SAFE FOOD COALITION

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

RE: Dockets No. FDA-2011-N-0145, § 303, Authority to require import certifications for food; and FDA-2011-N-0146, § 307, Accreditation of third-party auditors.

Thank you for this opportunity to comment initially on the import provisions under Title III of the FDA Food Safety Modernization Act (FSMA). Title III places responsibilities on importers and the Food and Drug Administration (FDA) for assuring the safety of imported food. This comment is written by the Center for Science in the Public Interest and submitted on behalf of the Make Our Food Safe Coalition and the Safe Food Coalition.[1]

Consumers appreciate having ready access to imported foods, which supply fresh fruits and vegetables throughout the year and bring diversity to our dinner tables. Imported foods make up approximately 15% of the average American's diet, and in some categories of FDA-regulated foods, imported products are the majority. However, it is critical that these imports meet food safety standards set by the FDA.

Each year foodborne illness causes 48 million illnesses, 130,000 hospitalizations and 3,000 deaths, some of which are caused by imported products.[1] As consumer

[1] The following members of the Make Our Food Safe Coalition and the Safe Food Coalition have signed onto this comment: Center for Science in the Public Interest, Center for Foodborne Illness Research and Prevention, Consumer Federation of America, Government Accountability Project, National Consumer League, STOP Foodborne Illness, and The Pew Charitable Trusts.

[2] Comment by Stephen Stich, Director, New York State Department of Agriculture and Markets, that 70 percent of 300 recalls issued by the New York State Department of Agricultural Markets were for imported foods, Meeting Transcript, pp. 172-73, (March 29, 2011); Julie Schmit, U.S. Food Imports Outrun FDA Resources, USA Today, March 18, 2007 (quoting New York official that 80 percent of food recalls initiated by the State Department of Agriculture and Markets over two years were for imported products and a corporate vice president for food safety that his company sees no difference in the safety of product produced domestically or overseas).

advocates, we applaud the passage of the FSMA and urge the FDA to implement its imported food title consistently with the law's prevention-based, public health focus.

Consumer organizations believe that facility inspections and audits are vital to effective implementation of the FSMA. Inspections provide official verification that a company is meeting the requirements for implementation of the process controls portion of the FSMA and provide a government-certified check on the system. Government verification is essential for what is in actuality an industry-developed and administered program. In addition, when violations are found, the FDA must be prepared to take appropriate administrative action such as:

- administrative detention,
- refusal to admit food for which a required import certification is lacking or with respect to which an establishment has refused to permit entry of U.S. inspectors, or
- judicial enforcement action.

A meaningful inspection and enforcement regime will provide general and specific deterrence against violations among importers, and will ensure that those companies seeking to play by the rules are not put at a competitive disadvantage compared to those who may be seeking to cut costs by failing to comply with FDA safeguards.

In analyzing components of the new law, consumer organizations have prioritized authorities that could be doing inspections and audits by their level of trustworthiness relative to protecting public health. FDA inspections are considered the most trustworthy to enforce the new Act, followed by inspections by another U.S. government agency. Inspections by a foreign government, export certification inspections/audits, and lastly, private third- party audits are considered somewhat less trustworthy, as they may not have the same public health objective or may not be supported by the same level of expertise, training, resources, and accountability as are FDA inspectors.

Consumer organizations would like the FDA to consider the following principles in developing the programs for third-party certification under section 307:

- Third-party certification is authorized for imported food only; the law does not permit it for domestic facilities.

- The FDA should evaluate the mission of the certifying entity to ensure there is adequate conflict of interest protection for consumers.
- The FDA should rigorously apply to all third-party auditors the conflict of interest requirements and the restriction on third-party auditing firms conducting audits for the FDA within 13 months of a consultative audit. These restrictions should apply to all third parties, including foreign national governments, other U.S. agencies, and other third-party agents and auditors. The FDA must ensure that third parties are not implicitly delegated governmental functions that are inherently the FDA's responsibility, such as decisions on whether or not to take enforcement action against a violation.
- The FDA must adopt and conduct oversight to ensure compliance with strong accreditation requirements for third-party auditors, with clear and transparent criteria, adequate resources, and accountability.
- The FDA must take steps to ensure that the third-party auditors have the expertise, training, and capacity to undertake effective audits.

In reviewing the elements of Title III, consumer organizations have agreed on the following general concepts to guide the FDA's development of regulations under the FSMA.

1. In general, we do not want resources for domestic inspection redirected to pay for foreign inspections, although there are some recognized exceptions. For example, seafood is a high-risk food, of which 80% is imported, so foreign inspections would be at least equally important to ensuring consumer protection.

2. We agree that the FDA could work with other federal agencies to meet the FSMA inspection schedules for imports. For example, the USDA's Food Safety and Inspection Service is in 34 countries, the National Oceanic and Atmospheric Administration is conducting seafood facility inspections in other countries, and inspectors with the USDA's Animal and Plant Health Inspection Service work at export check-points in many countries to approve fruits and vegetables (checking

for disease and insect contamination). It is important that regardless of what agency is conducting the facility inspection, its principal focus must be on protecting public health and that personnel engaged in food safety inspection activities receive adequate training.

3. We agree that foreign national governments can be used to certify products coming to the U.S. Moreover, the U.S. should not duplicate a foreign inspection that has already been done by a trusted foreign national government that has programs adequate to ensure that approved products originating from that country meet U.S. standards. Again, it is important that regardless of what agency is conducting the facility inspection, its principal focus must be on protecting public health and that personnel engaged in inspection activities be properly trained.

While we want to encourage the FDA to rely on other countries with strong food safety programs, we remain concerned about how to address the foreign facility inspections in countries with weak national programs.

Finally, there are a number of issues that we would like the agency to discuss with stakeholders as they are developing the regulations:

1. How will the FSMA provisions referring to "known food safety risks" be interpreted?
2. How will the history of compliance be evaluated for individual facilities?
3. When and how will the agency implement the mandatory certification section of the law? Can the agency define specific instances (like outbreaks or contamination events triggering recalls) that will require mandatory certification?
4. Does the FDA have an implementation blueprint for the "building capacity" authority of foreign governments under section 305? Will it employ the FDA's foreign offices, import certification, and third-party certification?

Thank you for this opportunity to submit these initial comments and questions in anticipation of the FDA's implementation of the import provisions of the FSMA.