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

**Submitted electronically at [www.regulations.gov](http://www.regulations.gov)**

**RE:** Docket FDA-2011-N-0528; Food Safety Modernization Act Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates for Fiscal Year 2012; 76 *Federal Register* 45820, August 1, 2011

Dear Sir or Madam:

The American Frozen Foods Institute (“AFFI”), the American Bakers Association (“ABA”), the Grocery Manufacturers Association (“GMA”), the Institute of Shortening and Edible Oils (“ISEO”), the National Confectioners Association (“NCA”), and the National Fisheries Institute (“NFI”) are pleased to submit the attached comments in response to the Food and Drug Administration’s August 1, 2011 Federal Register Notice titled, “Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates For Fiscal Year 2012” (the “Fees Notice”).

AFFI is the national trade association that promotes and represents the interests of all segments of the frozen food industry. Members of AFFI manufacture and distribute frozen foods throughout the United States and globally, and many receive ingredients from foreign suppliers. Although AFFI’s membership comprises many of the largest food companies in the world, the institute prides itself on also representing the interests of small and mid-sized frozen food companies.

ABA is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 700 baking facilities and baking company suppliers. Some of these companies are small businesses. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The

baking industry generates more than \$70 billion in economic activity annually and employs close to half a million highly skilled people.

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policy makers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The \$2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over \$1 trillion in added value to the nation's economy.

The ISEO is a trade association representing the refiners of edible fats and oils in the U.S. Its member companies process over 20 billion pounds of edible fats and oils annually, which approximates 90-95% of the edible fats and oils produced in the U.S. These oils are used as baking and frying fats, salad and cooking oils, margarine and spreads, confectionary fats and as ingredients in a wide variety of foods.

NCA is the not-for-profit trade association of the confectionery industry. NCA represents over 400 companies that manufacture chocolate, confectionery, and gum products in the United States and another 250 companies that supply those manufacturers. The majority of our manufacturing members are small and medium-sized companies. There are about 70,000 confectionery manufacturing jobs across the United States.

NFI is the nation's leading advocacy organization for the seafood industry. Its member companies represent every element of the industry, from the fishing vessels at sea to national seafood restaurant chains. From responsible aquaculture, to a marketplace supporting free trade, to ensuring consumers have the facts on the health benefits of fish and shellfish, NFI and its members support and promote sound public policy based on scientific research.

Our organizations appreciate the opportunity to provide input as FDA implements the reinspection fees provisions of FSMA. Please contact us if you have further questions.

Sincerely,



Robert A. DeHaan  
Vice President for Government Affairs & General Counsel  
National Fisheries Institute

And on behalf of:  
American Frozen Food Institute  
American Bakers Association  
Grocery Manufacturers Association  
Institute of Shortening and Edible Oils  
National Confectioners Association

**UNITED STATES FOOD AND DRUG ADMINISTRATION**  
**FOOD SAFETY MODERNIZATION ACT**  
**DOMESTIC AND FOREIGN FACILITY REINSPECTIONS, RECALL, AND**  
**IMPORTER REINSPECTION USER FEE RATES FOR FISCAL YEAR 2012**

**DOCKET No. FDA-2011-N-0528**

**COMMENTS**

**OF THE**

**AMERICAN FROZEN FOOD INSTITUTE, THE AMERICAN BAKERS  
ASSOCIATION, THE GROCERY MANUFACTURERS ASSOCIATION, INSTITUTE  
OF SHORTENING AND EDIBLE OILS, THE NATIONAL CONFECTIONERS  
ASSOCIATION, AND THE NATIONAL FISHERIES INSTITUTE**

**WASHINGTON, D.C.**  
**NOVEMBER 30, 2011**

The American Frozen Foods Institute (“AFFI”), the American Bakers Association (“ABA”), the Grocery Manufacturers Association (“GMA”), the Institute of Shortening and Edible Oils (“ISEO”), the National Confectioners Association (“NCA”), and the National Fisheries Institute (“NFI”) hereby submit these comments in response to the Food and Drug Administration’s August 1, 2011 Federal Register Notice titled, “Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates For Fiscal Year 2012” (the “Fees Notice”). These six groups (collectively, the “Commenters”), whose members provide hundreds of millions of safe and nutritious meals to consumers every year, appreciate the opportunity to comment on the record in this proceeding.

