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FY2016 Appropriations: Selected Federal Food Safety Agencies

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January 14, 2016

Congressional Research Service
7-5700
www.crs.gov
R44309

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

The Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House and Senate Appropriations Committees oversee the budgets of two principal federal food safety agencies at the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS). FDA, an agency of the Department of Health and Human Services, is responsible for ensuring the safety of the majority of all domestic and imported food products (except for meat and poultry products). FSIS, an agency at the U.S. Department of Agriculture, regulates most meat, poultry, and processed egg products.

Combined appropriations and fees collected to cover food safety activities at FDA and USDA totaled an estimated $2.4 billion in FY2015, more or less evenly split between the two agencies. FSIS is responsible for roughly 10%-20% of the U.S. food supply, while FDA is responsible for the remaining 80%-90%. In the past few years, appropriators have increased funding for FDA's Foods program activities—one of the agency's primary program areas focused on food safety activities—more than doubling it from $435.5 million in FY2005 to $903.4 million in FY2015. In addition, FDA's food safety activities receive other program-level funding as part of FDA's overall budget. (FDA's Foods program accounts for about one-third of FDA's total appropriation.) FDA reports that food safety funding at FDA totaled $1.2 billion in FY2015.

The FY2016 Agriculture appropriation was enacted in December 2015, as part of an omnibus appropriations act (P.L. 114-113). For FDA's food safety activities, including Food Safety Modernization Act (FSMA, P.L. 111-353) implementation, the enacted FY2016 appropriation provides for a $104.5 million increase in budget authority, nearly matching that requested in the Administration's FY2016 budget ($109.5 million). This could raise the budget authority for FDA's food safety activities to more than $1.3 billion annually. The enacted FY2016 appropriations provide $987.3 million for FDA's Foods program, which is identical to the amount requested by the Administration. Separately, for FSIS, the enacted FY2016 Agriculture appropriation is $1.015 billion, above the Administration's requested appropriation ($1.012 billion).

These congressional appropriations would be augmented by existing (currently authorized) user fees. The Administration's FY2016 request for FDA and FSIS proposed a series of new user fees to augment both agencies' food safety activities. As in previous budget debates, however, appropriators did not include any new user fee proposals as part of either agency's FY2016 appropriations. The FY2016 appropriation further contains a number of policy riders for a range of FDA and USDA food safety and other food-related programs.

Increased funding for food safety activities at FDA is largely in response to additional responsibilities following the enactment of the FDA FSMA in the 111th Congress. FSMA was the largest expansion of FDA's food safety authorities since the 1930s. FSMA authorized additional appropriations and staff for the agency's food safety activities, and also provided limited additional funding through industry-paid user fees. However, according to FDA, during the past five years (FY2011-FY2015) it has received increases to its funding base totaling $168 million for enacted changes to its food safety programs. Previously, FDA had reported that an additional $400 million to $450 million per year above the FY2012 base is needed to fully implement FSMA. FDA officials continue to note that without additional funding there will be a significant funding gap for FSMA implementation. FSMA did not directly address meat and poultry products under USDA's jurisdiction.

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Background

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply.[1] Federal responsibility for food safety rests primarily with the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS). FDA, an agency of the Department of Health and Human Services, is responsible for ensuring the safety of the majority of all domestic and imported food products (except for meat and poultry products).[2] FSIS, an agency at the U.S. Department of Agriculture, regulates most meat, poultry, and processed egg products.[3] The Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House and Senate Appropriations Committees appropriate funds for all of FDA and FSIS. The FY2016 Agriculture appropriation was enacted in December 2015, as part of an omnibus appropriation (P.L. 114-113).

Including enacted funding provided in the FY2016 Agriculture appropriation, combined appropriations and fees collected to cover food safety activities at FDA and USDA will total an estimated $2.5 billion in FY2016, more or less split between the two agencies (**Table 1**). As such, funding (and staffing levels) between FDA and FSIS is disproportionate to the volume of the food supply that each agency regulates for safety. FSIS is responsible for roughly 10%-20% of the U.S. food supply, while FDA is responsible for the remaining 80%-90%.[4]

In recent years, congressional appropriators have increased funding for FDA food programs, more than doubling funding over the past decade. Largely, that has been in response to comprehensive food safety legislation enacted in the 111th Congress, as part of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). FSMA was the largest expansion of FDA's food safety authorities since the 1930s.[5] Among its many provisions, FSMA authorized increased frequency of inspections at food facilities, tightened record-keeping requirements, extended oversight to certain farms, and also mandated product recalls. It requires food processing, manufacturing, shipping, and other facilities to conduct a food safety plan of the most likely safety hazards, and to design and implement risk-based controls. It also mandates improvements to foodborne illness surveillance systems and increased scrutiny of food imports. FSMA did not directly address meat and poultry products under USDA's jurisdiction.

