



May 22, 2014

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information [Docket No. FDA-2014-N-0053]**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments as per the Food and Drug Administration's (FDA) request for comments, scientific data and information regarding the "Designation of High-Risk Foods for Tracing" [Docket No. FDA-2014-N-0053]. In addition to this executive summary, PMA submits the attached document that provides specific, detailed comments on the proposal. PMA is the largest trade association representing companies in the fresh fruits and vegetables industry globally. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

The overarching objective for PMA is to increase the consumption of fresh fruits and vegetables on a global basis. PMA serves its members by providing a forum to make business connections and by providing them with the information they need to make decisions that will enhance their businesses and deliver fresh fruits and vegetables to consumers. It is in this role of educator that PMA's food safety and technology efforts are focused. During the initial discussions on the Food Safety Modernization Act (FSMA), PMA provided industry expertise to congressional staff and FDA to help inform them of current science and industry practices. PMA is also a strong supporter of the development of fresh produce-based science as indicated by the association's founding support of the Center for Produce Safety (CPS). CPS is a unique research foundation focused exclusively on produce-related food safety research in collaboration with



industry and government. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations benefit from CPS research.

In developing these comments to the proposed criteria for the “Designation of High-Risk Foods for Tracing,” PMA staff has relied on numerous in-depth discussions with its members to gather feedback on issues of significance regarding this FSMA proposal. We also engaged the PMA Science and Technology committee on several occasions to get their input and guidance. This committee is composed of industry experts from around the industry: small producers to very large, technology vendors, growers, processors, retailers and foodservice representatives. Their insights have proven to be invaluable in sorting through this proposal and developing comments based on their collective experience. We have also participated as speakers in regional forums and events on FSMA and have met individually with PMA members and non-members alike to discuss the impacts of this proposal.

Executive Summary

Assuring the safety of produce and enhancing produce traceability are top priorities for the global produce industry. Implications of this proposal are important to PMA members’ businesses and to the industry overall. PMA strongly supports advancing food traceability in ways that are meaningful and that focus industry efforts to protect public health. PMA supports the implementation of science-based and risk-based regulations throughout the supply chain that use appropriate preventive controls to address hazards associated with the commodity, practices and procedures employed during the production, handling and holding of fresh produce. PMA believes that FDA has done an admirable job in drafting the FSMA proposed criteria for the “designation of high-risk foods for tracing.” PMA believes, however, that FDA has taken an overly simplistic and broad-brush approach in identifying “high-risk foods for tracing.” The FDA approach to identifying and designating “high-risk foods for tracing,” which ultimately drives regulatory policy for individual entities, should incorporate the risk to consumers by individual entities that manufacture, process, pack or hold foods and not be solely based on broad industry-wide characterizations of risk. It is patently unfair that entities that have implemented robust preventive controls be burdened with additional tracing requirements due to the industry segment as a whole being designated a “high-risk” food category. It is suggested that FDA consider using an integrated “food category” data and “individual entity data” approach to make the determination as to which entities



that manufacture, process, pack or hold foods within a given food category should be designated as “high-risk food” producers. Use of integrated “food category” and “individual entity” data to determine “high-risk” food status would provide the benefit of focusing the burden of additional tracing recordkeeping on firms that have demonstrated lack of implementation of appropriate preventive controls, while not burdening firms that have implemented robust and effective preventive controls. Identifying specific food categories by entity combinations would also incentivize entities to implement appropriate preventive controls and/or move to lower-risk practices where such options are available.

PMA has also provided comment that FDA may wish to consider developing specific and varied evaluation criteria for various food categories that would take into account differences in procedures, practices and processes for each food category. It may prove very useful to evaluate facilities that manufacture, process, pack or hold raw agricultural commodities in a manner different from, for example, low-acid canned food facilities. A one-size-fits-all approach to evaluating food risk will likely prove difficult, overestimating risk for some foods while underestimating risk for other food categories.

