

# FY2020 and FY2021 Agriculture Appropriations: Federal Food Safety Activities

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## FY2020 and FY2021 Agriculture Appropriations: Federal Food Safety Activities

Various federal, state, and local jurisdictions share responsibility for the safety of the U.S. food supply. Federal regulation of food safety primarily rests with two agencies—the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) and the U.S Department of Health and Human Service's Food & Drug Administration (FDA). FSIS is responsible for ensuring the safety of most meat, poultry, and processed egg products. FDA's Foods Program, which represents about one-third of FDA's total budget, is responsible for ensuring the safety of the majority of other domestic and imported food products.

#### **SUMMARY**

#### R46851

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The Agriculture appropriations bill—formally known as the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act—funds FDA and USDA food safety activities. Congress enacted FY2020 Agriculture appropriations in the Further Consolidated Appropriations Act, 2020 (P.L. 116-94, Division B) in December 2019. In December 2020, Congress enacted FY2021 Agriculture appropriations in the Consolidated Appropriations cycles, Congress passed two Coronavirus Disease 2019 (COVID-19) relief bills that augmented FSIS meat and poultry processing inspections—the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136) in March 2020 and the American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) in March 2021.

FSIS annual appropriations totaled \$1,054 million in FY2020 and \$1,076 million in FY2021. The agency received an additional \$33 million from the CARES Act to support its meat, poultry, and egg inspection programs. ARPA provided FSIS with \$100 million to offset the cost to small and very small meat, poultry, and egg processors of overtime inspection fees during the COVID-19 pandemic.

FDA's Foods Program received appropriations of \$1,088 million in FY2020 and \$1,099 million in FY2021. These funds are divided between the Center for Food Safety and Applied Nutrition (CFSAN) and field activities. In 2011, Congress enacted the FDA Food Safety Modernization Act (FSMA; P.L. 111-353); since 2011, the appropriations for FDA's Foods Program have increased by roughly 55%, adjusted for inflation. FSMA was the largest expansion of FDA's food safety authorities since the 1930s, and as such, FDA continues to its efforts to implement the law and its regulations. The increased authority and funding is in recognition that over the past few decades, FDA has had to adapt to the increasing variety and complexity of the U.S. food supply, including rising demand for products produced outside the United States, as well as developments such as emerging microbial pathogens, natural toxins, and technological innovations in production and processing.

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ederal regulation of food safety primarily rests with two agencies—the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) and the U.S Department of Health and Human Service's (HHS's) Food & Drug Administration (FDA). FSIS is responsible for ensuring the safety of most meat, poultry, and processed egg products. FDA's Foods Program, which represents about one-third of FDA's total budget, is responsible for ensuring the safety of the majority of other domestic and imported food products. The Agriculture appropriations bill—formally known as the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act—funds FDA's Foods Program and FSIS.

Congress enacted FY2020 Agriculture appropriations in the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) in December 2019. For FY2021, Congress enacted Agriculture appropriations in the Consolidated Appropriations Act, 2021 (P.L. 116-260) in December 2020. The House Appropriations Committee reported an Agriculture appropriations bill (H.R. 7610, H.Rept. 116-446); the Senate Appropriations Committee released a draft measure and explanatory statement in November 2020.

In addition to setting budgetary amounts, Agriculture appropriations bills include policy-related provisions that direct how the executive branch should carry out a specific appropriation. Both the House and the Senate appropriations committees reported Agriculture appropriations bills for FY2020 (H.R. 3164, S. 2522), as well as separate committee reports (H.Rept. 116-107 and S.Rept. 116-110).<sup>1</sup> These provisions have the force of law if they are included in the text of the appropriation, but their effect is generally limited to the fiscal year indicated.

The explanatory statement that accompanies the final appropriation, and the House and the Senate report language that accompanies the committee-reported bills, also provides policy instructions. These documents do not have the force of law but often explain congressional intent, which the agencies are expected to follow. The committee reports and explanatory statement may need to be read together to capture all of the congressional intent for a given fiscal year.

