



CRS Report for Congress

Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007

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Summary

The Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85), while primarily concerned with drug and device regulation and their user fees, also contains several provisions on food safety. As enacted, the law requires the Secretary of Health and Human Services to establish, for pet foods, processing and ingredient standards, updated labeling requirements, and an early warning and surveillance system to identify adulteration and associated outbreaks of illness. The Secretary is to work with states to improve the safety of produce and strengthen state food safety programs. The Act requires the Secretary to create a registry for reporting of foods (including human and animal foods) with safety problems, which will help identify the supply chain of the reportable food. Alerts are to be issued for such foods, with records maintained and available for inspection. Additional provisions require attention to aquaculture and seafood inspection, environmental risks associated with genetically engineered seafood products, imported foods, pesticide monitoring, and ginseng dietary supplements.

On September 27, 2007, the President signed the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85, H.R. 3580) into law. The Act primarily addresses issues such as regulation and user fees for prescription drugs and medical devices, clinical trials, pediatric research incentives, and conflicts of interest.¹ However, the Act also contains several provisions on food safety that address recent concerns about contaminated pet food and tracking adulterated foods. This report reviews the food safety provisions of the statute, their history, and certain issues surrounding their passage. It will not be updated.

¹ These issues are described in considerable detail elsewhere. For further information, see CRS Report RL34102, *FDA Legislation in the 110th Congress: A Side-By-Side Comparison of S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, Sarah A. Lister, Donna V. Porter, and C. Stephen Redhead.

Background

The original language of the Senate bill on FDA reform (S. 1082), as introduced, did not contain any provisions on food safety. However, around the time that the Committee on Health, Education, Labor and Pensions (HELP) was considering the bill, health problems with food ingredients from China used in pet food came to the nation's attention. It was ultimately determined that wheat gluten and rice protein concentrate, common pet food ingredients, had been tainted with melamine (an industrial chemical used in the manufacture of plastics, flame-retardants, and other products) to increase the nitrogen content of the products. The contamination of pet food is believed to have led to the death of hundreds of cats and dogs in the United States. Some contaminated feed was also found in feeds given to food-producing animals, but federal officials determined that the situation was unlikely to pose a human food safety risk. Following this news, Senator Durbin and Representative DeLauro introduced the Human and Pet Food Safety Act of 2007 in their respective chambers (S. 1274 and H.R. 2108, respectively) to address the problem of pet and human food contamination. The bills were assigned to committee, but no further action has been taken.

With the FDA legislation on drugs and devices moving forward in the Senate, Senator Durbin introduced as an amendment to S. 1082 several food safety provisions contained in his bill. The amendment passed the Senate 94 to 0 and was sent as part of the FDA reform bill to the House. The FDA reform bill that passed the House, H.R. 2900, did not include any food safety provisions. During the conference on S. 1082 and H.R. 2900, certain changes were made to the legislation, including renumbering it as H.R. 3580 and modifying the final language in the food safety provisions, which are outlined below. The provisions on food safety would primarily establish new statutory authorities. Any amendments to current law are noted, where appropriate.

Food Safety Provisions in P.L.110-85

The food safety provisions are contained in Title X of P.L. 110-85, the FDA Amendments Act of 2007. This title generally amends the Federal Food, Drug, and Cosmetic Act (FFDCA), which defines "food" as "articles used for food or drink for man or other animals."² As a result, unless otherwise stated in FDAAA, provisions affecting food apply equally to human foods and animal feeds, including pet food.

Section 1001. Findings. This section contains various findings about the safety and integrity of the U.S. food supply, illnesses and deaths caused by contaminated food, the task of preserving the safety of the food supply, and the current level of U.S. food imports and inspections.

Section 1002. Ensuring the Safety of Pet Food. This provision requires that within two years, the Secretary, in consultation with other stakeholders, shall, by regulation, establish processing and ingredient standards for pet food, as well as update nutrition and ingredient labeling on pet food. The Secretary will have one year to establish by regulation an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. The Secretary

² FFDCA § 201(f) [21 U.S.C. § 321(f)].

shall, in establishing such a system, use surveillance and monitoring mechanisms similar to, or in coordination with, those used by the Centers for Disease Control and Prevention (CDC), consulting with relevant professional organizations and working with existing networks to inform veterinarians and others during a pet food recall.

