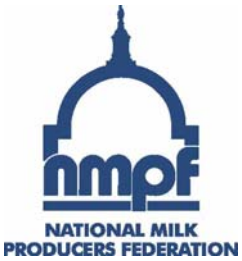

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association




November 30, 2011

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

**RE: Food and Drug Administration (FDA) Docket No. FDA-2011-N-0528 – Food Safety Modernization Act Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates for Fiscal Year 2012**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) are pleased to provide comments to the Food and Drug Administration (FDA) regarding implementation of the facility and import reinspection fee provisions of the FDA Food Safety Modernization Act (FSMA).

IDFA represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies representing a $110-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 220 dairy processing members and their 175 divisions, subsidiaries, and joint ventures run nearly 575 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. In addition, 320 member companies provide processing equipment and supplies, packaging equipment and materials, ingredients and a wide variety of products and services to the dairy processing industry. More than 15 state and regional trade associations are also members of IDFA.

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 31 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. Visit www.nmpf.org for more information.

IDFA and NMPF supported passage of FSMA and we recognize that a robust food safety system is crucial for both public health and the success of our member companies. Section 107 of FSMA amends section 743 of the Federal Food, Drug, and Cosmetic Act to establish fees for domestic and foreign facility reinspections, certain importer reinspections at the port of entry, and the failure to comply with a mandatory recall order. Recognizing that the FDA has not previously had authority to charge user fees for food facility and import reinspections, the agency's plans to implement Section 107 (as specified in the Federal Register Notice published August 1, 2011, 76 Fed. Reg. 45820) have raised a number of questions that require clarification. We commend FDA for issuing Guidance for Industry on September 30, 2011 that announced plans to curtail full implementation of the new fees pending further consideration and collaboration with industry. These comments highlight the several areas where we believe additional thought and clarification are needed, focusing on the hourly fees themselves, practical application of the fees, and assessment of the fees for facility and import reinspections.

### A. Hourly Rates for Facility and Import Reinspections

The hourly rates that FDA plans to assess are unnecessarily high. The rates of $224 for domestic work and $325 for work when foreign travel is required would equate to annual costs of $465,920 and $676,000 respectively per employee (based on 2080 hours in a paid staff year, as in FDA's calculations). The Federal Register Notice indicates that FDA calculated these rates using full-time-equivalent (FTE) costs per hour, which include costs for indirect and supporting functions such as budget, facility, human resources, information technology, security, and administrative support. However, FSMA only permits FDA to recover "100% of the costs of the reinspection-related activities," which are the direct costs for the reinspection itself.

We understand that in determining the hourly costs based on FTE expenses, FDA was following the model it has previously exercised when implementing other user fee programs such as the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee and Modernization Act (MDUFMA). That precedent does not fit this situation. When FDA implemented PDUFA, for example, it was appropriate to assess FTE costs because new employees were being hired and the agency needed to recover their cumulative costs. However, FSMA's reinspection fees are only intended to reimburse the agency for certain activities conducted by its employees during very finite periods of time. They are not intended to build a new workforce, as with the other user fee programs.

The personnel whose time will be billed to companies for reinspections are already FDA employees. Therefore, FDA has no added expenditures for overhead activities like human resources, information technology, or administrative support. Rather, the only expense is the amount of direct inspection time lost by diverting these employees from engaging in other responsibilities. In essence, the only cost is the dollar amount of the opportunity cost incurred by conducting a reinspection instead of a traditional inspection. Thus, we request that FDA reconsider its hourly rates to assess only the direct costs, rather than the FTE cost. As a point

of comparison, overtime costs charged by the U.S. Department of Agriculture's Food Safety and Inspection Service are just $53.92 per hour.

### B. Practical Application of Fees

Our members need to know when they will be subject to reinspection fees and should have a reasonable idea of the amount they will be assessed. To provide transparency about its plans and answer the numerous questions that have arisen, FDA should issue written guidance about reinspection fees. This guidance should clarify the following points:

- The specific instances when reinspection fees will and will not be assessed;
- The activities for which fees will and will not be charged, both for facility and import reinspections;
- Estimated amounts of the fees that the agency expects to charge in typical situations;
- A detailed protocol for dispute resolution about fee bills; and
- That the cost of the use of in-training inspectors should not be included in reinspection fees as this is not required for the reinspection but rather it is a training tool for FDA.

We also feel strongly that industry should not be billed for travel time because this penalizes foreign facilities and domestic facilities located in rural areas. Instead, FDA should only bill its out-of-pocket travel expenses, such as airfare, hotel, and reasonable meals. Finally, the fee assessment bills need to be sent out in a timely manner and should itemize the specific time and expenses that are being charged.

