



Submitted electronically via regulations.gov

February 22, 2021

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

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Re: Requirements for Additional Traceability Records for Certain Foods (Sept. 23, 2020), Docket No. FDA-2014-N-0053

Dear Sir or Madam,

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule *Requirements for Additional Traceability Records for Certain Foods* to implement Section 204 of the FDA Food Safety Modernization Act (FSMA). IDFA represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate \$159 billion in wages and \$620 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers. Together, they represent 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. IDFA can be found at www.idfa.org.

IDFA has long supported FDA's implementation of FSMA, and we similarly support FDA fulfilling its mandate under Section 204 of FSMA by establishing recordkeeping requirements to facilitate faster traceback investigations during foodborne illness outbreaks or recalls. We agree that faster traceback capabilities can provide significant public health benefits.

For this reason, the dairy industry has been working to implement more effective traceability systems for some time. The Innovation Center for US Dairy was created several years ago under the U.S. dairy industry's check-off program, and in 2009 embarked on a goal of improving traceability in the dairy industry. Subsequent work led to the development of *Guidance for Dairy Product Enhanced Traceability*¹ and an associated *Dairy Traceability Checklist*². In addition to providing information on the components of a traceability system, the guidance provides multiple examples of dairy product supply chains from origination to the retail store shelf, identifying the various points of creation, transformation, and/or transfer. These examples help provide dairy producers and processors with

¹ Dairy Management, Inc.- Innovation Center for U.S. Dairy. [Guidance for Dairy Product Enhanced Traceability](#). Version 3; July 15, 2020.

² Dairy Management, Inc. – Innovation Center for U.S. Dairy. [Dairy Traceability Checklist](#).

clear models in which to build their own traceability systems. In addition, the guidance provides several examples of mock recalls that help dairy processors create more robust recall systems built on effective traceability systems. The checklist (which in practice can be used as an audit) contains 21 points that are needed to have an effective traceability system. This approach has allowed the dairy industry to implement effective and pragmatic traceability systems that meets the need to track and trace their products. We believe the Guidance for Dairy Product Enhanced Traceability is a good example, though not the only one, of an effective tool in large part because it provides dairy processors the flexibility to develop their own systems that include the 21 key components.

Based on the dairy industry's experience with traceability systems, we are concerned that the Proposed Rule would impose a restrictive recordkeeping system that is more burdensome and complicated than is necessary to realize the goal of faster traceback investigations. If the goal is to have the recordkeeping system adopted for foods and by entities that are not covered by the Proposed Rule, as FDA has indicated is the case, then the rule should be as clear, simple and flexible as possible to accommodate the wide range of industry practices and supply chains and to make it easy to implement, similar to the Guidance for Dairy Product Enhanced Traceability.

To that end, IDFA encourages FDA to provide greater flexibility and simplify the rule to be less prescriptive, restrictive and burdensome for covered entities, which will facilitate more widespread adoption and achieve greater public health benefits. **Rather than focusing on specific records that must be retained and the information that must be included, we encourage FDA to adopt an outcome-focused (i.e. performance-based) standard requiring covered entities to be able to connect their outgoing product with incoming ingredients and respond to FDA information requests within a particular timeframe.** Provided this outcome can be achieved, FDA should allow entities greater flexibility in how they develop their records to satisfy the requirement. Such a simplified approach would enable faster adoption among industry and would substantially reduce the burden on smaller entities.

Although IDFA and its members would prefer a more outcome-focused, flexible system, below we are offering our comments on the ways in which FDA can simplify the framework of the Proposed Rule and reduce its burden on covered entities.

Executive Summary

Our comments that follow include both detailed and high-level comments. Our detailed comments focus on areas of concern to our members regarding issues fundamental to the framework of the Proposed Rule, such as its scope, the level of complexity of recordkeeping requirements, and the requirement to produce records in an electronic, sortable spreadsheet. Our high-level comments, while equally important, provide feedback and suggestions on more discrete components of the Proposed Rule.

Both our detailed and high-level comments reflect the following themes.

- Our members are committed to achieving the goal of faster traceback investigations, but the work it will take to achieve this goal is time- and resource-intensive. FDA should allow entities the time to build the systems and procedures necessary to comply and support a smooth implementation process.
- IDFA is disappointed that its comments were not incorporated into the risk-ranking model FDA used to identify foods on the Food Traceability List (FTL). As a result, we are concerned the model differed too significantly from the criteria in FSMA Section 204 and in some circumstances resulted in the selection of foods for which traceability records would not provide a significant benefit.

- FDA should have a scientific basis for each item on the FTL, as well as foods containing foods on the FTL as an ingredient. IDFA encourages FDA to refine the cheeses identified on the FTL based on science and risk. To help support this analysis, we will be supplementing our comments with the results of our own risk-ranking analysis performed in conjunction with the University of Wisconsin.
- Both the Critical Tracking Events and the Key Data Elements should be simplified and revised to provide greater flexibility to account for industry practices and current recordkeeping requirements.
- The requirement to provide an electronic, sortable spreadsheet to FDA will not be feasible for most entities. FDA needs to reconsider its approach to record production to ensure it is workable for all entities.
- In practice, the scope of impact of the Proposed Rule will be much broader than FDA has considered and therefore the economic impacts need to be more thoroughly considered.

Our detailed and high-level comments follow below.

