



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-0529 (Burden of FSMA Fee Amounts on Small Business)

Dear Sir or Madam:

The American Frozen Food Institute (AFFI), the American Bakers Association (ABA), the National Confectioners Association (NCA), the National Fisheries Institute (NFI), and the Retail Bakers of America (RBA) are pleased to submit these comments to the Food and Drug Administration (FDA) in response to its request for comments regarding the impact for small businesses of fees being implemented under the FDA Food Safety Modernization Act (FSMA). In 2010 and earlier, our organizations worked with Congress to ensure support for a strong and equitable food safety bill.

About Our Organizations

- 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.
- 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 advocate for all facets of the commercial seafood industry, from fishermen to processors, wholesalers to restaurants, importers to domestic producers. NFI members, many of them small businesses, provide hundreds of millions of meals to American families every year.
- RBA is committed to the success of the retail baking industry. Our members are local neighborhood bakeries, supermarket bakeries, and educators. Together with our members, we create industry-specific training programs and develop small business programs. We foster the community of retail bakeries providing a forum for exchange of industry and business information, as well as networking, learning opportunities and mentoring among bakers, future and existing. RBA members bring consumers quality bakery foods from supermarket bakery departments, independent bakeries and foodservice facilities.

Comments

It is important that FDA consider the impact of FSMA's user fees for small businesses because these businesses already face numerous challenges by virtue of their size. Additionally, for some small businesses the fees could have disproportionately adverse impacts on a firm's financial viability, as compared to larger firms.

Because small businesses play an essential role in the American economy, federal agencies are required to give careful consideration to the effects of their regulations on small businesses. The “deep national commitment” to small businesses is reflected in the Regulatory Flexibility Act, 5 U.S.C. § 601-612, which emphasizes the importance of recognizing “differences in the scale and resources of regulated entities.” 1/ Additionally, President Obama has emphasized that his administration “is firmly committed to eliminating excessive and unjustified burdens on small businesses.” 2/

To assist the agency in developing guidelines for the imposition of reinspection fees on small businesses, we offer the following recommendations:

- Because of the absolutely vital role that small businesses play in our economy and the understanding that larger firms would generally be better able to absorb the costs associated with such fees, as compared to small firms, which would be disproportionately impacted, our members believe a reduced reinspection fee is appropriate for all small businesses. Furthermore, firms should not first have to demonstrate a particular hardship to qualify for reduced fees. This approach will help avoid overly burdensome penalties for otherwise healthy and productive businesses and will encourage continued operation and economic growth after being assessed these fees and following successful resolution of the food safety issues cited.
- FDA should define the term “small business” consistent with the Small Business Administration’s (SBA’s) regulations. 3/ SBA has defined “small business” as a firm with 500 employees or less for those types of businesses that fall under each of our associations’ primary membership. Application of this same definition for purposes of FSMA’s fees would provide consistency across federal regulations, regulatory certainty for small businesses and administrative efficiency for SBA. 4/

1/ See Memorandum for the Heads of Executive Departments and Agencies: Regulatory Flexibility, Small Business, and Job Creation, 76 Fed. Reg. 3827 (Jan. 21, 2011).

2/ *Id.*

3/ 13 C.F.R. Part 121.

4/ FDA has used the SBA definition for small businesses in the past when determining business size in allowing additional time for compliance with new FDA regulations pertaining to foods and dietary supplements. See, e.g., 21 CFR 120.1(b)(1) (juice HACCP), 72 Fed. Reg. 34752, 34807 (June 25, 2007) (providing small businesses with under 500 employees an extended date for compliance with good manufacturing practices for dietary supplements).

Our small business members already are familiar with their qualification under SBA's regulations and it could be unnecessarily burdensome for them to reassess their eligibility under a different set of parameters established only for purposes of FSMA's reinspection fees. In contrast, adopting a definition linked to annual revenues, tax status, or other financial indicia would unjustifiably exclude firms that in many instances have modest resources and small payrolls, but whose revenues reflect commodity and other food industry businesses that cycle through comparatively large amounts of cash in a given year. Similar to other small businesses, these firms would find it difficult to contend with a large (and disproportionate) FSMA fee assessment, and thus they should be classified as small businesses for purposes of such fees.

- Small businesses should be assessed fees as a fixed percentage (e.g., 50%) of the regular fee, subject to a maximum fixed dollar cap of the fees that can be imposed for each reinspection. FDA should establish specific fixed caps for both on-site facility reinspections and import reinspections at the border. Moreover, import reinspection fees should have a lower dollar-amount cap than on-site facility reinspection fees because on-site inspections should be reasonably expected to take more time than an import inspection conducted at the border.
- Similarly, although it is important to develop guidelines that protect small businesses' economic interests, the rules on fee reductions should not insulate a small business from being held accountable financially in instances of repeated non-compliance, following a previous reinspection. Therefore, if a second reinspection is required for the same problem about which FDA had already performed a reinspection of the same facility (or same product, if an import inspection) within the previous 12 months, the full fee should be assessed.
- In no circumstance should any fee reductions for small businesses be passed on by increasing the fees for large businesses. The funding for legitimate fee reductions for small businesses must be borne by FDA's appropriated budget. The statutory limitation on FDA collections to the "full cost" of the reinspection must be interpreted on a facility-by-facility basis, so that a large facility may not, statutorily, be assessed a fee greater than FDA's costs for conducting that particular reinspection. The manner for assessing fees on large businesses may not be used to subsidize the reduced fees for small businesses.

- These limitations and caveats would provide small businesses with greater financial certainty about the potential impact of FSMA fees; would free up small business resources for investing in infrastructure, training, etc., to help ensure compliance with FDA's food safety requirements; and of course would not disturb, in any way, FDA's underlying enforcement authority.

On behalf of the aforementioned associations and the hundreds of small businesses we represent, thank you for the opportunity to provide these comments. Please do not hesitate to contact us if we may be of assistance.

Sincerely,

Donna M. Garren, Ph.D.
Vice President of Regulatory and Technical Affairs
American Frozen Food Institute