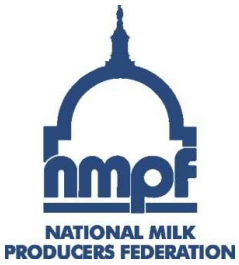
International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association



Via electronic submission

May 22, 2014

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

Re: Docket No. FDA-2014-N-053; Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information

Dear Sir or Madam:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a $125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's nearly 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

IDFA and NMPF supported passage of the Food Safety Modernization Act (FSMA) and have been pleased to assist the agency in its work to implement FSMA's many provisions. Strong collaboration between the agency and all stakeholders can help ensure clear, straight-forward regulatory requirements that improve food safety. Accordingly, after carefully reviewing the Food and Drug Administration's (FDA) draft model for determining high-risk foods under Section 204 of FSMA, we want to share our views regarding how the model could be revised and improved.

IDFA and NMPF believe the agency's current approach needs considerable revision. As a general matter, the approach is not consistent with Section 204 of FSMA. It is inconsistent with both the goal of the provision – identifying which foods need additional recordkeeping requirements in order to protect the public and to prevent or mitigate a foodborne illness outbreak – as well as the statutory factors Congress directed FDA to consider when making this determination. Most importantly, any model FDA uses to designate high-risk foods for tracing must sufficiently consider steps taken during manufacturing to reduce the possibility of contamination so that foods that undergo a validated pathogen kill step are not subject to additional recordkeeping requirements. We detail these and other concerns in the comments that follow.

I. The Proposed Model is Not Consistent with FSMA Section 204

a. The Model is Not Aligned with the Purpose of Identifying High-Risk Foods

Section 204(d)(2)(A) of FSMA directs FDA to designate high-risk foods for which additional recordkeeping requirements "are appropriate and necessary to protect the public health." These recordkeeping requirements, as described in Section 204(d)(1), are intended to "rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak . . . ." Accordingly, there are two companion questions any model must answer – whether the food presents a high risk of foodborne illness to consumers, and whether additional recordkeeping requirements for that food are necessary and appropriate to protect the public health.

FSMA prescribes a number of factors to help FDA make this determination. IDFA and NMPF assert that the most critical of these is "the steps taken during the manufacturing process to reduce the possibility of contamination" (FSMA Factor 4). We believe the model used to designate high-risk foods be weighted such that when a company applies a validated kill step to its finished food product—such as pasteurization—that food should not be considered high-risk and in need of additional tracing-related recordkeeping requirements. Such foods would not present a high-risk of contamination and would not likely result in a foodborne illness outbreak. Indeed, the importance of strong manufacturing controls is one of the central principles of food safety and is why Hazard Analysis and Critical Control Point (HACCP) and pre-requisite programs were developed.

In addition, FDA should consider the use of hurdle technology which can be used to ensure that pathogens are eliminated or controlled. One example of hurdle technology in the dairy industry is the use of ultra-pasteurization combined with the use of aseptic packaging. Another example would be pasteurized processed cheese, which has an excellent food safety record because of a thermal processing step in combination with the hurdles of salt (low water activity), pH, and addition of antimicrobials. FSMA places the responsibility on food manufacturers to conduct a hazard analysis and identify and implement preventive controls. As a result, strong manufacturing controls (and the use of a validated pathogen kill step in particular) should preclude a food from being considered high-risk. Ultimately, a finished pasteurized milk product should not be considered a high-risk food, whereas a raw, unpasteurized milk product should be.

In addition, FDA must consider whether additional recordkeeping requirements "are appropriate and necessary to protect the public health." These are recordkeeping requirements needed to track and trace food beyond those currently required by other FDA labeling and recordkeeping requirements. Most dairy foods already are subject to the "one-up, one-back" requirements of Section 414 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Consistent with the language of the statute, FDA

should consider existing tracing-related recordkeeping requirements when designating any food as high-risk for tracing purposes. Moreover, for those foods which are subject to existing "one-up, one-back" requirements and which do not present a high risk of foodborne illness to consumers (because they have been processed in a way to reduce that likelihood or because the nature of the hazard does not pose a risk of foodborne illness) additional recordkeeping requirements are not "necessary and appropriate" in order "to protect the public health" and "prevent or mitigate a foodborne illness outbreak."

Undeclared food allergens exemplify both of these principles. Although undeclared allergens properly trigger a recall, they are not the cause of foodborne illness outbreaks. Moreover, food recalls due to undeclared allergens are effectively carried out today without the need for additional recordkeeping requirements. As such, the statutory conditions for additional record-keeping are not triggered. Accordingly, the mere presence of an allergen in a food should not automatically make it a candidate for enhanced tracing-related recordkeeping requirements.

b. The Model is Not Aligned with the Statutory Factors for Determining High-Risk Foods

IDFA and NMPF also are concerned that FDA has drafted a complex model that does not align with the statutory factors for determining high-risk foods for tracing-related recordkeeping requirements. This is readily apparent from Figure 1 of the draft approach where the agency attempts to illustrate how the criteria in its model relate to the factors in FSMA. It appears that FDA is trying to force the FSMA factors into an existing risk ranking model that may not be fully appropriate for such broad application. As a result, FDA adds criteria not included in the statute and other statutory factors are merged into a single criterion. For example:

