AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

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Re: Petition Requesting Rulemaking to Prohibit Research and Promotion Boards from Using Agricultural Commodity Assessments to Fund Animal Testing

Dear Ms. Porter and Mr. Purdy,

Pursuant to 5 U.S.C. § 553(e) and 7 C.F.R. § 1.28, I am submitting the attached petition for rulemaking (PFR) urging the Agricultural Marketing Service to prohibit research and promotion boards from using agricultural commodity assessments to fund animal testing. A hard copy of any document cited in the PFR will be provided upon request.

Thank you for your attention to this matter.

Sincerely,

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Petition
Before the United States Department of Agriculture
Agricultural Marketing Service

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Submitted by People for the Ethical Treatment of Animals

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I. INTRODUCTION

People for the Ethical Treatment of Animals (PETA) submits this petition pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 553(e), and 7 C.F.R. § 1.28, requesting that the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) commence rulemaking proceedings to prohibit assessments collected by research and promotion (R&P) commodity boards from being used to fund experiments on animals for certain agricultural products.[1] Specifically, the proposed amendments prohibit R&P boards, and their employees and agents, from engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing, unless if explicitly required by law, under the following orders (hereinafter collectively referred to as "Orders"):

- Blueberry Promotion, Research, and Information Order ("Blueberry Order")
- Hass Avocado Promotion, Research, and Information Order ("Hass Avocado Order")
- Mango Promotion, Research, and Information Order ("Mango Order")
- Mushroom Promotion, Research, and Consumer Information Order ("Mushroom Order")
- Sorghum Promotion, Research, and Information Order ("Sorghum Order")
- Soybean Promotion and Research Order ("Soybean Order")
- Watermelon Research and Promotion Plan ("Watermelon Plan").

R&P programs (also known as checkoff programs) promote and provide research and information for a particular agricultural commodity and are directed by industry-governed boards that are appointed by the U.S. Secretary of Agriculture and overseen by AMS. An R&P board oversees the day-to-day management of a program and carries out a program's order (i.e., plan). The proposed amendments align with an R&P board's principal duty under the Orders—to fund activities to strengthen the overall demand for the agricultural commodity covered by the program and to increase the size of the market for that commodity—by eliminating wasteful spending on tests that have no scientific relevance to human food consumption and that the law does not require. Every year, R&P boards levy steep assessment fees on farmers—agricultural commodity producers, handlers, processors, and importers—and a portion of this money bankrolls cruel and lethal tests on animals purportedly to support dubious human health claims for marketing food products to consumers. These tests have caused thousands of animals to be poisoned, force-fed, starved, radiated, bled, suffocated, beheaded, vaginally douched, and dissected just to promote blueberries, watermelons, and other common foods.

Some R&P boards have already adopted practices consistent with this petition. In 2023, the National Mango Board stated that it "is not funding any research studies that involve animals and

[1] 5 U.S.C. § 553(e) provides that "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 7 C.F.R. § 1.28 states that interested persons may file petitions in accordance with 5 U.S.C. § 553(e) "for the issuance, amendment or repeal of a rule . . . with the official that issued or is authorized to issue the rule," and that "[a]ll such petitions shall be given prompt consideration and petitioners will be notified promptly of the disposition made of their petitions."

does not plan to do so in the future."[2] In a 2022 Request for Proposal for investigating watermelon consumption's potential human health benefits, the National Watermelon Promotion Board expressly precluded animal or in vitro studies from consideration.[3] During the previous year, the Hass Avocado Board adopted a public policy banning the funding and conducting of tests on animals.[4] Also, in 2021, the chair of the U.S. Highbush Blueberry Council (USHBC or "Blueberry Council") Health Research Committee stated during the North American Blueberry Council/USHBC Spring Conference & Meetings that the Blueberry Council can do great work without animal research.[5] The chairman made this statement subsequent to the USHBC posting on Facebook on December 11, 2020: "We do not fund research involving animals. All third-party researchers who receive USHBC grants are required to follow a science-based, ethical approach to ensure unbiased results." The Blueberry Council Health Research Committee's guidelines for research and proposals continue to prioritize human clinical studies.[6]

The recent shunning of animal testing by these boards is comparable to a growing practice among dozens of major food and beverage manufacturers of establishing corporate policies against animal testing. National and international studies have consistently found that most consumers oppose animal testing, as described herein. In other words, animal testing does not increase agricultural commodities' marketing and promotional appeal. Enlightened industry participants have responded to the consumer's preference accordingly.

As the 2023 Farm Bill stalemate prolongs a state of economic uncertainty for farmers and adds to their challenges of dealing with federal underfunding,[7] proceeding with the proposed amendments to curb wasteful spending is especially pressing. PETA urges AMS to amend its

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[2] National Mango Board, GOOGLE (2023), https://maps.app.goo.gl/xzVjqJvJi7EpdEjBA (responding to RM Miller's review).

[3] NATIONAL WATERMELON PROMOTION BOARD, REQUEST FOR PROPOSAL—NUTRITION RESEARCH (2022), https://s3.wp.wsu.edu/uploads/sites/2002/2021/12/Nutrition-RFP-2022.pdf ("Uncontrolled intervention studies, animal studies or in vitro studies are not acceptable.").

[4] Research Opportunities, LOVE ONE TODAY, https://research.loveonetoday.com/research-opportunities/ (last visited Mar. 1, 2024) ("The [Avocado Nutrition Center] does not support, fund, or conduct animal research."); s*ee also Hass Avocado Board Bans Animal Experiments*, COASTAL VIEW (Feb. 3, 2021), https://www.coastalview.com/news/hass-avocado-board-bans-animal-experiments/article_2d5a416c-6672-11eb-b906-63997546ead0.html.

[5] Spring Conference & Meetings – Day 4, YOUTUBE (Mar. 19, 2021), https://www.youtube.com/watch?v=u1TGBziyG8I.

[6] *See, e.g.*, Letter from USHBC Health Research Committee to Faculty and Senior Researchers (Oct. 8, 2021), https://foodprofessionals.blueberry.org/wp-content/uploads/sites/3/2021/10/V3-Proposed-LOI-memo_10.8-1.pdf ("A priority for funding will be given to human clinical studies.").

[7] *See, e.g.*, Paul Johnson & Zack Pistora, *Flipping U.S. Farm Bill Right Side Up Will Be Better for Kansas, Farmers and Environment*, KANSAS REFLECTOR (Sept. 16, 2022, 3:33 AM), https://kansasreflector.com/2022/09/16/flipping-u-s-farm-bill-right-side-up-will-be-better-for-kansas-farmers-and-environment/ (explaining that the Conservation Stewardship Program (CSP) and Environmental Quality Incentives Program (EQIP) are underfunded federally: "In 2020, only 18% of eligible CSP applicants in Kansas were funded and just 23% of EQIP eligible applicants were."); Erin Jordan, *Conservation Programs Offer Climate Solutions, but Vastly Underfunded*, THE GAZETTE (Nov. 16, 2023, 9:36 AM), https://www.thegazette.com/agriculture/conservation-programs-offer-climate-solutions-but-vastly-underfunded/ ("Fewer than one-quarter of Iowa applications for cost sharing through the Environmental Quality Incentives Program (EQIP) and the Conservation Stewardship Program (CSP) were funded in fiscal 2022.").

regulations to prohibit funding animal testing with the assessments collected by R&P boards for marketing agricultural commodities under the Orders.[8]

II. DESCRIPTION OF PETITIONER

PETA is a Virginia non-stock corporation and an animal-protection charity dedicated to protecting animals—including those used in experimentation—from neglect, abuse, and all forms of cruelty. PETA entities have more than nine million members and supporters globally, and PETA U.S. is the largest animal rights organization in the world. PETA operates, in part, to promote and advance the principle that animals are not ours to experiment on or abuse in any other way and carries out its mission through, inter alia, public education, investigations, research, animal rescue, legislation, special events, celebrity involvement, and protest campaigns.

III. LEGAL FRAMEWORK

AMS oversees twenty-two agricultural commodity R&P boards and ensures that "all projects conducted by the boards are in accordance with the appropriate Act, Order, and the AMS Guidelines."[9] The USDA appoints board members who develop orders for programs of generic promotion, research, and information for agricultural commodities authorized under particular acts.[10] The boards fund these activities, which are meant to "maintain or increase the overall demand for the agricultural commodity covered by the program and increase the size of the market for that commodity," by imposing mandatory assessments on farmers (e.g., commodity producers, processors, and importers).[11] Penalties for failing to remit an assessment include late fees, interest charges, and potentially hefty civil penalties.[12]

The proposed regulatory action is authorized pursuant to the following.

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[8] A hard copy of any document cited in this petition will be provided upon request.

[9] Research & Promotion Programs, USDA, https://www.ams.usda.gov/rules-regulations/research-promotion (last visited Mar. 1, 2024); Letter from Greg Ibach, Under Secretary, Mktg. & Regul. Programs, USDA, to Dina Titus, U.S. House of Representatives (Nov. 19, 2020), https://www.peta.org/wp-content/uploads/2021/03/11.19.20-USDA-response-re-animal-testing-checkoff-boards.pdf.

[10] *Guidelines for AMS Oversight of Commodity Research and Promotion Programs*, USDA 5 (Jan. 2020), https://www.ams.usda.gov/sites/default/files/media/RPGUIDELINES092015.pdf; *see also, e.g.*, 7 U.S.C. § 7414(b)(1), (2)(B).

[11] 7 U.S.C. § 7401(a), (b)(7); *id*. § 7416(a).

[12] *See, e.g.*, *id*. §§ 7416(e), 7419(c) (subjecting a person who willfully violates an order or regulation under the Commodity Research, Promotion, and Information Act of 1996 to a maximum civil penalty of $10,000 for each violation), 7807(c)(1)(A) (subjecting a person who violates an order or regulation under the Hass Avocado Promotion, Research, and Information Act of 2000 to a maximum civil penalty of $10,000 for each violation), 6107(c) (subjecting a person who willfully violates an order or regulation under the Mushroom Promotion, Research, and Consumer Information Act of 1990 to a maximum civil penalty of $5,000 for each violation), 4910(b)(1) (subjecting a person who fails or refuses to pay, collect, or remit any assessment or fee required of the person under the Watermelon Research and Promotion Act to a maximum civil penalty of $5,000 for each violation).