**Introduction.**

Congress enacted the Food Safety Modernization Act, Public Law No. 111-353, on January 4, 2011 (the “FSMA”). The FSMA is the first comprehensive food safety reform legislation enacted by Congress in the postwar period. As noted by one of the FSMA’s lead Senate sponsors, many of the Commenters were significant supporters of the legislation from its introduction through enactment.<sup>1</sup> The Commenters look forward to continuing to work with FDA to ensure effective implementation of the FSMA requirements.

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<sup>1</sup> “I also want to thank the consumer, public health, and industry groups who have helped us craft a strong bill for their support: Consumer Federation of America, Center for Science in the Public Interest, Consumers Union, Trust for America’s Health, Grocery Manufacturers of America, American Feed Industry Association, American

Section 107 of the FSMA establishes, for the first time under the modern FDA, a system of fees for costs incurred by the agency in direct oversight of food industry firms. Section 107 imposes mandatory fees under three narrowly defined circumstances: (1) certain domestic and foreign facility reinspections following initial inspections; (2) failure to comply in some respect with mandatory recalls arising under either sections 412(f) or 423 of the Federal Food, Drug and Cosmetic Act (the “FFDCA”); and (3) certain import reinspections following initial inspections.

The FSMA authorizes FDA to collect fees to cover the costs of conducting these specific oversight activities, but expressly prohibits collection of these fees for other purposes: “The Secretary shall make all of the fees collected pursuant to clause (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.”<sup>2</sup> The FSMA caps FDA’s authority to collect fees in a given fiscal year at \$20 million for fees associated with mandatory recalls, and at \$25 million for fees associated with facility and import shipment reinspections.

The Fees Notice provides additional detail, describing more fully the three specific categories of interactions to which fees apply and also the methodology FDA proposes to use in calculating the hourly rate upon which the fees will be based. The Fees Notice includes a number of examples to illustrate when fees will (and will not) be triggered.

Detailed though they are, Section 107 and the Fees Notice leave a number of priority issues unaddressed or unresolved. The Commenters commend FDA for issuing the September 30, 2011 fees guidance (the “Fees Guidance”) regarding FDA’s plans for fully implementing Section 107.<sup>3</sup> Many questions remain unanswered, however, and clarification is needed in numerous areas. Accordingly, the Commenters urge the agency to issue additional guidance that resolves the outstanding issues discussed in these and other comments and provides thorough transparency to FDA’s approach to fees.

The Commenters support and join in GMA’s concurrently-filed comments regarding the methodology and costs approach proposed by FDA in the Fees Notice. The Commenters write separate comments here to focus on significant issues related to facility and import reinspections.

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Frozen Food Institute, Food Marketing Institute, National Fisheries Institute, and American Spice Trade Association.” Floor Statement of Senator Richard J. Durbin, 155 Cong. Rec. No. 37, at S2693 (Mar. 2, 2009).

<sup>2</sup> Citing to new FFDC 743(b)(3); see Fees Notice, 76 Fed. Reg. 45820 (Aug. 1, 2011) (acknowledging this limitation).

<sup>3</sup> The Fees Guidance is referenced in the Federal Register. See 76 Fed. Reg. 62073-74 (Oct. 6, 2011).

## **General Comments.**

These comments focus on the timing, scope, and events that appear to trigger the application of Section 107 fees. Before turning to issues raised by the Fees Notice and the September Fees Guidance, the Commenters offer some general comments applicable to both facility and import reinspections.

