



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

August 12, 2010

### **S. 510**

#### **Food Safety Modernization Act**

*As reported by the Senate Committee on Health, Education, Labor, and Pensions  
on December 18, 2009, incorporating a manager's amendment  
released on August 12, 2010*

#### **SUMMARY**

S. 510 would require the Department of Health and Human Services (HHS) to strengthen federal efforts related to ensuring the safety of commercially distributed food. S. 510 also would broaden the Food and Drug Administration's (FDA's) authority to regulate food products, and would require the agency to assess fees on the responsible party for each domestic and foreign food factory, warehouse, and establishment to cover the costs of reinspecting those facilities, as well as on importers and exporters of food products to cover the costs of administering import and export programs. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. As a result, the FDA's expenditures would be classified as discretionary spending, and the collections of fees would be recorded as offsets to discretionary spending.

CBO estimates that implementing the bill with the manager's amendment would increase spending subject to appropriation, on net, by about \$1.4 billion over the 2011-2015 period, assuming annual appropriation action consistent with the bill. Enacting the bill also could increase revenues and direct spending from new criminal penalties; therefore, pay-as-you-go procedures apply. However, CBO estimates that any such collections would be insignificant, yielding a negligible net impact in each year.

S. 510 would impose a number of mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on individuals and entities that manufacture, process, pack, transport, distribute, receive, or hold articles of food. CBO estimates that the total cost of those mandates would probably exceed the threshold established in UMRA for private-sector entities (\$141 million in 2010, adjusted annually for inflation) in at least one of the first five years the mandates are in effect. Because of the small number of public-sector entities affected, CBO estimates that the costs of mandates in the bill would fall well below the intergovernmental threshold (\$70 million in 2010, adjusted annually for inflation).

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 510 with the manager’s amendment is shown in the following table. The costs of this legislation fall within budget functions 300 (natural resources and environment) and 550 (health).

	By Fiscal Year, in Millions of Dollars					2011- 2015
	2011	2012	2013	2014	2015	
<b>CHANGES IN SPENDING SUBJECT TO APPROPRIATION <sup>a</sup></b>						
Food and Drug Administration (FDA)—Fees and Related Spending						
Collection of New Fees						
Estimated Authorization Level	-15	-27	-47	-63	-89	-241
Estimated Outlays	-15	-27	-47	-63	-89	-241
Spending of New Fees						
Estimated Authorization Level	15	27	47	63	89	241
Estimated Outlays	10	23	44	65	88	230
Net Changes from Fee Authority						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	-5	-4	-3	2	-1	-11
New FDA Activities Not Supported by Fees						
Estimated Authorization Level	11	53	182	318	583	1,147
Estimated Outlays	1	37	159	311	559	1,067
Other Federal Agencies						
Estimated Authorization Level	83	85	86	86	87	427
Estimated Outlays	24	59	80	85	87	335
Total Changes						
Estimated Authorization Level	94	138	268	404	670	1,574
Estimated Outlays	20	92	236	398	645	1,391

Note: Components may not sum to totals because of rounding.

a. Enacting the legislation would also increase revenues and direct spending by less than \$500,000 per year, with negligible net effects for each year.

## **BASIS OF ESTIMATE**

For this estimate, CBO assumes that S. 510, incorporating the manager's amendment, will be enacted near the start of fiscal year 2011, that appropriation actions necessary to implement the bill will occur for each year beginning with 2011 to fund the regulatory activities authorized under the bill, and that outlays will follow historical patterns for similar activities.

### **Major Provisions**

S. 510 would broaden the FDA's authority to regulate food facilities and would establish new requirements for those facilities. That broadening includes:

- Mandating the renewal of registration on a biennial basis of all establishments that import, export, manufacture, process, pack, or hold food for consumption in the United States, and specifying certain inspection, recordkeeping, and reporting requirements for such facilities;
- Requiring any person who produces, manufactures, processes, packs, distributes, receives, imports, or holds an article of food to permit an officer or employee designated by the Secretary of HHS to have access to their records relating to articles of food that may be adulterated;
- Requiring that any food facility that violates a food-related requirement of the Federal Food, Drug, and Cosmetic Act that consequently requires a reinspection or a mandatory food recall to pay a fee to cover the costs of the reinspection or food recall;
- Requiring accredited third-party auditors and audit agents to pay a fee to cover the costs of establishing and administering an accreditation system;
- Requiring food imported or offered for import into the United States to provide certification that the article complies with established requirements; and
- Reviewing and evaluating epidemiological data at least every two years to identify the most significant food-borne contaminants and resulting hazards, setting national performance standards to minimize the occurrence of such hazards, and establishing national standards for preventive controls, hazard analysis, safe growing, harvesting, packing, sorting, storing, and importing raw agricultural products.