A. Commodity Research, Promotion, and Information Act of 1996 ("1996 Act")

The 1996 Act authorizes the USDA to establish agricultural commodity research and promotion programs, administered through orders, to carry out a combination of activities (e.g., promotion, research, industry information, and consumer information) funded by mandatory assessments.[13] "Agricultural commodity" encompasses "agricultural, horticultural, viticultural, and dairy products," such as blueberries, mangos, and sorghum.[14] The activities are meant to "(1) strengthen the position of agricultural commodity industries in the marketplace; (2) maintain and expand existing domestic and foreign markets and uses for agricultural commodities; [and] (3) develop new markets and uses for agricultural commodities."[15] To achieve this end, the 1996 Act confers broad authority "to develop and carry out research, promotion, and information activities designed to expand, improve, or make more efficient the marketing or use of the agricultural commodity covered by the order in domestic and foreign markets,"[16] and authorizes an order to contain authority to take any action that is not inconsistent with the purpose of the 1996 Act.[17]

1. Blueberry Promotion, Research, and Information Order ("Blueberry Order")

The Blueberry Order, created under the authority of the 1996 Act, 7 U.S.C. §§ 7411–7425, and codified at 7 C.F.R. part 1218, is administered by the Blueberry Council with oversight by USDA's AMS. With a goal of "strengthen[ing] the blueberry industry's position in the marketplace; maintain[ing] and expand[ing] existing markets and uses for blueberries; and [carrying] out programs, plans, and projects designed to provide maximum benefits to the blueberry industry," the Blueberry Order confers on the Blueberry Council the power and duty "to develop programs and projects, and enter into contracts or agreements . . . for the development and carrying out of programs or projects of research, information, or promotion, and the payment of costs thereof with funds collected pursuant to [the Blueberry Order]."[18] The Blueberry Order prohibits the Blueberry Council, its employees, and its agents from engaging in certain activities that may undermine this goal (e.g., actions that would be a conflict of interest) and using funds collected by the Blueberry Council for an expressly prohibited purpose (e.g., lobbying activities), and engaging in false or misleading advertising.[19] The Blueberry Council must terminate any program, plan, or project that "does not contribute to an effective program of promotion, research, or information."[20]

2. Mango Promotion, Research, and Information Order ("Mango Order")

The Mango Order, created under the authority of the 1996 Act, 7 U.S.C. §§ 7411–7425, and codified at 7 C.F.R. part 1206, is administered by the National Mango Board ("Mango Board")

[13] *See id*. §§ 7411(b), 7415(c), 7416.
[14] *Id*. § 7412(1).
[15] *Id*. § 7411(a)(6).
[16] *Id*. § 7415(c).
[17] *Id*. § 7415(g)(1).
[18] 7 C.F.R. § 1218.47(e), (n).
[19] *Id*. §§ 1218.48, 1218.54(d).
[20] *Id*. § 1218.54(c).

with oversight by USDA's AMS. With the goal of "strengthen[ing] the mango industry's position in the U.S. domestic market; maintain[ing] and expand[ing] existing markets and uses for mangos; and [carrying] out programs, plans, and projects designed to provide maximum benefits to the mango industry," the Mango Order confers on the Mango Board the power and duty "to develop programs and projects, and enter into contracts or agreements . . . for the development and carrying out of programs or projects of research, information, or promotion, and the payment of costs thereof with funds collected pursuant to [the Mango Order]."[21] The Mango Order prohibits the Mango Council, its employees, and its agents from engaging in certain activities that may undermine this goal (e.g., actions that would be a conflict of interest), using funds collected by the Mango Board for an expressly prohibited purpose (e.g., lobbying activities), and engaging in false or misleading advertising.[22] The Mango Board must terminate any program, plan, or project that "does not contribute to an effective program of promotion, research, or information."[23]

3. Sorghum Promotion, Research, and Information Order ("Sorghum Order")

The Sorghum Order, created under the authority of the 1996 Act, 7 U.S.C. §§ 7411–7425, and codified at 7 C.F.R. part 1221, is administered by the Sorghum Promotion, Research, and Information Board ("Sorghum Board") with oversight by USDA's AMS. With a goal of "strengthen[ing] the sorghum industry's position in the marketplace; maintain[ing] and expand[ing] existing markets and uses for sorghum; and [carrying] out programs, plans, and projects designed to provide maximum benefits to the sorghum industry," the Sorghum Order confers on the Sorghum Board the power and duty "to develop programs and projects, and enter into contracts or agreements . . . for the development and carrying out of programs or projects of research, information, or promotion, and the payment of costs thereof with funds collected pursuant to [the Sorghum Order]."[24] The Sorghum Order prohibits the Sorghum Board, its employees, and its agents from engaging in certain activities that may undermine this goal (e.g., actions that would be a conflict of interest), using funds collected by the Sorghum Board for an expressly prohibited purpose (e.g., lobbying activities), and engaging in false or misleading advertising (including promotion, research, and information activities).[25] The Sorghum Board must terminate any program, plan, or project that "does not contribute to an effective program of promotion, research, or information."[26]

B. Hass Avocado Promotion, Research, and Information Act of 2000 ("Hass Avocado Act")

The Hass Avocado Act authorizes the USDA to establish a "program of promotion, research, industry information, and consumer information," funded by mandatory assessments, to "(1) strengthen the position of the Hass avocado industry in the domestic marketplace; and (2)

[21] *Id*. § 1206.36(e), (n).
[22] *See id*. §§ 1206.37, 1206.50(d).
[23] *Id*. § 1206.50(c).
[24] *Id*. § 1221.110(e), (n).
[25] *Id*. § 1221.111.
[26] *Id*. § 1221.121(c).

maintain, develop, and expand markets and uses for Hass avocados in the domestic marketplace."[27] To achieve its purpose, the Hass Avocado Act includes an "Other Terms and Conditions" provision authorizing the Hass Avocado Order to "contain such other terms and provisions, consistent with this chapter, as are necessary to carry out this chapter."[28]

> Hass Avocado Promotion, Research, and Information Order ("Hass Avocado Order")

The Hass Avocado Order, created under the authority of the Hass Avocado Act, 7 U.S.C. §§ 7801–7813, and codified at 7 C.F.R. part 1219, is administered by the Hass Avocado Board with oversight by USDA's AMS. To carry out its goal—"to strengthen the Hass avocado industry's position in the domestic marketplace; to maintain and expand existing domestic markets and uses for Hass avocados; to create new domestic markets; and to carry out programs, plans, and projects designed to provide maximum benefits to the Hass avocado industry"[29]—the Hass Avocado Order confers on the Hass Avocado Board the power and duty to develop and implement

> programs, plans, and projects for Hass avocado promotion, industry information, consumer information, or related research, to contract or enter into agreements with appropriate persons to implement the programs, plans, and projects, and to pay the costs of the implementation of contracts and agreements with funds collected under [the Hass Avocado Order].[30]

The Hass Avocado Order expressly prohibits making any false or misleading statements "with respect to the attributes or use of any agricultural product."[31]

C. Mushroom Promotion, Research, and Consumer Information Act of 1990 ("Mushroom Act")

The Mushroom Act authorizes the USDA to establish and implement a "program of promotion, research, and consumer and industry information," funded by mandatory assessments, to "(1) strengthen the mushroom industry's position in the marketplace; (2) maintain and expand existing markets and uses for mushrooms; and (3) develop new markets and uses for mushrooms."[32] To achieve this, the Mushroom Act includes an "Other Terms and Conditions"

[27] 7 U.S.C. § 7801(b); *see also id*. § 7804(d)(2), (h).
[28] *Id*. § 7804(o) (giving the example of including a provision for the assessment of interest and a charge for each late payment of assessments).
[29] 7 C.F.R. § 1219.38(j).
[30] *Id*. § 1219.38(h).
[31] *Id*. § 1219.42(c)(2).
[32] 7 U.S.C. §§ 6101(b), 6104(g).

provision authorizing the Mushroom Order to "contain such terms and conditions, not inconsistent with this chapter, as are necessary to effectuate this chapter."[33]

Mushroom Promotion, Research, and Consumer Information Order ("Mushroom Order")

The Mushroom Order, created under the authority of the Mushroom Act, 7 U.S.C. §§ 6101–6112, and codified at 7 C.F.R. part 1209, is administered by the Mushroom Council with oversight by USDA's AMS. With a goal of "strengthen[ing] the mushroom industry's position in the marketplace; maintain[ing] and expand[ing] existing markets and uses for mushrooms; develop[ing] new markets and uses for mushrooms, and [carrying] out programs, plans, and projects designed to provide maximum benefits to the mushroom industry,"[34] the Mushroom Order confers on the Mushroom Council the power to develop programs, plans, and projects, and "enter into contracts or agreements . . . for the development and conduct of programs, plans, or projects . . . and for the payment of the cost thereof with funds collected and received pursuant to [the Mushroom Order]."[35] The Mushroom Council must terminate any program, plan, or project that "does not contribute to an effective program of promotion, research, consumer information, or industry information."[36]

D. Soybean Promotion, Research, and Consumer Information Act ("Soybean Act")

The Soybean Act authorizes the USDA to establish and implement a "program of promotion, research, consumer information, and industry information," funded by mandatory assessments, and "designed to strengthen the soybean industry's position in the marketplace; to maintain and expand existing domestic and foreign markets and uses for soybeans and soybean products, and to develop new markets and uses for soybeans and soybean products."[37] To achieve this, the Soybean Act includes an "Incidental Terms and Conditions" provision authorizing the Soybean Order to "provide terms and conditions, not inconsistent with the provisions of this chapter, as necessary to effectuate the provisions of the order."[38]

Soybean Promotion and Research Order ("Soybean Order")

The Soybean Order, created under the authority of the Soybean Act, 7 U.S.C. §§ 6301–6311, and codified at 7 C.F.R. part 1220, is administered by the United Soybean Board ("Soybean Board") with oversight by USDA's AMS. With a goal of "strengthen[ing] the soybean industry's position in the marketplace and . . . maintain[ing] and expand[ing] domestic and foreign markets and uses for soybean and soybean products produced in the United States,"[39] the Soybean Order confers

[33] *Id.* § 6104(j) (giving the example of including provisions for the assessment of a penalty for each late payment of assessments).
[34] 7 C.F.R. § 1209.39(l).
[35] *Id.* § 1209.38(a), (j).
[36] *Id.* § 1209.40(c).
[37] 7 U.S.C. §§ 6301(b), 6304(f).
[38] *Id.* § 6304(r).
[39] 7 C.F.R. § 1220.212(n).

on the Soybean Board the power to develop "plans or projects for promotion, research, consumer information, and industry information"[40] and the duty "to enter into contracts or agreements . . . for the development and conduct of [such] activities . . . and for the payment of the cost thereof with funds collected through assessments."[41] The Soybean Board must terminate any plan or project that "does not further the purposes of the Act."[42]

E. Watermelon Research and Promotion Act ("Watermelon Act")

The Watermelon Act authorizes the USDA to establish and carry out a "program of research, development, advertising, and promotion designed to strengthen the watermelon's competitive position in the marketplace, and establish, maintain, and expand domestic and foreign markets for watermelons."[43] To achieve this end, the Watermelon Act permits a plan to "establish[] and carry[] out research and development projects and studies to the end that the marketing and use of watermelons may be encouraged, expanded, improved, or made more efficient, and for the disbursement of necessary funds for such purposes."[44] The Watermelon Act authorizes a plan to "contain terms and conditions incidental to and not inconsistent with the terms and conditions specified in this chapter and necessary to effectuate the other provisions of the plan."[45]

Watermelon Research and Promotion Plan ("Watermelon Plan")

