

AMENDMENTS ADOPTED TO THE  
AGRICULTURE APPROPRIATIONS BILL  
FOR FY 2016

Full Committee Markup  
House Appropriations Committee  
Wednesday, July 8, 2015

AG 1140 to VJ

Rep. Robert Aderholt

**Managers' Amendment to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2016**

In the bill:

Page 2, line 14, reduce the first dollar amount by \$1,772,000 (and conform the Committee Report accordingly).

Page 3, line 4, reduce the dollar amount by \$708,000 (and conform the Committee Report accordingly).

Page 3, line 9, reduce the dollar amount by \$1,064,000 (and conform the Committee Report accordingly).

Page 10, line 1 – insert “thirty days after” in between “until” and “the”

Page 10, line 9 – before the period, insert “; *Provided further*, That such certification shall set forth in detail the factual basis for the certification and the Department’s plan for ensuring these changes are maintained in the future: *Provided further*, That such certification shall be subject to prior consultation with the Committees on Appropriations of both Houses of Congress”

Page 35, line 19, increase the dollar amount by \$75,083,085 (and conform the Committee Report accordingly).

Page 35, line 22, increase the dollar amount by \$1,772,000 (and conform the Committee Report accordingly).

At the end of the bill (before the spending reduction account), insert the following:

“SEC. \_\_. None of the funds made available by this Act may be used to implement, administer, or enforce the rule entitled “Importation of Beef From a Region in Argentina” published by the Department of Agriculture in the Federal Register on July 2, 2015 (80 Fed. Reg. 37935 et seq.) or the rule entitled “Importation of Beef From a Region in Brazil” published by the Department of Agriculture in the Federal Register on July 2, 2015 (80 Fed. Reg. 37923 et seq.) until the Secretary of Agriculture— (1) conducts a comprehensive risk evaluation that includes a quantitative risk assessment of importing beef produced in Argentina and Brazil; and (2) makes additional site visits to beef slaughtering and processing facilities in Argentina and Brazil and submits to the Committee on Appropriations a report on each such site visit not later than 90 days after the date on which the visit occurs.”

At the end of the bill (before the spending reduction account), insert the following:

“SEC \_\_\_\_\_. None of the funds made available by this Act may be used to carry out any activities or incur any expense related to the issuance of licenses under section 3 of the Animal Welfare Act (7 U.S.C. 2133), or the renewal of such licenses, to class B dealers who sell dogs and cats for use in research, experiments, teaching, or testing.”

In the report:

Page 4 – In the line for the 2016 budget estimate, strike “\$47,328,000” and insert “\$47,308,000”.

Page 4 – In the table, in the line for Office of the Assistant Secretary for Administration, strike “\$836” and insert “\$816” and in the line for Total, strike “\$47,328” and insert “\$47,308”.

Page 10 – After the third heading, insert:

*“Food Safety Outreach.”*—The Committee is aware that for fiscal year 2015, the FDA and USDA are soliciting proposals for the establishment of one national and four regional food safety training centers. The Committee encourages the Secretary to ensure that funds are used efficiently to deliver education and technical training to producers in cooperation with nongovernmental and community-based organizations serving small and mid-sized farmers, producers, and processors, and other federal food safety agencies, as authorized in the FSMA.”

Page 10 – After the last heading, insert:

*“Urban Agriculture.”*—The Committee acknowledges the need for an expanded USDA role in support of urban agriculture, in American cities. Support from the Department is lacking for urban producers who often have different needs than rural producers. Therefore, the Committee directs USDA to evaluate policies and programs and deliver a report to the Committees on Appropriations of the House and Senate explaining how to further advance urban agriculture.”

*“CCC Payments to Growers.”*—The Committee directs the Secretary to provide, not later than 120 days after the date of the enactment of the bill to which this Committee Report pertains, a report on the amount of emergency funds that are transferred from the CCC to poultry owners and contract growers, respectively, to address outbreaks of HPAI.”

