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

April 29, 2011

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 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 focuses on sections 303 and 307 concerning implementation of certification and accreditation provisions in the new law.

The purpose of FSMA is to improve protection of public health through a prevention-based program for assuring that food purchased and consumed in the U.S. is produced in a manner to assure that it is unadulterated. CSPI appreciates the challenge this poses in a global food marketplace, in which at least 15 percent of the food in a typical American’s diet is imported.

To compensate for the lack of direct authority to enforce safety standards in foreign countries, FSMA sets out a system that holds importers accountable for the food they import. FSMA also provides tools through which FDA can extend its reach to assure high-risk foods from foreign countries meet U.S. standards for safety. This comment remarks on three areas where FDA can implement its new authority to best advantage.

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1 Pub. L. No. 111-353 § 301 et seq. [Hereinafter footnotes that reference only section (§) numbers are references to the public law].
FDA must move quickly to establish national standards for accreditation and certification programs. These standards can be consistent with international treaty obligations without surrendering our national prerogative to set standards reflective of U.S. food protection goals.

FDA should implement its certification system in a way that provides standardized information to border agents. Using standardized certification forms requiring specific information will ensure the integrity of the system and its ability to protect American consumers from contaminated products.

FDA should align its import certification program with existing import monitoring systems such as the prior notice system. This would provide for more efficient administration of the program.

Having participated for many years in international food safety standard setting activities, CSPI supports strong national food safety systems, and the right of individual governments to set national food safety standards. FDA has this responsibility for the foods it regulates. In adopting FSMA, Congress directed the agency to set its own standards for safety, accreditation and certification.

These standards could have a basis in GFSI or in the existing Codex Alimentarius framework, as this would allow importers to recognize the basic framework that FDA is enforcing. But the key is that the importers, certification bodies and auditors must all work to a single standard, to ensure that the food that they are approving to come into the U.S. actually meets our national standards.

CSPI believes the following recommendations will best enable FDA to accomplish its mission of ensuring the safety of imported food.
1. Certification System Must Be Capable of Assuring Compliance With U.S. Law.

FSMA requires the agency to issue model accreditation standards. The law is clear that in establishing these systems, FDA must provide sufficient oversight to ensure the full enforcement of our national standards. Thus, FDA must establish accreditation standards and certification requirements that provide assurance that entities that are conducting these activities are capable of ensuring compliance with our food safety laws and standards.

FDA may also consider the recommendations of the Codex Alimentarius. Under Codex guidance, a country may use officially recognized third-party certification bodies if it has set defined criteria they are to follow. Codex defines the official accreditation system by reference to the government agency on whose behalf a certification is required. This guidance protects FDA's right to establish standards that are consistent with the appropriate level of protection provided by U.S. law.

2. FDA Should Establish a Standardized System.

A. Standardize Certificates and Information Reported.

Certifications should be submitted in a standardized format that permits border agents to recognize the product and understand the risks covered by the certification. Under FSMA, FDA may require certifications on imports that have known food safety risks, originate from high-risk areas, or for which the agency has science-based evidence of risk. This authority is consistent with international trade law that permits each country to set an appropriate level of protection.

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2 § 307 (amending the Federal Food, Drug, and Cosmetic Act by adding § 808(b)(2)).
5 § 303(b).
and require certifications. To be an effective tool for preventing unsafe food from entering the country, a certification needs to present its information clearly and consistently. To accomplish this, FDA will have a uniform format and define the content that every certification must include, regardless of the type of entity where it originates. The certificate must clearly reference the identity of the certifying agent – whether an accredited third-party certifier (governmental, cooperative or other) or a national government.

FSMA gives the Secretary broad discretion in setting forth a certification’s content. A certification must be detailed enough to permit the Secretary to make a determination that the food meets applicable safety requirements. Also, certificates may be shipment-specific or a listing of certified facilities.