It is imperative, first of all, to provide fair notice to food industry firms that a fee has begun to accrue. A company needs to know when it is subject to a reinspection, both for its domestic or foreign facility and for products it imports through a U.S. port of entry. FDA should clearly specify the scope of situations when fees apply and give clear notice to individual companies when applying the fees. Next, under the FSMA, FDA may charge only for direct costs of reinspections, that is, the actual time FDA staff spends in a facility or at a port of entry (e.g., assessing a specific shipment, writing reports, and lab analysis). In particular, travel time and other indirect costs should not be charged as they do not represent a direct cost of reinspection.

Next, FDA stated in its Fees Guidance that the agency will not apply fees for facility reinspections to cases in which the initial facility inspection occurred before October 1, 2011. The Commenters urge FDA to also expressly commit to this posture going forward with respect to import reinspections. That is, once the agency begins applying reinspection fees for imports, such reinspection fees should not be assessed for situations involving products/firms placed on Import Alert or country-wide Import Alerts that originated prior to October 1, 2011.

The overall FSMA fees ceilings (of \$20 and \$25 million for mandatory recalls and for reinspection, respectively) cited above are aggregated industry-wide and therefore will not help firms predict an individual firm's financial exposure – except in the unlikely case of a firm incurring fees that push FDA up against either of those two caps. FDA should provide estimates, based on past experience, of the amount of fees companies should expect both for a facility reinspection and for the different types of import reinspections. FDA could provide a range, based on a limited and a more extensive reinspection need. This is necessary for companies to be able to understand and plan for the fee levels to which they could be exposed and in the case of import reinspection fees, to establish a cost of doing business when determining whether or not to request permission to recondition a refused shipment or to import product that may be impacted by an Import Alert.

Though the Fees Notice makes a brief reference to the invoices that FDA will issue, significant additional clarification is needed. Invoices should be sent in a timely manner (e.g., within 30 days) and should itemize the expenses/time for which a facility is being charged. FDA must provide a fair process to dispute both the applicability and the calculation of fees allegedly owed in an individual case, along with a mechanism for deferring collection activity so that firms

with legitimate questions can avoid premature and onerous debt collection efforts while the dispute is being resolved.

The Fees Guidance appears to speak to this issue. The penultimate Q & A in the Fees Guidance states that

because FDA recognizes that for some small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, for Fiscal Year 2012 FDA intends to consider waiving, in limited cases, some or all of a fee based on severe economic hardship, the nature and extent of the underlying violation, and other relevant factors. FDA is currently developing a guidance document to outline the process through which firms may request such a reduction in fees. FDA does not intend to issue invoices for reinspection or recall order fees until this guidance document has been finalized.

This statement references small businesses only and, apparently, refers to a process that will only apply to fees incurred in FY 2012. However, it is essential that FDA establish a mechanism for disputing the accuracy of the calculation of fees for all affected firms, whether they are small businesses or not. Accordingly, FDA should confirm that it will standardize a process for firms to request review and correction of fees billed in error to an individual firm under the Fees Notice. Again, this process should apply to any business that receives a Section 107 fees bill – not just small businesses – and it should apply to fees assessed by FDA in any year – not just in FY 2012.

The Commenters supported the agency's decision to extend the comment period applicable to the Notice and to entertain comments on both the FY 2012 and FY 2013 schedule of fees contemplated by FDA. The Commenters also appreciate FDA's commitment to distribute an information sheet during all initial facility inspections; that sheet should reflect agency commitments made to industry and in the Fees Guidance.

Lastly, given the material impact that this notice will have on industry, the implementing guidance should be reviewed by OMB. Executive Order 13422, amending Executive Order 12866, specifies that agencies must tailor guidance documents to impose the least burden and take into account their cumulative costs based on a cost/benefit analysis. The Fees Notice (and any subsequent clarification of it) would be a "significant guidance document" because it could adversely affect in a material way the food sector of the economy, competition, jobs, and public health. Accordingly, the guidance must be provided to OMB in advance of being issued for regulatory review.

### **Import Reinspections at the Ports of Entry.**

Beyond issues that apply to Section 107 fees universally, significant issues concerning the Fees Notice's proposal for fees for import reinspection remain outstanding. The Commenters appreciate this statement in the Fees Guidance:

The agency is still evaluating comments received in response to the August 1, 2011 Federal Register notice establishing fee rates for Fiscal Year 2012 (76 FR 45820). Recognizing the particular complexities involved in these issues, FDA is not in a position to assess import reinspection fees until the agency has resolved these issues and the agency notifies the public.

