



Division of Dockets Management (HFA-305)  
Food and Drug Administration  
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Rockville, MD 20852  
<http://www.regulations.gov>

**Re: Designation of High-Risk Foods for Tracing; Docket No. FDA-2014-N-0053**

The United Fresh Produce Association appreciates the opportunity to comment on FDA's proposed approach for designating foods as high-risk for the purpose of enhanced recordkeeping requirements ("High Risk Designation").

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

United Fresh has long been the leader in continual enhancement of produce safety, bringing together food safety experts from across the industry to share understanding and drive process improvement, publish educational materials and best practice documents for multiple commodities and practices, and provide sound scientific input on potential policy actions by local, state, federal and international regulatory bodies.

United Fresh was a strong advocate for the Food Safety Modernization Act during its development. At its Board of Directors meeting January 20, 2007, United Fresh unanimously adopted the following guiding legislative principles for a food safety regulatory framework for produce:

- Produce safety standards must be consistent and applicable to all produce grown anywhere in the United States, or imported into the country.
- Produce safety standards must be mandatory, with sufficient federal oversight, in order to be most credible to consumers.
- Produce safety standards must allow for risk-based, commodity-specific food safety practices based on the best available science.

In preparing our comments on the High Risk Designation proposal, we have implemented a widespread and intensive discussion with member companies with expertise at each stage of the produce supply chain from field to table.

We appreciate FDA's efforts to meet the Congressional intent of the Food Safety Modernization Act, specifically section 204(d)(2)(A), which requires FDA to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. However, we believe that Congress may have erred in its wording of the section, potentially leading to severe unintended and unnecessary consequences.

First, "high risk" and the need for traceability are not connected. United Fresh staff and member companies participated in the pilot program performed for FDA by the Institute of Food Technologists (IFT), and we agree with the primary recommendation in the IFT report that "FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification." The need to trace implicated foods back to the source of contamination and forward to all other potentially contaminated foods can occur in any commodity, regardless of prior linkage to foodborne outbreaks. This has been demonstrated time and again in produce (e.g., cucumber, celery, papaya, sweet peas) as well as non-produce commodities that are linked to foodborne outbreaks for the first time and must be traced effectively. Further, requiring enhanced recordkeeping will not make "high risk" foods safe, only potentially better assure their traceability in the event of a recall or outbreak, as would be necessary for any food regardless of calculated risk. Therefore, we submit that it is unnecessary for FDA to designate a food as "high risk" in order to require adequate and accurate recordkeeping to enable traceability.

Second, no food is inherently "high risk". As FDA appropriately describes in the preamble to its proposed Produce Safety rule, risk and the potential for contamination are more appropriately ascribed to handling practices rather than to the commodity itself. Using the 2010 listeriosis outbreak linked to fresh-cut celery as an example, in FDA's report the celery was identified as the vehicle for the outbreak because of the handling and facility sanitation practices in that one operation. The vehicle could as easily have been any commodity handled in that operation, not because of some inherent vulnerability of celery. To consider that occurrence as evidence that celery is high risk would be inappropriate, unfair and unscientific. The same can be said of any food where inappropriate handling practices were the root cause of the contamination.

Third is the consequence of a "high risk" designation to public perception and confidence in the safety of the food. In our support of the Food Safety Modernization Act, we solicited Congress and subsequently FDA to develop fair and practical regulations that would reaffirm consumers' confidence in products grown, packed or manufactured by compliant operations. In our comments to the proposed Produce Safety rule, we supported ascribing risk to growing and handling practices rather than entire commodities. Designating entire commodity groups as high risk would have the consequence of damaging consumer confidence and dooming efforts by any company included in that designation to demonstrate the safety and reduced risks of their food safety practices. For example, using the proposed use of the Reportable Food Registry classifications, if Fresh Produce – Raw Agricultural Commodity were declared high risk, that designation would apply unfairly to lemons, cherries, radishes and artichokes as well as to fresh produce commodities that have been implicated in foodborne outbreaks. Even if the designation were only applied to, for example, tomatoes, that would apply to all fresh tomatoes regardless of growing and handling conditions. Indeed, the fundamental purpose of the proposed Produce Safety rule is that the produce coming from compliant operations will not be high risk. While we agree that all tomatoes should have adequate and accurate recordkeeping to enable traceability, designating all tomatoes as high risk will neither improve their safety nor consumer perception of their safety.

