THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

May 21, 2014

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration,
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

Dear Sir or Madam:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on the draft approach to designate high-risk foods (HRFs) for tracing.

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.

The Food Safety Modernization Act (FSMA) requires FDA to designate HRFs for which additional recordkeeping requirements are appropriate and necessary to protect the public health. The draft approach is a semi-quantitative assessment which employs seven criteria to evaluate a specific food-hazard pair. Foods, categorized using the FDA Reportable Food Registry categorization scheme, will be combined with chemical and microbial hazards. Each food-hazard pair is evaluated using seven criteria which are assigned numerical values from 0 to 9; all criteria values are summed resulting in a total risk score. The total risk score is then used to designate HRFs through relative ranking – comparison to the total risk scores of other food-hazard pairs. Six of the seven food-hazard evaluation criteria are human health and food-related factors while the seventh deals with economic impact.

The FSMA statute requires that a list of HRFs be developed to more expeditiously traceback a food during a foodborne illness outbreak in order to protect public health. While the intent to protect public health is applauded and most certainly paramount, the assignment of risk to a food is a difficult task for the following reasons:

1. Criteria 2, 3 and 6 employ a score assigned to each food-hazard pair that is based on hospitalization rates, likelihood of contamination and consumption, respectively. The criteria, alone, are not comparable to a health guidance level to estimate the public health impact of consumption of a food-hazard pair. However, if criteria 3 and 6 are combined, along with consumption quantities and body weight, exposure could be estimated and compared to a health guidance level (e.g., level of health concern for a chemical or pathogen). For example, exposure was estimated using a probabilistic combination of data from a toxicological database and a dietary survey for produce-pesticide combinations (food-hazard pairs) and compared to a health guidance level. [1] Since criteria 2, 3 and 6 are not comparable to a health guidance level, it is suggested that FDA employ methods, similar to 1, to account for a food-hazard's impact on public health.

2. Criterion 4 employs a score assigned to each food-hazard pair that is predicated on growth potential and shelf life. Figure 3 in the draft describes a scoring grid that assigns 0 for non-growth food-hazards such as a food with an allergen or virus and a 9 for food-hazard pairs with a long shelf life and strong growth potential. It is not clear which food-hazard pairs will achieve a 9 as those foods with a long shelf life, e.g., retorted canned foods, would not have a strong growth potential. Which food-hazard pairs would be given a score of 9? Please list some examples of food-hazard pairs with scores ranging from 0-9. How would these scores be used to compare the food-hazard's impact on public health?

3. Criterion 5 employs a score assigned to each food-hazard pair dependent on the ability to control contamination during processing. The likelihood of contamination and control measures used for a food-hazard pair are combined so that a higher score, from 1 to 9, is given in which a food-hazard does not receive a kill-step, for example, and has a high contamination probability. Which food-hazard pairs would be given a score of 9? Please list some examples of food-hazard pairs with scores ranging from 0-9. Since the food-hazard's impact on public health is addressed in the exposure calculation (discussed above), it is unclear how criterion 5 will used to estimate risk? It is suggested

[1] http://www.hindawi.com/journals/jt/2011/589674/

that the draft approach use only criteria that can be compared to a health guidance level to assess impact of the food-hazard on public health.

4. Foods listed as a HRF may fluctuate per developing food safety practices. As control strategies become more effective for a particular food-hazard, the risk of foodborne illness decreases.[2] What will the process be for foods moving from high risk to low risk and vice versa? How frequently will the list be updated?

5. Many foods have a variety of potential chemical and microbial hazards. How will risk from chemical and microbial hazards be combined for a food?

6. The RFR food categorization scheme will be used to assign like foods to groups. Certain foods may have a low to negligible risk associated with foodborne illness, yet they are in the same RFR group as others with a much higher risk. How will these lower/negligible risk foods be represented accurately? What about foods with mandatory controls across the entire industry? For example, pasteurization for almonds.

Recommendations for Improvement

We are fully aware of the direction and limitations provided by Congress regarding high risk foods. FMI believes that foods are not high risk, hazards are high risk. The emphasis of FDA should be on preventing, controlling and eliminating hazards in foods.

Congress gave FDA additional recordkeeping authority on HRFs. As FMI commented in July 2013[3] in response to Docket No FDA–2012–N–1153:

> "For product tracing to be effective, critical mass is needed in the food industry. If only certain foods are traced, there will be too many holes in the records that the system will not be effective and more time will be spent tracking down missing information. If systems are in place and employees are trained, it is easy to capture more information. The process of identifying a list of high risk foods has not been an easy one for FDA. FMI proposes that FDA incentivize the industry to have voluntary product tracing for all foods."

It is our opinion that a product tracing program for some foods will not be effective. Once product tracing is implemented, tracing the majority of foods makes more sense and will assist investigators with trace back and trace forward inquiries in order to protect public health.

---

[2] http://naldc.nal.usda.gov/download/3755/PDF

[3] http://www.fmi.org/docs/default-source/comments-filed/fda-fsma-report-on-product-tracing-(july-3-2013).pdf?sfvrsn=0

Request for Comments by FDA – Questions posed by FDA in *Federal Register* Notice

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

   In lieu of the assignment of risk to specific foods or food groups, FDA should instead focus on the preventive, versus reactive, intent of FSMA. For example, the produce safety and Hazard Analysis and Preventive Controls proposed regulations highlight food safety programs designed to reduce hazards in food that can lead to foodborne illness. Through adopting practices such as Good Agricultural Practices (GAPs) and Current Good Manufacturing Practices (cGMPs), farms and manufacturers can prevent food hazards. However, a list of risky foods does little to address the preventive design of FSMA, especially as the level of risk in a food can change through many factors, including industry, government and academia research and development of food safety practices to mitigate food hazards. The FSMA statute gives FDA the authority to put the list of foods on the FDA website and publish notices regarding updates in the *Federal Register*.

2. *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?*

3. *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?*

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

5. *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?*

6. *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?*

The RFR categorizes food using food characteristics and manufacturing processes, FMI wonders how granular the HRF list will be. If all foods will be broken into the RFR categories there are likely to be casualties of food that are not high risk landing in a high risk group. FMI seeks further clarification on this issue.

7. *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?*

   Food allergen risks should not be included in this methodology or food list. Food allergies are a serious health issue and research is needed on the medical issues related to the immune response to food allergens, and in the food industry to identify the best preventive practices to reduce cross-contact of allergens. Foods containing common allergens are not high risk. It is the unexpected immunological response that makes the food high risk to certain individuals. This specific issue should be addressed through research, education and communication.

FMI fully understands the complexity in developing a list of HRFs. We appreciate your consideration of these comments. Please contact me at (202) 220-0614 or sbarnes@fmi.org if you have any questions.

Sincerely,

Stephanie Barnes
Regulatory Counsel

Josh M. Katz, PhD
Director, Food Safety Programs

Hilary Thesmar, PhD, RD, CFS
Vice President, Food Safety Programs