AMENDMENTS TO THE AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL FY2023

Full Committee Markup

House Appropriations Committee

June 23, 2022





BISHOP #1 Agriculture

HOUSE APPROPRIATIONS COMMITTEE

June 23, 2022

Fiscal Year 2023 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Bill

Manager's amendment

In the bill

On page 5, line 20, strike "\$38,059,000" and insert "\$9,559,000".

On page 9, line 15, strike "\$1,736,129,000" and insert "\$1,737,629,000".

On page 11, line 17, strike "\$71,305,000" and insert "\$57,305,000".

On page 31, line 9, strike "\$115,000,000" and insert "\$95,000,000".

On page 41, line 24, strike "fourth" and insert "fifth".

On page 68, line 24, strike "\$6,483,171,000" and insert "\$6,484,171,000".

On page 70, line 21, strike "\$1,243,007,000" and insert "\$1,244,007,000".

On page 110, strike lines 12-25 and insert the following:

SEC. 763. There is appropriated to the Department of Agriculture, for an additional amount for "Agricultural Programs—Processing, Research, and Marketing—Office of the Secretary", \$5,000,000, which shall remain available until expended, for necessary expenses, under such terms and conditions determined by the Secretary, related to testing soil, water, or agricultural products for per- and polyfluoroalkyl substances (PFAS) at the request of an agricultural producer, assisting agricultural producers affected by PFAS contamination with costs related to mitigate the impacts to their operation that have resulted from such contamination and indemnifying agricultural producers for the value of unmarketable crops, livestock, and other agricultural products related to PFAS contamination: *Provided*, That the Secretary shall prioritize such assistance to agricultural producers in states and territories that have established a tolerance threshold for PFAS in

a food or agricultural product: *Provided further*, That, not later than 90 days after the end of fiscal year 2023, the Secretary shall submit a report to the Congress specifying the type, amount, and method of such assistance by state and territory and the status of the amounts obligated and plans for further expenditure, and include improvements that can be made to U.S. Department of Agriculture programs, either administratively or legislatively, to increase support for agricultural producers impacted by PFAS contamination and to enhance scientific knowledge on PFAS uptake in crops and livestock and PFAS mitigation and remediation methods and disseminate such knowledge to agricultural producers.

On page 111, strike lines 1-14.

On page 111, at the end of the bill before the short title, insert the following new section:

Sec. XXX. Any future compliance date for any provision of the Food and Drug Administration's final rule entitled "Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt" (86 Fed. Reg. 31117, June 11, 2021) for which the agency is exercising enforcement discretion or that is stayed as a result of objections timely filed under 21 U.S.C. 371(e)(2), shall be established no earlier than January 1 of the year that is three years after either:

- a) Final action upon such objection(s) is taken by the Secretary of Health and Human Services; or
 - b) The party withdraws such objection(s).

On page 111, at the end of the bill before the short title, insert the following new section:

Sec. __. In addition to the amount of reimbursement for administrative and operating expenses available for crop insurance contracts described in subsection (a)(2)(F) of section III of the 2023 Standard Reinsurance Agreement (SRA) that cover agricultural commodities described in section 101 of title I of the Specialty Crops Competitiveness Act of 2004 (7 U.S.C. 1621 note), there is hereby appropriated \$50,000,000, to remain available until expended, to pay, with respect to such contracts for the 2021 reinsurance year, an amount that is equal to the difference between the amount to be paid pursuant to the SRA for the applicable reinsurance year and the amount that would be paid if such contracts were not subject to

a reduction described in subsection (a)(2)(G) of section III of the SRA but subject to a reimbursement rate equal to 17.5 percent of the net book premium.

On page 111, at the end of the bill before the short title, insert the following new section:

Sec. XX. There is appropriated to the Department of Agriculture, for an additional amount for "Agricultural Programs—Processing, Research, and Marketing—Office of the Secretary", \$10,000,000, which shall remain available until expended, for necessary expenses to address assistance for disasters occurring in calendar year 2022.

In the report

On page 14, in the paragraph entitled "Aflatoxin Research", after the period insert the following and make conforming changes in the report:

The Committee provides \$1,500,000 to support these efforts.

