



Food and Drug Administration Globalization Act

**Testimony of Caroline Smith DeWaal
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Center for Science in the Public Interest
before the
House Subcommittee on Health
of the House Committee on Energy and Commerce**

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My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by over 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you, Chairman Pallone, Chairman Dingell, Ranking Member Deal and the Members of this Subcommittee for the opportunity to comment on the discussion draft of the Food and Drug Administration Globalization Act.

In the past two years, repeated outbreaks, Congressional hearings, and nationwide recalls have turned the tragic statistics of 76 million illnesses, 325,000 hospitalizations and 5,000 deaths annually due to food-borne illnesses into a problem familiar to almost every consumer. Who hasn't checked where their melon was grown or searched their pantries for everything from peanut butter to canned chili?

The impact of food-borne disease has been fully described in previous hearings before this Subcommittee. With this hearing, Congress begins the process of solving problems in our

food safety system. But I don't want us to forget the victims of our antiquated and broken food safety system. Victims like Ashley Armstrong, who at three years of age suffered acute kidney failure and months of dialysis after eating *E. coli*-tainted spinach. Mora Marshall, who at 86 years of age was hospitalized and will spend the rest of her life in a nursing home after eating *Salmonella*-tainted peanut butter. These are individuals we need to remember and the illnesses we need to prevent as we search for ways to assure the Food and Drug Administration (FDA) has the resources and authority it so sadly lacks today.

The loss of consumer's confidence in food safety has been widely documented. For example, last year the Food Marketing Institute documented a 16 percent decline in consumer confidence in the safety of food they purchase at grocery stores.¹ In July, *USA Today* found 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.² In December, the Thompson West Research poll found 61 percent of Americans worry about the safety of their food.³ And consumers are not the only ones affected. The food industry bears substantial costs when the actions of one company results in a nationwide outbreak or recall. After the spinach outbreak in 2006, spinach farmers reported losing \$350 million, and had still not recovered when a second leafy green outbreak occurred in August 2007.⁴ The Peter Pan peanut butter outbreak cost ConAgra more than \$140 million, including \$55 million in lost sales.⁵ Congress needs to act now to address FDA's deficiencies or risk repeated outbreaks

¹ Food Marketing Institute, U.S. Grocery Shopper Trends 2007, 66.

² Elizabeth Weise, *Buying Only U.S. Food is a Tall Order*, USA TODAY, July 10, 2007, available at http://www.usatoday.com/news/health/2007-07-10-american-goods_N.htm.

³ Thompson West Research, *Consumers Worried About Product Safety*, Dec. 18, 2007, at <http://west.thomson.com/news/releases/productsafety.aspx>.

⁴ Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA TODAY, Sept. 20, 2007, available at http://www.usatoday.com/money/industries/food/2007-09-20-spinach-main_N.htm.

⁵ Mike Hughlett, *E. coli Outbreak Kills Meat Company: Huge Costs Seen in Fixing Problems*, The Chicago Trib., ¶ 9-11, Oct. 6, 2007, http://www.chicagotribune.com/features/lifestyle/health/chi-sat_toppsoct06,1,4231570.story.

imposing costs on the public and industry for health care services, business interruption, and lost confidence.

The Food and Drug Administration Globalization Act Advances Food Safety

CSPI has long advocated for Congress to create a modern food safety oversight system in the federal government. We have analyzed 16 years of outbreak data, and reached the firm conclusion that the current system is fundamentally flawed in its approach to food safety, and that far-reaching reform is needed. We have also suggested a unified food safety agency as one mechanism of improvement, bringing together the dysfunctional inspection programs at the FDA and USDA in a new agency focused on public health.

While the FDA Globalization Act does not contain such sweeping reform, nonetheless, the improvements that it proposes are essential to address the gaps and weaknesses in FDA's current food safety program. It builds upon the improvements of the Bioterrorism Act of 2002, but adds a fundamental new structure to FDA's food safety program in the form of new written plans at the producer and processor level. These plans create a food safety foundation that has not existed before at FDA and weaves together the distinct threads of inspection reform, improved oversight of imports and better funding into a coherent whole.