*“U.S.-Mexico Cooperation.”*— The Committee directs the Secretary of Agriculture to work with his Mexican counterpart to develop a US-Mexico working group to increase cooperation between the two countries in a similar manner as the “Beyond the Borders Initiative” between the United States and Canada. The working group shall develop proposals and create potential solutions aimed at facilitating commerce through improvements in the efficiency of the inspection process on both sides of the border, integrating small and large producers into the trade supply chain, and improving border wait times and transportation costs, among others.”

*Institute of Medicine (IOM) Study.*—The Committee strongly urges the Secretary of Agriculture to engage the IOM to conduct a study on the process supporting the recommendations of the eighth edition of the *Dietary Guidelines for Americans* (DGA). The study should include, but not be limited to, an analysis of the following: how the DGA can ensure a nutritionally sufficient diet for all Americans; how transparency of the committee selection process can be improved; how the Nutrition Evidence Library (NEL) is used and how NEL reviews are conducted; what the evidence base was for the eighth edition recommendations; and how the DGA can ensure proper nutrition advice for a range of individual factors including metabolic, and other disease conditions.”

Page 11 – Under the heading “Drought Resilience”, add at the end of the second sentence: “, including in the U.S. territory of Puerto Rico.”

Page 11 – After the second full paragraph, insert:

*Food Manufacturing Efficiencies.*—The Committee is aware of the potential for many new and promising food manufacturing processes and technologies. The nation's food supply can be made safer, more secure, better and more affordable through such means as automation of equipment and modifying processes along the entire supply chain to work more efficiently and use less water, energy and other resources. The Committee urges the Department to promote enhanced technology, processes, and data analysis throughout the food manufacturing industry.”

Page 14 – After the second heading, insert:

*Historically Black Colleges and Universities (HBCUs).*—This year marks the 125th Anniversary of the signing of the Second Morrill Act of 1890, which provided land-grant status to selected HBCUs. For over 125 years, these HBCUs have had a long-standing tradition of institutional commitment to excellence in teaching, scholarship, and service. The legacy of these land-grant universities will be further strengthened based on current and future investments and on the quality of research and graduates produced in the fields of agriculture, STEM, and related academic areas. These schools are to be applauded for the significant contributions they have made to our nation.

However, the Committee is concerned regarding the financial challenges the schools continue to face, particularly, the lack of state matching funds and other resources. The Department is directed to develop and submit a plan of action to the Committees on Appropriations of the House and Senate not later than 180 days after enactment of this Act to cooperatively work with the states to meet the matching grant requirements for research and extension activities.”

Page 17 – strike the second paragraph and insert:

“The Committee directs ARS to execute an agreement with APHIS within 90 days of enactment of this Act by which APHIS will conduct inspections that are consistent with the Animal Welfare

Act at each ARS research facility that uses animals in research. Inspection reports shall be provided to the Committees on Appropriations of the House and Senate immediately after they are completed. The Committee provides funding within the APHIS budget to cover the costs anticipated with this new responsibility. The Committee further directs the Department to provide a report at the same time it submits its fiscal year 2017 budget request regarding implementation of this directive and the findings of the APHIS inspections.

In addition, the Committee is very concerned that the failure by USDA to ensure that MARC had a functioning IACUC indicates that there was a total lapse in management at every level. Instead of addressing that failure, the department's response appears to be to add new staff to do work that should have been done by existing staff."

Page 17 – strike the fifth paragraph and insert:

"The Committee requests a detailed report on all of the actions taken by ARS to respond to the allegations in the article, including actions taken to correct any deficiencies or improve current policies and procedures. This report should be submitted to the Committees on Appropriations of the House and Senate, by October 1, 2015."

Page 18 – After the first heading, insert:

*"Co-Location of Researchers.*—The Committee encourages ARS to develop a plan to maximize its investments in plant science facilities and research by taking advantage of the synergies and efficiencies realized through the co-location of USDA researchers in state-of-the-art facilities with university and other stakeholders."