FSMA also authorized additional appropriations and staff for FDA's food safety activities. It provided limited additional funding through industry-paid user fees. Funding for FSIS has remained mostly unchanged in recent years. Staffing levels differ substantially between the two agencies: FSIS staff number around 9,000 full-time equivalents (FTEs), while FDA's food-related staff, who cover more than food safety, number about 3,700 FTEs.

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[1] For more information, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Renée Johnson.

[2] FDA's food safety authorities rest primarily in the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301, *et seq*.).

[3] Laws governing FSIS include the Federal Meat Inspection Act (FMIA, 21 U.S.C. §§601, et seq.), the Poultry Products Inspection Act (PPIA, 21 U.S.C. §§451, et seq.), and the Egg Products Inspection Act (EPIA, 21 U.S.C. §§1031, et seq.).

[4] FDA's share of the U.S. food supply is approximated by backing out the reported 10%-20% of foods under USDA's jurisdiction. The 20% estimate is based on information reported by GAO in "Revamping Oversight of Food Safety," prepared for the 2009 Congressional and Presidential Transition, and appears to represent proportions of total spending for food consumed at home. The 10% estimate is based on data from USDA-ERS on U.S. per capita food consumption at http://www.ers.usda.gov/data/foodconsumption/. See also DHS, "National Infrastructure Protection Plan: Agriculture and Food Sector Snapshot," http://www.dhs.gov/food-and-agriculture-sector.

[5] P.L. 111-353 amended the Federal Food, Drug, and Cosmetic Act (FFDCA).

Although Congress authorized funds to be appropriated in FSMA, it did not provide the full funding needed for FDA to perform these expanded activities under the law. After FSMA was signed into law in January 2011, concerns were voiced about whether there would be enough money to overhaul the U.S. food safety system and also whether expanded investment in this area was appropriate in the budgetary climate that has since prevailed.[6] Prior to enactment, the Congressional Budget Office (CBO) estimated that fully implementing FSMA could increase net federal spending subject to appropriation by about $1.4 billion over a five-year period (FY2011-FY2015).[7] This cost estimate covered activities at FDA and other federal agencies and did not include offsetting revenue from the collection of new user fees authorized under FSMA.[8] During the debate leading up to FSMA, Congress considered imposing a new facility registration fee that might have offset some of the costs of fully implementing the requirements under the new law but ultimately such fees were not enacted. Prior to enactment, CBO estimated that about $240 million in new fees would be collected from FY2011-FY2015.[9] Taking into account these new fees, CBO estimated that covering the five-year cost of new requirements within FDA, including more frequent inspections, would require additional outlays of $1.1 billion.

FDA continues to implement regulations under FSMA.[10] According to FDA, during the past five years (FY2011-FY2015), the agency has received increases to its funding base totaling $162 million for enacted changes to its food safety programs, after accounting for permanent base reductions due to sequestration and other differences from enacted amounts as reported by FDA.[11] Including enacted increases for other food safety activities, FDA's budget authority for food safety and FSMA implementation has totaled $168.4 million (**Table 2**). Previously, FDA reported that an additional $400 million to $450 million per year above the FY2012 base is needed to fully implement FSMA.[12] Available FDA funding for FSMA implementation and other food safety activities has been lower than what FDA has said it needs to fully implement the law.

FSMA also authorized an increase in FDA staff, which was expected to reach 5,000 by FY2014.[13] FDA reports actual staffing levels at 3,700 FTEs in FY2015 (**Table 1**).

[6] See "Food Safety Bill Advocates Expect Funding Fight," *Food Safety News*, January 4, 2011.

[7] CBO, cost estimate, "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," August 12, 2010, https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/costestimate/s5101.pdf. Estimated total costs would be covered by a combination of user fees and direct appropriations (budget authority).

[8] FSMA authorized additional appropriations and staff for FDA's future food safety activities and authorized new user fees. New fees authorized under FSMA include an annual fee for participants in the voluntary qualified importer program and three fees for certain periodic activities involving reinspection, recall, and export certification. FSMA, P.L. 111-353, §§107 and 401. Details of these annual and periodic fees are presented in CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

[9] As estimated by CBO, these fees would have been phased in as follows: $15 million in FY2011; $27 million in FY2012; $47 million in FY2013; $63 million in FY2014; and $89 million in FY2015.