Section 1003. Ensuring Efficient and Effective Communications During a Recall. During an ongoing recall of human or pet food, the Secretary shall work with relevant stakeholders to collect and aggregate pertinent information through existing networks of communication, including in electronic form, and post information regarding the recall on FDA's website in an easily accessible form.

Section 1004. State and Federal Cooperation. The Secretary shall work with the states on activities and programs that assist in improving the safety of food, including fresh and processed produce, to facilitate coordination and cost-effectiveness. The Secretary shall encourage states to strengthen their food safety programs, especially for retail commercial food establishments, and establish procedures and requirements for ensuring that processed produce is not unsafe for human consumption. The Secretary may provide assistance to states in implementing their food safety programs in the following areas: advisory, technical, training, laboratory, and financial. Under an agreement with a federal, state, or local agency, the Secretary may use, on a reimbursable basis, the personnel, services, and facilities of the agency to assist states.

Section 1005. Reportable Food Registry. The Act amends the FFDCA to create a new section 417 that requires the Secretary, within one year, to establish a Reportable Food Registry within FDA, to which instances of "reportable foods" (excluding infant formula) may be submitted via electronic portal by public health officials and others. Reportable foods are those for which there is a reasonable probability that exposure will cause serious adverse health consequences or death to humans or animals. The Act requires individuals who own or manage FDA-registered food facilities (so-called "responsible parties") to report to FDA within 24 hours if they are aware of an instance of reportable food, and to investigate the cause of the adulteration if the food originated with the responsible party. No report to FDA is required if the responsible party detected the adulteration prior to any transfer of the food or if the adulteration was corrected or the food was destroyed. The Secretary shall promptly review and determine the validity of information submitted for the purpose of identifying reportable food and shall exercise other existing food safety authorities to protect public health. The Secretary shall issue an alert if a food is a reportable food. The Act outlines the data elements required for reporting to FDA for the registry.

Information and records provided to the registry are accessible pursuant to the Freedom of Information Act. Reports to the registry do not constitute admissions that a product caused or contributed to a death, serious injury, or serious illness. Failure to provide a report, or the falsification of a report, is prohibited.

The Secretary shall create a numbering system that allows reports to be linked and amended and that identifies the supply chain for the reportable food. The Secretary shall promptly review a report and require the responsible party to notify appropriate parties in the supply chain and submit a subsequent report or amend a previous report with further information as it becomes available. The Secretary shall share information and coordinate regulatory efforts with the U.S. Department of Agriculture (USDA) for any

report on a food product that is within USDA's jurisdiction. The Secretary shall work with state and local public health officials to share information and coordinate regulatory efforts, while reducing duplication, to ensure coverage of the safety of the food supply chain, including food establishments not registered with the FDA (e.g., restaurants). Records must be maintained and available for inspection, if needed. The Secretary of Homeland Security shall be notified immediately if it is suspected that such food may have been deliberately adulterated. Within nine months, the Secretary shall issue guidance to industry about submitting reports to the electronic portal and providing notification to other persons in the supply chain for a reportable food.

Section 1006. Enhanced Aquaculture and Seafood Inspection. The Secretary is authorized to enhance FDA's aquaculture and seafood inspection regime consistent with international agreements and U.S. law. The provision requires a report to Congress within six months of enactment that describes the specifics of the inspection program, the feasibility of developing traceability systems for catfish and seafood products to both foreign and domestic processing plants, and an assessment of the risks associated with contaminants and banned substances. The Secretary may enter into partnerships with the states to implement this inspection program for aquaculture and seafood import products.

Section 1007. Consultation Regarding Genetically Engineered Seafood Products. The FDA Commissioner shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with any genetically engineered seafood products, including the impact on wild fish stocks.

Section 1008. Sense of Congress. This provision states that it is vital for Congress to provide FDA with additional resources, authorities, and direction to ensure the safety of the U.S. food supply, and to provide additional inspectors to improve FDA's ability to safeguard the U.S. food supply. Further, the Secretary should prioritize entering into agreements with U.S. trading partners with regard to food safety, because of the increased volume of international trade in food products, and Congress should work to develop a comprehensive response to the issue of food safety.

Section 1009. Annual Report to Congress. The Secretary shall submit an annual report to the appropriate congressional authorizing and appropriations committees that includes the number and amount of imported food products aggregated by country and type of food, a listing of the number of FDA inspectors of imported food and the number of inspections performed, and aggregate data on the findings of inspections, including data on the violations and enforcement actions used to follow up on the findings and violations.

