

AMENDMENTS TO THE AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RELATED AGENCIES
APPROPRIATIONS BILL FY2021

Full Committee Markup
House Appropriations Committee
July 9, 2020

#1
Adopted VV

**BISHOP #1
Agriculture**

HOUSE APPROPRIATIONS COMMITTEE

July 9, 2020

Fiscal Year 2021 Agriculture, Rural Development, Food and Drug Administration
and Related Agencies Bill

Manager's amendment

In the bill

On page 2, line 14, strike "\$47,366,000" and insert "\$47,638,000".

On page 2, line 17, strike "\$6,236,000" and insert "\$6,508,000".

On page 5, line 9, strike "\$88,126,000" and insert "\$73,354,000".

On page 8, line 8, strike "\$5,809,000" and insert "\$6,109,000".

On page 9, on line 10, strike "\$1,451,712,000" and insert "\$1,453,712,000".

On page 11, between line 6 and line 7, insert:

BUILDINGS AND FACILITIES

For the acquisition of land, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities as necessary to carry out the agricultural research programs of the Department of Agriculture, where not otherwise provided, \$11,200,000 to remain available until expended, to be allocated for ARS facilities co-located with university partners.

On page 20, line 19, strike "\$1,087,552,000" and insert "\$1,088,552,000".

On page 106, on line 18, insert the following:

Sec. XXX. The Secretary, acting through the Chief of the Natural Resources Conservation Service, may use funds appropriated under this Act for the Watershed and Flood Prevention Operations Program and the Watershed Rehabilitation Program carried out pursuant to the Watershed Protection and Flood Prevention Act (16 U.S.C. 1001 et seq.), and for the Emergency Watershed Protection Program carried out pursuant to section 403 of the Agricultural Credit Act of 1978 (16 U.S.C. 2203) to provide technical services for such programs pursuant to section 1252(a)(1) of the Food Security Act of 1985 (16 U.S.C. 3851(a)(1)), notwithstanding subsection (c) of such section.

Sec. XXX. (a) The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (Commissioner), shall explore and, if it determines to be feasible, implement a number a number of options for regulating the export of shrimp to the United States from other countries, such as sampling of products prior to export to the United States, increasing foreign inspections of export facilities, increased seafood importer inspections, foreign surveillance inspections at overseas manufacturing sites, enhanced import screening, higher rates of examination and sampling, use of third-party audits, and formal seafood arrangements with foreign competent authorities.

(b) The Commissioner shall especially consider the following: (1) that appropriate controls are applied to shrimp feed and production ponds, processing plants, and facilities throughout the chain of distribution to determine compliance with seafood safety requirements; (2) dedicate its inspectional effort to determine compliance with seafood arrangements, once established, from any dedicated funds; (3) provide an annual report to the Committee before the end of fiscal years 2021, 2022, and 2023 with the reporting requirement goal being to provide the Committee information related to FDA's oversight of the safety of shrimp products imported into the United States.

Sec. XXX. Section 7605(b) of the Agriculture Improvement Act of 2018 (7 U.S.C. 5940 note; Public Law 115-334) shall be applied by substituting "September 30, 2021" for "the date that is 1 year after the date on which the Secretary establishes a plan under section 297C of the Agricultural Marketing Act of 1946".

Sec. XXX. None of the funds made available by this or any other act may be used to restrict the offering of low-fat (1% fat) flavored milk in the

National School Lunch Program or School Breakfast Program, as long as such milk is not inconsistent with the most recent Dietary Guidelines for Americans published under section 301 of the National Nutrition Monitoring and Related Research Act of 1990.

Sec. XXX. The Commissioner of the Food and Drug Administration shall develop a plan within 180 days of enactment that would allow the Agency to identify, detain and refuse all FDA regulated products originating from foreign establishments that did not allow FDA investigators immediate physical access to the registered establishment and its records to determine a registered establishment's ongoing compliance with FDA laws and regulations. Any foreign establishment that meets these criteria may be placed on import alert. This import alert would be specific for this foreign establishment, focus on detaining all products from this establishment.

Sec. XXX. In administering the pilot program established by section 779 of division A of the Consolidated Appropriations Act, 2018 (Public Law 115-141), the Secretary of Agriculture may, for purposes of determining entities eligible to receive assistance, consider those communities which are "Areas Rural in Character": *Provided*, That not more than 10 percent of the funds made available by Section 772 may be used for this purpose.