Let me explain. The introduction of HACCP systems, initiated by both FDA and USDA in the 1990s, began the movement to a modern food safety system. HACCP stands for "Hazard Analysis and Critical Control Points" systems, and it puts responsibility and accountability for food safety on the processor of the food, that person or entity that expects to make a profit by selling food to the public. Most important, however, is that it creates a duty for industry to implement systems to prevent problems rather than simply react. USDA's HACCP requirements

covered the entire meat and poultry industries. FDA's approach was much more limited, requiring only the seafood and juice industries to adopt HACCP systems.

While full-blown HACCP systems may not be appropriate for every segment of the food industry, there is an element of HACCP that is appropriate, and it forms the centerpiece of the FDA Globalization Act. The requirement that food processors and producers identify possible hazards linked to their food and outline a control plan provides a core responsibility for industry to know the food safety profile of their products and to have written plans to address those hazards. If FDA determines that certain performance standards are necessary for one type of process, the written plans are the vehicle to determine how the standards are being implemented.

This written plan is the responsibility of the processor or food producer, the entity that knows their process best. Farmers, for example, know the environmental conditions and weather in the area better than any regulator, and therefore should be in the driver's seat when it comes to food safety. But the written plans also create an opportunity for the FDA inspector or a third party auditor to understand the thinking of those in charge of food production at every factory or farm. Instead of starting from zero with every inspection, FDA can begin with an understanding of the process controls that are in use in every facility. If there are gaps in the hazard analysis, these can be pointed out and addressed. If there are failures in the system, they can be understood as being either a failure to execute the written plan, or a failure to fully understand the hazards. Most importantly, failures can be caught earlier, before food gets to the market.

I have toured food facilities in many parts of the world. From Kansas to Colorado, from New Zealand to the Netherlands, I have never encountered a food plant that wasn't excited to show me their food safety plan. These are widely used in most segments of the industry. Sometimes they are full-blown HACCP plans. Other times, they encompass sanitation plans and

tracing systems along with less stringent process control systems. But as you walk through the plant, you see the stations where the employees are checking systems and documenting their findings for review by plant managers. These control systems are fundamental to food production, and should form the core of a modern food safety system for both domestic and imported products, as proposed in the FDA Globalization Act. While written plans provide a platform for the systematic audits of food plants, they will only be effective if FDA has the capacity to inspect the plants regularly.

Voluntary Certification Program Could Improve Import Safety

The FDA Globalization Act takes an approach to improving the safety of imports that is already widely used in the retail sector today. The voluntary certification program for imported food contained in the discussion draft is an important provision, but truly only the minimum Congress should require to assure imported food is safe. CSPI would like to see certification made mandatory and there is strong support for this approach. Congress recently approved mandatory certification for children's toys under the Consumer Product Safety Commission Reform Act.⁶ If the safety of imported toys children play with is subject to mandatory certification, why would Congress impose a lesser standard for the imported foods children eat?

Mandatory certification of imports was recommended by the President's Interagency Working Group on Import Safety for certain products.⁷ The Grocery Manufacturers Association (GMA) "Four Pillars" plan discusses a Mandatory Quality Assurance Program for Importers that acts as a certification requirement. So, the question is not whether certification has a place, but how it is implemented.

⁶ H.R. 4040, 110th Cong. § 10 (2007).

⁷ *Action Plan for Import Safety*, Interagency Working Group on Import Safety, Nov. 2007, 23.

The FDA Globalization Act proposes a voluntary certification program for all types of food. It would allow FDA to certify facilities, provides FDA with authority to accredit foreign governments, other governmental bodies, or private agencies as certifying agents of FDA, and establishes incentives to encourage certification. Aspects of the certification model in the Act have already been tested in another statute. The National Organic Program uses certifying agents to evaluate compliance with the Organic Foods Production Act.