Beyond the regular appropriations, Congress passed Coronavirus Disease 2019 (COVID-19) relief bills that augmented FSIS meat and poultry processing inspections in response to the disruptive effects of COVID-19 on meat and poultry inspection operations.

This report provides a brief overview of the FY2020 and FY2021 appropriations that address food safety activities at FDA and FSIS,<sup>2</sup> as well as additional funding for FSIS for meat and poultry inspection-related activities in response to the COVID-19 pandemic. It does not specifically address funding levels for other federal agencies or other USDA agencies that may play a role in ensuring the safety of the nation's food supply.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> For the Senate Appropriations Committee FY2021 subcommittee drafts, see U.S. Senate Committee on Appropriations, "Committee Releases FY21 Bills in Effort to Advance Process, Produce Bipartisan Results," press release, November 10, 2020, at https://www.appropriations.senate.gov/news/committee-releases-fy21-bills-in-effort-to-advance-process-produce-bipartisan-results.

<sup>&</sup>lt;sup>2</sup> For further analysis of appropriations for agriculture, see CRS Report R45974, *Agriculture and Related Agencies: FY2020 Appropriations*; and CRS Report R46437, *Agriculture and Related Agencies: FY2021 Appropriations*.

<sup>&</sup>lt;sup>3</sup> For example, the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service oversees animal and plant health, including preventing the introduction of foreign diseases and pests. USDA's Agricultural Marketing Service establishes quality and marketing grades and standards for a range of agricultural products. USDA's research agencies also are involved in food safety, providing federal funding and collaborating with universities and research institutions.

## **Federal Food Safety Activities**

Various federal, state, and local jurisdictions share responsibility for the safety of the U.S. food supply.<sup>4</sup> Federal regulation of food safety primarily rests with two agencies—USDA's FSIS and HHS's FDA. FSIS is authorized to regulate the safety of meat, poultry, catfish, and egg products through the Federal Meat Inspection Act (FMIA, 21 U.S.C. §601 et seq.), Poultry Products Inspection Act (21 U.S.C. §451 et seq.), and Egg Products Inspection Act (21 U.S.C. §1031 et seq.). FSIS conducts continuous inspections of regulated domestic facilities to ensure that meat, poultry, and egg products are safe, unadulterated, and properly labeled; the agency conducts regular, periodic inspections of imported meat, poultry, and egg products for the same purpose.

FDA is responsible for ensuring the safety of foods not covered by FSIS. This includes edible crops, manufactured foods, and food ingredients. Appropriations for FDA's Foods Program provide funding for all food activities, including food safety—implemented by the Center for Food Safety and Applied Nutrition (CFSAN)—as well as food-related field activities, such as inspections and investigations, conducted by the Office of Regulatory Affairs (ORA).<sup>5</sup> FDA's food safety authorities rest primarily in the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.), as amended including by the FDA Food Safety Modernization Act (FSMA; P.L. 111-353).

FSIS received \$1,054 million in discretionary appropriations for FY2020 and \$1,076 million for FY2021. Enacted discretionary appropriations for FDA's Foods Program totaled \$1,088 million for FY2020 and \$1,099 million for FY2021. This funding distribution reflects greater increases in congressional appropriations for FDA compared with FSIS since FY2011 (**Table 1** and **Figure 1**). The increase in funding is due to the enactment of FSMA, which ushered in FDA's largest expansion of food safety regulations since the 1930s.

<sup>&</sup>lt;sup>4</sup> For more information, see CRS Report RS22600, The Federal Food Safety System: A Primer.

<sup>&</sup>lt;sup>5</sup> For U.S. Food & Drug Administration (FDA) FY2020 and FY2021 Budget Authority crosswalk documents, see https://www.fda.gov/about-fda/reports/budgets.