The Watermelon Plan, created under the Watermelon Act, 7 U.S.C. §§ 4901–4916, and codified at 7 C.F.R. part 1210, is administered by the National Watermelon Promotion Board ("Watermelon Board") with oversight by USDA's AMS. The Watermelon Board's policy entails "carry[ing] out an effective, continuous, and coordinated program of research, development, advertising, and promotion in order to: (a) Strengthen watermelons' competitive position in the marketplace, (b) Maintain and expand existing domestic and foreign markets, and (c) Develop new or improved markets."[46] The Watermelon Board endeavors to "carry out programs and projects which will provide maximum benefit to the watermelon industry."[47] To carry out its policy and objective, the Watermelon Board has the power to make rules and regulations to effectuate the terms and conditions of the Watermelon Plan,[48] and the duty to "develop programs and projects . . . and enter into contracts or agreements . . . for the development and carrying out of programs or projects of research, development, advertising or promotion, and the payment of the costs thereof with funds received pursuant to this Plan."[49] The Watermelon Board is

[40] *Id.* § 1220.211(a).
[41] *Id.* § 1220.212(h).
[42] *Id.* § 1220.230(b).
[43] 7 U.S.C.§ 4901(b).
[44] *Id.* § 4907(e). The Watermelon Act defines "plan" to mean an order issued by the Secretary of Agriculture. *Id.* § 4902(7).
[45] *Id.* § 4907(h).
[46] 7 C.F.R. § 1210.330.
[47] *Id.* § 1210.330.
[48] *Id.* § 1210.327(b).
[49] *Id.* § 1210.328(d).

prohibited from "us[ing] false or unwarranted claims on behalf of watermelons"[50] and is required to terminate a program or project that does not advance the purposes of the Watermelon Act.[51]

IV. STATEMENT OF FACTUAL BACKGROUND

Several of the R&P agricultural commodity boards overseen by AMS use a portion of the assessments levied on farmers, as described above, to fund cruel and deadly tests on animals in which animals are poisoned, force-fed, starved, irradiated, bled, suffocated, beheaded, vaginally douched, or dissected, purportedly to establish human health claims for marketing the agricultural products and ingredients that their respective board represents. Experiments published from 2015 to the present used at least 1,690 mice, 1,088 rats, and 62 pigs. The following describes a sampling of the experiments funded by assessments collected by the respective R&P boards.

Blueberry Council

- Experimenters repeatedly starved mice, repeatedly took their blood, repeatedly injected them with a chemical that induces menopause, douched their vaginas, fed them a high-fat diet with blueberries, injected them with insulin, and killed and dissected them.[52]
- Experimenters fed rats strawberries or blueberries, forced them to perform a series of stress-inducing psychomotor and cognitive tests (including grabbing wires while suspended, walking or balancing on accelerating rotating rods, and swimming in a maze), repeatedly injected them with a chemical, and killed and dissected them. [53] Experimenters killed five rats before the end of the experiment owing to excessive weight loss.[54]
- Experimenters fed rats blueberries, changed their cage mates daily, repeatedly restrained them in tubes smeared with cat food with a cat in the room (inducing post-traumatic stress disorder-like symptoms in the rats), forced them to perform a stress-inducing behavioral test, killed and dissected them.[55]
- Experimenters injected mice with cancer cells, fed them blueberries or black raspberries, and killed them.[56]

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[50] *Id.* § 1210.331(d).
[51] *Id.* § 1210.331(e).
[52] Carrie M. Elks et al., *Blueberries Improve Glucose Tolerance Without Altering Body Composition in Obese Postmenopausal Mice*, 23 OBESITY 573, 573–80 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4340720/pdf/nihms630067.pdf.
[53] Barbara Shukitt-Hale et al., *The Beneficial Effects of Berries on Cognition, Motor Behaviour and Neuronal Function in Ageing*, 114 BRIT. J. NUTRITION 1542, 1542–49 (2015), https://www.cambridge.org/core/journals/british-journal-of-nutrition/article/beneficial-effects-of-berries-on-cognition-motor-behaviour-and-neuronal-function-in-ageing/751902ED1F6B94DFEC9AB7FB8C89C0DA.
[54] *Id.*
[55] Philip J. Ebenezer et al., *The Anti-Inflammatory Effects of Blueberries in an Animal Model of Post-Traumatic Stress Disorder (PTSD)*, 11 PLOS ONE (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5014311/pdf/pone.0160923.pdf.
[56] Farrukh Aqil et al., *Lung Cancer Inhibitory Activity of Dietary Berries and Berry Polyphenolics*, 6 J. BERRY RSCH. 105, 105–114 (2016), https://content.iospress.com/download/journal-of-berry-research/jbr120?id=journal-of-berry-research%2Fjbr120.

- Experimenters fed mice a high-fat diet with blueberries, took their blood, and killed and dissected them.[57]
- Experimenters fed rats blueberries, restrained them in plastic tubes, rendered them cognitively impaired by irradiating them, forced them to perform confusing and stress-inducing memory tasks, killed them by cutting off their heads, and dissected them.[58]
- Experimenters fed mice a high-fat diet, cut off 70% of their stomachs, starved them, injected them with glucose, took their blood, and killed and dissected them.[59]
- Experimenters fed mice a high-fat diet, repeatedly starved them, repeatedly took their blood, cut off 70% of their stomach, inserted a catheter into their arteries, and killed and dissected them.[60]
- Experimenters fed rats a high-fat diet with blueberries, repeatedly starved them, force-fed them glucose, repeatedly took their blood, and killed and dissected them.[61]
- Experimenters fed mice a high-fat diet with blueberries and killed and dissected them.[62]
- Experimenters surgically injured rats' brains, fed them blueberries, forced them to perform stress-inducing behavioral tests such as getting through mazes, and killed and dissected them.[63]
- Experimenters fed mice a high-fat diet with or without blueberries, repeatedly starved them for sixteen hours, injected them with glucose and insulin, repeatedly took their blood, and killed and dissected them.[64]
- Experimenters fed mice a high-fat, high-sucrose diet with blueberry powder, ruptured their hearts to kill them, dissected them, collected their feces, and repeatedly force-fed the feces to

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[57] Amanda N. Carey et al., *Blueberry Supplementation Attenuates Microglia Activation and Increases Neuroplasticity in Mice Consuming a High-Fat Diet*, 22 NUTRITIONAL NEUROSCIENCE 253, 253–63 (2017), https://pubmed.ncbi.nlm.nih.gov/28931353/ (linking to the full text).

[58] Shibu M. Poulose et al., *Neurochemical Differences in Learning and Memory Paradigms Among Rats Supplemented with Anthocyanin-Rich Blueberry Diets and Exposed to Acute Doses of 56Fe Particles*, 12 LIFE SCIS. IN SPACE RSCH. 16, 16–23 (2017), https://pubmed.ncbi.nlm.nih.gov/28212704/ (linking to the full text).

[59] Anne K. McGavigan et al., *TGR5 Contributes to Glucoregulatory Improvements After Vertical Sleeve Gastrectomy in Mice*, 66 GUT 226, 226–34 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5512436/pdf/nihms875806.pdf.

[60] Anne K. McGavigan et al., *Vertical Sleeve Gastrectomy Reduces Blood Pressure and Hypothalamic Endoplasmic Reticulum Stress in Mice*, 10 DISEASE MODELS & MECHANISMS 235, 235–43 (2017), https://journals.biologists.com/dmm/article/10/3/235/2254/Vertical-sleeve-gastrectomy-reduces-blood-pressure.

[61] Sunhye Lee et al., *Blueberry Supplementation Influences the Gut Microbiota, Inflammation, and Insulin Resistance in High-Fat-Diet-Fed Rats*, 148 J. NUTRITION 209, 209–19 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6251676/pdf/nxx027.pdf.

[62] Erin D. Lewis et al., *Dietary Supplementation with Blueberry Partially Restores T-Cell-Mediated Function in High-Fat-Diet-Induced Obese Mice*, 119 BRIT. J. NUTRITION 1393, 1393–99 (2018), https://www.cambridge.org/core/journals/british-journal-of-nutrition/article/dietary-supplementation-with-blueberry-partially-restores-tcellmediated-function-in-highfatdietinduced-obese-mice/CB66AB7DEECFBD804AEBB5368A0860F8.

[63] Gokul Krishna et al., *Blueberry Supplementation Mitigates Altered Brain Plasticity and Behavior After Traumatic Brain Injury in Rats*, 63 MOLECULAR NUTRITION & FOOD RSCH. (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6684386/pdf/nihms-1036314.pdf.

[64] Weixiang Liu et al., *Whole Blueberry Protects Pancreatic Beta-Cells in Diet-Induced Obese Mouse*, NUTRITION & METABOLISM (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6530052/pdf/12986_2019_Article_363.pdf.

another group of mice, force-fed them glucose, repeatedly took their blood, killed, and dissected them.[65]

Hass Avocado Board

- Experimenters fed mice a high-fat diet, repeatedly force-fed them an avocado ingredient, starved them for eight hours, injected them with glucose and insulin, repeatedly bled them from their tails, killed them by suffocating them and draining their blood, and dissected them.[66]

Mango Board

- Experimenters injected mice with cancer cells, repeatedly force-fed them mango extracts, and killed and dissected them.[67]
- Experimenters fed mice a high-fat diet with mangoes, starved them, took their blood, and killed and dissected them.[68]
- Experimenters fed rats mangoes or pomegranates, fed them a chemical that induces colitis, and killed and dissected them.[69]
- Experimenters fed rats mangoes, fed them a chemical that induces colitis, and killed and dissected them.[70]
- Experimenters fed rats mango juice, repeatedly fed them a chemical that induces colitis, and killed and dissected them.[71]

[65] Arianne Morissette et al., *Blueberry Proanthocyanidins and Anthocyanins Improve Metabolic Health Through a Gut Microbiota-Dependent Mechanism in Diet-Induced Obese Mice*, 318 AM. J PHYSIOLOGY-ENDOCRINOLOGY & METABOLISM E965, E965–E980 (2020), https://journals.physiology.org/doi/epdf/10.1152/ajpendo.00560.2019.
[66] Nawaz Ahmed et al., *Avocatin B Protects Against Lipotoxicity and Improves Insulin Sensitivity in Diet-Induced Obesity*, 63 MOLECULAR NUTRITION & FOOD RSCH. (2019), https://pubmed.ncbi.nlm.nih.gov/31609072/ (linking to the full text).
[67] Matthew J. Nemec et al., *Polyphenolics from Mango (Mangifera Indica L.) Suppress Breast Cancer Ductal Carcinoma in Situ Proliferation Through Activation of AMPK Pathway and Suppression of mTOR in Athymic Nude Mice*, 41 J. NUTRITIONAL BIOCHEMISTRY 12, 12–19 (2017), https://pubmed.ncbi.nlm.nih.gov/27951515/ (linking to the full text).
[68] Babajide Ojo et al., *Mango Supplementation Modulates Gut Microbial Dysbiosis and Short-Chain Fatty Acid Production Independent of Body Weight Reduction in C57BL/6 Mice Fed a High-Fat Diet*, 146 J. NUTRITION 1483, 1483–91 (2016), https://pubmed.ncbi.nlm.nih.gov/27358411/ (linking to the full text).
[69] Hyemee Kim et al., *Comparison of Anti-Inflammatory Mechanisms of Mango (Mangifera Indica L.) and Pomegranate (Punica Granatum L.) in a Preclinical Model of Colitis*, 60 MOLECULAR NUTRITION & FOOD RSCH., 1912, 1912–23 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5026564/pdf/nihms789477.pdf.
[70] Hyemee Kim et al., *Mango Polyphenolics Reduce Inflammation in Intestinal Colitis—Involvement of the Mir-126/PI3K/AKT/Mtor Axis in Vitro and in Vivo*, 56 MOLECULAR CARCINOGENESIS, 197, 197–07 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5053910/pdf/nihms789476.pdf.
[71] Hyemee Kim et al., *Polyphenolic Derivatives from Mango (Mangifera Indica L.) Modulate Fecal Microbiome, Short-Chain Fatty Acids Production and the HDAC1/AMPK/LC3 Axis in Rats with DSS-Induced Colitis*, 48 J. FUNCTIONAL FOODS 243, 243–51 (2018), https://www.sciencedirect.com/science/article/pii/S1756464618303451.

