CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

July 24, 2009

H.R. 2749
Food Safety Enhancement Act of 2009

As ordered reported by the House Committee on Energy and Commerce on June 17, 2009

SUMMARY

H.R. 2749 would require the Department of Health and Human Services (HHS) to strengthen federal efforts related to ensuring the safety of commercially distributed food. H.R. 2749 would also broaden the Food and Drug Administration's (FDA's) authority to regulate food products, and would require the agency to assess fees on food facilities, as well as importers and exporters of food products to cover the costs of registering and inspecting facilities authorized in the bill. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriations acts.

CBO estimates that:

- Implementing the bill would increase spending subject to appropriation, on net, by about $2.0 billion over the 2010-2014 period, assuming annual appropriation action consistent with the bill; and

- Federal revenues from civil penalties for food related violations of the Federal Food, Drug, and Cosmetic Act would increase by $10 million over the 2010-2014 period and by $20 million over the 2010-2019 period.

H.R. 2749 would impose a number of mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on individuals and entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. CBO estimates that the total cost of those mandates would exceed the threshold established in UMRA for private-sector entities ($139 million in

2009, adjusted annually for inflation) in each year, beginning with 2010. Given the limited number of public entities affected by the requirements, CBO estimates that the costs of intergovernmental mandates would fall below the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2749 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2010	2011	2012	2013	2014	2010-2014
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Food and Drug Administration (FDA)						
Collection of New Fees						
Estimated Authorization Level	-209	-241	-290	-333	-368	-1,441
Estimated Outlays	-209	-241	-290	-333	-368	-1,441
Spending of New Fees						
Estimated Authorization Level	209	241	290	333	368	1,441
Estimated Outlays	66	199	309	352	372	1,298
Net Changes from Fee Authority						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	-143	-43	19	19	4	-144
FDA Activities Not Supported by Fees						
Estimated Authorization Level	-35	4	459	777	1,109	2,314
Estimated Outlays	-35	-9	368	749	1,084	2,157
Total Changes in Spending Subject to Appropriation						
Estimated Authorization Level	-35	4	459	777	1,109	2,314
Estimated Outlays	-178	-51	387	768	1,088	2,014
CHANGES IN REVENUES						
Estimated Revenues from Civil Penalties	2	2	2	2	2	10

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

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 2749 will be enacted near the start of fiscal year 2010, that the full amounts authorized will be collected (starting in fiscal year 2010) to fund FDA's regulatory activities authorized under the bill, and that outlays will follow historical patterns for similar activities.

H.R. 2749 would broaden the FDA's authority to regulate food facilities. Such authority would include:

- Mandating the annual registration 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, manufacture, processes, packs, transports, 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, misbranded, or otherwise in violation of the Federal Food, Drug, and Cosmetic Act;

- Requiring any food facility that violates a food-related requirement of the Federal Food, Drug, and Cosmetic Act that consequently requires a reinspection or food recall shall pay a fee to cover the costs of the reinspection or food recall; and

- Reviewing and evaluating epidemiological data every two years to identify the most significant food-borne contaminants and resulting hazards, and setting national performance standards to minimize the occurrence of such hazards, and establishing national standards for risk-based preventive controls, hazard analysis, safe growing, harvesting, processing, packing, sorting, transporting, and holding of raw agricultural products.

H.R. 2749 also would require the FDA to inspect registered food facilities on a risk-based schedule beginning no later than 18 months after enactment. The Secretary of Health and Human Services may recognize federal, state, and local officials, and agencies and representatives of foreign countries to conduct inspections. The frequency of the inspections shall be determined by the category of the facility:

- A category 1 facility is a high-risk facility that manufactures or processes food and must be inspected at least once every 6 to 12 months;

- A category 2 facility is a low-risk facility that manufactures or processes food and must be inspected at least every 18 months to 3 years; and

- A category 3 facility is a facility that holds food and must be inspected at least every 5 years.

Based on information from the FDA, CBO estimates this bill would require about 360,000 domestic and foreign food facilities be inspected on a risk-based frequency schedule. This estimate assumes the magnitude of the inspections required in the risk-based inspection schedule will lead the FDA to recognize agencies and representatives of foreign countries to help fulfill the bill's requirements for inspection frequency.

The bill also would require the Secretary of HHS to design and implement a tracing system for food located in the United States or for import into the country. The bill would explicitly exempt all food products and facilities regulated by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act from the requirements in H.R. 2749.

Spending Subject to Appropriation

CBO estimates that implementing H.R. 2749 would increase spending subject to appropriation, on net, by $2.0 billion over the 2010-2014 period, assuming appropriation action consistent with the bill. The effect on discretionary spending by federal programs reflects the authorized funding relating to the federal regulation of food products.

The gross costs for FDA to administer the new regulatory activities authorized under the legislation—about $3.5 billion over the 2010-2014 period—would be partially covered by fees assessed on registered food facilities, importers, and exporters.

Collection of New Fees. H.R. 2749 would amend and modify the Federal Food, Drug, and Cosmetic Act to authorize the FDA to collect fees to help defray some of FDA's costs of performing food safety activities. The bill would create two new fee programs: a facility reinspection and recall fee program, and an importer registration fee program. The bill also would amend two current categories of fees: food facility registration fees, and export certification fees.

