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: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human consumption[1]

Docket No. FDA–2011–N–0921

Dear Sir or Madam:

On January 16, 2013, the Food and Drug Administration (FDA) published in the Federal Register a proposed rule entitled Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the "Proposed Rule"). 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 including section 105 which directs FDA to issue the Proposed Rule. We believe the regulations issued to implement section 105 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.

[1] 78 Fed. Reg. 3504 (January 16, 2013).

Exemption of Produce Rarely Consumed Raw

FMI is concerned with the exhaustive list of items exempted from the Proposed Rule in §112.2 that are considered "rarely consumed raw". We are concerned for several reasons:

1. The exemptions are written into the regulation and will not be easily changed in the future. If exemptions are granted, we recommend that they be in a guidance document that can be updated based on the latest available science including public health data. For example, what will happen in the future if one of the commodities on the exhaustive list becomes a source of contamination? If the exemption is written into the regulation, then the commodity will remain exempt from produce safety regulations. If FDA creates a guidance document that is easier to modify, updates to the product list could easily be made based on the best available science and risk assessments.

2. Another concern is that several of the items are consumed raw or are juiced raw. Food trends also change over time and what we consume cooked today might be a popular raw food in a decade. In addition, a number of these items—such as asparagus and bok choy—may be cooked lightly by consumers and not necessarily subject to a kill step at home.

Effective food safety programs rely on prevention of contamination. To exempt products because they are not raw foods or will eventually be exposed to a heat treatment goes against the premise of effective food safety programs.

FMI recommends that all produce be subject to the produce safety rule and that the emphasis for all farms be prevention of contamination. If exemptions are granted the Proposed Rule should reference a guidance document with the list of exempted commodities. Consumption trends including juicing of fruits and vegetables must be considered before granting any exemptions.

Standards and Analytical Methods

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 also applies to the analytical methods that are required by the regulation.

Analytical methods improve with time. In the past few decades we have seen great advances in laboratory methodology. Instead of listing methods from 2013 in the regulations limiting the industry to those methods for decades to come, FMI recommends that FDA refer to a guidance document where the appropriate analytical

laboratory method can be made available to the industry. The Proposed Rule mentions that equivalent methods would be acceptable; however, the process of proving equivalence can be expensive and cumbersome. It would be more efficient for FDA to simply list the allowed methodologies in guidance documents on the FDA website without requiring each company to individually submit equivalent methods.

Providing a guidance document with the standards and allowed methods will allow the industry flexibility to adopt the latest technologies as advances are made. The standards could also be updated as we learn more about the important factors in on-farm food safety controls.

Direct Farm Marketing (Qualified) Exemption

While FMI acknowledges the statutory requirement for FDA to require an exemption for certain small farms directly marketing produce to end-users in 21 USC 350h(f), we have concerns with such an exemption.

With the popularity of local foods, many retailers are working with small farms in their communities and want to support small farmers, but are not willing to sacrifice food safety. Retailers are working with local farms to identify food safety training programs and help farmers obtain GAP and other certifications. This assists the farmers and helps the retailers because they have more suppliers and they know the suppliers meet minimum food safety requirements. Exempting small farms selling directly to restaurants and retail establishments makes the food safety programs for produce farmers even more complex. The burden on smaller produce farmers could increase, because if they sell to multiple “qualified end users,” their customers could be asking for different programs or have different requirements. With the FSMA produce safety rule as the baseline, the entire industry could be assured that the produce safety standards are in place.

Labeling for Produce Grown by Exempted Facilities

Produce grown by exempted facilities is required to be prominently and conspicuously labeled with the name and complete business address of the farm where the produce was grown in accordance with section §112.6. If a food packaging label is not required the name and business address must be displayed prominently and conspicuously at the point of purchase. The obligation to display this information should be borne by the exempted farm and not retailers. Any related enforcement should similarly be directed to the farm and not retailers and wholesalers.

Many retailers are working with small local farms to help them implement food safety plans in order to become suppliers to grocery stores and supermarkets. Minimal standards often include the harmonized GAP standards or other equivalent programs.

FMI proposes that small farms exempt under the Proposed Rule, but meeting GAP standards, the leafy green marketing agreement, or any GFSI benchmarked program, be exempt from the labeling requirement at retail.

Exemption for Farms with Annual Food Sales of Less than $25,000

FDA is not statutorily required to provide a complete exemption from the Proposed Rule for very small businesses as it has done in completely excluding farms with annual food sales of less than $25,000. FMI disagrees with providing this exemption and believes it should be removed. This exclusion is not science or risk-based. Produce contamination can occur in any operation that uses unsafe processes and practices.

***Listeria* Testing of Sprouts**

Sections §112.144 and §112.145 require testing for *L. spp* and *L. monocytogenes* for facilities growing, harvesting, packing, and holding sprouts. FMI strongly emphasizes food safety plans based on prevention of contamination. We realize that with some products, environmental and even final product testing might be warranted. When testing is required that might require recalling product, we strongly recommend that all product be held under "test and hold" protocols until test results are negative. From the retail industry's perspective, releasing product prior to receiving test results and facing a potential recall with positive results, puts the supply chain at risk, harms the reputation of the entire category, and leads to a decrease in consumer confidence in all companies involved. In addition, public health is not protected because the product has typically been consumed before results are returned. Managing pathogen testing is essential so that supply chain partners communicate, product is held when appropriate, and public health and consumer confidence protected.

Economic Analysis

We encourage FDA to revisit the economic analysis, have more conversations with and collect more information from the produce industry before finalizing the final rule. The true economic impact of this rule needs to be evaluated and understood by the entire industry before finalizing.

Thank you for consideration of these comments and we look forward to working with FDA as you finalize and implement the Proposed Rule and other FSMA regulations.

Sincerely,

Erik Lieberman
Regulatory Counsel

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