With that pledge in mind, the Commenters urge FDA to clarify the Fees Notice and/or Guidance as it pertains to import reinspections. New Section 743(a)(2)(A)(ii) of the FFDCFA defines reinspections to which that fees apply to include "with respect to importers, 1 or more examinations conducted under [FFDCFA] section 801 subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction." (Emphasis supplied.)

The first and fundamental question here is what constitutes an initial "examination" that triggers fees on a subsequent interaction concerning the same product. The Fees Notice correctly states that, for a fee to be assessed, "there must be two sets of examinations," the second one strictly limited to a determination of compliance with the outcomes of the initial inspection.<sup>4</sup> Congress in Section 107 clearly intended fees to apply only after noncompliance was found during an initial inspection and follow-up inspection or examination is required to determine if compliance has been achieved – that is, to restrict the FSMA fees regime to situations in which additional examinations are required. And, as FDA puts it: "These additional examinations must be conducted specifically to determine whether compliance has been achieved to [FDA's] satisfaction."<sup>5</sup> (Emphasis supplied.)

This principle – that fees apply only to examinations required to ensure that previously documented noncompliance has been corrected and that compliance has been achieved – must be FDA's lodestar in determining when FSMA fees apply in every circumstance at the port of entry.

Region-wide and country-wide Import Alerts for detention without physical examination are a good place to start. The Commenters urge FDA to confirm that FSMA fees will not apply to petitions for removal from region- or country-wide Import Alerts if FDA originally imposed

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<sup>4</sup> 76 Fed. Reg. at 45823.

<sup>5</sup> 76 Fed. Reg. at 45823.

the Import Alert without reference to the petitioner in question. In other words, if a company's own actions were not the cause of the Import Alert, then fees should not be applied in seeking relief from the Import Alert. A number of reasons compel this policy. Most obviously, the firm involved by definition did not cause FDA to impose the Import Alert and indeed in the past may have cleared hundreds of entries of the product prior to and subsequent to the product being placed on Import Alert. This fact clearly distinguishes FDA review of the petition for removal – which is in essence an appeal for regulatory relief – from an inspection intended to resolve issues occasioned by a company's alleged noncompliance. Further, such a review involves only paperwork and not physical inspection of food – “detention without physical examination” – and thus is not properly deemed an “inspection” in the first place.

Furthermore, additional examinations must be just that – examinations of food at the port of entry. If an importer satisfactorily resolves all outstanding issues arising from an initial inspection without need of a second physical examination of the food article in question, the interaction with FDA incident to the initial examination cannot be the basis for fees to accrue. On this point, the Fees Notice is contradictory, stating first that FDA review of laboratory analyses submitted to show that a food is not contaminated for purposes of admissibility is subject to fees but then stating that review of evidence that a food is not misbranded or adulterated (including, presumably, sampling results) that is submitted to demonstrate compliance is not a “second examination.”<sup>6</sup> This apparent discrepancy, or the lack of clarity as to the distinction between these situations, underscores the significant confusion regarding the circumstances when reinspection fees will be imposed for imports.

FDA in the Fees Notice states that “when an entity requests removal of food from an Import Alert and provides supporting information, FDA considers its review of this information, along with any other related examination it undertakes in considering the request, to be” subject to Section 107 fees, but then appears to exempt from that requirement petitioning firms not “sufficiently related to the request for removal.”<sup>7</sup> These statements are confusing and potentially contradictory, and they should be clarified to establish a bright-line rule that a petitioning firm not responsible for the Import Alert at issue should not be required to pay fees to have the firm's removal petition fully and fairly considered. In addition, it is not clear if a firm will need to provide “evidence that the problems or conditions that led to the alert, even if widespread in the region or country, did not apply to its food”<sup>8</sup> with each subsequent request seeking admission of an article of food detained due to a regional or country-wide Import Alert in order to not be assessed a reinspection fee. The Commenters suggest that the agency establish a procedure that recognizes that once this determination is made, it would apply to all subsequent shipments.