	USDA FSIS		HHS FD	A Foods Program
Year	FTEs	Appropriation (\$ millions)	FTEs	Appropriation (\$ millions)
FY2011	9,465	١,007.١	3,605	836.2
FY2012	9,35 I	١,004.8	3,611	866.1
FY2013	9,158	975.3	3,642	796.6
FY2014	8,933	1,005.0	3,650	900.3
FY2015	8,938	1,018.9	3,667	903.4
FY2016	9,160	1,025.6	3,841	998.3
FY2017	9,243	١,040.3	3,905	1,025.5
FY2018	8,902	1,056.8	3,861	١,059.3
FY2019	8,507	1,049.3	3,758	١,059.9
FY2020	8,107	I,054.3	3,816	I ,087.2
FY2021ª	9,075	1,075.7	3,838	١,099.2

#### Table 1. FSIS and FDA Appropriations, FY2011-FY2021

**Sources:** CRS, from enacted appropriations and annual agency budget justifications for the U.S. Food & Drug Administration (FDA). See FDA, "Budgets," at https://www.fda.gov/about-fda/reports/budgets; and U.S. Department of Agriculture (USDA), Office of Budget & Program Analysis, "Congressional Justifications: Archived USDA Explanatory Notes," at https://www.usda.gov/obpa/congressional-justifications.

**Notes:** FTEs = Full-Time Equivalents (federal employees); FSIS = Food Safety and Inspection Service; HHS = U.S. Department of Health and Human Services. Reductions in FY2013 appropriations represent each agency's FY2013 sequestration operating plans. Figures are rounded and are not adjusted for inflation.

a. Data for FY2021 are as enacted. All other figures are actual.



#### Figure 1. FSIS and FDA Appropriations, FY2011-FY2021

**Source:** CRS, using data from the U.S. Food & Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) (see **Table 1**).

User fees—generated when regulated industries pay for certain activities—provide funding to supplement FDA and FSIS discretionary appropriations. Activities such as export certifications and reinspections may generate user fees for FDA's Foods Program. Enacted user fees for FDA's Foods Program have been approximately \$11 million annually since 2016 (**Table 2, Figure 2**). Overtime and holiday user fees for inspections of regulated egg, poultry, and meat processing facilities, as well as user fees for voluntary inspections (collected as FSIS trust funds), provide supplemental funding to regular appropriations.<sup>6</sup>

Year	USDA FSIS User Fees (\$ millions)	HHS FDA Foods Program User Fees (\$millions)
2011	77	0
2012	182	27
2013	211	17
2014	203	17
2015	215	10
2016	259	11
2017	247	11
2018	234	11
2019	235	11
2020	269	11
2021	245	11

#### Table 2. FSIS and FDA User Fees, FY2011-FY2021

**Source:** CRS, from enacted appropriations and annual agency budget justifications for the U.S. Food & Drug Administration (FDA). See FDA, "Budgets," at https://www.fda.gov/about-fda/reports/budgets; and U.S. Department of Agriculture (USDA), Office of Budget & Program Analysis, "Congressional Justifications: Archived USDA Explanatory Notes," at https://www.usda.gov/obpa/congressional-justifications.

**Notes:** Data for 2016-2020 USDA FSIS User Fees are actual figures as reported by the agency. All other figures are enacted.

<sup>&</sup>lt;sup>6</sup> Voluntary inspections are services the Food Safety and Inspection Service (FSIS) is not required by law to perform, but processors may want to participate in such inspections for marketing or other purposes, including export certificates. See FSIS, "Voluntary Reimbursable Inspection Services - Revision 1 Amendment 2," at https://www.fsis.usda.gov/policy/fsis-directives/12600.1.



**Source:** CRS, using data from the U.S. Food & Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) (see **Table 2**).

## Food Safety and Inspection Service: Food Safety Activities

FSIS is responsible for inspecting U.S. supplies of meat, poultry, catfish, and processed egg products to ensure that they are safe, unadulterated, and properly labeled.<sup>7</sup> The FSIS Meat and Poultry Inspection Program conducts continuous inspections at domestic meat and poultry plants and ensures that state inspection programs have standards that are at least equivalent to federal standards. FSIS's Egg Products Inspection Program ensures that liquid, frozen, and dried egg products are safe, unadulterated, and properly labeled. In addition, FSIS inspects U.S. imports of meat, poultry, and egg products and ensures that they are produced under standards equivalent to U.S. standards.

