



## Consumer Federation of America

May 13, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Docket No. FDA-2014-N-0053

To Whom It May Concern:

Consumer Federation of America<sup>1</sup> is pleased to comment on the Food and Drug Administration notice concerning the Designation of High-Risk Foods for Tracing (Docket No. FDA-2014-N-0053).

Section 204(d)(A)(2) of the Food Safety Modernization Act requires FDA to “designate high risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health.” FSMA requires FDA to base each designation on the following:

- the known safety risks of the food, including the history and severity of foodborne illness outbreaks attributed to the food;
- the likelihood that a particular food has a high risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms;
- the point in the manufacturing process of the food where contamination is most likely to occur;
- the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

In order to carry out these requirements under FSMA, FDA proposed a model as part of its Draft Approach for Designation of High-Risk Foods. FDA is seeking comment on its model and approach. CFA agrees that FDA should weight the criteria equally in the model as each is an important factor in determining the risk of the food.

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<sup>1</sup> CFA is an association of nearly 300 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations. CFA’s Food Policy Institute was created in 1999 and engages in research, education and advocacy on food safety, agricultural biotechnology, food and agricultural policy, and nutrition.

CFA notes that the food categories FDA proposes to use for its Reportable Food Registry are different from food categories used by the Centers for Disease Control in its work on food attribution. FDA should work with CDC to develop more consistent categories in order to better align the RFR information and the attribution work being developed by CDC and promote broader consistency.

In previous comments to the agency on product tracing (Docket No. FDA-2012-N-1153), CFA emphasized the importance of FDA requiring a uniform set of recordkeeping requirements for all FDA-regulated foods and not only high-risk foods. FDA needs to be able to efficiently and accurately trace all products, including ingredients, through the supply chain. While the statutory language in FSMA refers only to high-risk foods, CFA does not believe that such an approach is sufficient to protect the public. CFA urged FDA to develop a standard set of product tracing requirements that can be applied to all FDA-regulated food products and to pursue efforts to encourage all food producers to comply with those product tracing requirements.

For Criteria 1: Frequency of Outbreaks and Occurrence of Illnesses, CFA agrees that links to outbreaks and illnesses are important factors to consider in determining the risk of the food. Much of the available illness data is linked to outbreaks; however relying solely on outbreak data would be insufficient to protect the public. Therefore it is essential that FDA incorporate into its model information about sporadic illnesses that aren't part of foodborne illness outbreaks. *Campylobacter*, for example, is a frequent cause of foodborne illness, but the vast majority of cases occur as isolated, sporadic events, not as part of recognized outbreaks. Assuring that sporadic illness data is considered in FDA's model is essential. FDA should also continue to work with CDC and other agencies in improving food attribution data, which is critical for the accuracy of this methodology.

For Category 3: Likelihood of Contamination, FDA proposes to use USDA's Microbiological Data Program (MDP) as a source of contamination data. While fairly robust, that program ended in 2012 so information in that database will be historical, not current. FDA should develop a similar surveillance program in order to provide more current data on the safety of fresh produce.

For Category 5: Manufacturing Process Contamination Probability/Intervention, CFA questions how FDA will apply this particular factor. FDA states that it will "take into account available control measures and interventions that have been validated and can be applied during manufacturing to eliminate, reduce (to acceptable levels), or otherwise control a hazard." FDA further states that it will look for evidence of consistent or inconsistent implementation of interventions across industry. CFA questions how FDA will do this. While there are some interventions that are likely to be broadly and routinely applied such as pasteurization of milk, many other interventions are applied on a facility by facility basis and their effectiveness is determined by the adequate application in the facility. Not every facility applies the same intervention and not every intervention is necessarily effective unless it is adequately applied. CFA questions how FDA will be able to use this factor in its model without sufficient data to know how interventions are being applied in every facility.

For Category 6: Consumption, FDA states that it will use consumption databases such as the National Health and Nutrition Examination Survey (NHANES) in developing consumption scoring. CFA notes that in FDA's proposed rule on produce safety (Docket No. FDA-2011-N-0921), the agency relied on NHANES data to develop a list of foods that the agency considered to be "rarely consumed raw." However that data was clearly not up to date in terms of current consumer trends. CFA encourages FDA to seek out

other data sources that may provide additional and more updated information about consumption patterns.

In the Notice, FDA asks whether the agency's approach should consider non-public health related economic impacts. In the list of factors to consider, Congress focused on public health factors that could increase the risk to consumers. In other places in FSMA, Congress directed FDA to consider economic impacts on the industry or on small producers. However in this case, it seems clear that Congress intended the focus to be on public health impacts. So it would not be appropriate to consider economic impacts that are not related to public health.

Finally, Section 204 (d)(2)(B) is clear that Congress expects FDA to revise the list as appropriate, including adding or removing foods to the list. As such, FDA should develop and communicate to stakeholders how frequently the agency intends to revise the high risk designation list and the methodology to do so.

The importance of revising the list is clear from past incidents where previously "low-risk" foods became associated with nationwide foodborne illness outbreaks, sickening consumers. Several years ago, most stakeholders would have identified peanut butter as a "low-risk" food. After multiple contamination events that sickened numerous consumers, peanut butter can no longer be considered "low-risk." Further, ingredients of processed products, such as spices, are increasingly being implicated in foodborne illness outbreaks.

CFA appreciates the opportunity to provide comments on this notice.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Waldrop". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Chris Waldrop  
Director, Food Policy Institute