Detailed Comments

I. The Food Traceability List (FTL)

Concurrent with its release of the Proposed Rule, FDA posted a tentative FTL, which includes commodities FDA selected using the risk-ranking model the agency developed based on the factors Congress identified in Section 204 of FSMA. FDA proposes that the Proposed Rule would apply to those foods listed on the FTL (hereinafter, we refer to these foods as “listed foods”), as well as any food that includes a listed food as an ingredient, absent certain exemptions. Of relevance to the dairy industry, the FTL includes cheeses, other than hard cheeses, as well as several commodities that may be used as ingredients in dairy products, such as nut butters, fresh tropical tree fruits, and fresh herbs.

IDFA’s members have several concerns regarding the risk-ranking model FDA used to generate the FTL. There also are several areas where FDA should provide greater clarity concerning the FTL, including how it would be updated, as well as how the Proposed Rule would apply to commodities not listed on the FTL, but which contain a listed food as an ingredient.

A. Risk-Ranking Model

FDA does not appear to have incorporated IDFA’s comments on the proposed risk-ranking model.³ In those comments, we identified several concerns with the proposed risk-ranking model which remain in FDA’s final risk-ranking model.

First, the risk-ranking model is not consistent with FSMA Section 204. It appears FDA sought to fit the six FSMA factors into an existing risk-ranking model that may not be appropriate for the purpose of identifying high-risk foods requiring further recordkeeping. For instance, FDA combined FSMA factors 3 (“the point in the manufacturing process of the food where contamination is most likely to occur”) and 4 (“the likelihood of contamination and the steps taken during the manufacturing process to reduce the possibility of contamination”) into a single criterion (criterion 5), which reduced the impact of FSMA factors 3 and 4. As a result, the risk-ranking model does not reflect the statutory factors for determining high-risk foods.

³ We are providing our comments on the proposed risk-ranking model as an attachment to these comments.

Second, FDA did not select appropriately representative foods. As we detailed in our comment on the draft risk-ranking model, FDA should have chosen representative foods from a larger number of categories that reflect the diversity of the dairy industry, but instead it relies upon the Reportable Food Registry (RFR) categories.

Third, FDA's approach of scoring foods based on individual criteria and the weighting of individual criterion could cause food scores to be over-inflated, especially for subjective criteria.

Finally, IDFA continues to promote a risk-ranking system based on the inherent risk of the food, rather than on individual differences in manufacturing environments. We are concerned that the risk-ranking model places too much weight on poor processing conditions that have occurred at specific entities, rather than on the inherent food risk of a particular product. This is apparent in the fact that manufacturing environment risk (Criterion 5), in some cases, may also already be reflected in Criterion 1 (recalls/outbreaks) and Criterion 3 (overall risk of contamination), thereby compounding the impact of manufacturing environment risk (e.g., post-kill step contamination due to lack/failure of hygiene practices). We believe that inherent product risk, strongly focusing on intrinsic factors and processing preventive controls applied, should be heavily weighted such that one-off and isolated losses of manufacturing environment control do not skew overall ranking results, placing what are generally safe product types onto the FTL.

B. Inclusion of Cheese on the FTL

We encourage FDA to refine the scope of cheeses included on the FTL based on science and risk. While we appreciate FDA's clarification of the types of cheeses it considers to be included on the FTL, we continue to have questions and concerns regarding the scope of cheeses included. In addition, when FDA identifies a particular variety of cheese for which a standard of identity exists as included on the FTL, it is not clear whether FDA would consider a cheese to be included on the FTL if it meets the standard of identity, or whether the evaluation would be based on some other metric such as the moisture level of the cheese. If the latter, our interpretation is that any cheese with a moisture content greater than 39% would be included on the FTL, but not all such cheeses present a risk sufficient for inclusion on the FTL. From a scientific, food safety standpoint, it is widely recognized that water activity (a_w), not percent moisture, is the more appropriate determinant of microbial activity and growth. Moreover, it is not clear whether retailers or other entities that receive cheese will be able to assess whether a cheese is or is not included on the FTL.

To assist FDA in identifying the varieties of cheese that present a public health risk sufficient to warrant inclusion on the FTL, IDFA is in the process of performing a detailed risk-ranking analysis in coordination with the University of Wisconsin, and we plan to share our findings with FDA before the Final Rule is implemented. The analysis will focus on the Model Criterion 4 (growth potential, with consideration of shelf life) and Criterion 5 (manufacturing process contamination probability and industry-wide intervention). We hope that this work will help the agency define clearer, science-based and risk-driven parameters for assessing whether a specific type of cheese is or is not on the FTL. Accordingly, we respectfully request FDA review this additional information before finalizing the FTL.