- FSMA does not direct FDA to consider the percent of the population that consumes a particular food (FDA criterion 6). If FDA considers this criterion, and particularly if FDA does not weight other factors properly, popular foods are more likely to be considered high-risk even if those foods are subject to preventive controls and processing steps that make the foods safe and they have not been associated with foodborne illness outbreaks. FSMA's direction for FDA to consider the "likelihood that consuming a particular food will result in foodborne illness due to contamination" does not mean that FDA should consider consumption rates. If anything, this factor speaks more to the routine interplay between the food handler/consumer and the particular properties of a given food (e.g., is the food likely to be subjected to temperature abuse, do handlers/consumers routinely and properly cook the food, do they consume small amounts at time, etc.)

- FSMA identifies "the point in the manufacturing process of the food where contamination is most likely to occur" and "the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination" as two separate factors (factors 3 and 4). FDA's draft approach, however, merges these into one criterion (criterion 5), which has the effect of minimizing the impact of these elements. This is especially problematic as the application of a validated pathogen kill step in the manufacturing process should effectively prevent a food product from being designated as needing additional tracing-related recordkeeping requirements. Therefore FSMA factor 4 is an independent factor and the most significant which should receive more weight than other factors. Further, the point where contamination is "most likely to occur" (FSMA factor 3) should be construed more broadly to reflect the point in the overall supply chain where contamination may occur,

not the point within the manufacturing process. The latter is typically facility-specific and would not reflect industry-wide or intrinsic risk.

II. Additional Concerns and Considerations

IDFA and NMPF also have the following concerns with respect to FDA's draft model for designating high-risk foods:

- Selecting Representative Foods. IDFA and NMPF understand that FDA intends to select representative foods from each food category in the Reportable Food Registry (RFR) for use in the risk-ranking model. Based on the current proposal, we believe that is a mistake. The RFR lumps all dairy products together in one category - "Dairy". The justification given for using the RFR commodity definitions is that they include product characteristics as well as manufacturing processes. However, the dairy industry includes a wide variety of products each with a unique set of intrinsic and extrinsic parameters including ice cream, yogurt and cultured dairy products, butter, hard cheeses, soft cheeses, sour cream, cottage cheese, dips, canned sweetened condensed and evaporated milks, pasteurized flavored and unflavored fluid milks, dried milk and whey powders as well as raw milk and raw milk products. Additionally, each of these products employs unique combinations of processing steps (pasteurization and heat treatments, separation, evaporation, concentration, drying, fermentation, ageing, freezing, modified gas packaging, salting, etc.).

  Because of the unique combinations of product characteristics and manufacturing processes, some of these products are virtually risk-free, while others such as raw milk are inherently risky. For example, yogurt has never caused a single illness outbreak in the United States. In stark contrast, according to the Centers for Disease Control and Prevention (CDC), from 1998 through 2011, raw milk and raw milk products were responsible for 148 outbreaks. To make matters worse, the number of outbreaks related to raw milk is increasing – from 30 outbreaks in the 3-year span 2007-2009 to 51 in 2010-2012. Further, the CDC also has concluded that raw milk was 150 times more likely to cause foodborne illness outbreaks than pasteurized milk, and such outbreaks had a hospitalization rate 13 times higher than those involving pasteurized dairy products. Raw milk is clearly a high-risk food, and combining both pasteurized and unpasteurized dairy products into a single category makes no sense. To do so completely ignores the fact that, because of pasteurization, dairy products represent a mere 1-2% of reported foodborne illness outbreaks, with over 70% of those specifically attributed to raw milk and raw milk cheeses.

  Accordingly, FDA should choose representative dairy foods from a larger number of categories that reflect the diversity of this industry and should ensure that the risks presented by foods such as raw milk and raw milk products do not affect the risk scores of other dairy products. For example, the list of food categories in the most recent food registration system does differentiate dairy products by placing them into three separate categories (Cheese, Ice Cream and Milk) and goes further with respect to cheese by breaking that into four subcategories – soft ripened cheese, semi-soft cheese, hard cheese and other cheese. IDFA and NMPF would recommend using the food facility registration system categories, and to do so on an ongoing basis, as those categories may be updated from time to time.

With respect to updating, we note that yogurt does not appear to be expressly included in any category, so we would recommend that FDA amend the facility registration by adding a category specifically for yogurt which would include yogurt, Greek yogurt, drinkable yogurt and other fermented milks and cultured dairy products. Right now yogurt is likely included in category #26 (Milk, Butter or Dried Milk Products) which includes "other milk origin products," which is hardly appropriate for such a desirable mainstream dairy product as yogurt with intrinsic properties (e.g. low pH) not shared by fluid milk and other dairy products. Finally we would urge FDA to list raw milk in its own category "Raw Milk for Consumption and Raw Milk Products" which would include raw milk cheeses. To be explicitly clear, raw milk products should not appear in any subcategory of the three dairy product categories.