### FY2020 and FY2021 Appropriations: Selected FSIS Provisions

FSIS discretionary appropriations amounted to \$1,054 million in FY2020 and \$1,076 million in FY2021, divided among four main subaccounts: federal inspections, international inspections, state inspections, and Public Health Data and Communication Infrastructure System (PHDCIS, **Table 3**). In addition to inspecting domestic meat, poultry, catfish, and processed egg product

<sup>&</sup>lt;sup>7</sup> FSIS is authorized to conduct inspections under the Federal Meat Inspection Act (21 U.S.C. §601 et seq.), Poultry Products Inspection Act (21 U.S.C. §451 et seq.), Egg Products Inspection Act (21 U.S.C. §1031 et seq.), and Humane Methods of Slaughter Act (7 U.S.C. §1901 et seq.). The 2008 farm bill (P.L. 110-246, §11016) and the 2014 farm bill (P.L. 113-79, §12106) authorize FSIS to inspect Siluriformes (catfish) under the Federal Meat Inspection Act (FMIA).

facilities, FSIS also performs audits of foreign country inspection systems to ensure compliance with USDA's regulatory requirements. State inspectors perform meat, poultry, catfish, and processed egg product inspections under a cooperative agreement with FSIS.<sup>8</sup> PHDCIS provides assistance for detecting, alerting, or blocking cyberattacks from domestic and foreign entities.<sup>9</sup> Appropriations for FSIS increased by approximately 26% from 2011 to 2021, adjusted for inflation.<sup>10</sup>

Compared with FY2020, FY2021 FSIS appropriations increased by roughly \$22 million, or 2%. This increase includes \$4.5 million for consumer safety inspector (CSI) reclassification from the GS-8 to the GS-9 full performance level.<sup>11</sup> According to USDA, reclassification of the CSI to the GS-9 full performance level is to enable FSIS to more effectively and efficiently accomplish the mission and manage its workforce. Another \$1 million is allocated to offset inspector overtime costs for the inspection of certain wild caught invasive catfish species.<sup>12</sup>

	FY2020	FY2021
FSIS Subaccount	(\$ millions)	(\$ millions)
Federal inspections	936	957
State inspections	67	67
International inspections	17	17
PHDCIS	34	34

#### Table 3. FY2020 and FY2021 Appropriations for FSIS Subaccounts

Source: CRS, using FY2020 and FY2021 joint explanatory statements.

Notes: PHDCIS = Public Health Data and Communication Infrastructure System. Figures are rounded.

Language in the enacted FSIS FY2020 and FY2021 appropriations—along with directives in the joint explanatory statements—address numerous concerns, including restrictions on poultry imports from China, horse slaughter, and Brazilian raw beef imports.

Congress prohibits the use of Chinese poultry products in the school lunch and other federal nutrition programs.<sup>13</sup> The enacted FY2020 and FY2021 appropriations also prevent FSIS from using funds to finalize the proposed rule entitled "Eligibility of the People's Republic of China (PRC) to Export to the United States Poultry Products from Birds Slaughtered in the PRC" unless USDA takes additional steps to ensure the equivalence of China's poultry slaughter inspection system with the U.S. system, among other requirements.<sup>14</sup> Given continued concerns about

<sup>&</sup>lt;sup>8</sup> Under the cooperative agreement, FSIS covers 50% of the costs for state inspection and 60% for inspections under the Cooperative Interstate Shipment program.

<sup>&</sup>lt;sup>9</sup> See USDA, 2021 USDA Budget Explanatory Notes-Food Safety and Inspection Service, at https://www.usda.gov/ sites/default/files/documents/food-safety-fsis-fy2021-congressional-justification.pdf (hereinafter 2021 USDA Budget Explanatory Notes-FSIS).

<sup>&</sup>lt;sup>10</sup> Inflation was calculated using the 2012 GDP (chained) price index and data from **Table 1**. See White House, "Table 10.1—Gross Domestic Product and Deflators Used in the Historical Tables: 1940–2026," at https://www.whitehouse.gov/omb/historical-tables/.

<sup>&</sup>lt;sup>11</sup> For more information on consumer safety inspectors conversion, see 2021 USDA Budget Explanatory Notes-FSIS.