With more than 10 million lines of imported food entering the country through 350 ports of entry next year, it is vital that certifications provide useful and timely information at the point where it can be used by FDA or Customs and Border Security as the agencies are approving imports for entry. To ensure consistency, FDA should design a form that certifiers are to use. A certification should identify at a minimum –

- The food of concern,
- The associated risk or risks for which certification is required,
- The registration number, name and location of the exporting facility or farm,
- Contact information for the U.S. importer or their agent,
- The name and contact information of the certifying agent, and
- The basis for certifying the product (equivalence, comparability or equality of the exporter’s controls),

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7 SPS Agreement, Art. 8 and Annex C.
8 § 307 (amending the Federal Food, Drug, and Cosmetic Act by adding § 808(c)(2)(B)).
9 § 303(b).
The date of the last audit.

This level of information should not be difficult for industry to comply with since FDA already requires a similar level of information for its export certification program. In the case of a certification in the form of “listed facilities,” this information should be on file for each facility.

B. Standardize Definition of High Risk Foods.

Another way FDA could make certifications more consistent is to require certifications per se for all products of animal origin under FDA’s jurisdiction, which would include seafood, eggs, dairy, and other animal-based products. The European Union considers all food of animal origin to be high-risk, requires equivalency determinations and certifications, and limits the ports through which such food may enter. Meanwhile, the U.S. only subjects meat and poultry to this type of stricter oversight, which is under U.S. Department of Agriculture (USDA) regulation.

It is important to observe that while products of animal origin comprise 43 percent of the American diet, they accounted for 53 percent of outbreaks between 1998 and 2007, according

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12 Adding a complication to import programs, Congress recently transferred catfish to USDA’s jurisdiction, meaning importers will likely face disparate treatment depending on whether they are importing shrimp or catfish from Southeast Asia.

to attribution data published by CSPI. Given the large volume of animal products regulated by FDA, it is essential that the oversight of these products be standardized across the government. Subjecting all foods of animal origin to a higher standard would make FDA’s program more consistent with both the USDA and the EU programs, and is clearly supported by the public health information available from CDC and the states. Harmonizing the treatment for products of animal origin would provide importers with greater certainty as to certification requirements, align the treatment of U.S. exports with that of foreign imports, and simplify administration of FDA’s new authority under FSMA’s sections 303, 305 and 307. It would also provide greater assurance to consumers that all imported foods of animal origin are meeting U.S. safety standards.

3. Certification Should Be Part of the Prior Notice System.

FDA should make accreditation and certification management part of the prior notice system to ensure seamless oversight of imported food. The purpose of prior notice is to provide FDA with information to evaluate it for entry into the U.S. or for additional inspection, and failure to provide notice is grounds for refusing the shipment at the border. Certification would allow FDA to better evaluate high-risk products and determine whether to refuse or admit the food. Clearly the two systems are complimentary and should be located within the same system. Operating the certificate program within the prior notice system would give Customs and FDA officials more complete information for evaluating a shipment before it arrives at the port of entry. It would also simplify filing because prior notice already has an electronic

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15 21 U.S.C. § 381(m).
16 § 303(b) (amending 21 U.S.C. § 381 by adding subsection (q)(2)(C)(ii)).
In addition to efficiency, a single office to oversee the certification and prior notice system would permit closer coordination and a more predictable import system. For example, food that the prior notice system consistently evaluates as needing border inspection may also be a target for certification. Information provided by the certification system could be used to inform decisions at the prior notice stage. Conversely, auditing (through border inspections) to verify that the foreign certification program is working as desired, could be facilitated through the prior notice system.

When fully implemented, the prior notice could carry a shipment-specific certificate as an addendum or provide sufficient information for matching the shipment’s origin to a certified facility in the case of a listing of certified facilities.

Conclusion

FDA is responsible for establishing a certification system for imported food that can protect public health by ensuring food purchased and consumed in the U.S. is reasonably free from microbial and other hazards. CSPI appreciates the difficulty of meeting this goal. We believe the suggestions offered above are the best suggestions for implementing the relevant provisions of the bill. However they are not the only steps FDA should take toward establishing a truly effective food safety system for imported food. CSPI encourages the agency to implement the import system authorized under FSMA with public health protection (and not importer convenience) as its major focus.

\[\text{\footnotesize Note: FDA is required to provide for electronic submission of certifications under 21 U.S.C. § 381(q)(5) as added by § 303.}\]
It is to that end that we submit these comments and request their consideration as FDA prepares regulations to effectuate Title III of FSMA.

Sincerely,

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