Under current law, both domestic and foreign food facilities are required to register with the FDA; however, periodic renewal is not required and the FDA does not have authority to collect fees. The bill would mandate annual registration for all food facilities and require an annual fee of $500 adjusted for inflation. The legislation also would authorize the FDA to collect fees for food (including animal feed) export certificates under the current export certification program.

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 appropriations 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 FDA to regulate food products would be classified as discretionary spending because the authorized amounts would be available for obligation subject to appropriation action. Amounts collected would be available to cover FDA's administrative costs to regulate food products at any point in the future.

Importer registration fees could only be collected and made available to defray the costs of registering importers and enforcing compliance with good importer practices. Export certification fees could only be collected and made available to cover the cost of issuing such certifications. Reinspection and recall fees could also only be collected and made available to cover the costs of such activities. The fees program for food facility registration could be collected and made available to defray the costs of food safety activities, which are defined in the bill as expenses incurred in connection with food safety activities.

Assuming appropriation action consistent with the bill, CBO estimates that implementing the program to assess fees to cover new FDA costs associated with regulating food products would increase collections and subsequent spending of those fees by about $1.4 billion over five years, and would result in a net decrease in discretionary outlays of about $140 million over the 2010-2014 period. (Spending of fees would lag slightly behind their collection.)

FDA Activities Not Supported by Fees. Because of the magnitude of the inspections required under the bill, CBO estimates the fees collected would not offset all of the costs of the new requirements. The net additional inspections and administrative activities not covered by fees would increase discretionary outlays, on net, by $2.2 billion over five years. This amount incorporates savings to the FDA for food safety activities conducted under current law that would be replaced by fees in the bill. For example, in 2010, CBO anticipates the FDA will save $35 million relative to its current appropriation level for activities that would be funded through new fees.

Revenues

The bill would expand the FDA's authority to assess civil penalties for food related violations of the Federal Food, Drug, and Cosmetic Act. Such violations include the introduction into interstate commerce of certain adulterated or misbranded foods. Based on information provided by the FDA regarding recent enforcement activity, CBO

estimates that the bill would increase revenues from civil penalties by $20 million over the 2010-2019 period.

The bill could also increase revenues from criminal penalties, which are recorded as revenues, deposited in the Crime Victims Fund, and later spent. CBO expects that any additional revenues from criminal penalties would not be significant.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 2749 would impose a number of mandates, as defined in the UMRA, on individuals and entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. CBO estimates that the total cost of those mandates would exceed the threshold established in UMRA for private-sector entities ($139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010. Given the limited number of public entities affected by the requirements, CBO estimates that the costs of intergovernmental mandates would fall below the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

The bill would require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States or export to other countries to register with the Secretary of HHS and pay an annual fee. Under current law, all of those facilities are required to register with the Secretary except for facilities holding food for export, but the annual fee would be a new requirement. CBO estimates fees would total almost $210 million in 2010 and rise to almost $370 million by 2014. The costs of those payments alone would exceed the threshold established by UMRA.

The bill also would place new requirements on entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. In general, the costs of those mandates on the private sector would depend on future guidance and regulations established by the Secretary. For example, the Secretary would be required to develop science- and risk-based standards, to establish a tracing system for food located in the United States or for import into the country, and to develop safety and security guidelines for the importation of food. It is unclear how those requirements would be implemented and how they would affect the food industry. Therefore, CBO cannot estimate the cost to private entities of those provisions.

The bill would require owners, operators, and agents of facilities to conduct hazard analyses, implement and monitor preventive controls, institute corrective actions when necessary, repeat hazard analyses at least every two years, and maintain records of these activities. They also would have to develop food safety plans that outline how facilities would meet these requirements. High-risk facilities that manufacture or process food, also referred to as "category 1 facilities," would be required to test finished products for the presence of contaminants and submit the results of the tests to the Secretary. The Secretary would have the option to establish guidance or regulations, which would determine the extent of the requirements for complying with these provisions of the legislation.

The bill also would require entities, among other things, to be prepared to present all records related to the production, manufacture, processing, packing, transporting, distribution, receipt, holding or importation of an article of food; to report to a food registry; to use accredited laboratories recognized by the Secretary for analytical testing of an article of food; to notify the Secretary of the identity and location of an article of food that is believed to be adulterated or misbranded; to maintain records with respect to infant formula for at least one year after the expiration of the shelf life; and to identify the country in which the final processing occurred and for unprocessed food to identify the country of origin of the food. Under current law, many entities may already have the capability to meet some of those requirements, but entities such as farms and restaurants that are not currently subject to any of those requirements previously could incur significant costs to comply with their respective mandates.

Mandates in the bill would extend to some public entities, including public colleges and universities that operate farms and a limited number of tribal entities that produce and package food items for resale. Given the limited number of public entities affected, however, CBO estimates that the costs of the mandates would fall below the intergovernmental threshold ($69 million in 2009, adjusted annually for inflation).

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