Even without this additional data, there are four categories of cheese that FDA should clarify are not included on the FTL: 1) low acid canned food (LACF) cheese; 2) process cheese; 3) cream cheese; and 4) cottage cheese. First, LACF cheeses should not be included on the FTL because they are subject to a scheduled process, including thermal processing, to ensure the finished product does not present a health hazard. In addition, these cheeses were considered as a separate commodity under the risk-ranking process. As such, FDA should clarify that LACF cheeses are not listed foods. Second, process cheese should not be included on the FTL because these products also undergo a kill step (in addition to the pasteurization of milk) as part of the production process and present a lower degree of risk than other cheeses that do not undergo pasteurization. The type of cheese used to make

pasteurized process cheese is irrelevant – the finished product presents the same low-risk profile. Third, in the production of cream cheese, the curds commonly undergo a cook step as part of the make process. Lastly, cottage cheese, which is typically produced in Grade “A” milk plants regulated under the Pasteurized Milk Ordinance (PMO), has been shown to not support the survival and/or growth of vegetative and sporeformer pathogenic bacteria when produced using common industry production practices and following standard good manufacturing and hygiene practices, and particularly with the use of certain inhibitory preservatives (e.g., sorbates).⁴

To address these four cases above, if the current listing is retained, IDFA suggests the following be added in the list of cheeses in the FTL:

Includes all cheeses made with either pasteurized or unpasteurized milk, other than hard cheeses. Includes soft ripened/semi-soft cheeses (e.g., brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster) and soft unripened/fresh soft cheeses (e.g., ~~cottage~~, chevre/goat, ~~cream~~, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna). Includes cream cheese produced without a kill step; excludes cream cheese produced with a kill step. Excludes pasteurized process cheese and listed cheeses destined for use in pasteurized process cheese and pasteurized prepared cheeses as provided in § 1.1305(d)(3). **

** See *Additional Comments* section on page 14 below with suggested addition of § 1.1305(d)(3) providing an exemption for process cheese due to the kill step used in the make process.

C. Inclusion of Foods Containing Listed Foods as Ingredients

The Proposed Rule would apply both to listed foods, as well as foods that contain a listed food as an ingredient. IDFA agrees that Section 204 directed FDA to establish recordkeeping requirements for foods it designates as high risk, but FDA does not have a basis for extending the recordkeeping requirements to commodities that do not present a significant public health or safety risk solely because they contain a listed food as an ingredient. Frozen pizza is a commodity that is separate and distinct from cheese, even if the frozen pizza contains a listed cheese as an ingredient. Notably, FDA considered frozen pizza in its risk ranking assessment, and frozen pizza did not produce a high enough score to be considered “high risk.” Therefore, FDA does not have a basis to identify frozen pizza as a high-risk food simply because it contains cheese as an ingredient.

It also is unclear how the proposal to include foods that contain a listed food as an ingredient within the scope of the Proposed Rule would work. For instance, are fresh herbs considered an ingredient in dried herbs? Our understanding is that FDA considers dried herbs and fresh herbs to be two distinct commodity categories and that only the former is a listed food. However, it is not clear how dried herbs would remain outside the scope of the Proposed Rule if the fresh herbs used as an ingredient in the dried herbs do not undergo radiation or some other kill step.

We understand that FDA’s intent was to require additional traceability records for foods such as bagged salad mixes, in which leafy greens are an ingredient. We encourage FDA to find a solution to this issue that is based on science and draws appropriate distinctions between foods that require additional recordkeeping and those that do not based on risk. We note, for example, that bagged salads could be considered “fresh cut vegetables.”

We propose that FDA revise the proposed rule so that it only applies to those foods on the FTL. Foods that contain listed foods as ingredients should not be within the scope of the rule unless they otherwise are a listed food (e.g., a deli salad contains tomatoes). Under such an approach, an entity receiving

⁴ Challenge studies conducted by Dr. Kathleen Glass, University of Wisconsin, Food Research Institute, (unpublished). Presented at the 2005 National Conference on Interstate Milk Shipments and provided to FDA Milk Safety Branch. IDFA can provide copies to FDA upon further request.

a listed food would be required to maintain receiving records, but no additional recordkeeping (e.g., transformation, shipping) would be required if the listed food was converted into or used in a non-listed food (e.g., fresh herbs became dried herbs, cheese was added to frozen pizza).

D. Clarification of Scope of Listed Foods

IDFA appreciates the additional detail FDA recently added to the FTL and the guidance it offered concerning the scope of listed foods. Further clarification is needed, however, for covered entities to fully understand the scope of foods in each of the listed commodities. It also would be helpful if FDA would clarify the foods that fall within the categories of commodities not included on the FTL. While we appreciate that FDA likely cannot provide exhaustive lists of foods included in listed and non-listed categories, more comprehensive examples of the foods in these commodity categories and the analysis supporting such determinations, will significantly help eliminate confusion about the scope of the Proposed Rule.

E. Revisions to the FTL

IDFA requests that FDA elaborate on the procedures it will follow when it removes or adds a listed food on the FTL. When it comes to removing listed foods, we request that FDA reconsider the FTL every 2 years, re-evaluating the listed foods on a rolling window basis. Using this approach, we anticipate that some foods may be removed from the list as instances of recalls or outbreaks associated with the food decrease over time. In addition, the final rule should include the factors FDA will consider when it performs a reanalysis, and FDA should release to the public its analysis for each food. Performing a reevaluation on a planned timeline also will give stakeholders notice that FDA is reevaluating the FTL prior to FDA posting a notice in the *Federal Register* that it has determined a change may be appropriate, and industry could submit data to FDA in advance of such reconsideration periods. The final rule also should detail the process for adding a food to the FTL, including what will trigger a food being added to the list, and the scientific basis that will support that conclusion.

We also urge FDA to follow the notice and comment procedures used for proposed regulations when it adds or removes a food from the FTL. The FTL defines the scope of the Proposed Rule and is, by extension, a component of the regulation and affects entities' rights and obligations. It therefore is necessary for FDA to follow notice and comment rulemaking procedures for changes to the FTL, as it would for any changes to the regulations.