[10] For more information on FDA's rulemaking and implementation of FSMA, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

[11] CRS communication with FDA budget staff, December 4, 2015. See also comments by FDA's Michael Taylor, "The Future Is Now for the Food Safety Modernization Act," *Food Safety News*, March 17, 2015.

[12] FDA, *Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)*, May 2013.

[13] FSMA, P.L. 111-353, §401. By fiscal year, staff level increases were authorized to a total of not fewer than: 4,000 staff members (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014).

Table 1. Food Safety Appropriations

(FTEs as indicated, and budget and appropriation figures in millions of dollars)

Agency/Year	Federal full time Equivalents (FTEs)	Appropriation[a]	Total Program Level, Food Safety (incl. other funding and fees)[b]
HHS Food and Drug Administration (FDA)			
FY2009 Actual	2,995	712.8	NA
FY2010 Actual	3,387	783.2	NA
FY2011 Actual	3,605	836.2	1,107.4
FY2012 Actual	3,611	866.1	1,144.7
FY2013 Actual, Operating Plan (post-seq.)[c]	3,642	796.6	1,069.1
FY2014 Actual	3,650	900.3	1,188.0
FY2015 Actual	3,744	903.4	1,214.5
FY2016, Enacted	NA	987.3	NA
FY2016, Administration Request	4,196	987.3	NA
USDA Food Safety and Inspection Service (FSIS)			
FY2009 Actual	9,343	1,091.3	1,226.5
FY2010 Actual	9,401	1,018.5	1,176.6
FY2011 Actual	9,465	1,006.4	1,187.0
FY2012 Actual	9,351	1,004.2	1,170.8
FY2013 Actual, Operating Plan (post-seq.)[c]	9,158	976.7	1,162.0
FY2014 Actual	8,933	1,010.5	1,170.0
FY2015 Actual	9,194	1,016.5	1,206.7
FY2016, Enacted	NA	1,014.9	NA
FY2016, Administration Request	8,930	1,011.6	1,190.5

Sources: CRS, from P.L. 114-113 and annual agency budget justifications for FDA (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm) and FSIS (http://www.obpa.usda.gov/explan_notes.html). The "Appropriation" amount excludes all user fees. Estimated "Total Program Level, Food Safety" for FDA was provided by FDA budget staff (October-December, 2015). NA = Not available.

Notes:

a. Reflects appropriations for "Foods Program" only (excluding existing or proposed user fees). Appropriators specify amounts for product-specific programs in FDA. The Foods Program includes all food activities, not only those focused on food safety.

b. For FDA, reflects available funding for total food safety activities all across FDA programs and also user fees. For FSIS, includes existing fees and trust fund for overtime, holiday, and voluntary inspection.

c. Based on each agency's FY2013 sequestration operating plans, and FY2014 operating plans. For more information see CRS Report R43110, *Agriculture and Related Agencies: FY2014 and FY2013 (Post-Sequestration) Appropriations*.

Table 2. Changes to FSMA and FDA Food Safety Program Funding Compared to Previous Fiscal Year, FY2011-FY2015

($ million)

Fiscal Year	Reported by FDA[a]		Enacted Changes (Reported by Congressional Appropriators)	Citation in Legislation
	Total Food Safety Changes	Net FSMA Changes		
FY2011	+61.3	+59.8	+61.5	Increases per conference table provided to FDA
FY2012	+37.3	+39.0	+39.0	FSMA Increases per conference agreement (p. 185)
FY2013	-75.7[b]	-14.6[b]	+12.5	FSMA increases per S.Rept. 112-163 (p. 77), less permanent base reduction due to sequestration
FY2014	+118.9	+53.5	+53.5	FSMA increases per S.Rept. 113-46 (p. 79)
FY2015	+28.5	+24.0	+27.5	Food safety increases per *Congressional Record*, December 11, 2014 (p. H9314)
Subtotal	**+$168.4**	**+$161.7**	**+$193.4**	—
FY2016 Enacted[c]	NA	NA	+104.5	Explanatory text, Division A, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2016 (p. 29)

Sources: CRS, from P.L. 114-113 and various House and Senate bill and subcommittee reports, and conference reports, as well as information provided by FDA budget staff. Information is not available to account for each of the differences between the FDA-reported amounts and amounts reflected in enacted legislation; however, the majority of the overall difference is attributable to permanent base reductions due to sequestration in FY2013.