PMA also raises a number of clarifying questions regarding:

- How will FDA score “hazards reasonably likely to occur”?
- What constitutes a “high-risk” score?
- What is the periodicity of review of the “high-risk” designation?
- How will FDA score foods when there are data gaps?

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of the proposed rules and policies. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on this FSMA proposal. Attached are those comments.

Thank you for the opportunity.

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Comments provided by the Produce Marketing Association

“Designation of High-Risk Foods for Tracing”

The Food and Drug Administration’s (FDA) “Designation of High-Risk Foods for Tracing” specifically details proposed criteria that would be used evaluate food categories for the “high-risk” food designation. Produce Marketing Association’s (PMA) comments below fall into two categories: General Comments and Comments Regarding Specific Proposed Criteria.

General Comments:

PMA Comment: FDA’s Approach to Determining “High Risk Foods”

PMA believes that FDA has taken an overly simplistic and broad-brush approach to identifying “high-risk foods for tracing.” The FDA proposed approach of identifying and characterizing entire food categories as “high-risk” is overly simplistic because procedures, practices, processes and the implementation of preventive controls to control hazards during the manufacturing, processing, packing or holding of foods ultimately determine whether or not a food is of “high-risk” to consumers. The evaluation of individual entities’ implementation of appropriate preventive controls is not accounted for in FDA’s current proposal for the designation of “high-risk” foods.

FDA’s proposed means of identifying “high-risk” foods uses criteria and factors that would typically be used in a “risk assessment” or as a “risk ranking” tool to grossly compare or estimate the risk of adverse health consequences across broad food categories. “Risk assessment” and “risk ranking” tools provide a means for comparison of the public health risk associated among various broad food categories and provides useful information to inform public health policy. However, the FDA approach to identifying and designating “high-risk foods for tracing,” which ultimately drives regulatory policy for individual entities, should also incorporate the risk to consumers by individual entities that manufacture, process, pack or hold foods and not be solely based on broad industry-wide characterizing criteria for risk.

The use of “industry-wide” data or compliance trends are inappropriate to use to determine regulatory requirements for individual entities, as it does not take into account



differences in implementation between and among various enterprises. Entities that have implemented robust preventive controls will be burdened with additional tracing requirements due to the industry segment as whole being designated a “high-risk” food category. This is patently unfair. The FDA proposed scheme also does not take into account regional difference between firms that manufacture, process, pack or hold particular produce items.

Additionally, FDA proposal to use the classification of foods or categories of food for risk ranking be based on the Reportable Food Registry (RFR) commodity definitions is overly broad and the entire produce category would be placed in one of two categories: Produce-Fresh Cut or Produce-Raw Agricultural Commodities(RAC). This is overly simplistic and has the potential to create a situation where ALL produce, which encompasses literally hundreds of commodities with different risk profiles, would be grouped into one category. As per the discussion above the use of “industry-wide” categorization is inappropriate to use to determine regulatory requirements for individual entities, as it does not take into account differences in implementation between and among various enterprises.

It is suggested that FDA consider using an integrated “food category” data and “individual entity” data approach to make the determination as to which entities that manufacture, process, pack or hold foods within a given food category should be designated as “high-risk” food producers.

Individual entity data that should be considered are:

- the results of FDA inspections (FDA Form 483 significant findings) and state inspections,
- primary Reportable Food Registry (RFR) reports, and
- foodborne illness outbreaks associated with that entity.

Use of integrated “food category” and “individual entity” data to determine “high-risk” food status would provide the benefit of focusing the burden of additional tracing recordkeeping on firms that have demonstrated lack of implementation of appropriate preventive controls while not burdening firms that have implemented robust and effective preventive controls.



Additionally, the FDA proposal attempts to characterize overall implementation of preventive controls for an entire industry segment. This characterization will be difficult to accurately measure and ascertain. Even if compiled, overall industry-wide implementation data will only provide the FDA with an average value, which does not take into account industry diversity with regard to implementation of appropriate preventive controls. The risks of an individual operating entity and level of their implementation of preventive controls must be taken into account.