S. 510 also would require the FDA to inspect registered domestic food facilities on a risk-based schedule beginning on the date of enactment. In meeting the inspection requirements specified in the bill, the Secretary of HHS would be able to recognize other entities to conduct inspections, including federal, state, and local officials, and agencies and representatives of foreign countries. The frequency of the domestic inspections would be determined by the risk category of the facility:

- A “high-risk” facility, as determined by the FDA, would be a facility that manufactures or processes food and would have to be inspected at least once in the five-year period following the date of enactment, and not less than once every three years thereafter; and
- A “non-high-risk” facility would have to be inspected at least once in the seven-year period following the date of enactment, and not less than once every five years thereafter.

The bill also would require the FDA to inspect no fewer than 600 foreign facilities in the first year following the date of enactment. The FDA would be required to double the number of foreign inspections in each year thereafter.

Based on the inspection schedule specified, CBO estimates that this bill would require about 50,000 domestic and foreign food facilities to be inspected in 2015. In fiscal year 2009, the FDA inspected about 7,400 domestic and foreign food establishments.

The bill also would require the Secretary of HHS to establish several pilot projects to explore and evaluate methods of tracking and tracing food in the United States or for import into the country. While S. 510 would broaden the FDA’s authority to regulate food facilities, nothing in this bill would alter or limit the authority of the Secretary of Agriculture under the laws administered by that Secretary, including, for example, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

### **Spending Subject to Appropriation**

CBO estimates that implementing S. 510 would increase spending subject to appropriation, on net, by \$1.4 billion over the 2011-2015 period, assuming appropriation actions consistent with the bill.

The gross spending for the FDA to administer the new regulatory activities authorized under the legislation—about \$1.3 billion over the 2011-2015 period—would be partially covered by fees assessed on registered food facilities, importers, and exporters. In 2010,

the FDA received about \$780 million in funding for the Center for Food Safety and Applied Nutrition and related activities. Under S. 510, funding for those activities would grow over time, with an increase of approximately \$583 million (excluding fees) by 2015.

**Collection of New Fees.** S. 510 would amend and modify the Federal Food, Drug, and Cosmetic Act to authorize the FDA to collect fees to help defray some of the FDA's costs of performing food safety activities. The bill would create new fee programs including: a facility reinspection and recall fee program for mandatory recalls, an importer fee program for voluntary qualified entities, and a fee program to support accreditation of third-party auditors.

The legislation also would authorize the FDA to collect fees for food (including animal feed) export certificates under the current export certification program. Fees are currently collected for drugs and devices that are issued export certifications.

Fees authorized by the bill would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. As a result, those collections would be credited as an offset to discretionary spending.

**Spending of Fees by FDA to Regulate Food Products.** Spending of the new fees assessed by the FDA to regulate food products would be classified as discretionary spending because the collections would be available for obligation subject to appropriation action.

Fees collected would only be available to cover the costs of activities specified in the bill:

- Reinspection and recall fees could only be collected and made available to cover the costs of such activities.
- The importer fees could only be collected and made available to defray the administrative costs of registering importers in the Voluntary Qualified Importer Program.
- Accreditation fees could also only be collected and made available to cover the costs of administrative activities for the program.
- Export certification fees could only be collected and made available to cover the FDA's cost of issuing such certifications.

Assuming annual appropriation actions consistent with the bill, CBO estimates that implementing the program to assess fees to cover new FDA costs associated with

regulating food products would yield \$241 million in collections and result in \$230 million in subsequent spending of those fees over five years. (Spending of fees would lag slightly behind their collection.)

**FDA Activities Not Supported by Fees.** CBO estimates the fees collected would not offset all of the costs of the new requirements in S. 510. The additional inspections and administrative activities not covered by fees would increase discretionary outlays by \$1.1 billion over five years beginning in 2011. That amount incorporates savings to the FDA for food safety activities conducted under current law that would henceforth be funded by fees in the bill. The spending total also reflects the cost of authorized grants to states and certain other entities to enhance food safety.