Notes:

a. As reported by FDA. For enacted changes for all food safety activities, the amounts reflect changes for FSMA implementation and other food safety activities. For enacted FSMA changes, the amounts reflect FDA-reported difference between amounts reported by the Agricultural Appropriations Subcommittees and those reported by FDA (provided October through November 2015).

b. Reflects permanent food safety base reductions due to sequestration. For background information, see CRS Report R43110, *Agriculture and Related Agencies: FY2014 and FY2013 (Post-Sequestration) Appropriations*.

c. Enacted FY2016 Consolidated Appropriations (P.L. 114-113).

FDA officials have continued to claim that without additional funding, as requested by the Administration, there will be a significant funding gap for FSMA implementation.[14] State agriculture officials and representatives of the National Association of State Departments of Agriculture (NASDA) have continued to push for full FSMA funding so that front-line state officials can prepare for implementation.[15] Food industry groups have asked congressional appropriators for increased budget authority for FDA to fully implement FSMA, at levels requested by the Administration, in order to maintain consumer confidence.[16] Public health and

[14] Testimony to the Senate Appropriations Committee, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, from Stephen Ostroff, acting commissioner, FDA Food and Drugs, September 16, 2015.

[15] See letter dated September 21, 2015, to House and Senate committee appropriators from NASDA.

[16] See, for example, letter dated April 15, 2014, to House and Senate committee appropriators from 20 industry groups, including Costco Wholesale Corp., Wal-Mart Stores, GMA, and the Produce Marketing Association.

consumer safety groups, as well as victims of food-borne illness, have also continued to call for additional food safety funding.[17]

FDA's Food Safety Activities

For FDA's food safety activities, including FSMA implementation, the enacted FY2016 Agriculture appropriation provides for a $104.5 million increase in budget authority, nearly that requested in the Administration's budget ($109.5 million).[18] This increase in budget authority is more than double what the House and Senate FY2016 committee bills had previously proposed: The House committee bill (H.R. 3049) would have increased funding for FSMA by $41.5 million, whereas the Senate (S. 1800) would have increased funding by $45.0 million bill. Both the House and Senate committees had noted that these increases and previous increases provided since FY2011 "should assist the FDA in preparation for the implementation of FSMA prior to the effective dates of the seven foundational proposed rules."[19] Both committee reports specify budgeted amounts for the following program areas: Inspection Modernization and Training; the National Integrated Food Safety System; Education and Technical Assistance for Industry; Technical Staffing and Guidance Development; Import Safety; and Risk Analytics and Evaluation.

The enacted FY2016 appropriations provide $987.3 million for FDA's Foods program—one of the agency's primary program areas focused on food safety activities. This amount is identical to that requested by the Administration (**Table 1**).[20] FDA's Foods program covers the agency's food safety activities, as well as certain other food-related programs. Its budget in FY2015 accounted for about one-third of the agency's total appropriation.[21] FDA's Foods program plays a major food safety role. The program has the primary responsibility for assuring that the nation's food supply, quality of foods, food ingredients, and dietary supplements (and also cosmetic products) are safe, sanitary, nutritious, wholesome, and properly labeled. In recent decades FDA's Foods program has had to adapt to the increasing variety and complexity of the U.S. food supply, including rising import demand for products produced outside the United States, as well as other market factors including emerging microbial pathogens, natural toxins, and technological innovations in production and processing.

[17] See, for example, letter dated November 10, 2014, to House and Senate committee appropriators (from 75 people or their relatives who became sick from eating contaminated foods) as well as letters dated October 1, 2014, and October 27, 2015 (signatories include the American Academy of Pediatrics, the American Public Health Association, and the Pew Charitable Trusts, among other health groups). See also testimony to the House Appropriations Committee, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, from Michael F. Jacobson, Center for Science in the Public Interest, March 20, 2014.

[18] FDA, "President's FY 2016 Budget Request: Key Investments for Implementing the FDA Food Safety Modernization Act (FSMA)," February 2015, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm432576.htm. This requested increase would cover inspection modernization and training; building a National Integrated Food Safety System; education and technical assistance for industry; technical staffing and guidance development; oversight of imported foods and the development of a new food import system; and risk analytics and evaluation.

[19] H.Rept. 114-205, S.Rept. 114-82.

[20] It is not possible to track appropriations or spending for FDA's total food safety budget from readily available information. Congressional appropriators direct or encourage FDA to use funds for a specific purpose, such as food safety; however, the bills and committee reports provide only the Foods program overall amounts. It is therefore difficult to track appropriations or spending on a subset of activities (such as food safety) over time. **Table 1** therefore primarily focuses on the appropriated amounts for the total Foods program to allow for reliable comparisons over time.

[21] FDA's enacted budget authority totaled $2.6 billion for FY2015. See FDA's budget justification, p. 18, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf.