Finally, we are concerned that a list of high risk commodities has the potential to be used for purposes other than to identify foods for which additional recordkeeping requirements are appropriate and necessary, much in the same way that facility registration has been proposed for separating operations that are "farms" from "facilities", or how the RFR categorizations are being proposed here. Consequently, we are even more concerned that the proposed model is deeply flawed.

Therefore, we respectfully urge FDA to discontinue efforts to designate any commodities, by whatever classification system, as inherently high risk and, instead, focus on identifying

commodities for which enhanced recordkeeping requirements are appropriate and necessary to protect the public health, even if that results in enhanced requirements for all foods.

**General Comments:**

The following general comments are specifically in regard to the proposed model for designating foods as high risk.

1. Attribution of risk to foods based on the Reportable Foods Registry (RFR) groupings would be inappropriate, unfair and unscientific. The 30 groupings of foods used by the RFR were not based on risk, so to use them for that purpose is unsupported. Further, would the risk attributed to a grouping be based on the history of the subcommodity most often linked to foodborne illness, the proportion of subcommodities in the grouping linked to foodborne illness, or some average of subcommodities? For example, how would Dairy be evaluated when the grouping includes hard cheeses and pasteurized milk as well as raw milk? Likewise Seafood, which includes raw oysters as well as canned salmon?
2. Attribution of risk to foods based on detections and recalls will be skewed by oversampling of one commodity vs. another. Also, detection is not synonymous with public health risk. For example, USDA's Microbiological Data Program tested thousands of fresh produce items and reported dozens of produce items with detectable pathogen contamination. Yet, despite detection late into the products' shelf-life, none of the lots reported were ever linked to a detectable outbreak.
3. The proposed approach offers no opportunity for a commodity identified as high risk to ever come off of the list. For example, the Tentative Model Criteria for ranking based on Frequency of Outbreaks and Occurrence of Illnesses proposes to use data since 1998, most of which would not be representative of today's mainstream fresh produce production practices. Consequently, a commodity linked to two outbreaks in 2001 that resulted in "thousands" of illnesses would still be considered a "9" risk in the proposed model, even if never linked to an illness again because practices had changed; the Hepatitis A-green onions pairing is one such example. Likewise, ranking based on Likelihood of Contamination proposes to use data more than a decade old, with no indication of when detection data would be considered "too old" to be representative of current risk.
4. Several of the Tentative Model Criteria are confounded. For example, C7. Economic Impact is heavily influenced by C1. Frequency of Outbreaks and Occurrence of Illnesses, C2. Severity of Illness and C6. Consumption. Economic impact will always be high when frequency and severity of illness are high and consumption is high. Likewise, as noted in the description of the model, Occurrence of Illnesses will be heavily influenced by Likelihood of Contamination and Consumption.
5. C5: Manufacturing Process Contamination Probability/Intervention is probably the Model Criteria most relevant to risk, yet it will be representative of practices at individual operations, not commodities. Contamination probability during manufacturing is proposed to be ranked by qualitative criteria, i.e., High: Recurring or frequent detection of contamination, Moderate: Known history of contamination and sporadic detection of contamination, and Low: Infrequent detection of contamination, or contamination introduced post manufacturing. These appear to be subjective; i.e., no rationale is provided as to how each will be judged, nor how incidents at poor performing operations will be weighted against the general commodity industry.
6. Consumption as a criterion has the potential to be misleading. While consumption of a contaminated food has the potential to cause more illnesses if consumption is high, it does not make a food high risk. For example, the 2003 USDA-FDA *Listeria monocytogenes* Risk Assessment inappropriately ranked pasteurized milk as a high risk because of consumption, even though no illnesses have ever been attributed to pasteurized milk and the process used by pasteurized milk operations make such an event not reasonably likely to occur. Likewise, low consumption does not make a food low risk, as public health is measured by the number of illnesses, not by the proportion of consumption that made consumers ill. Notably, that

same Risk Assessment ranked Unpasteurized Fluid Milk as a lower risk than pasteurized because of consumption.