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<sup>6</sup> 76 Fed. Reg. at 45824.

<sup>7</sup> 76 Fed. Reg. at 45824-25.

<sup>8</sup> 76 Fed. Reg. at 45824.

Similarly, FDA should confirm that a “repeat” problem on an entirely different shipment does not trigger reinspection fees – unless and until a true secondary inspection occurs. For example, if the problem with the first entry is due to an unauthorized substance found in product A, a second entry with the same substance on a different product B should not automatically trigger a reinspection fee. If the second entry is for the same food item but a different substance, there, too, no reinspection fee should attach until a second, discrete examination takes place to ensure compliance with the results of the first.

These outcomes are all consistent not only with Section 107 of the FSMA and the August 1 Fees Notice, but also with the logic of the situation at the port: If there has been no initial inspection of the food article in question, then there can be no “additional examination” to determine whether compliance has been achieved. And without an additional examination, FSMA fees cannot apply.

There are several additional points to consider: FDA should clarify that reinspection fees incurred for oversight of reconditioned or destroyed food not duplicate the existing fees sent to the Department of the Treasury. Food industry firms seeking to comply with this regulation should not be required to pay two sets of fees for the same regulatory services. Just as described below in connection with facility reinspections, FDA should develop guidance to ensure that Section 107 is implemented consistently at different ports of entry, with respect to similarly situated importers: whatever the rules of the road are, they should apply to food industry firms in the same way regardless of the port of entry. Lastly, the Commenters ask FDA to clarify plans to invoice the U.S. agents and clarify the liability for brokers/agents when they only serve as a “middleman.” There is concern that the U.S. agent program supporting the Bioterrorism Act requirements could be in jeopardy as existing U.S. agents evaluate the potential financial liability of being invoiced for the reinspection of a foreign facility for which they have traditionally held only a communications conduit relationship and “resign” from fulfilling this important role.

### **Domestic and Foreign Facility Reinspections.**

New FFDCA Section 743(a)(2)(A)(i) defines “reinspection” of domestic or foreign facilities that are subject to FSMA fees as

1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction.

The Fees Notice states that facility reinspection<sup>9</sup> fees apply specifically to facilities “which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FD&C Act.”<sup>10</sup> Although this clarification is helpful, the Fees Notice as it applies to domestic and foreign facility reinspections leaves critical issues unresolved and is prone to inconsistent implementation.

Paramount among these issues is what precisely triggers reinspection of a facility. For starters, companies do not always know if they have received an OAI designation. If that designation is in all circumstances an automatic trigger for the application of fees, companies deserve to be promptly informed when OAI status arises for any individual facility. Conversely, when a company is no longer considered to be in OAI status for particular inspections – and therefore not subject to FSMA fees – the company should receive prompt notice of that fact as well.

In addition, the Commenters urge FDA to confirm that the issuance of a Form 483 at the conclusion of an initial inspection is not a separate, additional trigger of Section 107 fees, and, indeed, that such issuance is irrelevant to the application of fees. Similarly, FDA should clarify whether a Warning Letter based on an inspection “material to food safety” signals that the follow-up inspection will be a “reinspection” subject to fees or whether a firm will receive a separate OAI notice. In addition, the “reinspection” should not commence (thus triggering Section 107 fees) when the agency reviews the firm’s response to a Warning Letter, but only when the inspection team is preparing for the actual on-site reinspection. Moreover, FDA should clarify that a Warning Letter based merely on the review of documents or labels and not a facility inspection would never be a trigger for a “reinspection” subject to the application of fees. The Fees Notice is silent on these questions, as well as whether there are circumstances outside of a Warning Letter that would trigger a fee that will be charged on the next inspection.

Inspectors at both domestic and foreign facilities also should bring an information sheet to any reinspection that clearly indicates that the facility will be charged for that inspection.