However, FDA's total budget for food safety programs and activities extends beyond the agency's Foods program, encompassing other food and veterinary medicine programs at FDA. As reported by FDA, the agency's budget for food safety activities totaled $1.2 billion in FY2015.[22] This amount includes most of FDA's Food program funding, along with aspects of other FDA program areas covering food additives, antimicrobial resistance, nutrition labeling and dietary supplements, cosmetics, and all related user fees, as well as administrative expenses associated with FDA headquarters and rent-related expenses.[23] Including the enacted FY2016 appropriation that provides for a $104.5 million increase in budget authority, this could raise the budget authority for FDA's food safety activities to more than $1.3 billion annually.

These congressional appropriations would be augmented by existing (currently authorized) user fees. These fees, as authorized under FSMA, include food and feed recall fees, food reinspection fees, and voluntary qualified importer program fees. In recent years these fees have generated less than $18 million per year. In addition to FSMA-authorized user fees, the Administration had reproposed a series of new user fees totaling $167.7 million to cover the cost associated with food facility registration and inspection, food imports, international couriers, and food contact notifications.[24] From FY2012 through FY2015, the enacted appropriations have not included these proposed user fees. Both the House and Senate reported bills explicitly did not include the Administration's proposed new fees. In addition, two members of the House Appropriations Committee, Representatives Rosa DeLauro and Sam Farr, have repeatedly called on the Administration to stop requesting additional user fees but rather to "request the resources [FDA] needs to fully implement [FSMA]."[25] Industry representatives also continue to actively oppose such fees.[26] User fees are generally established in law by the authorizing committees and not by appropriators.

Selected Food Safety Provisions

The enacted FY2016 Agriculture appropriation specifies that "none of the funds" made available be used to implement or enforce any FSMA requirements with respect to "the regulation of the distribution, sale, or receipt of dried spent grain byproducts of the alcoholic beverage production process, irrespective of whether such byproducts are solely intended for use as animal feed."[27] This reflects language in the House committee report that ensures dry and wet spent grains used for animal food are regulated equally under FSMA. The enacted FY2016 appropriation also provides $5 million for competitive grants to state agencies for local educational agencies and

[22] CRS communication with FDA budget staff, December 4, 2015.

[23] These program areas include portions of the budgets for the Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine, the Office of Veterinary Medicine, and the National Center for Toxicological Research.

[24] HHS, "Fiscal Year 2016, Food and Drug Administration, Justification of Estimates for Appropriations Committees," p. 27, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf. Reflects all proposed fees for the Foods program. Another $26.6 million from proposed fees would be available for HQ staff, rent, and other rent activities.

[25] For example, see letters dated September 2, 2015, from Representatives DeLauro and Farr to HHS and OMB, as well as letters dated August 27, 2014 (also 2014 press release "Representatives DeLauro, Farr Call on OMB and HHS to Nix User Fees and Fully Fund FSMA Implementation," August 2014).

[26] See letter dated August 26, 2015, to HHS and OMB from 65 trade associations, including the American Frozen Food Institute, the Grocery Manufacturers Association (GMA), the Food Marketing Institute, and the National Association of Manufacturers.

[27] Division A, §750.

schools to purchase equipment to serve healthier meals and improve food safety, among other goals.[28]

In addition, both the House and Senate committee reports include a number of provisions requiring FDA to take certain additional food safety actions and other related activities.[29] For example, both House and Senate appropriators make a number of recommendations regarding FSMA and FDA's ongoing efforts to develop regulations and guidance pertaining to the various provisions of the law. Both committee reports include language regarding FDA's Food Safety Centers of Excellence in supporting FSMA implementation, and also broadly encourage FDA to form partnerships under FSMA. The House committee reports would provide $2.5 million for FSMA implementation and interagency coordination between FDA and USDA's National Institute for Food and Agriculture (NIFA). Both committees also express concerns about the FSMA rulemaking process and potential economic impacts. For example, the Senate committee report expresses concerns about how FDA will determine whether and to what degree a farm or food business is subject to FSMA regulation. Both committees include language regarding the FDA's scientific integrity policy and scientific study data. The House committee report reminds FDA to submit required reports on schedule and to submit overdue scheduled reports. The inclusion of these provisions reflect a range of concerns that have been expressed by Members of Congress as FDA has developed regulations under FSMA, as well as concerns about extensive delays in FDA's rulemaking and implementation of FSMA.[30]