## Responses to Specific Requests for Comment

- *Considering available data, uncertainty with the data, and the intended methods, what alternative approaches should we consider to identify high-risk foods?*

We agree with the approach proposed by FDA in the Produce Safety proposed rule; i.e. to rank risk based on handling practices, not by commodity.

- *What additional criteria should we consider, within the bounds of the factors Congress mandated in section 204(d)(2)(A) of FSMA, to develop the list of high-risk foods? For example, in addition to the public health related economic impact of foodborne illnesses, which the draft approach takes into account, should the approach include nonpublic health economic impact factors, such as costs related to disruption in the food supply following a foodborne illness outbreak? If so, how should we determine these costs given the variety of foods and different market values for various foods?*

We respectfully disagree with the criteria set by Congress in FSMA, for the reasons described above. Costs related to disruption in the food supply following a foodborne illness outbreak would be confounded with Consumption and also not relevant to ascribing risk to a commodity.

- *What changes should we consider making to the scoring system to ensure the range of possibilities for the foods and hazards is comprehensive and to enhance the scoring?*

The scoring proposed in the model appears subjective (1, 3 and 9) and is described as "qualitative". As proposed, the scoring makes some situations appear to be inappropriately equal; for example, in Figure 2 of the proposed model, a commodity linked to 2 outbreaks between 1998 and 2003 and "thousands" of illnesses and a commodity linked to 15 outbreaks, including outbreaks in recent years, with thousands of attributed illnesses would both be scored as "9". If scoring is used, it should be credibly relevant to risk, likelihood of occurrence and impact on public health, and its values demonstrate appropriate risk ranking.

- *What changes should we consider making to the approach to better evaluate risk associated with animal food?*

No comment is offered.

- *The draft approach would equally weight the criteria. Should individual weights be assigned to each criterion? If so, which criteria should receive more weight and how should those weights be assigned?*

As noted above, several of the proposed criteria are confounded. Those that matter most are 1) potential for contamination by an adulterant to occur under current industry practices and the proportion of the industry that follows those practices, 2) the potential to mitigate the contamination (with or without control or an applied process) and the degree of mitigation (i.e., eliminate or reduce) under current industry practices and the proportion of the industry that follows those practices, and 3) the potential consequences to public health, measured by frequency and severity of illness attributed to those practices. That FDA does not have ready access to some of this information should not be a reason to prefer the proposed model.

- *The draft approach would utilize the food categorization scheme used for the Reportable Food Registry (Ref. 3). What other practical alternatives to this food categorization scheme should we consider in light of the practical constraints of evaluating individual commodities?*

As noted above, the food categorization scheme used for the RFR is not based on risk, and groups very low risk foods with foods that may be more likely to be linked to foodborne disease. That scheme also has no granularity to consider production or handling practices.

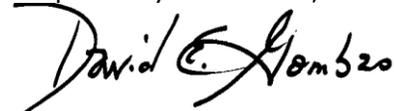
- *Adverse reactions may occur when allergic consumers are exposed to foods that contain undeclared allergens. Undeclared allergens may be present in a food through either mislabeling or cross-contact during processing and handling. Both situations present a risk to allergic consumers because they lead to incomplete or inaccurate product labels. How should food allergens, including the major food allergens defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108-282, Title II) (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans), be considered in the development of the high-risk food list?*

Foods that are themselves allergens are not a high-risk to the sensitive population, as those consumers already know to recognize and avoid those foods. Allergens are a good example of our point - that foods are not inherently high risk, it is the practices used in production, handling and distribution that assign risk - in that the primary risks attributed to allergens arise from mislabeling or unintended cross-contact, which can occur in any operation that handles allergens regardless of the other commodities handled. Operations that do not handle allergens will be low risk, but that does not make operations that do handle allergens high risk.

Should FDA disagree with our comments and proceed with a list of foods designated as high risk, we respectfully urge FDA to pilot such a list and its use before formalizing it in any regulation.

The members of United Fresh hope that FDA finds value in these considered comments, and we stand ready to clarify or assist FDA in these recommended changes to the proposed rule.

Respectfully submitted,



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