<sup>&</sup>lt;sup>12</sup> Consolidated Appropriations Act, 2021 (P.L. 116-260), p. H7885.

<sup>&</sup>lt;sup>13</sup> See the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), §738; P.L. 116-260, §737; Richard B. Russell National School Lunch Act (42 U.S.C. §1751 et seq.) and §17 (42 U.S.C. §1766) and §13 (42 U.S.C. §1761) of such act; and the school breakfast program under the Child Nutrition Act of 1966 (42 U.S.C. §1771 et seq.).

<sup>&</sup>lt;sup>14</sup> P.L. 116-94, §741. Also see FSIS, "Eligibility of People's Republic of China (PRC) to Export to United States

China's poor food safety record, Congress has added this provision to enacted appropriations bills since FY2015.

The enacted FY2020 and FY2021 FSIS appropriations also include restrictions on horse slaughter. FSIS is prohibited from using funds to pay for the salaries or expenses of personnel conducting equine slaughter inspections or enforcement activities.<sup>15</sup> Horses are an amenable species under the FMIA, and FSIS is responsible for horse slaughter inspection if the horsemeat is for human consumption.<sup>16</sup> Under this funding restriction, FSIS also is not permitted to operate a fee-for-service program for the inspection of horses for human consumption. Thus, appropriation language preventing FSIS inspection and enforcement activities relating to horsemeat means that it cannot be legally processed for human consumption.

Several Members of Congress have raised concerns over the safety of Brazilian raw beef imports. In 2017, USDA halted the import of fresh beef from Brazil citing recurring safety concerns.<sup>17</sup> According to USDA, in March 2017, FSIS began inspecting 100% of Brazilian meat imports. Subsequently, from March to June 2017, FSIS refused entry to 11% of fresh beef from Brazil due to observations of poor sanitary conditions and animal health. A January 2020 FSIS audit found that Brazil had implemented corrective actions to address these deficiencies and by February 2020, FSIS had lifted the ban on Brazilian beef imports.<sup>18</sup> That same month, several Members of Congress sent a bipartisan letter to USDA raising concerns about Brazil's ability to uphold adequate food safety standards.<sup>19</sup> The FY2021 appropriation directs FSIS to issue a report to Congress that identifies strategies the agency is using to ensure that Brazilian raw beef imports are meeting applicable U.S. standards.<sup>20</sup>

### **COVID-19 Relief Packages**

COVID-19 became a global pandemic in 2020. Outbreaks in meat and poultry processing facilities rapidly infected large numbers of workers, disrupting meat production and affecting retail meat supplies. Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136) in March 2020 to provide additional funds outside of the regular appropriations process. Among its provisions, FSIS received an additional \$33 million in supplemental funding to adjust how inspections are conducted due to the spread of COVID-19 in

Poultry Products from Birds Slaughtered in the PRC," 82 *Federal Register* 27625, June 16, 2017, at https://www.govinfo.gov///content///pkg/FR-2017-06-16/pdf/2017-12554.pdf.

<sup>&</sup>lt;sup>15</sup> P.L. 116-94, §739; and P.L. 116-260, §795. Authorized under §3 of the Federal Meat Inspection Act (21 U.S.C. §603), §903 of the Federal Agriculture Improvement and Reform Act of 1996 (P.L. 104-127, 7 U.S.C. §1901 note), and 9 C.F.R. §352.19 (or a successor regulation).

<sup>&</sup>lt;sup>16</sup> Livestock products amenable to the Federal Meat Inspection Act are prepared from cattle, sheep, swine, goats, horses, mules, and other equines.

<sup>&</sup>lt;sup>17</sup> USDA, "Perdue: USDA Halting Import of Fresh Brazilian Beef," press release, June 22, 2017, at

https://www.usda.gov/media/press-releases/2017/06/22/perdue-usda-halting-import-fresh-brazilian-beef.

<sup>&</sup>lt;sup>18</sup> USDA, "FSIS Lifts Suspension on Brazil's Exports of Raw Intact Beef Products to the U.S.," press release, February 21, 2020, at https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-february-21-2020-0.