While CSPI prefers a mandatory certification program, we are willing to support the voluntary approach put forward in the FDA Globalization Act as long as there are strong incentives to participate and appropriate safeguards to assure that those who don't participate nonetheless deliver safe products to our ports. These elements are both in the discussion draft. Facilities that are certified are rewarded with the ability to come in through all U.S. ports of entry; less frequent inspections; periodic (rather than pre-market) laboratory testing; and access to the Safe and Secure Food Importation Program. Under the program, no products can be denied entry simply because the source is not certified. But consumers are protected by the requirements that uncertified products must enter through ports where they can be inspected closely and must be tested for contaminants.

Key elements to modernizing food inspection for our domestic industry

Aside from proposing process control systems, the FDA Globalization Act provides a number of key provisions for modernizing food safety for the food industry operating in the U.S., including seafood, produce, eggs, dairy and many processed foods.

Annual Facility Registration: First adopted in 2002 in the Bioterrorism Act, the registration of domestic and foreign food facilities that intend to sell food to U.S. consumers is

an essential component of a modern food safety system. Annual registration, as proposed in the discussion draft, would improve the reliability of the current facilities list and assure facilities can be located and are held accountable. A reliable list also gives FDA a true picture of the community of food suppliers it should inspect.

***Recommendation** – The Committee could adopt a graduated fee so that smaller facilities or facilities that produce less risky products would pay less than large plants or producers of riskier products.*

Inspections: The FDA Globalization Act sets forth a mandatory minimum FDA inspection frequency of once every two years for uncertified facilities, or once every four years if they are certified. While CSPI would like to see more frequent inspections, with rates double that proposed in the bill, we strongly support the principle that food facilities should have a mandatory minimum inspection rate that at least puts them on par with plants that produce drugs and medical devices.⁸ In fact, I have been told by former FDA officials that food inspections are given the lowest priority at the Office of Regulatory Affairs because they lack any statutory mandate for inspection.

***Recommendation** –The minimum inspection frequency for food should be changed to once every year for uncertified facilities and once every two years if facilities are certified. In addition, the bill should include a specific proviso that FDA conducts more frequent inspections of high-risk facilities.*

On-Farm Food Safety Programs: The FDA Globalization Act requires producers of fresh fruits and vegetables to have a written plan for implementing process controls and to meet

⁸ FDA is required to inspect drug and device establishments at least once in a two year period. 21 U.S.C. § 360(h) (2006).

performance standards established by FDA. This requirement is to be implemented one year after FDA issues regulations on how growers are to comply with it.

***Recommendation** – Consider replacing the section with an amendment based on the Fresh Produce Safety Act, H.R. 5620, sponsored by Bruce Braley, which is pending in the Subcommittee on Health of the House Energy and Commerce Committee.*

Mandatory Recall and Civil Penalties: The FDA Globalization Act provides FDA with authority to order a recall of food that is adulterated or misbranded in a manner that may result in injury or illness. It also provides FDA with authority to assess a civil penalty of up to \$100,000 (individual) or \$500,000 (corporation) against anyone who commits a prohibited act. We strongly support these sections of the legislation, as we believe that stronger recall authority is warranted but should not remain the only solution to food safety problems. Civil penalties are more flexible, and can be used as a substitute for recalls when initiated for solely technical violations.

Key elements to modernizing food inspection for imported food

Certification Program: Voluntary certification solves the bottleneck problem inherent in moving from our existing open entry system to a certification program. The program encourages companies to become certified by providing strong incentives for participation. To better equip FDA with the resources to quickly certify facilities, the program includes accredited third-party certifying agents, including both foreign national governments (i.e. Canada, New Zealand); regional government (i.e. the European Union); and state governments (i.e. California, New York, or Florida). The bill provides some opportunities for private entities to become

certifying agents, but attempts to mitigate the risks by (1) specifying cooperatives as permissible agents and allowing FDA to expand the program to private entities only if they do not present any conflicts of interest issues; (2) conditioning continued accreditation on there being no outbreaks caused by products the agent certified and compliance with FDA requests; (3) providing FDA with authority to double check the agent's work without notice through inspections and audits; and (4) adding the filing of misleading or false food safety reports to the list of prohibited activities.