Page 21 – In the fourth paragraph, insert:

"and Hispanic Serving Institutions" after the word "Universities" in the heading and after the word "Universities" within the paragraph.

Page 21 – Before the fourth heading, insert:

*"Organic Agriculture.*—The Economic Research Service has cited industry statistics that "organic sales account for over four percent of total U.S. food sales." The Committee encourages USDA to ensure that the needs of the U.S. organic sector are more fully addressed through AFRI and to report back to the Committee with a plan for meeting this goal, including how the agency will ensure organic research conducted through AFRI is not duplicative of research conducted with mandatory funds through the Organic Agriculture Research and Extension Initiative and other research programs."

Page 28 – Before the fourth heading, insert:

*"Foreign Market Access Requests.*— Increasingly U.S. agriculture is facing non-tariff trade barriers, which are limiting the ability for U.S. agriculture to open and maintain access to key export markets. The Committee directs APHIS to review and update the list of foreign market

access requests submitted by U.S. producers, producer groups, companies and/or non-government agencies. All efforts should be made to assign the appropriate agency resources to opening and maintaining access to foreign markets for U.S. products. By March 2017, the agency should provide an update to the Committee on the number of foreign market access requests that have been successfully granted for U.S. agriculture; export volumes; the number of foreign market access requests that have been granted for imports to the U.S. market; the number of outstanding requests and the length of time each request has been pending before the agency. The agency should identify the limitations in achieving and maintaining foreign market access for U.S. agriculture.”

Page 29 – Under the heading “Huanglongbing Emergency Response”, insert “and Puerto Rico” after the word “Texas” in the third sentence.

Page 29 – Before the first heading, insert:

*“Light Brown Apple Moth.*—The Committee encourages APHIS to engage state and international regulatory bodies to deregulate the light brown apple moth. The Committee is concerned that if APHIS simply withdraws federal regulation without the necessary work with other regulatory officials, APHIS will only shift and not reduce the regulatory burden. Should APHIS withdraw the federal order for light brown apple moth, it must take steps to reduce the overall burden on growers.”

Page 58 – At the end of the first paragraph, insert:

“The Committee also expects the Departments to ensure the final guidelines do not conflict with sound scientific, nutritional guidance implemented by other federal agencies outside of USDA and HHS.”

Page 63 – Before the first heading, insert:

*“Biosimilars – Naming and Interchangeability.*—Five years post-enactment of the Biologics Price Competition and Innovation Act (BPCIA), FDA has only released guidances on general issues like scientific considerations in demonstrating biosimilarity, how exclusivity for innovator products may be applied, and how FDA will conduct industry/applicant meetings. These guidances do not address in any way the key considerations affecting patients or providers, such as what will biosimilars be named so that patients and their providers know which specific therapy a patient receives, for which indications can a biosimilar or interchangeable product be used, and scientific considerations for determining interchangeability. Due to the absence of these guidances the FDA was forced to approve biosimilar Zarxio with a “placeholder” name. The Committee finds this unacceptable and directs the FDA to issue naming and interchangeability guidances no later than November 30, 2015.”

Page 63 – Before the third heading, insert:

*“Centers of Excellence.*—The Committee is aware of the important contribution of CFSAN's Food Safety Centers of Excellence in supporting critical basic research as well as facilitating the

implementation of the Food Safety Modernization Act. The Committee encourages the agency to continue to fully utilize the Centers of Excellence to accomplish these goals and to enhance its level of support for Food Safety Modernization Act activities and to increase funding for base work.”

Page 66 – Under the third heading, strike the word “viable” both places that it appears.

Page 67 – Before the first heading insert the following:

“*Local Port Cooperation.*— The Committee directs FDA to work with local governments at high volume ports of entry to explore activities which reduce the risk of food borne illnesses and enhance the capacity of local officials in dealing with food borne threats.”