Section 204(d)(2)(B) of the Food Safety Modernization Act (FSMA) requires FDA to publish the list of “high-risk” foods on the FDA website of at the time when FDA issues final rules to establish the additional recordkeeping requirements for “high-risk” foods. Additionally, Section 204(d)(2)(A) of FSMA specifically states that the designation of “high-risk” foods must be based on six criteria:

- 1) Known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
- 2) Likelihood that a particular food has a high-potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
- 3) Point in the manufacturing process of the food where contamination is most likely to occur;
- 4) Likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- 5) Likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- 6) Likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

Sections 204(d)(2)(B) and 204(d)(2)(B) of FSMA apply to “facilities that manufacture, process, pack or hold foods that the Secretary designates under paragraph (2) as high-risk foods.” The FSMA statute does not preclude FDA from limiting the “high-risk” food designation to specific food category by entity combinations. This approach would take into account firm-specific information regarding proactive implementation of preventive controls and provide a more focused and narrow application of the “high-risk food designation for tracing.” Identifying specific food category by entity combinations would also incentivize entities to implement appropriate preventive controls and/or move to lower-risk practices where such options are available.



PMA Comment: Hazards Reasonably Likely to Occur

The FDA proposed approach to identifying foods that are designated as “high-risk” foods for tracing is problematic when more than one hazard is reasonably likely to occur in a particular food product, in that these types of food products will always receive a higher total or overall score. Many microbial hazards associated with fresh produce consumption are due to the fecal-oral route of contamination. This route of contamination is likely to have many different types of microbial hazards associated with it. Therefore there will likely be an over-estimation of risk, simply because of how the risk calculation is performed, whereby each hazard/food combination would trigger multiple analyses. It is recommended that FDA consider a consolidated approach to similar microbial hazards, in that for example the agents *E. coli* O157:H7 and *Salmonella* be combined in one analysis and not be double counted for risk ranking purposes.

PMA Comment: High Risk Score

It is unclear from the FDA proposal regarding “Designation of High-Risk Foods for Tracing” as to what total score would constitute the “high-risk” food designation. PMA requests clarification as to how FDA will determine what constitutes a “high-risk” food score. PMA also asks for clarification as to how FDA will report out which foods will be designated “high-risk”; that is, will there be categories reported out other than “high-risk”?

PMA Comment: Periodicity of Review

It is unclear from the FDA proposal regarding “Designation of High-Risk Foods for Tracing” as to how often food categories would be evaluated as to whether or not they are a “high-risk” food? PMA requests clarification as to how often re-evaluation of the “high-risk” food designation would be performed since industry practices, procedures, policies and the level of implementation of preventive controls are dynamic, not static. It is also unclear, and PMA requests clarification, as to how foods designated as “high-risk” could be re-evaluated and potentially removed of the “high-risk” food designation and what opportunities FDA will provide for requesting review of the “high-risk” food designation.



PMA Comment: Data Gaps

It is unclear from the FDA proposal regarding “Designation of High-Risk Foods for Tracing” as to how FDA will deal with data gaps for the proposed criteria. PMA requests clarification as to how FDA will deal with data gaps for the proposed criteria as they will undoubtedly occur.

PMA Comment: Food Category Specific Criteria

PMA suggests that FDA may wish to consider development of specific and varied evaluation criteria for various food categories that would take into account differences in procedures, practices and processes for each food category. It may prove very useful to evaluate facilities that manufacture, process, pack or hold raw agricultural commodities in a manner different from, for example, low-acid canned food facilities. A one-size-fits-all approach to evaluating food risk will likely prove difficult, overestimating risk for some foods while underestimating risk for other food categories. The Reportable Food Registry (RFR) commodity definitions would provide a good starting point for such individual criteria to be developed.

Comments Regarding Specific FDA Proposed Criteria:

PMA Comment: C1: Frequency of Outbreaks and Occurrence of Illnesses

- As per the general discussion above, this criteria likely overestimates risk for some raw agricultural commodities because it aggregates data irrespective of growing region, agro-ecological growing conditions and the entities involved in the manufacturing, processing, packing or holding of raw agricultural commodities. Thus it overestimates risk for some facilities and underestimates the risks for other facilities due to differences in procedures, practices, processes and preventive controls implemented by individual facilities.