On page 60, before the paragraph entitled "Healthy Food Financing Initiative", insert the following new paragraph:

Colonias and Farmworker Communities.—The Committee recognizes the challenges facing colonias and farmworker communities and urges the Department to work with other Federal agencies to identify best practices and other ways to further assist colonias communities and farmworkers. The Committee encourages USDA to explore strategies to adopt and address the unique participation challenges faced by rural communities in the border region colonias communities. Further, the Committee encourages the Secretary to support these communities with funds appropriated for the Rural Partnership Network. The Committee requests a briefing on these efforts within 90 days following enactment.

On page 67, after the paragraph entitled "Arts in rural communities", insert the following new paragraph:

Business and Industry Guaranteed Loans.—The Committee recognizes the expanded growth and interest in the Business and Industry

Loan program and encourages the Department to better forecast the needs of the program in fiscal year 2023 and future fiscal years to ensure continued lending activities throughout the year.

On pages 79-80, under the paragraph titled "Barriers to Accessing SNAP", after the last sentence insert:

The Committee encourages FNS to include in this report the impacts on SNAP benefits of the expiration of the PHE and related SNAP measures, and ways to promote equitable customer service, including through language access, and alternative eligibility system access options such as in person, online, and call center availability.

On page 86, after the paragraph entitled "510(k) Guidance", insert the following new paragraph:

2019 ALS Clinical Trial Guidance.—The Committee understands that FDA recognizes the critical unmet medical need for new, effective treatments for ALS. The burden of ALS for patients, their families and caregivers is devastating and the Committee urges FDA to reaffirm its commitment to its 2019 ALS Clinical Trial Guidance. Further, the Committee requests that FDA report to Congress within 90 days of the passage of this Act detailing the actions that FDA has taken to implement the 2019 ALS Clinical Trial Guidance.

On page 88, before the paragraph entitled "Chemicals in Foods", insert the following new paragraph:

Carbohydrates.—The Committee encourages the FDA to respond to a request from industry to use an alternative methodology related to carbohydrates in certain food and beverage products.

On page 91, before the paragraph entitled "Heparin", insert the following new paragraph:

Hand Sanitizer Safety.—The Committee appreciates FDA's ongoing efforts to remove unsafe hand sanitizer products from the market and recognizes FDA's website provides information and guidance to stakeholders on the risks of open refillable hand sanitizer dispensers.

On page 94, within the paragraph entitled "Olive Oil Standards of Identity" in the last sentence, strike "2021" and insert "2022".

On page 95, in the paragraph entitled "Orphan Products Grants Program (OPGP)", strike the second sentence and insert the following:

The Committee notes that this increase brings the total funding level within CDER for OPGP to \$24,000,000. In addition, the Committee notes that funding can be used for ALS clinical trials and investments in regulatory science to speed the approval of ALS treatments.

On page 98, in the paragraph entitled "Shrimp Products", after the period insert the following and make conforming changes in the report:

The Committee provides an additional \$1,000,000 for this activity.

On page 100, after the paragraph entitled "Tobacco Emissions Testing", insert the following new paragraph:

Tobacco Report.—The Committee requests that FDA, within 90 days, provide a report that identifies the status of each statutory requirement in the Tobacco Control Act which FDA was supposed to implement. For those statutory requirements that have not been implemented, the Committee requests that FDA provide a detailed response explaining the delay and when the requirements will be implemented.

Harris #1
FY 23- Agriculture

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL, 2023 OFFERED BY DR. HARRIS OF MARYLAND

Page 64, line 18, strike "\$231,378,000" and insert "\$230,378,000",

At an appropriate place, insert the following:

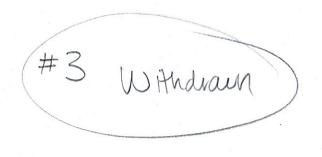
1	SEC (a) Not later than 90 days after the date
2	of enactment of this Act, the Secretary of Agriculture,
3	shallenterintoanagreementwiththeNationalAcademies
4	of Sciences, Engineering, and Medicine to conduct a study
5	in accordance with this section to identify the potential
6	public health and individual nutrition impacts of limiting
7	items eligible for purchase using supplemental nutrition
8	assistance program benefits to healthier options more
9	closely aligned to the thrifty food plan under the Food and
0	Nutrition Act of 2008 (7 U.S.C. 2011 et seq.).
1	(b) The study required by subsection (a) shall evalu-
2	ate the public health implications of making each of the
3	following changes to the allowable uses of supplemental
4	nutrition assistance program benefits under such Act:
15	(1) Removing the following items, as defined by
6	the Department of Agriculture report published in