Section 1010. Publication of Annual Reports. This provision requires the FDA Commissioner to submit to Congress and publish on the FDA website an annual report containing the results of the agency's pesticide monitoring program. The annual report is to include information and analysis similar to that found in the FDA's June 2005 report on pesticide residue monitoring, the results and analysis of the Ginseng Dietary Supplements Special Survey, and certain specified data and other information on interstate and imported shipments of food. Reports are to start with the fiscal years 2004-2006 combined into a single report. The FDA Commissioner, the Administrator of the

USDA Food Safety and Inspection Service (FSIS), the Secretary of Commerce, and the head of the USDA Agricultural Marketing Service (AMS) shall enter into a memorandum of understanding to permit inclusion in their reports of data from FSIS and AMS on meat, poultry, eggs, and certain raw agricultural products.

Section 1011. Rule of Construction. This provision indicates that nothing in the title affects the regulation of, or the adverse reporting system for, dietary supplements created under the Dietary Supplement Health and Education Act of 1994 (P.L. 103-417) or the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 (P.L. 109-462), respectively.

Related Activities

The 110th Congress has held numerous hearings on food safety in both chambers because several committees have FDA jurisdiction. While the primary focus has been the safety of imported food, concerns about food safety in general and steps to take in bringing the entire system up-to-date with current science, technology, and globalization of the food supply are the underlying issues. In addition, numerous bills have been introduced in both chambers on various aspects of food safety, several of which have been the subject of the hearings. While all the bills have been assigned to the appropriate committees, none has received any further action, except for the provisions in the FDA Amendments Act of 2007 discussed above.

The Administration has addressed the recent food safety problems in several ways. In May 2007, the FDA Commissioner appointed Dr. David Acheson to the new position of FDA Assistant Commissioner for Food Protection. In this position, he will serve as the coordinator for working with individual FDA product centers and the Office of Regulatory Affairs to coordinate FDA's food safety and security of the food supply assignments and commitments. In addition, Dr. Acheson will serve as the FDA Commissioner's direct liaison to the Department of Health and Human Services and other federal departments and agencies on interagency initiatives on food safety. In November 2007, he completed the integrated strategic plan for protecting the nation's food supply. The Food Protection Plan is organized by the core elements of prevention, intervention, and response to food safety problems, with particular emphasis on prevention. The report describes for each core element the action steps that the agency needs to take and includes legislative proposals needed to fully implement the plan.³ No time frame for implementation of the plan is provided in the report.

In July 2007, the President appointed a working group on the safety of imported products, including food, to conduct a comprehensive review of current import safety practices and to determine where improvements can be made. This group, headed by HHS Secretary Leavitt, was formed following the revelations about tainted pet food, unsafe tires, antibiotics in seafood, and contaminated toothpaste, all originating in China. Several public meetings and foreign trips were used by the working group to determine the current situation and develop options for the action plan. The group released its

³ The Food Protection Plan is available at [<http://www.fda.gov/oc/initiatives/advance/food/factsheet.html>].

Strategic Framework to promote import safety to the President on September 10, 2007.⁴ In November 2007, the working group released its Action Plan, which outlined the activities to be completed in 200 days.⁵ The action plan contains a number of actions specifically to protect the American food supply, which include the setting of safety standards in the FDA's Food Protection Plan; certification for the seafood inspection program and seafood inspectors stationed in Asian countries; establishment of a security and prosperity partnership for safe food and other products with Mexico and Canada; a memoranda of agreement with China on food and animal feed; foreign training on U.S. safety standards for meat, poultry, and eggs; and a marking requirement on imported food refused entry into the United States to prevent port-shopping. Other actions are planned for non-food imported goods.

Additional CRS Reports

- CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter.
- CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, by Judith A. Johnson, Donna V. Porter, Susan Thaul, and Erin D. Williams.
- CRS Report RL34102, *FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, Sarah A. Lister, Donna V. Porter, and C. Stephen Redhead.
- CRS Report RL34152, *Food Safety: Selected Issues and Bills in the 110th Congress*, by Geoffrey S. Becker.
- CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

⁴ Interagency Working Group on Import Safety, *Protecting Americans Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*, report to the President, September 10, 2007, available at [<http://www.importsafety.gov/report/index.html>].

⁵ Interagency Working Group on Import Safety, *The Action Plan for Import Safety: A Road Map for Continued Improvement*, report to the President, November 2007, available at [<http://www.importsafety.gov>].