production.[3]

Human Food Waste Generated at the Retail Level and Sold/Donated as Animal Food is Excluded from the Preventive Controls Rule for Animal Food

Section 103 of the FSMA applies only to the "owner, operator, or agent in charge of a facility." The term "facility" is defined in section 103 as "a domestic facility or foreign facility that is required to register under section 415." Section 415 expressly excludes retail food establishments such as supermarkets. "Such term does not include farms; restaurants; other retail food establishments . . ." It is clear that Section 103, and consequently the Proposed Rule, does not apply to human food waste generated at retail locations that is sold/donated as animal food because retail establishments are not registered food facilities.

Food Retailers and Wholesalers Often Do Not Know the Ultimate Animal Consumer of Human Food Waste

Nutrient requirements vary from species to species. Food retailers and wholesalers often do not know the ultimate species of the animal that is consuming the human food waste they donate or sell from food facilities. The Proposed Rule classifies nutrient imbalances hazards to animals as chemical hazards.[4]

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[3] 78 Fed. Reg. 64755.
[4] 78 Fed. Reg, 64829 (§ 507.33(b)(2)).

FDA notes that "Nutrient imbalance hazards can result from excessive levels of a nutrient in animal food leading to toxicity . . . or a nutrient deficiency in the food that can compromise the health of animals. . .Nutrient imbalances are particularly problematic for animal food because often one animal food type is the sole source of an animal's diet."[5]

In most instances, intermediaries purchase or otherwise receive human food waste diverted for animal food and either reprocess it or distribute it.

As retailers and wholesalers often do not know the ultimate animal consumer of their human food waste, requiring them to do a hazard analysis on such human food waste would be unworkable and would likely prevent them from continuing the sustainable practice of selling/donating human food waste generated from facilities into the animal food supply chain.

FMI believes that human food waste sold/donated into the animal food supply chain should not be required to consider nutrient imbalance hazards or otherwise be subject to subpart C of the Proposed Rule. Compliance with the Preventive Controls Rule for Human Food should suffice.

II. Animal Food Holding Facilities

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.[6] Many chains operate multiple distribution centers and large retailers may have 10, 20 or more than 30.[7] In terms of wholesalers, 1,098 wholesale grocery companies operate 1,679 distribution centers in the U.S.[8] 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.

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[5] 78 Fed. Reg. 64782.
[6] 2013 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains (Database accessed on April 12, 2013).
[7] Id.
[8] Id.

Supermarket Distribution Centers are Generally Exempt from the Subpart C of the Proposed Rule Because Typically the Only Activity they Engage in Related to Animal Food is Storage of Animal Food Not Exposed to the Environment

The Proposed Rule excludes facilities solely engaged in the storage of animal food not exposed to the environment from the scope of the rule. Facilities solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control are subject to the modified requirements in § 507.48.

Supermarket distribution centers typically handle only packaged pet food/treats not exposed to the environment, therefore they will be exempt from subpart C of the Proposed Rule. FMI supports this exemption.

Supermarket Distribution Facilities Hold Both Human and Animal Food and May Choose to Apply Requirements for the Preventive Controls Rule for Human Food to the Animal Food They Hold

Because the CGMP requirements in subpart B of the Preventive Controls Rule for Human Food will apply to supermarket distribution facilities, most such facilities will choose to simply apply those to the animal food that they hold rather than comply with separate regulatory regimes. Section 507.1(d) of the Proposed Rule permits this:

> If a facility is required to comply with subpart B of this part and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs or holds human food, then the facility may choose to comply with the requirements in subpart B or part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility.

FMI supports FDA providing for this option as it will simplify regulatory compliance.

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 section 103 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 animal foods is that no hazards are reasonably likely to occur.[9]

[9] 78 Fed. Reg. 64770/

Domestic Supplier Verification

FDA has indicated it intends to require domestic supplier verification in the final version of the Human Food Rule. FMI seeks clarification as to whether the agency intends to similarly require domestic supplier verification in 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 the 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."[10]

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.

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." This does not provide the public with sufficient information to provide meaningful

[10] 78 Fed. Reg. 64808.

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 for Human or Animal Food

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 animal or human 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 animal or human 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 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. 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. 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 materials from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe animal food and minimize the potential for contaminated animal food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the animal food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must 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 the raw material or other ingredient unless the receiving facility itself will control the identified hazard.[11]

FMI does not believe FDA should implement a mandatory domestic supplier verification regime for holding facilities. The Human and Animal Food Preventive Controls Rules themselves 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

[11] 78 Fed. Reg. 64836.

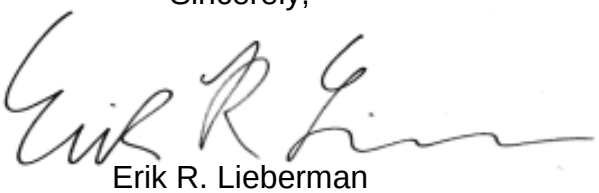
existing system is effective in our view and a one-size-fits-all FDA-mandated approach to supplier verification would be inconsistent with a risk-based approach and would impose unnecessary costs.

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

Congress explicitly prohibited FDA in the Human and Animal Food Preventive Controls Rules 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."[12] 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.

We appreciate your consideration of these comments. Please do not hesitate to contact me at elieberman@fmi.org or (202) 810-4044 if you have any questions.

Sincerely,



Erik R. Lieberman
Vice President and Chief Regulatory Counsel

[12] 21 U.S.C. 350g (n)(3)(D).