1	2016 entitled "Foods Typically Purchased by Sup-
2	plemental Nutrition Assistance Program (SNAP)
3	Households", from the categories of food that may
4	be purchased with such benefits:
5	(A) sweetened beverages,
6	(B) prepared desserts,
7	(C) salty snacks,
8	(D) candy, and
9	(E) sugars.
10	(2) Allowing such benefits to be used to pur-
11	chase all items as specified in the Department of
12	Agriculture report entitled "Thrifty Food Plan ,
13	2021" for the market-based categories except the
14	category "Other foods and beverages", as defined by
15	the report.
16	(3) Allowing such benefits to be used only to
17	purchase items that may be purchased under section
18	17 of the Child Nutrition Act (42 U.S.C. 1786),
19	commonly known as "WIC".
20	(c) Not later than 270 days after the date the agree-
21	ment described in subsection (a) is finalized, the National
22	Academies shall submit to the Congress a report con-
23	taining the findings and recommendations of the study descent for all the initial contents and in the study descent for all the st
24	scribed in subsection (b) and shall make such report avail-
25	able on a publicly accessible website.

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1 (d) There is appropriated to carry out this section2 \$1,000,000.





Rep. Mike Quigley FY23 – Labor-HHS-Ed Amendment #1

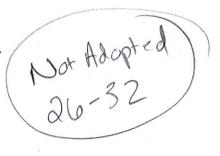
AMENDMENT TO AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL OFFERED BY MR. QUIGLEY OF ILLINOIS

Amendment to the Bill:

Page 68, line 24: Increase the dollar amount by \$20,000,000.

Page 72, line 21: At the end, strike the period and insert ": Provided further, that of the amounts made available under this heading, \$25,000,000 shall be made available to carry out the Rare Neurodegenerative Disease Grant Program authorized by Public Law 117-79, to remain available until expended."

#4



Harris #2 FY 23- Agriculture

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY Dr. Harris

At the end of the bill (before the short title), insert the following:

- 1 SEC. ____. None of the funds made available by this
- 2 Act may be to used to remove the requirement of the Food
- 3 and Drug Administration that mifepristone be dispensed
- 4 only in certain health care settings.



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#5 Adopted

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A6 RyAN # 1

AMENDMENT TO THE AGRICULTURE, RURAL DE-VELOPMENT, FOOD AND DRUG ADMINISTRA-TION, AND RELATED AGENCIES APPROPRIA-TIONS BILL, 2023

OFFERED BY MR. RYAN OF OHIO

Page 6, line 20, reduce the dollar amount by \$50,000,000.

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 In addition to amounts otherwise available, there is
- 3 appropriated to the Secretary of Agriculture \$50,000,000,
- 4 to remain available until September 30, 2023, to provide
- 5 relief payments for frontline grocery workers through the
- 6 Farmworker and Food Worker Relief Grant Program of
- 7 the Agricultural Marketing Service.



AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY Mr. FLEISCHMANN OF TENNESSEE

Page 111, after line 14, insert the following:

- 1 Sec. 764. None of the funds appropriated or other-
- 2 wise made available by this Act may be used to pay the
- 3 salaries or expenses of personnel of the Department of Ag-
- 4 riculture who enforce any provision of law or any policy
- 5 that decreases the stocks-to-use ratio for sugar to less
- 6 than 15.5 percent.





Rep. Henry Cuellar FY22 – Agriculture Amendment

STUDY ON WORKING CONDITIONS FOR WOMEN FARMWORKERS

New Report Language: "Strong working conditions for our farmworkers are critical to the resiliency of the food and agricultural supply chain. The Committee is supportive of USDA's efforts to improve working conditions for farmworkers, including for women farmworkers who are vulnerable to sexual assault and exploitation in the workplace. The Committee urges the Department to expand partnerships with appropriate entities to ensure the working conditions and challenges faced by women farmworkers are adequately investigated and incorporated into USDA's pilots and programs. The Committee requests the Department to conduct a study to 1) understand the work conditions and challenges, such as sexual assault, faced by women farmworkers; and 2) to develop recommendations on how the Department can promote improvements through its programs and pilots."