Finally, we encourage FDA to extend the effective date from 1 to 2 years after a new food is added to the FTL. Including a two-year period from FDA's announcement of the addition of a food to the FTL would align with the current proposed two years for compliance for all other foods initially included on the FTL.

II. CTEs, KDEs, and Traceability Program Records

The Proposed Rule will have far reaching effects beyond those foods listed on the FTL, and it is imperative that it be both simple and flexible to facilitate compliance and accommodate industry practices. The Proposed Rule would directly affect IDFA's members because certain cheeses are listed on the FTL and other dairy products like ice cream may contain nut butters as an inclusion and therefore would fall within the scope of the Proposed Rule. More broadly, the Proposed Rule likely will affect those commodities not on the FTL because entities will be forced adopt the rule as a uniform

standard. Indeed, we understand FDA's goal is that the proposed recordkeeping system will be adopted broadly among industry.

There are numerous circumstances we expect will cause the Proposed Rule to affect entities and foods technically outside the rule's scope. For example, the proposed partial exemption for foods that have undergone a kill step does not address how a subsequent recipient of the food will know the food has undergone a kill step. If a cheese manufacturer receives dried herbs for an herb cheese product and does not know whether the herbs have undergone radiation, the cheese manufacturer may require all information from herb supplier, even if technically exempt.

We also anticipate that distributors, brokers, retailers, and restaurants may not be able to create different recordkeeping systems for receiving foods on the FTL and foods exempt from the rule. To ensure compliance, they likely will request all information required for receivers from all their suppliers, regardless of whether the food or the supplier is exempt from the rule. As a result, all manufacturers will be required to comply with the recordkeeping requirements for shipping.

The broad application of the Proposed Rule's recordkeeping system underscores the importance of ensuring the rule is flexible and simple. Our comments below focus on the ways FDA can ensure the rule includes enough flexibility to accommodate industry practices and is simple enough that it can be adopted easily by entities of all sizes.

A. Critical Tracking Events

Because each CTE will trigger voluminous recordkeeping requirements, we urge FDA to consider carefully those activities that will fall within the scope of each CTE and exclude activities where maintaining KDEs is not necessary.

We strongly urge FDA to clarify that intracompany shipments do not constitute "shipping" or "receiving" even if the product changes location. We propose that FDA could achieve this objective by excluding from the definitions of "shipping" or "receiving" any shipments between shippers and receivers that are under the ownership or operational control of a single legal entity. We suggest that this exemption also include shipments to a third-party warehouse, provided the food continues to be owned by the entity under the same ownership or operational control of the entity that shipped the food to the third-party warehouse.

Without the proposed exemption above, companies will be required to maintain records that are not needed to perform a traceback investigation. Moreover, the recordkeeping burden would be 5-6x higher for some entities if they are required to maintain records for intra-company shipments, instead of only those records for products shipped to a purchaser.

B. Key Data Elements

IDFA considers reducing the KDEs required for each CTE to be one of the best options for simplifying the Proposed Rule. In many cases the information in a KDE is not necessary to achieve the goals of the Proposed Rule and would be overly burdensome for entities to collect and maintain in records and subsequently produce to FDA in an electronic sortable spreadsheet within 24 hours. We encourage FDA to limit the KDEs required to those that are necessary to facilitate faster traceback investigations. In particular, we note that this rulemaking should focus on those additional recordkeeping activities necessary for high-risk foods. Cheese manufacturers already are subject to the one-up, one-back recordkeeping requirements of the Bioterrorism Act in 21 CFR Part 1 Subpart J. Accordingly, much of the information FDA proposes to require is not necessary for cheese or other foods covered by these existing requirements. Rather than focusing on specific records that must be retained and the information that must be included, we encourage FDA to adopt an outcome-focused standard requiring covered entities to be able to connect their outgoing product with incoming ingredients. This narrowly

tailored approach more accurately reflects the additional recordkeeping required to address manufactured foods like cheese.

Examples of KDEs that should be removed or modified include the following:

- **Entry Number for Imported Products:** The requirement to maintain and pass forward the entry number for imported products is duplicative and consequently is not necessary to perform a traceback investigation.
- **Traceability Product Description:** A traceability product description is defined to include the food category term or code, category name, and trade description, which would include the brand name, commodity, variety, product name, and packaging size and style, depending on whether it is a single or multi-ingredient product. These required elements are not always consistent with industry practices for products. Industry does not, for instance, use a category term or code or a category description. Different parties also will often use different terms for the same product. A brand name also is an element that would not apply to many listed foods, because brand names are not used for raw or bulk materials used as ingredients. Moreover, these terms could be eliminated because they are not needed for a traceback investigation, so long as an entity knows its own terminology and is able to quickly identify the food in question.

To help simplify the elements required under this definition, IDFA suggests the following modifications:

“Traceability product description means a description of a food product typically used commercially for purchasing, stocking, or selling, and may include, as applicable, the category code or term, and category name, and must include the trade description. For single-ingredient products, the trade description includes, as applicable, the brand name, commodity, variety, packaging size, and packaging style. For multiple-ingredient food products, the trade description includes, as applicable, the brand name, product name, packaging size, and packaging style.”