**Other Federal Programs.** CBO estimates that implementing other provisions of S. 510 would increase discretionary spending by \$335 million over the 2011-2015 period, assuming the appropriation of the necessary amounts. The bill would authorize three grant programs outside the purview of the FDA: school-based allergy and anaphylaxis management grants; food safety training, education, extension, outreach and technical assistance grants; and food safety participation grants for states and Indian tribes. Along with the grant programs, S. 510 also would require the Environmental Protection Agency (EPA) to participate in food safety activities and would require the Centers for Disease Control and Prevention (CDC) to enhance its participation in food safety activities.

S. 510 would authorize the appropriation of \$30 million for fiscal year 2011 and such sums as may be necessary for fiscal years 2012 to 2015 for the Secretary of HHS to provide grants to local education agencies to implement voluntary food and anaphylaxis management guidelines. Based on the spending patterns of similar programs, CBO estimates this provision would cost \$107 million over the 2011-2015 period, assuming appropriation of the necessary amounts.

Enacting the bill would require the Secretary of HHS to enter into one or more memoranda of understanding or other cooperative agreements with the Secretary of Agriculture for fiscal years 2011 through 2015 to establish a grant program to provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers. Based on spending patterns of similar programs, CBO estimates that implementing this provision would cost \$21 million over the next five years.

S. 510 would authorize the appropriation of \$19.5 million for fiscal year 2010 and such sums as may be necessary for 2011 through 2015 for the Secretary of HHS to award grants to states and Indian tribes to expand participation in food safety efforts. CBO adjusted the authorized level for inflation to estimate a fiscal year 2011 amount of \$19.8 million. (CBO assumes there will not be any additional appropriations provided for

fiscal year 2010.) Based on spending patterns of similar programs, CBO estimates that implementing this provision would cost \$83 million over the 2011-2015 period.

Enacting the bill also would require EPA to develop regulations and participate in other activities related to decontamination and disposal plans. CBO estimates that EPA would incur costs of about \$2 million annually, subject to the availability of appropriated funds.

S. 510 would authorize the appropriation of \$24 million for each fiscal year 2011 through 2015 for the Secretary of HHS, acting through the Director of the CDC, to improve the collection, analysis, reporting and usefulness of data on foodborne illnesses by coordinating, expanding and integrating surveillance systems across federal, state, and local agencies. S. 510 would direct the CDC to allow public access to aggregated, de-identified surveillance data and, at least annually, publish reports on findings from the surveillance systems. Assuming the appropriation of the specified amounts, CBO estimates that implementing this provision would cost \$100 million over the 2011-2015 period.

S. 510 would also authorize the Secretary, acting through the Director of the CDC, to designate Centers of Excellence at selected state health departments. The Centers of Excellence would serve as resources for federal, state, and local public health professionals in preparing for and responding to outbreaks of foodborne illness. CBO estimates that, once fully phased-in, that activity would cost \$4 million annually, with spending totaling \$14 million over the 2011-2015 period, assuming the appropriation of necessary amounts.

### **Revenues and Direct Spending**

The bill would stipulate that the failure to comply with new requirements, such as mandatory recalls and risk-based preventive controls, could result in the assessment of civil or criminal penalties. CBO estimates that enacting this bill would have a negligible effect on revenues from civil or criminal penalties over the 2010-2020 period because of the relatively small number of cases likely to be involved. Collections of criminal penalties are deposited in the Crime Victims Fund and later spent without further appropriation. However, CBO estimates that any such collections and spending would be less than \$500,000 per year over both the 2010-2015 and 2010-2020 periods.

### **PAY-AS-YOU-GO CONSIDERATIONS**

Enacting S. 510 could result in revenues from new penalties; therefore, pay-as-you-go procedures apply. The net changes in outlays and revenues that are subject to pay-as-you-go procedures are shown in the following table.