Sec. XXX.-- Not later than 1 year after the date of enactment of this Act, the National Academy of Sciences, Engineering, and Medicine shall complete a review and provide a report to the Secretary of Agriculture, the Secretary of Health and Human Services, and the Congress, on the most recent edition of the dietary guidelines for Americans that includes the following:

(1) A comparative analysis of the scientific methodologies, review protocols, and evaluation processes used to develop the most recently issued guidelines as compared to recommendations included in the National Academy of Sciences, Engineering, and Medicine September 2017 report entitled "Redesigning the Process for Establishing the Dietary Guidelines for Americans".

(2) A comparative analysis of the scientific studies used to develop such guidelines to determine the dietary needs of Americans with diet-related metabolic diseases as compared to the most current and rigorous scientific studies on diet and diet-related metabolic diseases available.

(3) An analysis of how full implementation of the recommendations described in paragraph (1) would have affected the most recently issued guidelines.

In the report

On page 3, in the first paragraph under “Committee Provisions”, strike “\$47,366,000” and insert “\$47,638,000” and make conforming changes in the table.

On page 3, in the third paragraph under “Committee Provisions”, strike “\$6,236,000” and insert “\$6,508,000” and make conforming changes in the table; and at the end of that paragraph, add the following:

The Committee provides a total of \$1,000,000 for the Office of Tribal Relations.

On page 7, before the paragraph entitled “*National Finance Center*”, insert the following:

Lobsters.--The Committee is aware of the President’s memorandum on protecting the United States lobster industry, which is suffering from trade disruptions and the impact of COVID-19. The Committee directs the Secretary to review the memorandum and prioritize appropriate assistance to the lobster industry.”

On page 11, in the first paragraph under “Committee Provisions”, strike “\$88,126,000” and insert “\$73,354,000” and make conforming changes in the table.

On page 14, in the first paragraph under “Committee Provisions”, strike “\$5,809,000” and insert “\$6,109,000” and make conforming changes in the table on page 13.

On page 14, in the paragraph entitled “*Enhancing Land-Grant Coordination*”, strike “encourages” in the fifth line from the top and insert “provides \$300,000 for” and strike “universities” in the sixth and seventh lines from the top and insert “universities, including 1890 Institutions.”.

On page 17, in the first paragraph under “Agricultural Research Service, Salaries and Expenses”, strike “\$1,451,712,000” and insert “\$1,453,712,000” and make conforming changes in the table.

On page 19, in the paragraph entitled “*Cranberry Research*”, after the period insert the following:

In addition, the Committee provides an additional \$500,000 above the fiscal year 2020 level to address research challenges regarding disease control, growing productivity, and nutrient management.

On page 22, after the paragraph entitled “*Optimizing Facility Operations*”, insert the following:

Peanut Research.---The Committee provides an additional \$1,500,000 above the fiscal year 2020 level to support research activities to mitigate aflatoxin contamination in peanuts. The Committee directs ARS to enhance ongoing collaborations with land grant institutions to further advance research efforts.

On page 25, at the beginning of the first paragraph under “Committee Provisions” the first time it appears, insert the following and make conforming changes in the table:

The Committee provides \$11,200,000 for Buildings and Facilities.

On page 34, before the paragraph entitled “*Agriculture Quarantine Inspections*”, insert the following:

Agricultural Imports.---The Committee recognizes that there may be a need to update APHIS physical facilities, staff capabilities, and processes due to the increased volume of agricultural imports. The Committee requests a plan to address the needs of the programs, including steps to collaborate with stakeholders on supplemental inspection and pathogen identification services and to improve the transparency of the importation process.

On page 34, in the paragraph entitled “*Antimicrobial Resistance*”, strike “\$2,000,000,” and insert, “\$3,000,000”.

On page 41, after the second paragraph, insert the following:

Current Oversupply of Fresh Potatoes. —The committee encourages AMS to pursue purchases of fresh potatoes, including those that can also be used for processing and for frozen potato products.

On page 43, in the first paragraph under “Food Safety and Inspection Service” strike “1,087,552,000” and insert “1,088,552,000” and make conforming changes in the tables on pages 43 and 44.

On page 44, in the first paragraph under “Committee Provisions”, insert

, \$1,000,000 for the inspection of wild caught invasive species in the order siluriformes and family Ictaluridae, including blue catfish in the Chesapeake Bay,” after “investments”.

On page 57, in the paragraph entitled “*Placemaking: Revitalization of Rural Livable Places*”, strike “\$1,000,000,” and insert, “\$2,000,000”.

On page 64, in the paragraph entitled “*Technical Assistance and Training Grant Program*”, strike the last sentence and insert the following:

Up to \$5,000,000 of these resources shall be made available, on a competitive basis, to support the national apprenticeship/workforce development program to ensure a future pipeline of workers to provide clean and safe water for the public.