- **Location Identifier:** Often the unique identification code assigned to a physical location is not available under current practices or is not the same among different supply chain partners (e.g., shippers and receivers). Moreover, the location identifier is more detail than is necessary to perform a traceback investigation.
- **Location Description:** The physical name for a location description is not needed where the physical address, business name, and phone number also are provided.
- **Point of Contact for a Lot Code Generator:** A point of contact for a lot code generator is not always available under current industry practices. For instance, the point of contact may be multiple people who work at different times of day, or the individual fulfilling the position may change regularly. We do not think a point of contact is necessary, but should FDA maintain this requirement, we recommend that FDA allowing the point of contact to be a generic email address or position within the lot code generator’s organization (e.g., “sales manager”).
- **Information for Traceability Lot Code Generator:** The requirement for shippers to share with receivers the location identifier, location description, and point of contact for the traceability lot code generator would result in some entities sharing their confidential commercial information with the receiver. For instance, if a supplier shares with the receiving retailer the information for the contract manufacturer (co-manufacturer) used to produce a

product, it could result in the retailer purchasing the product directly from the co-manufacturer. For this reason, many companies treat the identities of their co-manufacturers as confidential commercial information. We recommend that FDA eliminate the requirement that shippers share the lot code generator information with receivers. Instead, this information could be obtained through the course of a traceback investigation as necessary.

C. Traceability Program Records

IDFA recommends that FDA eliminate the requirement for covered entities to maintain a list of all foods on the FTL that the entity ships. Maintaining such a list would be incredibly time consuming because it requires a case-by-case analysis of every ingredient and product, received, transformed, and then shipped by the company, and would need to be revised regularly to account for new products and ingredients or ingredient suppliers. The requirement also is overly broad, because it would include shipments of ingredients and semi-finished foods, as well as finished foods that are subject to a kill step. The burden of maintaining this list is not offset by any corresponding public health benefit, either, because when FDA is conducting a traceback investigation, it is focused on an identified food (or foods). A comprehensive list of the other listed foods a company ships will not assist in the traceback investigation. Accordingly, FDA should eliminate this requirement.

We also recommend that FDA clarify in the final rule that the requirement that reference records for different tracing events must be linked does not require that the records be electronically or digitally linked. FDA should make clear that records will be considered linked so long as an entity can use information on one record to identify additional relevant records. This clarification is necessary because some entities continue to use paper records.

D. Record Production to FDA

IDFA urges FDA to revise its proposed requirements for producing requested information to FDA to ensure that all covered entities can comply with the rule and to maintain the integrity of information provided to the agency. The Proposed Rule's requirement to produce an electronic, sortable spreadsheet to FDA within 24 hours of a request likely will not be feasible for most entities unless the scope of the request is very narrow. It would be much more feasible to produce information for one lot of food within 24 hours than 3 lots and certainly easier than 3 weeks of production. Even entities that already have sophisticated, electronic recordkeeping systems anticipate they could not meet this deadline, and we expect it would be all but impossible for entities with paper records systems. For example, even companies with electronic systems have multiple systems that are not "connected" and do not "talk" to each other. For example, the logistics systems that contain shipping information are not connected to production or batch records or to receiving records. IDFA also is concerned that due to proposed time constraint, entities may provide FDA with inaccurate information that must later be corrected, which could result in wasted time and resources by the agency.

Due to entities' inability to consolidate their existing records into a single electronic, sortable spreadsheet, the requirement to produce the spreadsheet within 24 hours may conflict with FSMA Section 204(d)(1)(E), which prohibits FDA from requiring the creation and maintenance of duplicate records. If entities are unable to consolidate their records into a single spreadsheet within 24 hours, they may be forced to adopt the routine practice of consolidating all mandatory information into a single location on a daily basis, so that they are prepared if they receive a request from FDA and do not risk being non-compliant if they fail to meet the 24-hour production requirement. The routine maintenance of the required data in a consolidated spreadsheet would require that entities duplicate their existing records in order to satisfy the Proposed Rule's requirements.

Our members have identified a preferred option for revising the record production requirement to ensure covered entities are able to meet their obligations under the rule without being required to duplicate their existing records. Rather than requiring that covered entities provide all requested

information within 24 hours in a sortable spreadsheet, FDA could instead require covered entities to acknowledge FDA's request for information and initiate discussion with the agency's primary contact regarding the scope of information needed to assist FDA's investigation, determine a reasonable time for producing the information and in what form it could be provided to FDA (e.g., in a sortable spreadsheet, simple table in an email, listing of lot codes, etc.). FDA could limit the scope of data covered entities must provide within the initial 24-36 hour timeframe, while providing additional information within a reasonable follow up period (e.g., 72 hours). We recommend that the information provided in the initial 36 hours could include easily accessible data such as the product, the name of the recipient, and the recipient's shipping address. The follow-up information provided to FDA could include more detailed information such as batch number, volume, time of production, etc. Much of this latter category of information is kept in paper records by many entities, including records on quantities received, produced, and shipped, and reconciling accurately product quantities and locations likely would take longer than 24 hours.