The enacted FY2016 appropriation contains a number of provisions related to fish and seafood labeling and safety. It clarifies that the term "Alaskan pollock" or "Alaska pollock" refer solely to fish harvested in the state waters or Alaska or in adjacent areas as defined in law.[31] Both the House and Senate reports had directed FDA to expedite consideration of whether it is appropriate to change the nomenclature on the Seafood List from "Alaska pollock" to "pollock," given ongoing concerns about misleading FDA labeling that allows pollock sourced from Russia or Korea to be sold as Alaskan pollock.[32]

Separately, the enacted law directs FDA to "not allow the introduction or delivery for introduction into interstate commerce of any food that contains genetically engineered salmon until FDA publishes final labeling guidelines for informing consumers of such content."[33] It directs FDA to spend "not less than $150,000" to "develop labeling guidelines" and "implement a program" to inform consumers whether salmon for sale is genetically engineered. This provision pertains to actions recently taken by FDA, approving a new animal drug application concerning a genetically engineered Atlantic salmon (AquAdvantage salmon).[34] The Senate report contains a series of

[28] Division A, §741.

[29] As noted in the explanatory text of the omnibus FY2016 act (Division A, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2016), "The explanatory text is silent on provisions that were in both the House Report (H.Rept. 114-205) and Senate Report (S.Rept. 114-82) that remain unchanged by this agreement, except as noted in this explanatory text" (p. 1).

[30] For more information, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

[31] Division A, §766.

[32] For more information, see, for example, press release from Representative Don Young, October 22, 2015, http://donyoung.house.gov/news/documentsingle.aspx?DocumentID=398499.

[33] Division A, §761.

[34] For more information, see CRS Report R43518, *Genetically Engineered Salmon*, and also FDA's website, http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm.

provisions related to seafood safety and directs FDA to publish updated advice to pregnant women on seafood consumption.[35] The Senate report further encourages FDA to address seafood economic integrity issues, particularly with respect to mislabeling of species, weights, and treatment.[36]

The enacted appropriation did not include a policy rider seeking to preempt or delay state laws that require mandatory on-package labeling of foods containing genetically engineered ingredients. The possible inclusion of such a provision in the omnibus was widely circulated in a series of press reports.[37] The Coalition for Safe Affordable Food, an industry coalition led by the Grocery Manufacturers Association (GMA), had supported the inclusion of language in the omnibus that would address state laws regarding such labeling,[38] consistent with provisions contained in a voluntary labeling bill, H.R. 1599, that would preempt current and future state laws from requiring mandatory labeling of genetically engineered foods.[39] H.R. 1599 passed the U.S. House of Representatives in July 2015. To date, a reported 30 states have introduced bills to label genetically engineered foods, including Maine, Vermont, and Connecticut. Some groups, such as the Center for Food Safety, have opposed legislative efforts to block states from implementing food labeling laws regarding genetically engineered ingredients.[40]

The Senate committee report also encourages FDA to resolve a dispute between the United States and the European Union over sanitation protocols on U.S. molluscan shellfish to expedite its audit of growing areas in Europe and to seek equivalency in sanitary standards to address ongoing trade concerns. The House committee further addresses illnesses associated with imported pet food, given FDA's estimate of approximately 5,000 reports (dating back to 2007) of pet illnesses, including pet deaths, which may be related to consumption of jerky treats. Many attribute these concerns to jerky pet treats imported from China.[41] House appropriators are asking FDA to provide a summary of all activities associated with the agency's ongoing investigation and requesting semi-annual reports on the status of its investigation. House appropriators further direct FDA to work with local governments at high-volume ports of entry to develop processes to reduce the risk of foodborne illnesses and support the capacity of local officials in dealing with foodborne threats.

[35] FDA recently published draft updated advice on fish consumption. See FDA, "FDA and EPA Issue Draft Updated Advice for Fish Consumption," FDA News Release, June 10, 2014.

[36] For more information on food fraud, see CRS Report R43358, *Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients* and CRS Report RL34124, *Seafood Fraud*.

[37] See, for example, articles from *Food Chemical News*: "Critics of GMO Labeling Rider Oppose Its Inclusion in Omnibus Spending Bill" (November 25, 2015); "No DARK Act Policy Rider, Groups Tell Congress" (December 4, 2015); "Food Industry Presses Congress for GMO Labeling Solution" (December 7, 2015); "Senate Democrat Warns Against GMO Label Rider" (December 9, 2015).

[38] See also letter from the Coalition for Safe Affordable Food to Members of Congress, December 4, 2015.

[39] For more information, see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*.