Page 67 – Before the last heading, insert:

“*Molluscan Shellfish.*— The Committee is concerned that non-tariff trade barriers continue to preclude trade in molluscan shellfish with European Union states. The Committee encourages the agency to expedite its audit of growing areas in Europe and to seek equivalency in sanitary standards where possible to allow a resumption of trade.”

Page 68 – Before the first heading, insert:

“*Over the Counter (OTC) Medicines for Children.*—The Committee is concerned that the FDA has not issued a proposed rule revising the monograph regulating the labeling of OTC cough and cold products for children. The Committee directs the agency to publish a proposed rule by November 30, 2015, based on scientific evidence for safety and efficacy in pediatric populations and taking into consideration the October 19, 2007 joint recommendations of its Pediatric Advisory Committee and Nonprescription Drugs Advisory Committee. While the Committee appreciates the agency's effort to explore possible improvements to the OTC drug monograph process; these efforts should not impede the prompt publication of this proposed rule.”

Page 74 – After the first heading, insert:

“*Internal Risk Management Transactions.*—The Committee is concerned that there is a lack of global coordination among regulators on the treatment of internal trades between affiliated entities. The Committee notes that international bodies left this to the discretion of national governments. As such, European and Japanese rules provide an exemption from margin requirements, with certain conditions, for internal trades between affiliates. In contrast, the U.S. market has proposed rules that would impose margin requirements on these trades. The Committee notes this will discourage prudent risk management by increasing the costs of these trades. These costs will be borne by the customers and result in reduced liquidity. The Committee urges the CFTC to recognize that such internal risk management transactions benefit customers. These requirements will result in regulatory arbitrage across jurisdictions. The

Committee directs the Commission to report to the Committees on Appropriations of both Houses of Congress, within 60 days of enactment of this Act, on the impact of the proposed rules on consumers and industries.”

Page 97 – In the column for FY 2016 Request, in the line for Office of the Assistant Secretary for Administration, strike “\$836” and insert “\$816”; in the line for Subtotal, Departmental Administration, strike “\$26,524” and insert “\$26,504”; in the line for Total, Office of the Secretary, strike “\$47,328” and insert “\$47,308”.



Harris

AG 19000010

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

At the end of the bill (before the spending reduction account), insert the following:

1        SEC. \_\_\_\_\_. Not later than 30 days after the date of  
2 the enactment of this Act, the Secretary of Health and  
3 Human Services shall publish a notice in the Federal Reg-  
4 ister clarifying that until the compliance date specified in  
5 the order published by the Food and Drug Administration  
6 in the Federal Register on June 17, 2015 (80 Fed. Reg.  
7 34650 et seq.), partially hydrogenated oils shall be consid-  
8 ered generally recognized as safe within the meaning of  
9 section 201(s) of the Federal Food, Drug, and Cosmetic  
10 Act (21 U.S.C. 321(s)).

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AG 1440  
VJ

**AMENDMENT TO AGRICULTURE AND RURAL  
DEVELOPMENT APPROPRIATIONS BILL  
OFFERED BY MS. DELAURO OF CONNECTICUT**

At the end of the bill (before the spending reduction account), insert the following:

1 SEC. \_\_. Notwithstanding any other provision of  
2 law—

3 (1) the Secretary of Agriculture shall implement sec-  
4 tion 12106 of the Agricultural Act of 2014 and the  
5 amendments made by such section (21 U.S.C. 601 note;  
6 Public Law 113-79), including any regulation or guidance  
7 the Secretary of Agriculture issues to carry out such sec-  
8 tion or the amendments made by such section; and

9 (2) the Secretary of Health and Human Services  
10 shall implement section 403(t) of the Federal Food, Drug,  
11 and Cosmetic Act (21 U.S.C. 343(t)), including any regu-  
12 lation or guidance the Secretary of Health and Human  
13 Services issues to carry out such section.

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