As an alternative approach, IDFA requests that FDA clarify that requested information must be produced in an electronic, sortable spreadsheet within 24 hours, unless otherwise agreed upon by FDA. This approach would provide entities longer than 24 hours to produce the electronic, sortable spreadsheet, depending on factors such as the circumstances surrounding the traceback investigation and the entity's capabilities to produce records. To achieve this change, we would suggest modifying the regulation for record production as follows:

"...you must make available, ~~within 24 hours of~~ when requested by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records you are required to maintain under this subpart, for the foods and date ranges specified in the request. The electronic, sortable spreadsheet must be made available within 24 hours of FDA's request, unless otherwise agreed upon. Upon request, FDA will agree to a later production date, when appropriate, based on factors such as the circumstances surrounding the traceback investigation, the volume of traceability lot codes or scope of production dates identified in the request, the volume of product corresponding to the traceability lot codes or production dates identified, the scope of listed foods involved, the scope of subsequent distribution of the foods identified in the request, the capabilities of the entity receiving the request, and other relevant factors.

This approach would retain the 24-hour production requirement, but it only would apply when FDA requests a very narrow scope of information that the entity can produce quickly in the required format.⁵

To the extent possible, IDFA also encourages FDA to alert entities to traceback investigations as soon as feasible. We recognize that the agency requires time to assess which lots will be included within the scope of its traceback investigation, but if FDA can provide entities with advance notice that they will be receiving a records request for a particular product around a general time, they can begin consolidating their records and be better prepared to respond to FDA's request in a timely manner. We also would support FDA discussing with entities the scope of their anticipated record request in advance of making the request, so that FDA and the entity can agree upon on the appropriate scope

⁵ We also suggest parallel changes to the general records availability provision under proposed § 1.1455(b)(1), to provide greater flexibility to account for many of the abovementioned limitations many in the industry currently face:

§ 1.1455(b)(1) You must make all records required under this subpart available to an authorized FDA representative as soon as possible but not later than 24 hours after the request, unless otherwise agreed upon. Upon request, FDA will agree to a later production date, when appropriate, based on factors such as the circumstances surrounding the request, the scope of records requested, the volume of listed foods involved, the scope of subsequent distribution of the foods identified in the request, the capabilities of the entity receiving the request, and other relevant factors.

of data needed to support FDA's investigation and an appropriate timeframe for delivering it in an electronic, sortable spreadsheet.

IDFA also requests that FDA limit the circumstances when information may be requested in two ways. First, FDA should specify that the request may only be issued by the director of the Center for Food Safety and Applied Nutrition (CFSAN), in consultation with the director of the Coordinated Outbreak Response and Evaluation (CORE) Network. By requiring requests for information to be issued by the CFSAN and CORE directors, FDA can ensure that the scope of information requested is appropriately tailored to the traceback investigation being performed.

Second, FDA should specify that a request may only be issued in circumstances where the data is necessary to help FDA prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death. With this change, FDA would make clear that provision of requested information is not required for a Class II or Class III recall, which we do not believe justifies such a request. We also note that FDA did not consider chemical hazards when determining those foods for which additional recordkeeping requirements are necessary. We therefore encourage FDA to clarify that misbranding due to undeclared allergens would not be grounds for such a request.

Finally, we recommend that FDA state it will exercise enforcement discretion with respect to any requirement to produce a sortable, electronic spreadsheet, should such requirement be retained in a final rule, and that it will not penalize entities making a good faith effort to comply with the requirement.

By adopting our suggested modifications to the CTEs, KDEs, traceability program records, and record production requirements, FDA can help reduce the burden on covered entities, thereby facilitating industry compliance and helping to ensure the rule's effectiveness.

III. Compliance and Enforcement

IDFA and its members are committed to working with FDA to facilitate faster traceback investigations and to successful implementation of the Proposed Rule. We wish to impress upon FDA, however, that adopting a new recordkeeping regime that uses terminology new to industry will be time- and resource-intensive. In addition, when updating their recordkeeping systems, covered entities will need to train their employees and, in many cases, purchase and implement new technologies. FDA can help facilitate compliance by providing guidance and training materials and by providing industry the time necessary to comply with the rule.

Below, we discuss some of the factors we think are important for FDA to consider as it develops its approach to compliance and enforcement of the rule, as well as suggestions to support the successful implementation of the rule.

A. Data Standardization

We anticipate that full implementation of the Proposed Rule will require the standardization of data among industry, a process that will take far longer than is provided for in the proposed compliance date. It is especially important for FDA to accommodate the standardization process in light of FDA's proposed approach of a single compliance date, as opposed to tiered implementation. The Proposed Rule would require that all entities must be prepared to comply with the rule simultaneously, when in reality only a limited number of companies with existing recordkeeping systems compatible with the Proposed Rule will be able to comply without undertaking substantial new investments.

The need to standardize data also will limit the ability of establishments to continue using paper records. Converting paper record data into digitized forms increases the potential for data corruptions, errors, and omissions that will hinder an establishment's ability to produce data in short periods of

time. Incorporating foreign suppliers into the data standardization process only compounds these challenges.

Accordingly, if the Proposed Rule continues to have a single compliance date, it should be extended to account for data standardization. We expect that a public/private partnership may be necessary to consider data standardization issues, as well as the adoption of a governance body to oversee and maintain these standards. Of course, all of this would take time and considerable effort and resources. FDA should extend the compliance data accordingly.

B. Compliance Date

In light of the concerns our members have identified related to the complexity and burden of the Proposed Rule, we suggest that FDA consider a “test phase” approach to implementing the rule. In the first phase, or the test phase, FDA should focus implementation of the final rule for only a few key categories of food that present the greatest level of public health risk (e.g., fresh leafy greens), rather than the full list of foods on the FTL. If this initial phase demonstrates that the proposed recordkeeping system is feasible and accomplishes the rule’s objectives, it would be expanded to other listed foods in the second phase of implementation. If further refinements to the rule are necessary, they can be made before compliance is required for all other listed foods.