Mushroom Council

- Experimenters fed rats white button mushrooms and forced them to perform several stress-inducing motor and cognitive tests (such as walking on balance beams and rotating rods and swimming through a water maze); fourteen rats died or had to be killed early because of excessive weight loss.[72]
- Experimenters fed mice white button mushrooms, starved them for fifteen hours, injected them with glucose, took their blood, and killed and dissected them.[73]
- Experimenters fed pigs white button mushrooms, repeatedly poked their anuses, took their blood, and killed and dissected them.[74]
- Experimenters fed genetically modified mice prone to atherosclerosis a high-fat diet with or without shiitake or portobello mushrooms, suffocated them to death, drained their blood, and dissected them.[75]
- Experimenters fed baby pigs white button mushrooms, killed them, and dissected their brains.[76]

Sorghum Board

- Experimenters fed rats sorghum bran and a chemical that induces colitis and killed and dissected them.[77]

Soybean Board

- Experimenters fed rats casein, soy protein, corn oil, soybean oil, or salmon oil and killed and dissected them.[78]

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[72] Nopporn Thangthaeng et al., *Daily Supplementation with Mushroom (Agaricus Bisporus) Improves Balance and Working Memory in Aged Rats*, 35 NUTRITION RSCH. 1079, 1079–84 (2015), https://pubmed.ncbi.nlm.nih.gov/26475179/ (linking to the full text).

[73] Yuan Tian et al., Prebiotic *Effects of White Button Mushroom (Agaricus Bisporus) Feeding on Succinate and Intestinal Gluconeogenesis in C57BL/6 Mice*, 45 J. FUNCTIONAL FOODS 223, 223–32 (2018), https://www.mushroomcouncil.org/wp-content/uploads/2021/02/Cantorna_PrebioticEffectJFF2018.pdf.

[74] Gloria I. Solano-Aguilar et al., *The Effect of Dietary Mushroom Agaricus Bisporus on Intestinal Microbiota Composition and Host Immunological Function*, 10 NUTRIENTS (2018), https://www.mdpi.com/2072-6643/10/11/1721.

[75] Sharon H. Kim et al., *Edible Mushrooms Reduce Atherosclerosis in Ldlr−/− Mice Fed a High-Fat Diet*, 149 J. NUTRITION 1377, 1377–84 (2019), https://pubmed.ncbi.nlm.nih.gov/31162580/ (linking to the full text).

[76] Gloria I. Solano-Aguilar et al., *The Effects of Consuming White Button Mushroom Agaricus Bisporus on the Brain and Liver Metabolome Using a Targeted Metabolomic Analysis*, 11 METABOLITES (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8625434/pdf/metabolites-11-00779.pdf.

[77] Lauren E. Ritchie et al., *Impact of Novel Sorghum Bran Diets on DSS-Induced Colitis*, 9 NUTRIENTS (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409669/pdf/nutrients-09-00330.pdf; Lauren E. Ritchie et al., *Polyphenol-Rich Sorghum Brans Alter Colon Microbiota and Impact Species Diversity and Species Richness After Multiple Bouts of Dextran Sodium Sulfate-Induced Colitis*, 91 FEMS MICROBIOLOGY ECOLOGY (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4573659/pdf/fiv008.pdf.

[78] Kaitlin H. Maditz et al., *Feeding Soy Protein Isolate and Oils Rich in Omega-3 Polyunsaturated Fatty Acids Affected Mineral Balance, but Not Bone in a Rat Model of Autosomal Recessive Polycystic Kidney Disease*, BMC NEPHROLOGY (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357150/pdf/12882_2015_Article_5.pdf; Kaitlin H. Maditz et al., *Feeding Soy Protein Isolate and N-3 PUFA Affects Polycystic Liver Disease Progression in*

- Experimenters injected mice with cancer cells, repeatedly injected them with an immunosuppressive drug and other substances, repeatedly force-fed them two plant ingredients, and killed and dissected them.[79]
- Experimenters repeatedly injected a soy ingredient into mice whose ovaries had been cut out, suffocated them to death, and dissected them.[80]
- Experimenters fed or repeatedly injected a soy ingredient into genetically modified mice who were prone to cystic fibrosis, suffocated them to death, took blood straight from their hearts, and dissected them.[81]
- Experimenters fed genetically obese mice a soy ingredient, suffocated them to death, and dissected them.[82]
- Experimenters fed mice a soy ingredient, suffocated them to death, and dissected them.[83]
- Experimenters fed mice soybean oil or coconut oil, starved them, took their blood, and killed and dissected them.[84]
- Experimenters injected mice with a carcinogen, fed them casein or soy protein, and killed and dissected them.[85]
- Experimenters fed genetically obese mice a soy ingredient and killed and dissected them.[86]

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a PCK Rat Model of Autosomal Polycystic Kidney Disease, 60 J. PEDIATRIC GASTROENTEROLOGY & NUTRITION 467, 467–73 (2015), https://pubmed.ncbi.nlm.nih.gov/25822773/ (linking to the full text).

[79] Mrinmay Chakrabarti & Swapan K. Ray, *Anti-Tumor Activities of Luteolin and Silibinin in Glioblastoma Cells: Overexpression of Mir-7-1-3p Augmented Luteolin and Silibinin to Inhibit Autophagy and Induce Apoptosis in Glioblastoma in Vivo*, 21 APOPTOSIS 312, 312–28 (2015), https://link.springer.com/article/10.1007/s10495-015-1198-x.

[80] Lana Leung et al., *Genistein Stimulates Jejunum Chloride Secretion Via an Akt-Mediated Pathway in Intact Female Mice*, 35 CELLULAR PHYSIOLOGY AND BIOCHEMISTRY, 1317, 1317–25 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4386721/pdf/nihms667780.pdf.

[81] Esa Rayyan et al., *Effect of Genistein on Basal Jejunal Chloride Secretion in R117H CF Mice Is Sex and Route Specific*, CLINICAL & EXPERIMENTAL GASTROENTEROLOGY 77, 77–87 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4321419/pdf/ceg-8-077.pdf.

[82] Shawn Catmull et al., *Dietary Genistein Rescues Reduced Basal Chloride Secretion in Diabetic Jejunum Via Sex-Dependent Mechanisms*, 40 CELLULAR PHYSIOLOGY & BIOCHEMISTRY 335, 335–346 (2016), https://karger.com/cpb/article-pdf/40/1-2/335/2439712/000452549.pdf; Richard M. Michelin et al., *Genistein Treatment Increases Bone Mass in Obese, Hyperglycemic Mice*, DIABETES, METABOLIC SYNDROME & OBESITY: TARGETS AND THERAPY, 63–70 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4801201/pdf/dmso-9-063.pdf; Sydney Schacht et al., *Dietary Genistein Influences Number of Acetylcholine Receptors in Female Diabetic Jejunum*, 2017 J. DIABETES RSCH. (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556993/pdf/JDR2017-3568146.pdf.

[83] Lana Leung et al., *Sex-Dependent Effects of Dietary Genistein on Echocardiographic Profile and Cardiac GLUT4 Signaling in Mice*, 2016 EVIDENCE-BASED COMPLEMENTARY & ALT. MED. (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4947657/pdf/ECAM2016-1796357.pdf.

[84] Poonamjot Deol et al., *Omega-6 and Omega-3 Oxylipins Are Implicated in Soybean Oil-Induced Obesity in Mice*, 7 SCIENTIFIC REPS. (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5624939/pdf/41598_2017_Article_12624.pdf.

[85] Kelly E. Mercer et al., *Soy Protein Isolate Inhibits Hepatic Tumor Promotion in Mice Fed a High-Fat Liquid Diet*, 242 EXPERIMENTAL BIOLOGY & MED. 635, 635–44 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5685258/pdf/10.1177_1535370216685436.pdf.

[86] Britton Odle et al., *Genistein Treatment Improves Fracture Resistance in Obese Diabetic Mice*, 17 BMC ENDOCRINE DISORDERS (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5299772/pdf/12902_2016_Article_144.pdf.

- Experimenters fed genetically modified mice, who were prone to cystic fibrosis, a soy ingredient, or a laxative, and killed and dissected them; forty-nine animals died of the disease before the experimenters could kill them.[87]
- Experimenters repeatedly force-fed genetically modified mice prone to diabetes a soy ingredient, injected them with cancer cells, starved them for fifteen hours, injected them with glucose and insulin, repeatedly took their blood, suffocated them to death, and dissected them.[88]
- Experimenters killed pregnant rats and dissected the babies' brains, and also injected another group of rats with a neurotoxin and repeatedly injected them with a soy extract.[89]

Watermelon Board

- Experimenters repeatedly force-fed rats watermelon or a watermelon ingredient, injected them with a carcinogen, and killed and dissected them.[90]
- Experimenters fed rats watermelon or a watermelon ingredient and took their blood.[91]
- Experimenters fed rats watermelon, took their blood, and killed and dissected them.[92]
- Experimenters fed rats an atherogenic diet with or without watermelon, suffocated them to death, took their blood, and dissected them.[93]
- Experimenters fed rats watermelon, repeatedly injected them with a carcinogen that induces colon cancer, and killed and dissected them.[94]
- Experimenters fed rats a high-fat diet with or without watermelon, fed them a chemical that induces colitis, starved them, suffocated them to death, and dissected them.[95]