 <sup>&</sup>lt;sup>19</sup> Letter from Members of Congress to former USDA Secretary Sonny Perdue, February 28, 2020, at

https://www.tester.senate.gov/files/Letters/2.28.2020%20Letter%20re%20Brazilian%20Beef%20Ban.pdf.

<sup>&</sup>lt;sup>20</sup> Congress directs FSIS to provide the report on Brazilian beef imports no later than 120 days after enactment. It is unclear whether FSIS has provided this report to Congress. House debate, *Congressional Record*, vol. 166, book III (December 21, 2020), at https://www.govinfo.gov/content/pkg/CREC-2020-12-21/pdf/CREC-2020-12-21-house-bk3.pdf.

meat and poultry processing plants. FDA did not receive COVID-19 relief funding from the CARES Act geared toward food safety.<sup>21</sup>

The FY2021 appropriations act (Division N) also included funds for COVID-19 relief. Congress directed FSIS to make assistance grants that relieve costs incurred in making improvements to meat and poultry slaughter and processing facilities, such as equipment modernization, modernization or expansion of existing facilities, and compliance with safety requirements (including food safety).<sup>22</sup> FSIS is directed to report to Congress on all assistance grants made and on possible improvements to the cooperative interstate shipment programs. A total of \$60 million is provided to carry out these directives for FY2021 through FY2023, with the funds to remain available until expended.

Division N also provides FSIS with funding to conduct and provide to Congress a study on the availability and effectiveness of federal loan and grant programs established to support meat and poultry slaughter facilities.<sup>23</sup> FSIS is to publish for public distribution a list of all loan, loan guarantee, and grant programs identified in the report. A total of \$2 million is appropriated to fulfill these directives.

Congress passed the American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) in March 2021. Under ARPA, USDA received \$100 million to reduce overtime inspection costs borne by federally inspected small and very small establishments engaged in meat, poultry, or egg products processing.<sup>24</sup>

## **FDA Food Safety Activities**

FDA's Foods Program budget accounts for roughly one-third of the agency's total appropriations. Since 2011, enacted appropriations for FDA's Foods Program increased by approximately 55% from 2011 to 2021, adjusted for inflation.<sup>25</sup> Increased funding between FY2011 to FY2021 followed the enactment of FSMA(P.L. 111-353), which included comprehensive food safety provisions. FSMA represented the largest expansion of FDA's food safety authorities since the 1930s. FDA continues to be engaged in implementing the law and its regulations.<sup>26</sup> This expansion is in response to the need for FDA to adapt to the increasing variety and complexity of the U.S. food supply in recent decades, including rising demand for products produced outside the United States, as well as emerging microbial pathogens, natural toxins, and technological innovations in production and processing.

<sup>&</sup>lt;sup>21</sup> P.L. 116-136; and P.L. 116-260, §2304 and p. 730.

<sup>&</sup>lt;sup>22</sup> P.L. 116-260, §764.

<sup>&</sup>lt;sup>23</sup> FSIS is to report to Congress on the results of this study to Congress no later than 60 days after enactment (roughly February 2021). It is unclear whether FSIS has met these directives. P.L. 116-260, §765.

<sup>&</sup>lt;sup>24</sup> P.L. 116-136, §1002(d).

<sup>&</sup>lt;sup>25</sup> Inflation was calculated using the 2012 GDP (chained) price index and data from **Table 1**. See White House, "Table 10.1—Gross Domestic Product and Deflators Used in the Historical Tables: 1940–2026," at https://www.whitehouse.gov/omb/historical-tables/.

<sup>&</sup>lt;sup>26</sup> Under the FDA Food Safety Modernization Act (FSMA; P.L. 111-353), FDA is responsible for more than 50 regulations, guidelines, and studies pertaining to food safety. For additional information, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

### FY2020 and FY2021 Appropriations: Selected FDA Provisions

FDA's Foods Program received \$1,088 million in FY2020 and \$1,099 million in FY2021, divided between CFSAN and ORA food-related field activities (**Table 4**). ORA receives approximately 70% of the funds Congress appropriates for the food program; however, some Members of the House Appropriations Committee have in recent years questioned ORA's use of funds to fulfill the prevention mandate of FDA's Foods Program.<sup>27</sup>