IDFA also strongly encourages FDA to provide a longer period for compliance than the two years provided in the Proposed Rule. Two years simply will not provide enough time for covered entities to digest the final rule, develop, budget, purchase and implement new technologies (as needed), communicate with supply chain partners, and update recordkeeping systems. While the phased approach described above is our preferred option, if FDA chooses to have a single, uniform compliance date, we suggest that a period of at least 4 years is necessary.

Finally, we urge FDA to ensure that all relevant guidance from the agency is issued well in advance of the compliance date, to ensure entities have an opportunity to consider and incorporate FDA’s guidance into their programs.

C. FDA Time and Cost Estimates

IDFA has reviewed FDA’s estimates for the recordkeeping burden of the Proposed Rule under the Paperwork Reduction Act (PRA) and its cost estimates for the Proposed Rule in the Preliminary Regulatory Impact Analysis (PRIA), and we are concerned FDA has significantly underestimated the time needed for preparing records and the financial costs of complying with the rule.

As a preliminary matter, FDA has only considered the costs for entities that manufacture, process, pack, or hold listed foods or foods containing a listed food as an ingredient and, for those entities, only to the costs associated with listed foods or ingredients. In reality, the Proposed Rule will likely affect all foods because it will require entities to revise their recordkeeping systems, and it would be more time- and energy-intensive to maintain two sets of recordkeeping systems than to apply the recordkeeping system necessary for compliance with the rule to all foods.

As a result, the Proposed Rule will require entities to collect and maintain records compliant with the rule for all foods, meaning the effect on covered entities will be greater than FDA anticipates, and the effect will extend to entities not covered by the scope of the rule. Indeed, we understand it is FDA’s intent that the rule be adopted broadly among industry as the standard recordkeeping protocol. FDA’s PRIA estimates 442,144 firms will be covered by the Proposed Rule, but the reality is that the requirements and costs would extend to entities that are exempt or otherwise not included in the scope of the proposed Rule. This expansion of the rule’s requirements beyond the scope of the rule, means the recordkeeping burden and costs of the rule will be far greater than FDA’s estimates.

Setting aside the issue of scope, FDA's discrete time and cost estimates are far, far too conservative. The following are but a few examples of the ways in which the true time burden and costs for the rule far exceed FDA's estimates:

- **Reading and Understanding the Rule:** The PRA estimates it will take firms 3.3 hours to read and understand the Proposed Rule. This estimate is perhaps the amount of time it would take to simply read the Proposed Rule, but it fails to account for the need to consider the rule's implications and how it would affect a particular entity. One of our members, for example, has devoted two employees working eight hours a day to review the Proposed Rule and account for the ways in which it would have to change its operations to comply with the rule.
- **FTL Lots Per Entity:** Both the PRA and PRIA base their estimates on the assumption that most entities (other than distribution centers and warehouses) will need to establish and maintain records for only 1,000 FTL lots. In reality most entities will be required to establish and maintain records for far more than 1,000 FTL lots. One of our members processes numerous lots for between 500 and 1000 SKUs each year, meaning the time and cost for this member will be several orders of magnitude higher than FDA estimates.
- **Capital Investments:** FDA estimates entities will require only \$7,500 in capital investments to comply with the rule. This estimate is far too low to account for the electronic solutions that will be necessary for entities that currently capture KDEs in paper form. We also expect that many entities will be required to install Wi-Fi in their establishments to ensure that any data collected electronically can be consolidated with substantial labor costs associated with uploading the data into a central repository. Depending on the size of the establishment, Wi-Fi installations can cost hundreds of thousands of dollars.

In addition to these specific examples, our members also have reported that FDA's time and cost estimates for the one-time activity of establishing recordkeeping systems, the ongoing task of maintaining records, training employees, and responding to an update to the FTL all are too low.

We raise these issues to underscore to FDA how difficult we expect it will be for entities to comply with the rule. Our members are dedicated to complying and working cooperatively with the agency to achieve the rule's objectives, but we ask that FDA recognize the challenges they will face in doing so.

Additional Comments

In addition to our detailed comments above, we also offer the following feedback on the Proposed Rule:

- **Complete Exemption for Kill Step:** IDFA supports FDA providing a complete exemption for foods that undergo a kill step, rather than the partial exemption from maintaining records after a kill step is applied. The kill step will help to eliminate any potential public health hazard, and any additional recordkeeping for such foods is unnecessary. We note, for example, that when food is transformed, receiving records are already required under Subpart J; and recordkeeping regarding a kill step would be maintained under the Preventive Controls rule. IDFA proposes the following revisions to proposed § 1.1305(d)... (3) a food on the Food Traceability List further processed in compliance with a food safety plan requiring one or more preventive controls that provide a kill step in processing or through validated cooking instructions.
- **Formulation as a Kill Step:** We request that FDA recognize in the final rule that a product's formulation can be a kill step. In other words, a product's pH, use of certain preservatives or

water activity level can render it unable or unlikely to support the survival or growth of pathogens, and recordkeeping should not be required for these foods.