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[87] Ryan Lord et al., *Consuming Genistein Improves Survival Rates in the Absence of Laxative in ΔF508-CF Female Mice*, 10 NUTRIENTS (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6213472/pdf/nutrients-10-01418.pdf.
[88] Guannan Huang et al., *Isoflavone Daidzein Regulates Immune Responses in the B6C3F1 and Non-Obese Diabetic (NOD) Mice*, 71 INT'L IMMUNOPHARMACOLOGY 277, 277–84 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6529284/pdf/nihms-1525619.pdf.
[89] Aurélie de Rus et al., *Neuroprotective Mechanisms of Red Clover and Soy Isoflavones in Parkinson's Disease Models*, 23 FOOD & FUNCTION (2021), https://pubs.rsc.org/en/content/articlelanding/2021/fo/d1fo00007a (linking to the full text).
[90] Joshua Beidler et al., *Effects of Watermelon and L-Arginine Consumption on Serum Lipid Profile, Inflammation, and Oxidative Stress in Rats*, 30 FASEB J. (2016), https://faseb.onlinelibrary.wiley.com/doi/10.1096/fasebj.30.1_supplement.lb289.
[91] Milica Kalaba et al., *Effect of Watermelon Powder Supplementation on Colonic Aberrant Crypt Foci Formation*, 30 FASEB J. (2016), https://faseb.onlinelibrary.wiley.com/doi/abs/10.1096/fasebj.30.1_supplement.lb280.
[92] Joshua Beidler et al., *Watermelon and L-Arginine Consumption Regulate Gene Expression Related to Serum Lipid Profile, Inflammation, and Oxidative Stress in Rats Fed an Atherogenic Diet*, 31 FASEB J. 431, 431–32 (2018), https://faseb.onlinelibrary.wiley.com/doi/abs/10.1096/fasebj.31.1_supplement.431.2 (linking to the full text).
[93] Mee Young Hong et al., *Watermelon and L-Arginine Consumption Improve Serum Lipid Profile and Reduce Inflammation and Oxidative Stress by Altering Gene Expression in Rats Fed an Atherogenic Diet*, 58 NUTRITION RSCH. 46, 46–54 (2018), https://pubmed.ncbi.nlm.nih.gov/30340814/ (linking to the full text).
[94] Meseret Fesseha & Mee Young Hong, *Effects of Watermelon Consumption on Cellular Proliferation, and Apoptosis in Rat Colon (P05-019-19)*, 3 CURRENT DEVS. IN NUTRITION (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6576223/pdf/nzz030.p05-019-19.pdf;Keith Glenn et al., *Effects of Watermelon Powder and L-Arginine Supplementation on Azoxymethane-Induced Colon Carcinogenesis in Rats*, 70 NUTRITION & CANCER 938, 938–945 (2018), https://pubmed.ncbi.nlm.nih.gov/30207495/ (linking to the full text).
[95] Mee Young Hong et al., *Effects of Watermelon Powder Supplementation on Colitis in High-Fat Diet-Fed and Dextran Sodium Sulfate-Treated Rats*, 54 J. FUNCTIONAL FOODS, 520, 520–28 (2019), https://www.sciencedirect.com/science/article/pii/S1756464619300647.

- Experimenters fed mice a high-fat diet with various parts of watermelon and killed and dissected them.[96]
- Experimenters fed mice a high-fat diet with various parts of watermelon, starved them, injected them with glucose, repeatedly bled them from their tails, took blood straight from their hearts, killed them by breaking their necks, and dissected them.[97]
- Experimenters fed mice a high-fat diet with watermelon, starved them, ruptured their hearts and broke their necks to kill them, and dissected their livers.[98]
- Experimenters fed mice a high-fat diet with watermelon or common amino acids, killed them, and dissected their livers.[99]
- Experimenters fed rats watermelon or a common amino acid, repeatedly injected them with a carcinogen to induce colon cancer, suffocated them to death, and dissected their colons.[100]

V. ARGUMENTS IN SUPPORT OF REQUESTED ACTION

A. Because Testing on Animals to Establish Human Health Claims for Marketing Food Products Is Misguided, Unscientific, and Not Legally Required, the Activity Fails to Effectuate the Purpose of the Orders and Must Not Be Authorized.

By permitting animal testing, AMS shirks its responsibility for ensuring that R&P board activities effectuate the purpose of the Orders. R&P boards are authorized to levy fees on farmers for funding activities that strengthen the position of the agricultural commodity in the marketplace by expanding, improving, or making the marketing of the agricultural commodity more efficient—none of which animal testing accomplishes.[101] Animal testing undertaken to support human health claims for marketing food products to consumers negates this effort because it wastes money funding tests that are not legally required and have no scientific relevance to human food consumption.

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[96] Alexandra Becraft et al., *Hepatic Metabolomic Analysis in Mice Fed a High Fat Diet with Watermelon and Watermelon Byproducts Shows Improved Lipid Metabolism and Reduction of Chronic Inflammation (P06-023-19)*, CURRENT DEVS. IN NUTRITION, 533 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6576095/pdf/nzz031.p06-023-19.pdf.

[97] Alexandra R. Becraft et al., *Intake of Watermelon or Its Byproducts Alters Glucose Metabolism, the Microbiome, and Hepatic Proinflammatory Metabolites in High-Fat–Fed Male C57BL/6 J Mice*, 150 J. NUTRITION 434, 434–42 (2020), https://pubmed.ncbi.nlm.nih.gov/31711172/ (linking to the full text).

[98] Mariana Buranelo Egea et al., *Intake of Watermelon and Watermelon Byproducts in Male Mice Fed a Western-Style Obesogenic Diet Alters Hepatic Gene Expression Patterns, as Determined by RNA Sequencing*, CURRENT DEVS. IN NUTRITION (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7442268/pdf/nzaa122.pdf.

[99] Mikayla Chen & Neil Shay, *Gene Expression Profiling in Liver of Mice Fed a High-Fat Diet Supplemented with Watermelon Flesh, Arginine, or Citrulline Shows Similar Pattern Changes*, CURRENT DEVS. IN NUTRITION 303, 303 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8181047/pdf/nzab037_013.pdf.

[100] Yuko Murase Hetrick et al., *Watermelon Powder Supplementation Reduces Colonic Cell Proliferation and Aberrant Crypt Foci by Upregulating p21$^{Waf1/Cip1}$ Expression*, 85 J. FUNCTIONAL FOODS (2021**),** https://www.sciencedirect.com/science/article/pii/S1756464621003169.

[101] *See, e.g.*, 7 U.S.C. §§ 7414(b), 7415(c).

1. Animal Testing Fails to Advance Human Health.

Health authorities acknowledge that animals are not suitable proxies for humans when used in biomedical research. The National Institutes of Health (NIH) strategic plan for 2016 to 2020 explains that "a novel drug, device, or other medical intervention takes about 14 years and $2 billion to develop, with a failure rate exceeding 95%"—despite success during preclinical animal testing.[102] The average probability of success for drugs explicitly aimed at the alimentary tract and metabolism, which is especially relevant for food-related research, is estimated to be only 4.46%, similar to the overall expectancy just noted.[103] NIH admits that "[p]etri dish and animal models often fail to provide good ways to mimic disease or predict how drugs will work in humans, resulting in much wasted time and money while patients wait for therapies."[104] Shortcomings of experiments on animals confound data and contribute to the poor translation of findings to the clinical setting. The field of nutrition research is not immune to this issue, particularly because nutrition plays an important role in many pathological conditions. A health claim established using animals has a low probability of accurate translation and reproducibility in humans, a problem widely acknowledged by regulatory bodies.[105]

Mice and rats are often the species of choice for experiments to make food health claims. However, rodents are scientifically unfit for human nutrition research. Some foods commonly consumed safely by humans are even toxic to them. For example, D-limonene, a terpene compound found in citrus oils (in orange and lemon peels) and mangoes, can cause renal tumors in male rats due to the accumulation of alpha 2u-globulin, a protein synthesized exclusively by adult male rats.[106] Persin, a fatty acid-like ingredient in avocados, can cause mastitis in lactating mice.[107] The following examples of important species differences relevant to some of the most common categories of health claims currently made for products on the market—such as regulating blood lipids and cholesterols, improving digestion, regulating the immune system, and producing anti-fatigue effects—explain why using rodents to establish human health claims is ill-advised and unscientific.

- **Regulating Blood Lipids and Cholesterols**

Bile acids are important in cholesterol excretion and lipid digestion and absorption. Rats lack a gallbladder and cystic duct, and the bile secreted by the liver travels to the intestine as it is made continuously and directly through the bile duct.[108] However, in humans, about half of the bile is

[102] *NIH-Wide Strategic Plan: Fiscal Years 2016-2020*, NIH 19 (2016), https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf.
[103] Fabio Pammolli et al., *The Productivity Crisis in Pharmaceutical R&D*, 10 NATURE 428, 431 (2011), https://www.nature.com/articles/nrd3405.
[104] *NIH-Wide Strategic Plan: Fiscal Years 2016-2020*, *supra* note 102, at 38.
[105] *See infra* Part V(A)(2).
[106] Jidong Sun, *D-Limonene: Safety and Clinical Applications*, 12 ALT. MED. REV. 259, 259, 261 (2007), http://www.cygnetenterprises.com/files/Limonene12-3.pdf.
[107] Peter B. Oelrichs et al., *Isolation and Identification of a Compound from Avocado (Persea Americana) Leaves Which Causes Necrosis of the Acinar Epithelium of the Lactating Mammary Gland and the Myocardium*, 3 NAT. TOXINS 344, 344–49 (1995).
[108] Nobuyoshi Shiojiri, *Development and Differentiation of Bile Ducts in the Mammalian Liver*, 39 MICROSCOPY RSCH. & TECH. 328, 328–35 (1997), https://pubmed.ncbi.nlm.nih.gov/9407543/ (linking to the full text).

stored in the gallbladder, where it becomes concentrated.[109] Rodents also synthesize unique bile acids called muricholic acids, which can have effects on farnesoid X receptor activation that are opposite to the effects of human forms of bile acids. This difference has major effects on cholesterol metabolism.[110]

There are also many species differences in metabolic enzymes between rodents and humans. The hepatic enzymes delta-5 and delta-6 desaturases (D5D and D6D) are important for the metabolism of fatty acids. They introduce double bonds to fatty acid chains and alter their functions. The activity of D5D is inversely related to type 2 diabetes (T2D), and the activity of D6D is directly associated with it.[111] Rats have a much higher D5D activity than humans,[112] and it is known that rodent models of T2D do not recapitulate human T2D.[113] Besides fatty acid metabolism, rodents have a unique cholesterol profile—higher high-density lipoprotein and lower low-density lipoprotein—owing to their lack of cholesteryl ester transfer proteins. This profile makes them resistant to diet-induced alterations in cholesterol metabolism and cholesterol-mediated pathology.[114] Researchers have commented that "the rat is not an appropriate human model for studies involving lipids"[115] and that "it is not possible to extrapolate directly from rat to human studies because of differences in plasma lipoprotein [cholesterol and triglycerides] metabolism between the species."[116]

- **Improving Digestion**

Nutrients go through several stages of digestion in different organs. The gastrointestinal (GI) tracts of humans and rats differ anatomically from the mouth all the way to the large intestine.[117] In the mouth, rats lack canines and premolars.[118] In the throat, the human pharynx connects the