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#8



Rep. Ashley Hinson FY 23-Ag FDA Amendment #1

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY Mg. Hinson

Page 71, line 1, strike "\$2,210,209,000" and insert "\$2,225,209,000".

Page 71, line 6, before the semicolon insert ", and \$15,000,000 shall be for coordinating programs and activities of the Food and Drug Administration with those of the Drug Enforcement Agency and U.S. Customs and Border Protection to combat the illicit importation of opioids, including fentanyl, through international mail facilities and land ports-of-entry".

On page 71, line 22, strike "\$364,375,000" and insert "\$349,375,000".



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Adopted

Pepashlythnson FY 23 AgFDA Amundment #Z

REPORT

In the report:

On page 6, after the paragraph titled "Spending Plans", insert the following:

Livestock Gene Editing Cooperation – As the Secretary of Agriculture develops regulations pertaining to the movement of animals modified or developed by genetic engineering, the Secretary shall consult with the Commissioner of the Food and Drug Administration to ensure any resulting regulations are coordinated.

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416 Not Adapted DJ-31

Rep. Guy Reschenthaler FYZ3-Ag Amendment#1

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY MR. RESCHENTHALER OF PENNSYLVANIA

In section 722 of the bill, strike "allowing or requiring information" and insert "requiring approved prescribing information".

In section 722 of the bill, insert "only" before "electronically".





Rep. Andy Harris FY23 – Agriculture, Rural Development, FDA Amendment #3

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY MR. HARRIS OF MARYLAND

Page 111, after line 14, insert the following:

SEC. 764. From any remaining unobligated balances from amounts made available under the heading "Agricultural Programs–Office of the Secretary" in title I of division B of the CARES Act (Public Law 116–136) and from amounts made available under section 751 of chapter 1 of subtitle B of title VII of division N of the Consolidated Appropriations Act, 2021 (Public Law 116–260), the Secretary shall make additional reimbursements to dairy farmers under the Pandemic Market Volatility Assistance Program to those producers whose initial reimbursements were limited by the five-million-pound per producer limitation as announced by the Department of Agriculture on August 19, 2021."

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#12



Rep. Ken Calvert FY23 AG-FDA Amendment # 1

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY MR. CALVERT OF CALIFORNIA

At the end of the bill (before the short title), insert the following:

- 1 Sec. ____. None of the funds made available by this
- 2 Act may be used to review or approve an application under
- 3 section 505(i) of the Federal Food, Drug, and Cosmetic
- 4 Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public
- 5 Health Service Act (42 U.S.C. 262(a)(3)) that is sub-
- 6 mitted by a sponsor located in Russia, unless such applica-
- 7 tion is for a drug that is intended to treat a serious or
- 8 life-threatening condition and for which there is an unmet
- 9 medical treatment need.



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#13



Rep. Hemma Bayler

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY Ms. HERRERA BEUTLER OF WASHINGTON

Page 74, line 14, before the period insert the following: "Provided further, That of the amounts made available under this heading for the Office of the Commissioner of Food and Drugs, 30 percent of such amount shall not be available for obligation or expenditure until the Commissioner submits to the Congress a report detailing the organizational failures leading to the infant formula crisis, including a plan on how the Food and Drug Administration will correct these deficiencies to prevent such a crisis in the future".



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Newhouse F423-Ag Revised

AMENDMENT TO AGRICULTURE AND RURAL DEVELOPMENT APPROPRIATIONS BILL OFFERED BY MR. NEWHOUSE OF WASHINGTON

At the end of the bill (before the short title), insert the following:

- 1 SEC. . The Secretary of Agriculture shall take
- such actions as may be necessary to prohibit the purchase
- 3 of agricultural land located in the United States by
- 4 companies owned, in full or in part, by the People's
- 5 Republic of China, Russia, North Korea, or Iran.