[40] J. Carman, "US Congress Blocks GMO Labeling DARK Act," *Sustainable Pulse*, December 16, 2015; and Food and Water Watch press release, "Wins and Losses: What the Omnibus Means for Our Food and Water," December 16, 2015. Opponents of such labeling efforts often refer to efforts to preempt or delay state laws as "Denying Americans the Right to Know" or "DARK Act."

[41] For more information, see FDA's "Questions and Answers Regarding Jerky Pet Treats" (http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm295445.htm) and status of FDA's investigation (http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm360951.htm).

Selected Other Policy Provisions

The enacted FY2016 Agriculture appropriation contains a number of other policy riders for a range of programs related to FDA's Foods program. Not all of these provisions are directly related to FDA's food safety activities; some involve other FDA food programs. For example, the enacted law prevents the use of any funds to implement the 2015 "Dietary Guidelines for Americans" unless USDA and the Department of Health and Human Services (HHS) comply with specified requirements.[42] Also, USDA is directed to engage the National Academy of Medicine to conduct a comprehensive study and to establish an advisory committee to further examine the issue.[43]

In addition, the enacted FY2016 appropriation prevents any funds from being used to implement policies "that would require a reduction in the quantity of sodium contained in federally reimbursed meals, foods, and snacks sold in schools" below a certain level set in regulation.[44] Both committee bills expressed concerns about FDA's "continued focus on voluntary sodium reductions and recommendations to remove the Generally Recognized as Safe (GRAS) status of sodium."[45] The appropriation also allows states to grant exemption to schools from certain whole grain requirements that took effect in July 2014.[46] The enacted law also prevents any funds from being used to enforce FDA's final regulations regarding restaurant menu labeling until a later specified date.[47] The enacted law further states that no partially hydrogenated oils (PHOs) shall be deemed unsafe or adulterated until FDA's formal phase-out starting in June 2018.[48] This provision reflects concerns expressed by the House committee about FDA's recent determination that PHOs are no longer considered GRAS.[49] The Senate committee report further expresses concern that FDA has not published the results of its study of consumer responses to nutrition labeling regarding added sugars.

Food Safety and Inspection Service

The enacted FY2016 Agriculture appropriation provides $1.015 billion to FSIS for FY2016, slightly more than the Administration's request of $1.012 billion but less than that enacted for FY2015 (**Table 1**). Appropriations would be augmented by existing (currently authorized) user fees that FSIS estimates to be nearly $180 million per year.[50] FSIS appropriations are divided into various subaccounts, and the enacted FY2016 appropriation provides for the following amounts: Federal ($898.8 million); State ($61.0 million); International Inspection ($16.7 million); Codex Alimentarius ($3.8 million); and the Public Health Data Communications Infrastructure System ($34.6 million). The enacted law does not include the Administration's reproposed user fee of $4

[42] Division A, §734. For more general information on the dietary guidelines, see CRS In Focus IF10118, *The Dietary Guidelines for Americans*.

[43] Division A, §735.

[44] Division A, §733(b).

[45] H.Rept. 114-205, S.Rept. 114-82. The committees would have also required FDA, in coordination with the Centers for Disease Control and Prevention (CDC), to study the matter further.

[46] Division A, §733(a).

[47] Division A, §747. FDA's final regulation is at 79 *Federal Register* 230: 71156-71259, December 1, 2014.

[48] Division A, §754. FDA's notice is at 80 *Federal Register* 116: 34650-34670, June 17, 2015.

[49] H.R. 3049, §751 (also H.Rept. 114-205).

[50] From recent FSIS congressional budget justifications (http://www.obpa.usda.gov/explan_notes.html). Reflects total non-federal funds, including fees for meat, poultry, and egg products inspection; fees for cost of national laboratory accreditation programs; and trust funds.

million to cover additional inspection costs associated with performance issues at inspected facilities.

Selected Food Safety Provisions

The enacted FY2016 Agriculture appropriation directs FSIS to continue to implement the catfish inspection program, as required under the 2014 farm bill (P.L. 113-79, §12106).[51] The agency promulgated final regulations in December 2015 and is expected to begin to implement the new rule starting in March 2016.[52] The explanatory text of the omnibus provides $2.5 million for FSIS to implement the program, as proposed in the Administration's budget.

In addition, both House and Senate committee reports include a number of provisions requiring FSIS to take certain additional food safety actions and other related activities.[53] The House report expresses concern about countering economic fraud and improving the safety of the U.S. seafood supply. Both committees encourage FSIS and USDA research agencies to support developing technologies that will provide rapid, portable, and easy-to-use screening of seafood at ports and at wholesale and retail locations. The House committee report further encourages innovation and modernization at slaughter and processing establishments regarding water-conserving technologies for hand-washing facilities. The Senate committee report directs FSIS to submit a report on its recruitment of inspection program personnel.