	_		
	Center for Food Safety and Applied Nutrition (CFSAN)	Office of Regulatory Affairs (ORA)	-
	Enacted Appropriation	Enacted Appropriation	FDA Foods Program Total
Fiscal Year	Enacted Appropriation (\$ million)	Enacted Appropriation (\$ million)	(\$ million)
FY2020	342	747	I,087
FY2021	344	755	۱,099

#### Table 4. Selected FDA Foods Program Appropriations for FY2020 and FY2021

**Sources:** CRS, from the FY2020 explanatory statement for Division B, at http://www.congress.gov/cgi-lis/ bdquery/z?d116:H.R.1865.See House Committee on Rules, *Division – Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2020: Congressional Directives,* at https://docs.house.gov/billsthisweek/20191216/BILLS-116HR1865SA-JES-DIVISION-B.pdf; and House debate, *Congressional Record,* vol. 166, book III (December 21, 2020), at https://www.congress.gov/116/crec/2020/12/21/ CREC-2020-12-21.pdf-bk3.

The FY2020 and FY2021 appropriations and directives in the joint explanatory statements address numerous concerns, including ongoing FSMA implementation, response capabilities for foodborne outbreaks, the National Antimicrobial Resistance Monitoring System (NARMS), and seafood safety.

As part of FSMA implementation, FDA's Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption (also known as the Produce Safety Rule, or PSR) establishes science-based minimum standards for safe on-farm production of fruits and vegetables grown for human consumption.<sup>28</sup> To implement the PSR, FDA has engaged in activities such as providing technical assistance, training, and guidance to farms, as well as conducting inspections to verify compliance.

To continue to facilitate FSMA implementation, the FY2020 appropriation directed CFSAN to fund, at least at the FY2019 level, food safety outreach to farmers that continued in 2020.<sup>29</sup> The

https://appropriations.house.gov/sites/democrats.appropriations.house.gov/files/HR%201865%20-

<sup>&</sup>lt;sup>27</sup> Letter from Rep. Rosa L. DeLauro and Rep. Sanford D. Bishop to Acting Commissioner Janet Woodcock, M.D., May 13, 2021, at

https://delauro.house.gov/sites/delauro.house.gov/files/documents/DeLauro%20Bishop%20Letter%20on%20FDA%20food%20ORA%20Budget.pdf.

<sup>&</sup>lt;sup>28</sup> For additional information, see CRS Report R46706, *Produce Safety: Requirements, Implementation, and Issues for Congress.* 

<sup>&</sup>lt;sup>29</sup> House Committee on Appropriations, Division – Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2020, p. 30, at

<sup>%20</sup>Division%20B%20-%20AG%20SOM%20FY20.pdf; and House debate, *Congressional Record*, vol. 166, book III, (December 21, 2020), p. H7892, at https://www.govinfo.gov/content/pkg/CREC-2020-12-21/pdf/CREC-2020-12-21-house-bk3.pdf.

FY2021 appropriation further directs FDA to continue working with small farms to clarify requirements for FSMA compliance and with states participating in the State Produce Implementation Cooperative Agreement Program (State CAP).<sup>30</sup> Congress also directed FDA to work with stakeholders on a wide-scale traceability system to help companies and government agencies more rapidly access data crucial to tracking foods implicated in disease outbreaks and subject to recalls.<sup>31</sup>

The enacted FY2020 and FY2021 appropriations prevent FDA from using funds to enforce FSMA produce safety standards on entities that grow, harvest, pack, or hold hops, wine grapes, pulse crops, or almonds.<sup>32</sup> PSR requirements generally apply to fruits and vegetables for human consumption intended to be eaten "raw" (i.e., in their natural form and not cooked or otherwise processed to control the growth of harmful bacteria). After the PSR went into effect in November 2015, producers of hops, wine grapes, pulse crops, and almonds argued that their products should be exempt from regulatory requirements because of the way they are processed and consumed. FDA considered the industry feedback and ultimately published guidance stating the agency's intent to exercise enforcement discretion for hops, wine grapes, pulse crops, and almonds.<sup>33</sup>