**CBO Estimate of Pay-As-You-Go Effects for S. 510, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager’s amendment released on August 12, 2010**

By Fiscal Year, in Millions of Dollars

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2010-2015	2010-2020
<b>NET INCREASE OR DECREASE (-) IN THE DEFICIT</b>													
Statutory Pay-As-You-Go Impact	0	0	0	0	0	0	0	0	0	0	0	0	0

**INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT**

S. 510 would impose a number of mandates, as defined in UMRA, on individuals and entities that manufacture, process, pack, transport, distribute, receive, hold, or import articles of food. CBO estimates that the total cost of those mandates would probably exceed the threshold established in UMRA for private-sector entities (\$141 million in 2010, adjusted annually for inflation) in at least one of the first five years the mandates are in effect. Because of the small number of public-sector entities affected, CBO estimates that the costs of mandates in the bill would fall well below the intergovernmental threshold (\$70 million in 2010, adjusted annually for inflation).

The bill would require facilities that manufacture, process, pack, receive, or hold food for consumption in the United States to register every two years with the Secretary of HHS and pay any fees associated with reinspection or recall activities. Under current law, all of those facilities are required to register once with the Secretary. The biennial registration and the fees would be new requirements. CBO estimates that the fees alone would total nearly \$15 million in 2011 and rise to approximately \$100 million in 2015.

The bill would also impose a number of mandates on the private sector that would depend on future guidance and regulations made by the Secretary of Health and Human Services:

- The bill would place new requirements on entities that manufacture, process, pack, transport, distribute, receive, hold, or import articles of food. For example, those entities would be required to follow new science-based standards for producing and harvesting raw agricultural commodities, to comply with additional record-keeping requirements for high-risk foods (as defined by the Secretary), and to



adhere to new safety and security guidelines for the importation of food, among other regulations.

- The bill would require owners, operators, and agents of facilities that manufacture, process, pack, or hold food to conduct hazard analyses, implement and monitor preventive controls, institute corrective actions when necessary, repeat hazard analyses at least every three years, and maintain records of those activities. They also would have to develop written plans that outline how facilities would meet those requirements. All records and written plans would have to be provided to the Secretary upon request.
- Additionally, those entities would have to present to the Secretary all records related to manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing an article of food and to use accredited laboratories recognized by the Secretary for analytical testing of an article of food. Under current law, many entities may already have the capability to meet those requirements, but some entities could incur additional costs.

It is unclear how those regulations and requirements would be implemented. However, because the new regulations would apply to a large number of entities, CBO estimates that the cost of all private-sector mandates in the bill would probably exceed the annual threshold (\$141 million in 2010, adjusted annually for inflation) specified in UMRA in at least one of the first five years the mandates are in effect.

Mandates in the bill would extend to some tribal entities that manufacture and package food items for resale. Given the limited number of tribal governments affected, however, CBO estimates that the costs of the mandates would fall below the intergovernmental threshold (\$70 million in 2010, adjusted annually for inflation).

## **PREVIOUS CBO ESTIMATE**

On July 24, 2009, CBO transmitted a cost estimate for H.R. 2749, the Food Safety Enhancement Act of 2009, as ordered reported by the House Committee on Energy and Commerce on June 17, 2009. H.R. 2749 and S. 510 would both expand the authority of the FDA to regulate food products. However, the two bills have different inspection schedules for food facilities.

H.R. 2749 would divide food facilities into three risk categories and would vary the inspection frequency from one to five years, whereas S. 510 has two risk categories for domestic facilities and would require a doubling of foreign inspections each year.

H.R. 2749 also would authorize the FDA to collect food facility registration fees to offset the inspection costs. In contrast, S. 510 would not authorize the FDA to collect food facility registration fees. Hence, CBO assumes those inspection costs under the Senate bill would be funded through appropriations. In estimating the costs of S. 510, CBO obtained updated information from the FDA on the number of facilities that would be subject to inspection under the bill.

CBO estimated that implementing H.R. 2749 would increase spending subject to appropriation, on net, by about \$2.0 billion over the 2010-2014 period, assuming annual appropriation actions consistent with that bill. Over the 2011-2015 period, CBO estimates that implementing S. 510 would have a net discretionary cost of about \$1.4 billion.

**ESTIMATE PREPARED BY:**

Federal Costs: Food and Drug Administration—Ellen Werble  
Centers for Disease Control and Prevention—Stephanie Cameron  
Environmental Protection Agency—Susanne Mehlman  
Education Grants—Justin Humphrey  
Revenues—Grant Driessen

Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum  
Impact on the Private Sector: Sarah Axeen

**ESTIMATE APPROVED BY:**

Holly Harvey  
Deputy Assistant Director for Budget Analysis