- **Exemption for Consumer-Applied Kill Step:** FDA also should provide an exemption for foods that will receive a kill step by the consumer. These foods are far less likely to result in a foodborne illness outbreak, and there would not be a public health benefit associated with maintaining more detailed records for these foods.
- **Written Disclosure for Produce Safety Rule Exemption:** We encourage FDA to clarify in the final rule that providing a written disclosure is not necessary for an entity to take advantage of the exemption for foods that are exempt from the Produce Safety Rule's (PSR) because they undergo commercial processing. We understand FDA will be revising this requirement under the PSR, and providing this written disclosure would eliminate much of the benefit of the proposed exemption. It is also not necessary in light of existing recordkeeping requirements in Subject J and in the Preventive Controls rule.
- **Exemption for Food for Research and Development:** IDFA encourages FDA to exempt food for research and development (R&D) from the Proposed Rule. We recommend that this exemption be similar in scope to the exemption for R&D foods under FDA's supplier verification regulations. In other words, the exemption should apply to food not intended for retail sale and not sold or distributed to the public, but should allow exempt R&D foods to be used in taste tests or other organoleptic testing.
- **Nut Butters:** We request that FDA clarify that the "nut butters" category on the FTL does not include commodities such as paste, chips, or flavors made from nut butters, as there is no basis for considering these foods to present a public health or safety risk and they are separate commodities considered as part of the risk-ranking model.
- **FSIS-Regulated Facilities:** FDA should clarify that facilities regulated solely by the Food Safety and Inspection Service (FSIS) are not covered by the rule.
- **Eliminate First Receivers:** IDFA supports FDA eliminating "first receiving" as a CTE. Even for a single food sourced through a common supplier, supply chains can vary from week to week or day to day. When entities source ingredients through a broker, for example, the ingredient may be sourced from multiple suppliers at different points in the supply chain (e.g., a farm or a distribution center), and it would be very difficult for entities to assess whether they are the first receiver of a listed food.
- **Clarification Regarding Continuous Processes:** In some production processes, a food on the FTL may be produced, but immediately transformed into another food. For example, a manufacturer may produce cream cheese, but then combine it with other ingredients and carry out additional processing steps to make a dip or another distinct product that is not "cream cheese." The cream cheese itself does not have any other purpose or use and therefore no lot code is assigned to it (it is part of a continuous process for the production of the finished good). FDA should clarify that the production of ingredients that will be immediately transformed do not require "creation" records. Establishing and maintaining such records would not serve any purpose and would be burdensome.
- **Supplier-Receiver Communications:** The Proposed Rule creates a framework where an individual entity's compliance is contingent upon receiving required information from its suppliers, yet entities have no control over their suppliers' compliance. To avoid supply chain disruptions and wasted food, we request that FDA clarify that if a shipper does not provide the required information to a receiver, the receiver may continue to use the food and will not be

considered out of compliance with the rule based on its supplier's failure to provide requisite information.

- **International Community:** Our experience with the Foreign Supplier Verification Programs rule has demonstrated the importance of ensuring our international partners understand FDA's regulations and their duties under them. We anticipate that educating the international community about the Proposed Rule will be imperative to ensuring a smooth implementation process, and we encourage FDA to lay out its plans for providing resource materials in multiple languages and educating the international community about the rule.

* * *

Our members share FDA's goal of protecting public health by increasing the speed of traceback investigations, and we are committed to ensuring this goal becomes a reality. Achieving FDA's proposal for a more interconnected recordkeeping system is going to be a time- and resource-intensive process, and we will need, time, guidance, and patience. It will likely also require further direct discussions and cooperation with the industry to find realistic, practical solutions. We therefore request that when a final rule is implemented, FDA take the same "educate before we regulate" to compliance and enforcement that it adopted with the initial rollout of the FSMA rules.

FDA can help ensure the time and resources devoted to compliance achieve commensurate public health benefits by ensuring the scope of the rule is appropriate, and by ensuring there is a sound scientific basis for including foods on the FTL. FDA also can promote the effective implementation of the rule by simplifying its proposal.

Considering the breadth of changes to the Proposed Rule that are necessary to accomplish these two tasks, we respectfully request that FDA take the time to work with the industry to find a more practical and effective way forward, then issue a supplemental proposed rule, which takes into account our and other industry members' comments. We expect that after FDA has taken all of industry's comments into account, the resulting revised rule will differ substantially from the original Proposed Rule. Accordingly, it will be necessary under the Administrative Procedure Act to provide stakeholders an opportunity to provide further comment on a revised proposal.

Issuing a supplemental proposed rule will allow FDA to engage further with industry to understand better the ways in which the Proposed Rule could be simplified or made more flexible to accommodate industry practices, and IDFA and its members would be pleased to participate in this collaborative process.

Please contact us if you have any questions related to our comments.

Respectfully submitted,

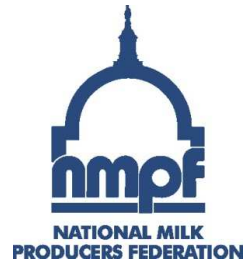


Joseph Scimeca, PhD
Senior Vice President, Regulatory and Scientific Affairs

Attachment: IDFA Comments on Docket No. FDA-2014-N-053; Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information (May 22, 2014)



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/dietitians, 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).

* * * * *

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,



Clay Detlefsen
Vice President & Counsel
International Dairy Foods Association



Beth Briczinski, Ph.D.
Vice President, Dairy Foods & Nutrition
National Milk Producers Federation