[109] Alan F. Hofmann, *The Continuing Importance of Bile Acids in Liver and Intestinal Disease*, 159 ARCHIVES OF INTERNAL MED. 2647, 2647–58 (1999), https://pubmed.ncbi.nlm.nih.gov/10597755/ (linking to the full text).
[110] Folkert Kuipers et al., *Beyond Intestinal Soap—Bile Acids in Metabolic Control*, 10 NATURE REVS. ENDOCRINOLOGY 488, 488–98 (2014), https://pubmed.ncbi.nlm.nih.gov/24821328/ (linking to the full text).
[111] Janine Kröger & Matthias B. Schulze, *Recent Insights into the Relation of Δ5 Desaturase and Δ6 Desaturase Activity to the Development of Type 2 Diabetes*, 23 CURRENT OP. IN LIPIDOLOGY 23(1), 4, 4–10 (2012), https://pubmed.ncbi.nlm.nih.gov/22123669/ (linking to the full text).
[112] K. J. Stone et al., *The Metabolism of Dihomo-γ-linolenic Acid in Man*, 14 LIPIDS 174, 174–80 (1979), https://pubmed.ncbi.nlm.nih.gov/423720/ (linking to the full text).
[113] P. Chandrasekera & John J. Pippin, *Of Rodents and Men: Species-Specific Glucose Regulation and Type 2 Diabetes Research*, 31 ALTEX 157, 157–76 (2014), https://www.altex.org/index.php/altex/article/view/315/308.
[114] Philip Barter & Kerry-Anne Rye, *Cholesteryl Ester Transfer Protein Inhibition to Reduce Cardiovascular Risk: Where Are We Now?*, 32 TRENDS IN PHARMACOLOGICAL SCIS. 694, 694–99 (2011), https://pubmed.ncbi.nlm.nih.gov/22088767/ (linking to the full text); Ying Chea Ha & Philip J. Barter, *Differences in Plasma Cholesteryl Ester Transfer Activity in Sixteen Vertebrate Species*, 71B COMPARATIVE BIOCHEMISTRY & PHYSIOLOGY 265, 265–69 (1982).
[115] Eduardo N. Siguel, *Cancerostatic Effect of Vegetarian Diets*, 4 NUTRITION & CANCER 285, 285–91 (1983), https://pubmed.ncbi.nlm.nih.gov/6878049/ (linking to the full text).
[116] P. M. Nishina et al., *Effects of Dietary Fibers on Nonfasting Plasma Lipoprotein and Apolipoprotein Levels in Rats*, 121 J. NUTRITION 431, 431–37 (1991).
[117] J. M. DeSesso & C. F. Jacobson, *Anatomical and Physiological Parameters Affecting Gastrointestinal Absorption in Humans and Rats*, 39 FOOD & CHEMICAL TOXICOLOGY 209, 209–28 (2001), https://pubmed.ncbi.nlm.nih.gov/11278053/ (linking to the full text).
[118] *Id.*

mouth and nasal cavity to the esophagus and larynx, whereas a rat's pharynx is divided into a respiratory region and a digestive region without an oropharynx.[119] A rat's stomach contains a forestomach, which is connected to the opening of the esophagus and functions to digest bacteria, and a glandular stomach, which functions more like the human stomach. A limiting ridge between the two stomach regions prevents rodents from vomiting, which is a key mechanism in humans for getting rid of toxins.[120] The large intestine of rats does not have the sigmoid designation, owing to the lack of a true pelvis, and has a relatively large cecum, which is the main site for microbial-assisted digestion.[121] The length of other components of the GI tract also differs significantly between humans and rats relative to both the length of GI subdivisions and body size, and the relative surface area of the small intestine of humans is approximately four times that of rats.[122] These anatomic dissimilarities contribute to metabolic differences. For example, humans can absorb nutrients more efficiently than rats because of the increased surface area of the walls within the small intestine.[123]

Rats have higher needs than humans for all essential amino acids, especially those that are sulfur-containing (methionine and cysteine).[124] The digestibility of some proteins also differs between rodents and humans. For example, rapeseed protein has a digestibility of 84% to 87% in humans compared to 95% in rats due partly to its resistance to human pepsin hydrolysis.[125] Endogenous nitrogen flow in humans is 45% higher than in rats.[126] Furthermore, the fractional protein synthesis rate is 143% per day for rats but only 22% to 50% for humans, suggesting a higher intestinal mucosa protein renewal in rats, which is evident from more efficient dietary nitrogen recycling within endogenous proteins.[127] These differences confound studies involving protein metabolism.

The stomach pH of rodents is about 10 to 1,000 times less acidic than that of humans.[128] As a result, in rats, bacteria reside in the stomach and throughout the GI tract, whereas in humans, bacteria are localized mainly above the stomach and below the distal ileum.[129] Bacteria metabolize nutrients and constantly change the composition of ingested meals, affect the absorption of some nutrients, and modify the host's metabolism, immunity, and many other

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[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] Amelie Deglaire & Paul J. Moughan, *Animal Models for Determining Amino Acid Digestibility in Humans—A Review*, 108 BRIT. J. NUTRITION, S273, S273–81 (2012), https://www.cambridge.org/core/services/aop-cambridge-core/content/view/7A146BF882D3C0300B090A2CA3DEBD5F/S0007114512002346a.pdf/animal-models-for-determining-amino-acid-digestibility-in-humans-a-review.pdf.
[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] Emma McConnell et al., *Measurements of Rat and Mouse Gastrointestinal Ph, Fluid and Lymphoid Tissue, and Implications for In-Vivo Experiments*, 60 J. PHARMACY & PHARMACOLOGY 63, 63–70 (2008), https://academic.oup.com/jpp/article/60/1/63/6141788?login=false.
[129] T. T. Kararli, *Comparison of the Gastrointestinal Anatomy, Physiology, and Biochemistry of Humans and Commonly Used Laboratory Animals*, 16 BIOPHARMACEUTICS & DRUG DISPOSITION 351, 351–80 (1995).

aspects of pathophysiology.[130] The gut microbiota digests dietary fibers that are otherwise not digestible by humans, prevents the accumulation of toxic metabolic byproducts, and facilitates fatty acid hydrolysis and uptake, to name a few functions. However, about 85% of the gut bug species in rodents are not present in humans.[131] Together with the differences in their distribution and localization, gut microbiota contributes to significant species differences, especially since there are at least ten times as many gut bacteria as human cells in the human body.[132]

- **Regulating the Immune System**

In addition to the differences in gut microbiota mentioned above, there are many other differences between mouse and human immune systems, including the anatomy of lymphoid tissue, ratios of white blood cell types, antimicrobial peptide profiles, cytokine profiles and functions, mechanisms for crosstalk between the adaptive and innate immune systems, antibody subtypes, development and regulation of lymphocytes, and activation of clotting factors.[133] Noting differences between rodents and humans, researchers have found the following:

> The two species diverged somewhere between 65 and 75 million years ago, differ hugely in both size and lifespan, and have evolved in quite different ecological niches where widely different pathogenic challenges need to be met—after all, most of us do not live with our heads a half-inch off the ground. However, because there are so many parallels there has been a tendency to ignore differences and in many cases, perhaps, make the assumption that what is true in mice—in vivo veritas—is necessarily true in humans. By making such assumptions we run the risk of overlooking aspects of human immunology that do not occur, or cannot be modeled, in mice.[134]

In 2013, an extensive and collaborative statistical analysis showed that the responses of mice following acute inflammatory stressors such as burns, trauma, endotoxin exposure, and sepsis were "close to random in matching their human counterparts" and supported the "higher priority for translational medical research to focus on the more complex human conditions rather than

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[130] Caitriona M. Guinane & Paul D. Cotter, *Role of the Gut Microbiota in Health and Chronic Gastrointestinal Disease: Understanding a Hidden Metabolic Organ*, 6 THERAPEUTIC ADVANCES GASTROENTEROLOGY 295, 295–08 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3667473/pdf/10.1177_1756283X13482996.pdf; Aafke W. F. Janssen & Sander Kersten, *The Role of the Gut Microbiota in Metabolic Health*, 29 FASEB J. 3111, 3111–23 (2015), https://pubmed.ncbi.nlm.nih.gov/25921831/ (linking to the full text).

[131] Ruth E. Ley et al., *Obesity Alters Gut Microbial Ecology*, 102 PNAS 11070, 11070–75 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1176910/pdf/pnas-0504978102.pdf.

[132] Inna Sekirov et al., *Gut Microbiota in Health and Disease*, 90 PHYSIOLOGICAL REVS. 859, 859–904 (2010), https://journals.physiology.org/doi/epdf/10.1152/physrev.00045.2009.

[133] Javier Mestas & Christopher C. W. Hughes, *Of Mice and Not Men: Differences Between Mouse and Human Immunology*, 175 J. IMMUNOLOGY 2731, 2731–38 (2004), https://journals.aai.org/jimmunol/article/172/5/2731/82520/Of-Mice-and-Not-Men-Differences-between-Mouse-and.

[134] *Id.*

relying on mouse models to study human inflammatory disease."[135] A 2014 study found fundamental differences in the innate immune response between the species, stating: "While in human blood mechanisms of immune resistance are highly prevailed, tolerance mechanisms dominate for the defense against pathogenic microorganisms in mouse blood."[136]

Vitamin C is an important antioxidant and has anti-inflammatory effects as well.[137] Ascorbic acid (vitamin C for humans) is synthesized in rodents (and most other animals) in the form of L-ascorbic acid from glycogen by the enzyme L-gulonolactone oxidase.[138] However, humans do not possess this enzyme and cannot synthesize it.[139] Instead, specific transport systems for vitamin C absorption through dietary sources have evolved for humans.[140] Such differences between humans and rodents have led researchers to call for abandoning rodent use in vitamin C–related studies.[141]

Animal testing done to support health claims that foods strengthen the human immune system against influenza virus infections is also problematic because "[t]here are … a number of drawbacks of the [mouse] model that make it unsuitable for addressing certain virological questions and can render data obtained in mice difficult to translate to the human situation."[142] Viral infection is species-specific, and mice cannot naturally catch human influenza virus. Experimenters usually have to use genetically modified strains of mice susceptible to viral infections.[143] In addition, mice do not get fever—but rather hypothermia—following infection,[144] and they do not cough or sneeze, either.[145] The virus does not even transmit between mice.[146]

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[135] Junhee Seok et al., *Genomic Responses in Mouse Models Poorly Mimic Human Inflammatory Diseases*, 110 PNAS 3507, 3507–12 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3587220/pdf/pnas.201222878.pdf.
[136] Josefin Zschaler et al., *Differences in Innate Immune Response Between Man and Mouse*, 34 CRITICAL REVS. IMMUNOLOGY 433, 433–54 (2014), https://pubmed.ncbi.nlm.nih.gov/25404048/ (linking to the full text).
[137] Mohammed S. Ellulu, *Obesity, Cardiovascular Disease, and Role of Vitamin C on Inflammation: A Review of Facts and Underlying Mechanisms*, 25 INFLAMMOPHARMACOLOGY 313, 313–28 (2017).
[138] Alexander J. Michels & Balz Frei, *Myths, Artifacts, and Fatal Flaws: Identifying Limitations and Opportunities in Vitamin C Research*, 5 NUTRIENTS, 5161, 5161–92 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3875932/pdf/nutrients-05-05161.pdf.
[139] *Id*.
[140] *Id*.
[141] *Id*.
[142] Nicole M. Bouvier & Anice C. Lowen, *Animal Models for Influenza Virus Pathogenesis and Transmission*, 2 VIRUSES 1530, 1530–63 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3063653/pdf/viruses-02-01530.pdf.
[143] The viruses used in experiments on animals are often adapted through serial passage in target hosts for easy infection. This is because human influenza virus receptors (α2,6-linked sialic acids) are not abundant in the upper airways of mice, who have a different receptor (α2,3-linked sialic acids). Aida Ibricevic et al., *Influenza Virus Receptor Specificity and Cell Tropism in Mouse and Human Airway Epithelial Cells*, 80 J. VIROLOGY 7469, 7469–80 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1563738/pdf/2677-05.pdf. The virus can adapt to the new host through serial passage and becomes distinct from the kind that predominantly affects humans.
[144] Jeannine A. Majde et al., *Detection of Mouse-Adapted Human Influenza Virus in the Olfactory Bulbs of Mice Within Hours After Intranasal Infection*, 13 J. NEUROVIROLOGY 399, 399–409 (2007), https://link.springer.com/article/10.1080/13550280701427069.
[145] Bouvier & Lowen, *supra* note 142.
[146] Anice C. Lowen et al., *The Guinea Pig as a Transmission Model for Human Influenza Viruses*, 103 PNAS 9988, 9988–92 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1502566/pdf/zpq9988.pdf.