The FY2020 and FY2021 appropriations also address foodborne outbreaks. Congress provided \$8 million in FY2020 and \$1 million in FY2021 for strengthening FDA's foodborne outbreak response capabilities.<sup>34</sup> Additionally, both the House and Senate committee reports urge FDA to define *ready-to-eat (RTE) foods* in guidance to industry in a manner that aligns with FSIS's approach.<sup>35</sup> Congress also directed FDA to consider available listeriosis research and to work with the National Institute of Food and Agriculture in its efforts to address foodborne pathogens.<sup>36</sup>

NARMS is another system developed to monitor foodborne pathogens. It consists of a surveillance system operated through a collaboration among FDA, FSIS, and the Centers for Disease Control and Prevention (CDC) to provide information on whether bacterial resistance in the food chain is increasing or decreasing.<sup>37</sup> The system also informs collaborators on the effectiveness of interventions designed to limit the spread of resistance. NARMS works by tracking changes in the antimicrobial susceptibility of intestinal bacteria. Under NARMS, the CDC tracks this in ill persons, with FDA tracking retail meats and USDA tracking food animals in the United States.

 $https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/RTE-Processed-Products.pdf.$ 

<sup>&</sup>lt;sup>30</sup> House debate, *Congressional Record*, vol. 166, book III, (December 21, 2020). The State Produce Implementation Cooperative Agreement Program (State CAP) is a cooperative agreement between FDA and the National Association of State Departments of Agriculture to implement or enhance state and territory produce safety programs. For additional information, see CRS Report R46706, *Produce Safety: Requirements, Implementation, and Issues for Congress.* 

<sup>&</sup>lt;sup>31</sup> H.Rept. 116-107.

<sup>&</sup>lt;sup>32</sup> P.L. 116-94, §746; and P.L. 116-260, §741.

<sup>&</sup>lt;sup>33</sup> See FDA, "FDA In Brief: FDA announces enforcement discretion to accommodate unique circumstances faced by producers of hops, wine grapes, pulse crops and almonds while continuing to protect the public health," press release, March 27, 2020.

<sup>&</sup>lt;sup>34</sup> House Committee on Appropriations, *Division – Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act*, 2020, p. 29; and House debate, *Congressional Record*, vol. 166, book III (December 21, 2020), p. H7891.

<sup>35</sup> USDA, "Ready-to Eat (RTE) Processed Products FSA Tool VS2," at

<sup>&</sup>lt;sup>36</sup> H.Rept. 116-446 and S.Rept. 116-110.

<sup>&</sup>lt;sup>37</sup> FDA, "FDA Releases 2018 NARMS Integrated Summary and NARMS Now: Integrated Data Featuring Genomic Data and Predicted Resistance," press release, December 11, 2020, at https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-2018-narms-integrated-summary-and-narms-now-integrated-data-featuring-genomic-data-and.

Congress also addressed the safety of food imports in the FY2020 and FY2021 appropriations. According to FDA, the United States imports upwards of 94% of its seafood supply.<sup>38</sup> The FY2020 appropriation provides \$5 million toward the Imported Seafood Pilot program to enhance the detection of potentially hazardous seafood. The FY2021 appropriation provides FDA with \$6 million for a Shrimp Import Inspection Pilot program.<sup>39</sup> In the FY2020 and FY2021 appropriations, House and Senate committees provide a number of directives for FDA, including that the agency support increased inspections at land ports of entry along the U.S.-Mexico border, as well as improve import review and increase monitoring of imported foods with disproportionately higher violation rates than domestic products.<sup>40</sup>

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<sup>&</sup>lt;sup>38</sup> See FDA, "FDA Moves into Second Phase of AI Imported Seafood Pilot Program," press release, February 8, 2021.

<sup>&</sup>lt;sup>39</sup> House debate, Congressional Record, vol. 166, book III (December 21, 2020), p. H7891, at

https://www.govinfo.gov/content/pkg/CREC-2020-12-21/pdf/CREC-2020-12-21-house-bk3.pdf.

<sup>&</sup>lt;sup>40</sup> S.Rept. 116-110 and H.Rept. 116-446.