



November 30, 2011

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

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

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates the opportunity to provide these comments regarding the Food and Drug Administration's (FDA's) plans to implement the reinspection fee provisions of the FDA Food Safety Modernization Act (FSMA). AFFI is the sole national trade association that promotes and represents the interests of all segments of the frozen food industry. AFFI fosters industry development and growth, advocates on behalf of the industry before legislative and regulatory entities, and provides additional value-added services for its members and for the benefit of consumers. AFFI members manufacture and distribute frozen foods throughout the United States and globally and are committed to ensuring that these products are produced in accordance with strict standards of safety and quality.

Through the establishment of new fees for food facility reinspections and certain import reinspections, Section 107 of FSMA will materially affect the entire food industry. AFFI is jointly submitting comments on reinspection fees with the American Bakers Association, the Grocery Manufacturers Association, the National Confectioners Association, and the National Fisheries Institute. We are filing this comment separately to highlight the several issues of paramount concern to our members.

Specifically, we want to direct the agency's attention to the following concerns regarding its plans to assess reinspection fees:

- Reinspection Fee Hourly Rates Should Only Include Direct Costs. FDA plans to assess fees at unreasonably high hourly rates of \$224/hour for domestic work and \$325/hour if foreign travel is required. As explained in the August

1, 2011 Federal Register Notice (76 Fed. Reg. 45820), these rates were calculated based on the full-time-equivalent (FTE) cost per hour, which includes overhead expenses such as human resources, information technology, administrative support, program management, and legal counsel. However, Section 107 of FSMA only permits FDA to collect the direct costs (“100 percent of the costs of the reinspection-related activities”), rather than indirect costs that include expenses such as overhead. The approach taken by FDA differs significantly from Congress’s direction in FSMA. The unreasonableness of FDA’s hourly rate structure is highlighted by the fact that the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) charges only \$53.92 per hour when billing for overtime at meat and poultry plants. FDA should bring its fees more in line with those of FSIS, as both are for food inspectional activities.

The precedent for considering FTE costs, FDA’s prior user fee programs, should not apply for reinspection fees. For example, it was appropriate to assess FTE costs when building a new workforce to implement the Prescription Drug User Fee Act (PDUFA), because new employees were being hired and their cumulative costs to the agency, including indirect administrative costs, needed to be recovered. However, the situation at hand for FSMA’s reinspection fees is distinctly different because FSMA only permits fees that reimburse FDA for the costs of “reinspection-related activities” themselves. The personnel who will conduct reinspections under FSMA are already employed by FDA. Unlike with PDUFA, FDA has no added overhead expenditures when conducting reinspections. FDA’s only costs are the amounts of direct inspection time lost by conducting a reinspection rather than an initial inspection.

Therefore, FDA should reconsider the hourly costs and reset the rates to impose only the direct costs of the FDA inspector’s time (e.g., actual time in a facility during a reinspection, writing reports, and lab analysis).

- FDA Should Not Charge an Hourly Rate for Travel Time. In keeping with only charging for direct costs of a reinspection, FDA should not charge an hourly rate for travel time, as such costs could be excessive and, for a distant facility, may be completely out of proportion to the cost of the reinspection itself. This is especially a problem for any reinspections of foreign facilities, or for reinspections of domestic facilities located more than an hour or two from the local FDA office. Instead, it would be far more reasonable for FDA to charge only its out-of-pocket costs for travel, such as airline, hotel, and related costs.
- FDA Should Provide Fair Notice When Fees Apply. Our members need to know when they will be subject to reinspection fees, both at facilities and for imports. FDA should inform facilities when an initial inspection is categorized as “Official Action Indicated” (OAI). Additionally, inspectors should bring an information sheet to any reinspection that clearly indicates that the facility will be charged for that reinspection. It also is important that importers be on notice when reinspection fees are being accrued. Companies also need to

be notified when the reinspection issue is closed (i.e., when the facility is no longer considered to be in OAI status, or when an import investigation is completed).

- Guidance is Needed to Clarify the Details. Additional guidance is necessary so that industry understands when reinspection fees will be assessed. For facility inspections, FDA should clarify the specific activities that will be charged. We encourage FDA to only charge the time that is necessary for an inspector to prepare for an inspection, physically assess the facility, and prepare a report afterwards. For import reinspections, the meaning of “reinspection” needs to be clarified so that importers understand the specific scope of situations when fees apply and what activities will be billed as part of a reinspection.
- FDA Needs to Specify the Scope of Import Entries Subject to Reinspection Fees. Importers bring food into the U.S. on a regular basis. Therefore, it is important for FDA to specify which import entries would be subject to an import reinspection fee, once an “initial” import entry is determined to be out of compliance. We believe that import reinspection fees should apply only when the second (or subsequent) import entry is for the same product as was subject to the initial inspection, having the same material food safety problem. Reinspection fees should not apply to second (or subsequent) import entries for different products from the same importer, or for the same product, but with a different food safety problem. Each product/problem should stand on its own—i.e., be subject to an “initial” examination before reinspection fees are applied to subsequent entries.
- FDA Should Take Precautions to Control Costs. FDA should only send the minimum number of inspectors needed to conduct a reinspection and should not stay in the facility longer than is necessary to assess its compliance in the area(s) that triggered the OAI designation. FDA also should not expand its use of the OAI designation as a means of increasing the circumstances when it can impose reinspection fees. For purposes of an import reinspection, as noted above, the agency should narrowly interpret the activities considered an initial inspection, such that reasonable limits are imposed on the situations when reinspection fees will be applied.

Thank you for the opportunity to provide these comments. If you need any further clarification or have questions about our comments, please do not hesitate to contact me or AFFI Director of Regulatory and International Affairs John Allan at (703) 821-0770.

Respectfully submitted,

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