THE VOICE OF FOOD RETAIL
Feeding Families Enriching Lives

December 15, 2014

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

Docket No. FDA–2011–N–0921

Dear Sir or Madam:

On September 29, 2014, the Food and Drug Administration (FDA) published in the Federal Register a supplemental proposed rule entitled Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (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 supported the enactment of the Food Safety Modernization Act (FSMA). 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] 79 Fed. Reg. 58434 (September 29, 2014).

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

The previous Produce Safety Rule ("Proposed Rule") included an exemption for farms with annual food sales of less than $25,000. FDA proposed to apply the produce safety regulation only to farms and farm mixed-type facilities with an average annual monetary value of all food sold during the previous 3-year period or more than $25,000 (on a rolling basis). Farms with average sales less than $25,000 during the previous 3-year period would be completely excluded from the rule's coverage. Under the Supplemental Rule, FDA would apply the $25,000 limit to sales of produce rather than sales of all food. FDA seeks comment on this proposed amendment.

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

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 produce safety standards are in place.

Guidance

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. In the past few decades we have seen great advances in science. Instead of listing methods from 2014 in the regulations limiting the industry to those methods for decades to come, FDA should publish guidance documents to ensure changes can be made as new science and technology emerge.

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

Sincerely,

Stephanie Barnes

Stephanie K. Barnes

Regulatory Counsel