Consistent with provisions contained in previous appropriation bills, the enacted law requires that FSIS have no fewer than 148 FTEs dedicated to the inspection and enforcement of the Humane Methods of Slaughter Act (HMSA). The Senate committee report further directs FSIS to ensure compliance with humane handling rules for live animals and to continue to provide certain annual reports to Congress.

Selected Other Policy Provisions

The enacted FY2016 Agriculture appropriation contains a number of policy riders regarding related USDA programs. It repeals mandatory country-of-origin-labeling (COOL) requirements for certain beef and pork products, following a recent World Trade Organization (WTO) dispute panel ruling siding with Canada and Mexico that could impose retaliation measures costing the United States more than $1 billion annually.[54] COOL requirements for poultry, lamb, fish, and fruit, vegetables, and nuts were not repealed. The enacted appropriation further states that "none of the funds" may be used for horse slaughter and inspection under the Federal Meat Inspection Act.[55] It also prevents the use of funds to purchase imported processed poultry products from

[51] Division A, §755. The catfish inspection program was originally transferred from FDA to FSIS in the 2008 farm bill (P.L. 110-246, §11016). The 2014 farm bill (P.L. 113-79; §12106) reconfirmed this provision.

[52] 80 *Federal Register* 231: 75590-75630, December 2, 2015.

[53] As noted in the explanatory text of the omnibus FY2016 act (Division A, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2016), "The explanatory text is silent on provisions that were in both the House Report (H.Rept. 114-205) and Senate Report (S.Rept. 114-82) that remain unchanged by this agreement, except as noted in this explanatory text" (p. 1).

[54] Division A, §759. For more information, see CRS Report RS22955, *Country-of-Origin Labeling for Foods and the WTO Trade Dispute on Meat Labeling*.

[55] Division A, §767. Previous FY2006 and FY2007 enacted appropriations prohibited FSIS from paying salaries and expenses for horse slaughter inspections. In addition, from FY2008 to FY2011 and FY2014 to FY2015, enacted appropriations also banned voluntary, fee-based horse slaughter inspections. Horse slaughter inspection bans were not in force during FY2012 and FY2013, but no horse slaughter facilities opened before the ban was reinstated in FY2014. For other information, see CRS Report RS21842, *Horse Slaughter Prevention Bills and Issues*.

China for use in the U.S. school lunch program and other feeding programs because of ongoing concerns about China's food safety programs.[56]

The enacted law also includes some other provisions that had been part of the House and Senate committee bills regarding USDA's rules governing the importation of beef from certain regions of Argentina and Brazil.[57] Specifically, it includes language requiring USDA's Animal and Plant Health Inspection Service (APHIS) to "establish a prioritization process for APHIS to conduct audits or reviews of countries or regions that have received animal health status recognitions by APHIS," among other requirements.[58]

President's Proposal: Single Food Safety Agency

The enacted FY2106 Agriculture appropriation does not address the proposal in the Administration's FY2016 budget request to establish a single food agency to provide "focused, centralized leadership, a primary voice on food safety standards, and clear lines of responsibility and accountability that will enhance both prevention of and responses to outbreaks of foodborne illnesses." The Administration's proposal would transfer existing food safety functions into a new agency within HHS. This proposal differs from legislation introduced in the 114th Congress as part of the Safe Food Act of 2015 (H.R. 609/DeLauro; S. 287/Durbin). H.R. 609 and S. 287 would create a single independent Food Safety Administration (FSA) by transferring and consolidating the food safety authorities at FDA and USDA, as well as portions of agencies under the Department of Commerce. Some groups who have traditionally favored the creation of a single food safety agency oppose the Administration's plan because it calls for consolidation of food safety operations within HHS. Some contend HHS does not have the necessary expertise or adequate resources to manage an expanded food safety function; others claim USDA has a better record regarding food safety inspection and enforcement and worry that transferring these functions to HHS will lower standards for meat and poultry inspection.[59] In general, large-scale reorganization of existing agencies is under the jurisdiction of the authorizing committees.

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[56] Division A, §730. For more information, see letter from several Members of Congress to congressional appropriators, http://delauro.house.gov/images/pdf/food_safety_chinese_chicken_letter.pdf.

[57] Committee-reported bills H.R. 3049, §749, and S. 1800, §743.

[58] Division A, §752.

[59] "Obama Proposes Single Food Agency, But Consumer Groups Oppose It," *Hagstrom Report*, February 2, 2015.