FDA's use of food facility registration database categories is further warranted by the application of Criterion #4 in the model, Growth potential/shelf life. Dairy products have widely varying shelf lives, which range from a few weeks for fluid milk products to as much as two years for ice cream or dried milk powders, to even longer for some aged hard cheeses. The growth potential varies widely as well, from strong for a pathogen like *Listeria monocytogenes* in a soft Hispanic cheese to, in effect, zero for any pathogen in ice cream. Because of the wide variation in shelf life that would be represented for the group "Dairy" as a whole, the scale for the time factor is likely to be compressed, ultimately skewing the scores for this criterion such that they don't appear to make sense when comparing individual dairy products. For example, a soft cheese with a high pH would score a 3 or a 9 (moderate shelf life/moderate or strong growth potential), the former of which is the same score represented by raw milk (short shelf life/strong growth potential). Given the known public health hazard represented by raw milk, this doesn't seem to be an accurate scoring system. This is deeply troubling to IDFA and NMPF and indicates that FDA may need to further refine the criteria and the model, including revising the food classifications (e.g., having separate categories for raw milk products and for specific types of cheeses).

- FDA's List of Foods Subject to Additional Tracing Requirements**.** FDA should implement Section 204 by publishing a list of foods *subject to additional tracing requirements*, but should not label that list as being comprised of *high-risk* foods. IDFA and NMPF are concerned that any list of foods designated as high-risk could be misunderstood by consumers, nutritionists/dieticians, food service companies, and grocery retailers or misused by product liability attorneys. In addition, FDA must ensure that such a list of foods subject to additional tracing requirements is not used for other purposes, such as inspection frequency/intensity or performance standards. FSMA uses "high-risk" in a number of different ways and in very different contexts. FDA should determine and use high-risk as specified by Congress in each separate statutory provision and should not use its list of foods subject to additional tracing requirements for other purposes. IDFA and NMPF also urge FDA to share its thinking regarding the manner and the frequency with which it will update or modify the list of foods subject to added tracing requirements.

- Lack of a "Cut-Off" Score for "High-Risk." Although the draft model provides a method for identifying risk scores associated with a given food, it does not explain what total score value will be used to identify or classify foods as "high-risk." It is not possible to evaluate the actual effects of FDA's draft model without this information.

- Contribution of Multiple Hazards. IDFA and NMPF are concerned that by summing food-hazard pair risk scores to determine a total risk score for a food, foods with multiple hazards will be more likely to be designated high-risk. FDA's approach should ensure that its model takes sufficient consideration of other factors – such as processing controls – to safeguard against foods with multiple hazards being more likely to be considered "high-risk" for tracing.

- Criteria Score Values. FDA proposes to group information and data into scoring bins with assigned numerical values (0, 1, 3, and 9). This could result in over-inflated score values, particularly for subjective criteria, if there is a tendency to rank risk higher than what it may actually be. To address this, the scoring bins should have evenly distributed values. In addition, for criteria 1, 4 and 5, high/high bin classifications should have the highest numerical value, not an equivalent score to another bin as is indicated Figure #3 which gives an equal score of 9 to a moderate or long shelf life product with a strong growth potential.

- Weighting of Criterion. Weighting of each criterion with a multiplier would help avoid inappropriate skewing of results. We recommend criterion #5 be given the highest multiplier.

- Pilot Testing for Model: IDFA and NMPF recommend FDA conduct a pilot test of its revised model for an illustrative cross section of food categories, and provide to the public, in a transparent way, how the scores were determined for each criterion and which food categories from among those in the pilot would receive a high-risk designation. It is essential for stakeholders to understand how the model would be applied in practice, and to have an opportunity to provide comment on it. Taking this step would go a long way to ensuring credibility and public acceptable of the final FDA model.

- Use of Appropriate Data: IDFA and NMPF recommend FDA carefully consider relevant data when designating high-risk foods. Data should reveal intrinsic risks associated with a particular food (e.g., low acid, no validated "kill step", etc.), rather than isolated contamination events or specific problems attributed to a particular facility (e.g., a breakdown of a sanitation/hygiene program). Data also should be timely and should ensure that food safety practices adopted by the food industry are accurately reflected in the results. FDA also should filter out foodborne illness outbreaks that are a result of isolated cases caused by non-customary end-user abuse/misuse, since these incidences do not represent an inherent food safety risk. Further, outbreak data must be from credible sources and must include information from state and/or federal agencies. We also caution FDA against using data from the RFR to determine likelihood of contamination. The RFR contains information not relevant to determining which foods are at high-risk of contamination as it reflects incidents relevant to specific facilities and contains reports that may meet the statutory criteria for reporting, but do not reflect a health risk (thereby negating the need for tracing records).

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In conclusion, FDA should ensure that its model clearly differentiates those products that pose a high-risk for consumers (e.g. raw milk) and for which added tracing requirements are necessary to protect the public health during foodborne illness outbreaks. This will help ensure any added regulatory recordkeeping requirements provide a commensurate public health benefit. We

appreciate the opportunity to present our views on this issue and thank FDA for engaging in a continued dialog with stakeholders on these important issues.

Respectfully submitted,

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