Nearly as important as the trigger for Section 107 fees is what specific activities count under the umbrella of a reinspection and are therefore billable as “reinspection-related costs” under new Section 743(a)(2)(B) of the FFDCA. FDA should charge facilities only for time spent by inspectors: (i) preparing for a reinspection; (ii) reinspecting the facility; and (iii) preparing a report about that specific reinspection, i.e., “arranging, conducting, and evaluating the results of

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<sup>9</sup> The Fees Notice notes that the FSMA does not define “reinspection” in the context of foreign facilities but proposes to apply Section 734(a)(2)(A)(i) to foreign facilities for the purpose of assessing FSMA fees. 76 Fed. Reg. at 45822-23.

<sup>10</sup> 76 Fed. Reg. at 45822.

reinspections.”<sup>11</sup> Other activities incidental to the reinspection – such as internal agency/Administration consultations, travel time, and separate oversight activity concerning the same facility – should not be counted. Indeed, the Fees Notice states that reinspection fees will be charged for time spent conducting the physical surveillance at the facility, and for time spent traveling to and from the facility. These costs cannot fairly be characterized as oversight activities directly related to a reinspection” of the facility.<sup>12</sup> Including such costs, moreover, unjustifiably penalizes foreign facilities and domestic facilities in rural areas, where costs for travel time in many cases will dwarf the costs attributable to time spent in the facility itself. In addition, any time spent on co-incident activities of any type conducted by the inspectors during reinspections (including while making arrangements or evaluating results) must not be included in the time for which fees are charged. If, during the time that the inspectors are physically at a facility, they engage in any activities that are not directly related to resolving the specific triggering OAI, that time invoiced should be proportionately reduced to reflect the actual percentage of time spent at the facility that was devoted solely to reinspection activities. Finally, FDA should not charge for inspectors brought along for “training” purposes, or for state inspectors who accompany their FDA colleagues.

The Commenters urge FDA to take a number of agency-wide steps in implementing facility reinspection fees. To guide reinspections, FDA should adopt a protocol that includes, for instance, commitments that the agency will assign only the minimum number of inspectors necessary to conduct a reinspection. Those inspectors should not stay at the facility longer than necessary to assess the facility’s compliance in the area(s) that triggered the OAI designation. And, of course, FDA should not expand its use of OAI designation as a means of increasing the circumstances when it can impose reinspection fees. The percentage of inspections designated as OAI should be consistent with the years prior to FSMA’s enactment.

Just as with import reinspections, FDA must ensure consistent application of Section 107 fee procedures across districts, so that a reinspection fee starts and ends at the same points and encompasses the same activities for similarly situated facilities. This applies equally to foreign facilities which should be subject to the same limits and reinspection procedures as their domestic cousins.<sup>13</sup> Finally, but significantly, the agency also should clarify whether reinspection fees apply for reinspections conducted by FDA after an inspection by state inspectors on behalf of the agency. FDA should also clarify that a state inspector that is not conducting an inspection on FDA’s behalf could not conduct a reinspection that would subject the company to a fee.

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<sup>11</sup> FFDC Section 743(a)(2)(B)(i). This argument also applies to import reinspections, which should not be subject to reinspection-related costs any broader in scope than those applicable to facility reinspections.

<sup>12</sup> 76 Fed. Reg. at 45822.

<sup>13</sup> The Commenters in particular support GMA’s comments critiquing the methodology underlying FDA’s proposed foreign facility fee rate.

**Conclusion.**

Section 107 is an important component of the FSMA, and the Commenters appreciate FDA's challenge to implement this provision along with numerous other FSMA priorities. Clear guidelines and consistent implementation of reinspection fees, however, must be numbered among those priorities. The Commenters accordingly request that FDA issue a Final Notice or other publication in the Federal Register that modifies the Fees Notice consistent with these comments.

Respectfully submitted,

American Frozen Food Institute  
American Bakers Association  
Grocery Manufacturers Association  
Institute of Shortening and Edible Oils  
National Confectioners Association  
National Fisheries Institute