### C. Facility Reinspection Fees

IDFA and NMPF appreciate FDA's announcement in its Guidance for Industry explaining that (1) no reinspection fees will be applied for any initial inspections that occurred before October 1, 2011 and (2) the agency will distribute an information sheet about reinspection fees during all initial inspections. We suggest that the agency also take the following actions to increase transparency for reinspections:

- Companies should be notified of an initial inspection's designation as Official Action Indicated (OAI) for reasons materially related to food safety, so that they are aware of the potential for a reinspection.
- FDA should confirm that issuance of Form 483 Inspectional Observations after an initial inspection does not itself trigger an OAI designation and a resulting reinspection for which fees apply.
- Inspectors conducting a reinspection should clearly identify it as such at the beginning of their visit. Additionally, FDA inspectors should distribute an information sheet at all reinspections that indicates the visit to be a reinspection and estimates the range of costs that will be assessed.

- Companies should be notified when the reinspection is considered "closed" and they are no longer in OAI status, such that no further reinspections will be conducted.

FDA should also clarify the specific activities that will be billed to a facility as part of a reinspection. We suggest that FDA should only charge facilities for the time necessary for an inspector to prepare for the inspection, inspect the facility, and prepare a report afterwards. Any internal agency discussions or consultations beyond this scope should not be billed to the facility that is being reinspected, as evaluations of compliance are a distinct issue from the reinspection itself.

Additionally, to control costs and ensure uniformity, FDA should take the following steps:

- The agency should not expand its use of the OAI designation as a means of increasing the circumstances when it can impose reinspection fees.
- FDA should only send the minimum number of inspectors necessary to conduct a reinspection.
- Inspectors should only stay at the facility for long enough to assess its compliance in the area(s) that triggered the reinspection.
- The same procedures and limits should be applied consistently across districts and between domestic and foreign reinspection.

### D. State Inspections of Dairy Products

A great number of our members process Grade A milk and milk products in accordance with the Pasteurized Milk Ordinance (PMO). These include virtually all of our members that process fluid milk as well as many other dairy companies which process Grade A milk products (such as cream, sour cream, and yogurt). These companies are all subject to quarterly state inspections under the umbrella of the National Conference of Interstate Milk Shippers (NCIMS). FDA has a long history of recognizing the states' primary inspectional role for these products. **Accordingly, reinspection fees under FSMA should not apply for state inspections/reinspections conducted under this regime, and we request that FDA affirm this in its next guidance document. 1/**

For other dairy products, we would ask the agency to clarify whether initial inspections conducted by state inspectors on FDA's behalf could serve as a predicate for an FDA reinspection and, if so, how the company would know it was in OAI status as a result of the state inspection.

1/ FDA sometimes inspects these dairy company facilities as well. Should FDA conduct an inspection that triggers an FDA reinspection, we understand the reinspection fees would apply.

### E. Import Reinspection Fees

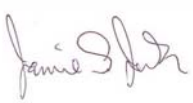
We commend the agency for its announcement that import reinspection fees will not be assessed until it addresses the concerns raised by stakeholders. The following are a few of the several specific issues relating to import reinspection fees that will require clarification before the fees are imposed:

- FSMA only permits reinspection fees if an examination occurs subsequent to an examination that identified a noncompliance materially related to a food safety requirement. What constitutes an initial "examination" that triggers fees on a subsequent examination?
- What specific activities will be billed for an import reinspection?
- What type of notice will be given to importers so that they understand that they are subject to reinspection fees?
- When does an import reinspection start and end?
- Will reinspection fees apply if an importer is listed on a country-wide Import Alert? We believe that fees should not apply solely on the basis of an importer's country of origin, but FDA should affirm this in written guidance.
- If an entry has the same problem as a previous entry, will this be considered a repeat problem that is subject to reinspection fees? For example, if there is an undeclared allergen in product A, would a second entry with the same undeclared allergen in a different product B trigger a reinspection fee? What if the second entry is for the same product A but with a different allergen? What if the second entry is for product B but with a different allergen? We urge FDA to limit reinspection fees to circumstances involving the same product/same problem and not extend it to other circumstances involving different products or different problems.
- What is the liability for brokers/agents when they only serve as a middleman? Will a U.S. agent that receives the bill be liable for payment when they have no direct responsibility for the import?

In conclusion, IDFA and NMPF encourage FDA to develop further guidance on application of FSMA's reinspection fees and to take these points in to consideration when doing so. We look forward continuing to working with FDA as the agency works to implement FSMA.

Sincerely,

Clay Detlefsen
Vice President & Counsel
International Dairy Foods Association



Jamie Jonker, Ph.D.
Vice President
National Milk Producers Federation