***Recommendation** – The Committee should phase in a mandatory certification program by requiring all foreign facilities to be certified within a certain period (such as five or 10 years).*

Other importer specific provisions:

Safe and Secure Food Importation Program: Certified foreign facilities can request recognition as Safe and Secure Food Importers and import food under expedited procedures.

Specific Ports of Entry: After a date specified by FDA, products from uncertified foreign facilities may only enter through ports located in metropolitan areas that have a federal laboratory. Certified foreign facilities can send products to any port.

Enforcement and Recall: FDA can deny entry to food imports from any country that delays or does not consent to an investigation when food from that country is linked to an outbreak of food-borne disease or found to be adulterated or mislabeled.

Registration of Importers: Commercial importers are required to register and pay a \$10,000 fee.

Unique Identifier for Importers: FDA is to assign a unique identification number to each registrant (facilities and importers) and may use the number for any purpose.

Dedicated Foreign Inspectorate: FDA is directed to establish a corps of inspectors dedicated to inspecting foreign facilities. The corps must have enough inspectors to inspect foreign facilities at least as frequently as it does domestic facilities.

Key elements addressing funding deficiencies in FDA’s Food Program

CSPI strongly supports efforts to increase funding for the food programs at FDA. As I testified last year, FDA’s food program is in critical condition.⁹ CSPI is working with the food industry and the Alliance for a Stronger FDA to educate members of Congress on the urgent need for greater appropriations.

We agree with the Committee that in any modernization plan, Congress must fully address funding for the new program, which the drafters have done in six separate provisions for raising fees in the discussion draft.¹⁰ However, I have several overarching concerns that I urge the Committee to consider. In developing fees for the bill, the committee must recognize that the start-up costs of a fee-based system are significant. The registration and certification systems carry administrative costs that could be applied to FDA inspection. In addition, there is the

⁹ “[I]ndustry and consumers together have estimated that the food program at FDA needs additional funding of approximately \$450 million for that agency to meet its basic program requirements [for FY 2008].” *H.R. 3610, The Food and Drug Import Safety Act: Hearing Before the House Subcommittee on Health*, 110th Cong. (2007) (statement of Caroline Smith DeWaal, Food Safety Director, CSPI) available at http://energycommerce.house.gov/cmte_mtgs/110-he-hrg.092607.DeWaal-testimony.pdf.

¹⁰ The fees included in the discussion draft are:

- A \$2,000 annual facilities registration fee.
- A fee on foreign governments and agents for accreditation in an amount sufficient to generate revenues equal to the accreditation program’s costs.
- A re-inspection fee in an amount sufficient to generate revenues equal to the costs of the re-inspection.
- An export certification fee in an amount sufficient to generate revenues equal to the costs of the service.
- A laboratory accreditation fee in an amount to generate revenues equal to the costs of the service.
- A \$10,000 annual importer registration fee.

significant risk that OMB will take any fee-based system and use it to reduce overall appropriations to the agency, such that FDA will be no better off with fees than without. Therefore we caution the committee to consider carefully these issues in approving any fees outlined in this bill.

FDA Globalization Act Melds the Best Ideas from Industry, Consumers and Government

The FDA Globalization Act has taken ideas from the range of reform plans submitted by stakeholders from industry, consumer organizations and FDA in the aftermath of outbreaks of 2006 and 2007. Last year, CSPI released its “White Paper: Building a Modern Food Safety System for FDA-Regulated Products,” the Grocery Manufacturers Association (GMA) released its “Four Pillars of Public-Private Partnership” plan, and FDA released its “Food Protection Plan.” Each plan carried elements for improving food safety that have been crafted into the FDA Globalization Act.

Each of these plans called for changes in the facility registration program, implementation of process controls, better safety standards, improvements to the inspection system, greater oversight of imported foods, and more investment in research. Additionally, the plans by CSPI and FDA sought better enforcement tools such as mandatory recall and the authority to refuse imports from countries that hindered FDA inspections.

While each stakeholder may differ over the particulars of how to implement reform, the FDA Globalization Act offers an unprecedented opportunity for Congress to pass strong food safety reform that reflects the best ideas offered for improving the current system.