Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: International Capacity Building With Respect to Food Safety; Public Meeting; Request for Comments [Docket No. FDA-2012-N-0437]

The Center for Science in the Public Interest (“CSPI”) submits the following comment on international food safety capacity building activities [Docket No. FDA-2012-N-0437]. We are a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. CSPI hosts Safe Food International (“SFI”), which coordinates the efforts of consumer organizations worldwide working to ensure a safer global food supply. Support for CSPI comes from the 850,000 subscribers to Nutrition Action Healthletter in the U.S. and Canada and from foundation grants.

Section 305 of the FDA Food Safety Modernization Act (“FSMA”), requires the agency to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their food industries that export food to the United States. The plan has six mandatory elements. These are provisions for (1) bilateral and multilateral agreements, (2) secure electronic data sharing, (3) mutual recognition of inspection reports, (4) training, (5) harmonization with the Codex Alimentarius and (6) multilateral acceptance of laboratory results. For the plan to be effective, these elements must be fitted underneath an umbrella program for assessing the food safety system of each country FDA will consider for a capacity building activity.

FDA should read section 305 together with the “Assessment of Food Safety Programs, Systems, and Standards” provision of section 303(b) (21 U.S.C. § 381(q)(7)). That provision gives FDA authority to assess foreign food safety programs, identify deficiencies, and establish a process for demonstrating the program has corrected them. CSPI and SFI have worked through the World Health Organization/Food and Agriculture Organization of the United Nations (“WHO/FAO”) to develop guidelines for assessing food safety systems. We believe a robust assessment program is essential to effectively targeting capacity building assistance.

For further consideration and guidance regarding capacity building in an international food safety context, we have enclosed copies of Guidelines for Consumer Organizations to Promote National Food Safety Systems, published by SFI with the concurrence of WHO/FAO,

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1 The Safe Food International website is http://safefoodinternational.org/index.html.
The Guidelines to Promote National Food Safety Systems provide an outline for the development and improvement of current national food safety guidelines, including framework components necessary for capacity building and improving regulatory standardization, trade, and safety assurance. Developed with input from the WHO/FAO, the document is a peer reviewed framework for identifying the eight elements of an effective food safety system.²

1. Effective and comprehensive food laws and regulations
2. Foodborne disease surveillance and investigation systems
3. An integrated and coherent food-control management structure
4. Effective inspection services
5. Capable recall and traceback systems
6. Food monitoring laboratories with a range of analytical capabilities
7. Information, education, communication, and training programs
8. Sufficient funding with transparent operations

The report Focus On: Food Import Safety, Food Safety Modernization Act uses border inspection refusals to identify countries where food safety systems may be inadequate. A country with a high rate of import refusals clearly should be targeted for a section 303(b) assessment leading to capacity building efforts. This type of analysis could also provide FDA with an on-going verification step to ensure an exporting country’s food safety system is effective.

CSPI believes the essential element of an effective foreign food safety capacity building plan is robust assessments of the food safety systems in countries that wish to export food to the U.S. As part of its capacity building plan, FDA should develop metrics for determining when a foreign food safety system fails to meet fundamental consumer protection requirements. Further, FDA should establish standards against which to measure a national system’s strengths and deficiencies, and identify areas that require focused improvements. We are pleased to provide these consumer-driven products to ensure a safer global food supply.

Sincerely,

Caroline Smith DeWaal
Director of Food Safety

Attachments (3)