PMA Comment: C4. Growth Potential / Shelf-life

- It is unclear what is meant by “Likely growth at temperature at which the food is intended to be held and stored, including refrigeration or room temperature.”
 - Clarification is requested regarding what is meant by “likely growth”?
How is growth defined and what is the quantitative measure of “growth”?
If growth is defined as a one log increase in human pathogens, many



microbial assays have a standard deviation of ± 1 log and this may prove difficult to accurately measure. The scientific community has engaged in lengthy technical discussions, including at the Conference for Food Protection, regarding time/temperature control for safety and what constitutes “rapid and prolific growth.” It is suggested that the definition of “growth” in this proposed criteria should be more explicitly defined.

- Clarification is requested regarding what is meant by “the temperature at which the food is intended to be held”? Is this the optimal storage temperature as determined by the facility that manufactures, processes and/or packs the food?
- As per the general comments above, how will FDA score these criteria if no data exist regarding the potential for growth of a specific human pathogen in a specific product of interest?
- This criteria likely overestimates the risk associated with raw agricultural commodities that have an extended or long-shelf life, in that they would likely receive a “high-risk” score for this criteria even if they have only a moderate potential for growth of human pathogens. It is also unclear how a “moderate” potential for growth is defined, and we ask for clarification.

PMA Comment: C5. Manufacturing Process Contamination Probability/Intervention

- PMA requests clarification of the descriptors used to describe “contamination probability during manufacturing” as it is unclear as to precisely what is meant by “recurring or frequent detection of contamination,” “sporadic detection of contamination” and “infrequent detection of contamination.”
- FDA’s proposed criteria for evaluating “steps taken to reduce contamination” as per the PMA comments above do not take into account preventive controls implementation differences between and among “industry” sectors and entities. This unfairly overestimates the risk posed by firms that have implemented appropriate preventive controls and underestimates others. Additionally, as per the PMA comments above, broadly characterizing “industry steps taken to reduce contamination” will be difficult to accurately measure and ascertain. Even if compiled, overall industry-wide implementation data will only provide the FDA with an average value, which does not take into account industry diversity with



regard to implementation of appropriate preventive controls. The risks of an individual operating entity and the level of their implementation of preventive controls must be taken into account when assessing whether or not a food should be considered “high-risk.”

- Proposed Criteria 5. Manufacturing Process Contamination
Probability/Intervention seems focused on evaluating “manufacturing level” contamination. PMA requests clarification as to how these criteria would be scored for raw agricultural commodities where there is no “manufacturing” or “substantial transformation” of the food product occurring in, for example, a facility that is a packing house.
- Proposed Criteria 5. Manufacturing Process Contamination
Probability/Intervention states: “The scoring would take into account available control measures and interventions that have been validated (e.g., FDA, 2009b and 2011b; NACMCF, 2010) and can be applied during manufacturing to eliminate, reduce (to acceptable levels), or otherwise control a hazard.” Many preventive controls for fresh produce raw agricultural commodities cannot be validated as they are pre-requisite programs that rely heavily on preventive measures like training and monitoring. The proposed criteria may be appropriate for manufactured foods where a “kill step” is applied like, for example, low-acid canned foods and pasteurized foods; however, it likely overestimates the risk of fresh produce raw agricultural commodities. Therefore, as referenced in the PMA general comments above, FDA may wish to consider developing specific and varied evaluation criteria for various food categories that would take into account differences in procedures, practices and processes for each food category.

PMA Comment: C6: Consumption

- The C6: Consumption criteria likely overestimates the risk of some commonly and highly consumed fresh produce raw agricultural commodities (e.g., bananas) due to extraordinarily high consumption rates. Therefore, as referenced in the PMA general comments above, FDA may wish to consider developing specific and varied evaluation criteria for various food categories that would take into account differences in consumption for each food category.

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