- **Producing Anti-Fatigue Effects**

Mice and rats vastly differ from humans in regard to muscle physiology and should not be used for human nutrition research. The performance of skeletal muscles is determined mainly by muscle fiber types, which are designated by myosin heavy chain (MyHC) protein isoforms expressed within. Mice and rats are the complete opposite of humans in terms of MyHC expressions.[147] Their skeletal muscle is predominantly composed of muscle fibers expressing MyHC IIb. In contrast, human skeletal muscle expresses MyHC I/β. (The overall MyHC isoform abundance in mice and rats is IIb > IIx > IIa > I/β, whereas, in humans, it is I/β > IIa > IIx.) Muscles expressing MyHC IIb tend to be larger fibers, contract faster, produce larger forces, are rich in glycolytic enzymes and tend to run on the anaerobic energy system, have low mitochondria and capillary density, and have low resistance to fatigue.[148] Muscles expressing MyHC I/β are the complete opposite; they are smaller, contract slower, produce smaller forces, are rich in mitochondria, capillary, and oxidative capacity and hence run on the aerobic energy system, and have high resistance to fatigue.[149] (Elite runners have more/bigger muscles expressing MyHC I/β; this can be an adaptive and acquired characteristic.)

The protein synthesis rate also differs between type II and type I muscle fibers. In response to food deprivation, there is a greater decrease in protein synthesis in type II fibers than in type I.[150] This is important because it translates to differential muscle function between mice or rats and humans under food deprivation.

Muscle glycogen, expressed relative to total body glycogen, is about ten times lower in mice than in humans.[151] Both mice[152] and rats[153] have about five to ten times more liver glycogen than muscle glycogen, whereas humans have three to eight times more muscle glycogen than liver glycogen.[154] Even though it is well documented that adequate muscle glycogen is important to sustain exercise in humans, accumulating evidence shows that muscle glycogen is not even necessary for mice to perform demanding muscle activities. For example, genetically modified

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[147] K. M. Haizlip et al., *Sex-Based Differences in Skeletal Muscle Kinetics and Fiber-Type Composition*, 30 PHYSIOLOGY 30, 30–39 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4285578/.
[148] Juleen R. Zierath & John A. Hawley, *Skeletal Muscle Fiber Type: Influence on Contractile and Metabolic Properties*, 2 PLOS BIOLOGY 1523, 1523–27 (2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521732/pdf/pbio.0020348.pdf.
[149] *Id.*
[150] Craig A. Goodman et al., *Muscle Fiber Type-Dependent Differences in the Regulation of Protein Synthesis*, 7 PLOS ONE (2012) (e37890), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358270/.
[151] Masato Kasuga et al., *Tissue Glycogen Content and Glucose Intolerance*, 111 J. CLINICAL INVESTIGATION 1282, 1282–84 (2003), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC154454/pdf/JCI0318526.pdf.
[152] Bartholomew A. Pederson et al., *Exercise Capacity of Mice Genetically Lacking Muscle Glycogen Synthase: In Mice, Muscle Glycogen Is Not Essential for Exercise*, 280 J. BIOLOGICAL CHEMISTRY 17260, 17260–65 (2005), https://www.jbc.org/action/showPdf?pii=S0021-9258%2820%2965904-X.
[153] K. M. Baldwin et al., *Substrate Depletion in Different Types of Muscle and in Liver During Prolonged Running*, 225 AM. J. PHYSIOLOGY 1045, 1045–50 (1973), https://pubmed.ncbi.nlm.nih.gov/4745201/ (linking to the full text).
[154] John L. Ivy, *Role of Carbohydrate in Physical Activity*, 18 CLINICS SPORTS MED. 469, 469–84 (1999), https://pubmed.ncbi.nlm.nih.gov/10410835/ (linking to the full text).

mice completely lacking muscle glycogen could run on treadmills until exhaustion, just like normal mice.[155] Genetically modified mice with over-accumulated muscle glycogen did not perform any better than normal mice did, either.[156]

In addition to glycogen, blood fatty acids and blood sugar are important fuel sources during exercise. However, as explained above, the metabolism of fatty acids and glucose is significantly different in mice and rats than in humans.

2. Animal Testing Is Not Legally Required to Establish Human Health Claims for Marketing Agricultural Products or Ingredients.

The United States, the European Union, and Canada all require human data—not animal data—to substantiate health claims for food. Recognizing that the "physiology of animals is different than that of humans,"[157] the U.S. Food and Drug Administration, the European Food Safety Authority, and the Food Directorate of Health Canada do not require studies on animals or accept them in isolation to make health claims.

a. U.S. Food and Drug Administration (FDA)

The FDA—a U.S. federal agency responsible for protecting public health by ensuring that the public gets accurate, science-based information to use foods to maintain and improve health[158]—does not require experiments on animals or accept animal data as stand-alone evidence for establishing health claims for foods. Authorized health claims in food labeling describe the relationship between a substance (i.e., the specific food or food component) and a disease, and have been reviewed and approved by the FDA.[159]

> [These claims] are allowed on food products or dietary supplements to show that a food or food component may reduce the risk of a disease or a health-related condition. Such claims are supported by scientific evidence and may be used on conventional foods and on dietary supplements to characterize a relationship between a

[155] Bartholomew A. Pederson et al., *Exercise Capacity of Mice Genetically Lacking Muscle Glycogen Synthase: In Mice, Muscle Glycogen Is Not Essential for Exercise*, 280 J. BIOLOGICAL CHEMISTRY 17260, 17260–65 (2005), https://www.jbc.org/action/showPdf?pii=S0021-9258%2820%2965904-X.
[156] Bartholomew A. Pederson et al., *Mice with Elevated Muscle Glycogen Stores Do Not Have Improved Exercise Performance*, 331 BIOCHEMICAL & BIOPHYSICAL RSCH. COMMC'NS 491, 491–96 (2005), https://pubmed.ncbi.nlm.nih.gov/15850786/ (linking to the full text).
[157] *Guidance for Industry: Evidence-Based Review System for Scientific Evaluation of Health Claims*, FDA (Jan. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evidence-based-review-system-scientific-evaluation-health-claims [hereinafter "*FDA Guidance*"] (Section III(B)).
[158] *FDA Mission*, FDA (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do.
[159] *FDA Guidance*, *supra* note 157 (Section II).

> substance (a specific food component or a specific food) and a disease or health-related condition (e.g., high blood pressure).[160]

The FDA evaluates the totality of scientific evidence and approves health claims only after determining that the evidence is in "significant scientific agreement."[161] The FDA's guidance document for industry, *Evidence-Based Review System for the Scientific Evaluation of Health Claims*, lists different types of evidence in order of their strength, beginning with human interventional studies—the most reliable category of studies for determining cause-and-effect relationship—followed by observational studies, research synthesis studies (reviews and meta-analysis), and, lastly, animal and *in vitro* studies.[162] The document states:

> Before the strength of the evidence for a substance/disease relationship can be assessed, FDA separates individual relevant articles on human studies from other types of data and information. FDA intends to focus its review *primarily on articles reporting human intervention and observational studies because only such studies can provide evidence from which scientific conclusions can be drawn about the substance/disease relationship in humans* . . . . FDA intends to use animal and *in vitro* studies as background information regarding mechanisms that might be involved in any relationship between the substance and disease.[163]

In its guidance document, the FDA discusses only human studies when it describes methods for evaluating and assessing the quality of studies (e.g., study design, data collection, the quality of the statistical analysis)—a process the FDA undertakes for studies that are not eliminated during the earlier evaluation.[164] When describing methods for evaluating the totality of scientific evidence, the FDA does not even mention animal studies.[165] The FDA's evidence-based review system for scientifically evaluating health claims in food labeling expressly recognizes that animal studies "do not provide information from which scientific conclusions can be drawn regarding the relationship between the substance and disease in humans."[166] Accordingly, the FDA does not accept animal data as stand-alone evidence for establishing health claims for foods and, as noted above, does not require experiments on animals.

b. European Food Safety Authority (EFSA)

The EFSA—the European Union (EU) agency "responsible for verifying the scientific substantiation of [health] claims"[167]—does not require tests on animals or accept animal data as

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[160] *Authorized Health Claims that Meet the Significant Scientific Agreement (SSA) Standard*, FDA (Mar. 7, 2022), https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard.
[161] *Id*.
[162] *FDA Guidance*, *supra* note 157.
[163] *Id*. (emphasis added).
[164] *Id*. (Section III(E)).
[165] *Id*. (Section III (F)).
[166] *Id*. (Section III(B)).
[167] *Health Claims*, EFSA, https://www.efsa.europa.eu/en/topics/topic/health-claims (last visited Mar. 1, 2024).

stand-alone evidence for establishing health claims for foods. The EFSA identifies several categories of health claims (i.e., statements on labels, advertising, or other marketing products that claim health benefits can result from consuming a given food).[168] For claims other than those based on the essentiality of nutrients,[169] EFSA describes the following requirements for the assessment of scientific evidence:

> In assessing each specific food/health relationship which forms the basis of a claim, the [EFSA Panel on Dietetic Products, Nutrition and Allergies ("EFSA NDA Panel")] makes a scientific judgement on the extent to which a cause and effect is established between the consumption of the food/constituent and the claimed effect (i.e. *for the target group under the proposed conditions of use*) by considering the strength, consistency, specificity, dose-response, biological plausibility of the relationship and by weighing the totality of the evidence. A grade is not assigned to the evidence.
>
> *Pertinent human (intervention and observational) studies are central for health claim substantiation.* Pertinent human intervention studies are at the top of the hierarchy that informs decisions on substantiation because it is of utmost importance to show that the food/constituent can exert the claimed effect in humans and that the effect is specific for the food/constituent, an information which *can only be obtained from human intervention studies* (EFSA NDA Panel, 2011b). Human intervention (and observational) studies can also provide evidence for a dose-response relationship and for consistency of the effect (or the association) across studies. Efficacy studies in animals and non-efficacy studies in humans, animals and/or in vitro (e.g. evidence for a mechanism

[168] *Id*. General function claims "refer to the role of a nutrient or substance in growth, development and body functions; psychological and behavioural functions; slimming and weight control, satiety or reduction of available energy from the diet." *"General Function" Health Claims Under Article 13*, EFSA, https://www.efsa.europa.eu/en/topics/topic/general-function-health-claims-under-article-13 (last visited Mar. 1, 2024). New function claims are "based on newly developed scientific evidence [for which] protection of proprietary data can be requested." *Health Claims*, *supra* note 167 (click on "What are EFSA's tasks under the Regulation?"). Other claims "refer to the reduction of disease risk or to children's development or health." *Claims on Disease Risk Reduction and Child Development or Health Under Article 14*, EFSA, https://www.efsa.europa.eu/en/topics/topic/claims-disease-risk-reduction-and-child-development-or-health-under (last visited Mar. 1, 2024).