On page 67, before “*Public Release of Information*”, insert the following:

National Waivers.—The Committee urges the Secretary of Agriculture to issue a nationwide waiver as soon as possible that extends the current Area Eligibility and Non-Congregate Feeding waivers and allows school districts to use Summer Foodservice Program and the Seamless Summer Option regulations for the duration of the 2020-2021 school year.

On page 80, after the paragraph entitled “*Animal Drug Compounding*” insert the following:

Animal Health Products.— The Committee notes livestock and pets need innovative animal health products to address unmet health and nutrition needs and encourages the FDA Center for Veterinary Medicine to prepare ideas for modernizing the innovation review process in the next Animal Drug User Fee Act reauthorization.

On page 83, in the paragraph entitled “*COVID-19 Response*”, insert at the end of the paragraph:

The assessment shall also include a section regarding the Emergency Use Authorization (EUA) process for COVID-19 tests and how the agency prioritized the processing of the applications, the comprehensiveness of the diagnostic result, and existing FDA-approved methods.

On page 84, strike the paragraph entitled “*Drug Compounding and Revised Draft MOU*” and insert the following:

Drug Compounding and Final MOU.---The Committee recognizes the FDA recently finalized the MOU for pharmacy compounding. The

Committee requests that FDA engage further with stakeholders to address concerns and to ensure that all of nearly all states can sign this important document.

On page 85, in the paragraph entitled “*Foreign Unannounced Inspections Pilots*”, after “India” in the third line from the bottom insert “and establish an additional pilot in China” and strike “this pilot” in the last sentence and insert “these pilots”.

On page 90, after “consumers.” in the second line from the top, insert the following:

The Committee directs the Commissioner of the FDA to brief the Committee by December 31, 2020 on the status of the agency’s progress in developing a U.S. Standard of Identity for different grades of olive oil.

On page 92, in the paragraph entitled “*Safeguarding Pharmaceutical Supply Chains*”, strike “and” in the fifth line from the bottom and add:

, and (4) discussion of any differences between the FDA’s policy and that of the Customs and Border Protection on a requirement for drug companies to list active pharmaceutical ingredients and their countries of origin on labels of imported and domestically produced finished drug products.

On page 93, strike the paragraph entitled “*Sodium Reduction.*” and replace it with the following:

Sodium Reduction.—The Committee is aware that U.S. Food and Drug Administration (FDA) is in the process of issuing guidance regarding voluntary sodium reduction targets in foods. The Committee encourages FDA to publish an updated draft of the short-term guidance for a 30-day comment period prior to finalization. Furthermore, within 120 days of enactment, the Committee requests the FDA provide a status update to the Committee on the publication of the short-term Final Guidance to Industry For Voluntarily Reducing Sodium, first published as draft in the Federal Register on June 2, 2016 (81 Fed. Reg. 35363).

On page 98, after “broadband program.”, insert the following:

Sec. XXX. —The bill includes language related to watershed programs.

Sec. XXX.—The bill includes language related to shrimp exported to the United States.

Sec. XXX. —The bill includes language related to hemp.

Sec. XXX. —The bill includes language related to milk.

Sec. XXX. —The bill includes language related to FDA-regulated products

Sec. XXX. —The bill includes language related to the ReConnect program

Sec. XXX. —The bill includes language related to the Dietary Guidelines.

On page 105, on the seventh line, strike “Gonzalez-Colon” and insert “Gonzalez-Colon”.

#2

BISHOP #2

Adopted VV

Agriculture

AMENDMENT TO THE AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2021

OFFERED BY MR. BISHOP OF GEORGIA

At the end of the bill (before the short title), insert the following (and make such technical and conforming changes as may be appropriate):

1 SEC. XXX

2 (a) Section 569D of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 360bbb-8d) is amended—

4 (1) in the section heading, by striking “CON-
5 TROLLED SUBSTANCES” and inserting “DRUGS
6 AND CONTROLLED SUBSTANCES”;

7 (2) by striking “controlled substance” each place
8 such term appears and inserting “drug or controlled sub-
9 stance”;

10 (3) in subsection (b), by striking “controlled sub-
11 stances” and inserting “drugs or controlled substances”;
12 and

13 (4) in subsection (c), by striking “or an official senior
14 to such Director” and inserting the following: “or the Di-

1 rector of the Center for Biologics Evaluation and Research
2 (or an official senior to either such Director)”.

3 (b) Section 801(a) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 381(a)) is amended by striking
5 “is a controlled substance subject to an order under sec-
6 tion 569D” and inserting “is a drug or controlled sub-
7 stance subject to an order under section 569D”.