[169] The NDA Panel considers claims that meet the following requirements on the relationship between the consumption of a nutrient and human body function(s) as claims based on the essentiality of nutrients:

> i. the nutrient is required for normal human body function(s), i.e. it has an essential mechanistic role in a metabolic function and/or it has the ability to reverse clinical signs and symptoms of its deficiency;
> ii. the nutrient cannot be synthesised by the body, or cannot be synthesised in amounts which are adequate to maintain normal body function(s);
> iii. the nutrient must be obtained from a dietary source.

General Scientific Guidance for Stakeholders on Health Claim Applications, 14 EFSA J. 11 (2016), https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4367.

> by which a food could exert the claimed effect) may be part of the totality of the evidence only if pertinent human studies showing an effect of the food/constituent are available.[170]

Consequently, the EFSA's scientific evaluation process precludes animal data as stand-alone evidence for establishing health claims for foods and does not require such data at all.

c. Food Directorate of Health Canada (FDHC)

The FDHC—the federal health authority in Canada "responsible for assessing health risks and benefits, setting standards, policies, and regulations, and providing advice and information regarding the safety and nutritional quality of food"[171]—categorizes health claims as either disease risk reduction or function claims.[172] Whereas function claims are "statements about the specific benefits a food has on normal body functions," disease risk reduction claims are "statements that link a food to a lower risk of developing a disease or condition."[173] For both types of claim, FDHC explains:

> Health Canada's evaluation of a health claim will be based on *human studies—intervention and/or prospective observational studies*. As such, the literature search strategy should be established with a focus on retrieving human studies. *The scientific uncertainties in extrapolating non-human data to humans limit the usefulness of non-human studies, such as animal and in vitro studies*. A submission guided by this document should thus be based on the retrieval and evaluation of human studies. If desired, non-human studies may be used to support the discussion on biological plausibility. This is, however, optional.[174]

By making animal studies non-compulsory evaluation criteria and failing to reference animal studies when discussing the validity of study designs, the FDHC reinforces that animal data is unacceptable stand-alone evidence for establishing health claims for foods.

The fundamentally significant species differences explain why testing on animals to establish human health claims for marketing food products is misguided, unscientific, and may lead to substantively misleading advertising. The policies of the FDA, EFSA, and FDHC reinforce this by requiring only human data to substantiate health claims for food. As AMS is responsible for ensuring that R&P board activities effectuate the purpose of the Orders (i.e., to make the

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[170] *Id*. at 12 (emphasis added).
[171] *Food Directorate*, CANADA (Sept. 22, 2021), https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/food-directorate.html.
[172] *Health Claims*, CANADA (Jan. 8, 2024), https://www.canada.ca/en/health-canada/services/food-nutrition/nutrition-labelling/nutrition-claims.html.
[173] *Id*.
[174] *Guidance Document for Preparing a Submission for Food Health Claims*, CANADA (Oct. 17, 2011) (emphasis added), https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-preparing-submission-food-health-claims-2009-1.html#a1-5 (Section 1.5).

marketing of agricultural commodities more efficient),[175] and all of the Orders either expressly prohibit misleading advertising or authorize terminating a program, plan, or project that does not contribute to an effective program of promotion, research, or information,[176] AMS must not continue to authorize the use of assessments to fund animal testing.

B. Funding Animal Testing Defies Congressional Intent by Failing to Serve a Vital Purpose for Farmers and Consumers.

Congress regarded the purpose of R&P boards' promotion, research, and information activities for their respective agricultural commodities as "vital to the welfare of persons engaged in the production, marketing, and consumption of such commodities."[177] However, since most consumers oppose animal testing, funding this activity threatens the position of the agricultural commodity in the marketplace. The policies of many major food manufacturers—companies that rely on consumer demand to drive sales—condone only those research approaches that do not involve animal testing.

1. Consumers and the Food Industry Oppose Animal Testing.

Animal testing does not increase the marketing and promotional appeal of agricultural commodities. Dozens of major food and beverage manufacturers have established policies against funding, conducting, or commissioning experiments on animals that are not explicitly required by law; AMS should do the same. Table 1 identifies a limited sampling of these companies. Many of these businesses (e.g., B&G Foods, General Mills, Flowers Foods, The Coca-Cola Company) use agricultural commodities (e.g., blueberries, mangos, mushrooms, sorghum, soybeans, watermelon) in their products.[178] Some companies (e.g., Chobani Global Holdings) have also extended the same anti-animal-testing policy to their suppliers (i.e., "Chobani does not fund, conduct, or commission any tests on animals unless they are explicitly required by law."),[179] thereby preventing any commodity supplier, subject to assessments under orders that fund animal testing, from supplying the manufacturer under the current scheme.

[175] *See, e.g.*, 7 U.S.C. § 7415(c).
[176] *See, e.g.*, 7 C.F.R. §§ 1218.54(c)–(d), 1221.111–.121(c).
[177] 7 U.S.C. § 7411(a)(3); *see also id*. §§ 6101(a)(5), 6301(a)(4), 4901(a)(5).
[178] *See, e.g.*, *Fruits + Veggies*, CASCADIAN FARM, https://www.cascadianfarm.com/products/fruits-veggies/ (last visited Mar. 4, 2024) (General Mills) (displaying products containing blueberries, mangos, and soybeans); *Mushrooms*, GREEN GIANT, https://greengiant.com/products/canned-vegetables/canned-vegetablesmushrooms/ (last visited Mar. 1, 2024) (B&G Foods); *21 Whole Grains and Seeds*, DAVES KILLER BREAD, https://www.daveskillerbread.com/21-whole-grains-and-seeds (last visited Mar. 1, 2024) (Flowers Foods) (listing organic sorghum flour as an ingredient); *Watermelon*, MINUTEMAID, https://www.minutemaid.ca/en/products/drinks/watermelon/ (last visited Mar. 1, 2024) (The Coca-Cola Company).
[179] *Supplier Code of Conduct*, CHOBANI (Nov. 15, 2022), https://www.chobani.com/supplier-code-of-conduct.

Entity	Corporate Policy Reference[180]
B&G Foods	*Animal Welfare*, B&G FOODS, https://bgfoods.com/about/responsibility/.
Barilla	*Animal Welfare*, BARILLA GRP., https://www.barillagroup.com/media/filer_public/39/e3/39e3a629-75cb-4bd9-8f7a-f9aa3bd97ae0/our_position_animal_welfare_barillagroup_2023.pdf.
Barry Callebaut	*Our Animal Testing Statement*, BARRY CALLEBAUT, https://www.barry-callebaut.com/en/group/forever-chocolate/ethical-sourcing-and-business#Animal%20testing.
Chobani Global Holdings, LLC	*Supplier Code of Conduct*, CHOBANI (Nov. 15, 2022), https://www.chobani.com/supplier-code-of-conduct.
The Coca-Cola Company	*Animal Health and Welfare Guiding Principles*, COCA-COLA CO. (Nov. 3, 2023), https://www.coca-colacompany.com/policies-and-practices/animal-health-and-welfare-guiding-principles.
Flowers Foods	*Our Commitment to Animal Welfare*, FLOWERS FOODS, https://flowersfoods.com/wp-content/uploads/2023/04/animal-welfare-commitment.pdf.
General Mills	*Animal Welfare Policy*, GEN. MILLS, https://www.generalmills.com/how-we-make-it/healthier-planet/sustainable-and-responsible-sourcing/animal-welfare.
Heineken	*Heineken Ingredients*, HEINEKEN, https://www.heineken.com/global/en/faq (click on "Are Heineken's ingredients tested on animals?").
The Hershey Company	*Animal Welfare*, HERSHEY, https://www.thehersheycompany.com/en_us/home/sustainability/sustainability-focus-areas/responsible-sourcing/priority-ingredients-and-materials/animal-welfare.html.
Ingredion	*Animal Testing Policy*, INGREDION, https://www.ingredion.com/content/dam/ingredion/pdf-downloads/corporate/sustainability-documents/Animal-Testing-Policy-05-11-21.pdf
Lindt & Sprüngli	*Other Frequently Asked Questions*, LINDT SPRUENGLI, https://www.lindt-spruengli.com/frequently-asked-questions (click on "Does Lindt & Sprüngli fund, conduct, or commission any tests on animals?").
McCain Foods	*Corporate Policy*, MCCAIN, https://www.mccain.com/information-centre/faqs/ (click on "What is McCain Foods position on animal testing?").
Molson Coors Beverage Company	*Governance & Ethics*, MOLSON COORS, https://www.molsoncoors.com/about/governance-and-ethics (click on "Animal Welfare").
Monde Nissin Corporation	*Company Quorn FAQ's*, QUORN, https://www.quorn.us/faqs/company#faqs (click on "Are animal studies/experiments carried out during the development of Quorn products?").
Pernod Ricard	*Global Environmental Policy*, PERNOD RICARD 5, https://www.pernod-ricard.com/sites/default/files/2021-08/Pernod-Ricard-Global-Environmental-Policy.pdf.

[180] All references were last visited on March 1, 2024.

Strauss Group	*Animal Welfare Policy*, STRAUSS GROUP 3, https://www.strauss-group.com/wp-content/blogs.dir/3/files/sites/3/Animal-welfare-Policy-Jan-2020-accessible.pdf.

Table 1. Food and beverage manufacturers that prohibit animal testing to establish human health claims for marketing their products and ingredients.

A 2018 Pew Research Center survey conducted among a nationally representative sample of 2,527 U.S. adults reported that the majority (52%) of the U.S. public opposes the use of animals in scientific research.[181] A 2015 Gallup poll, based on a random sample of 527 U.S. adults, reported that 67% of Americans are concerned or very concerned about the well-being of animals in laboratories.[182] A 2020 survey of 5,653 adults in EU member states reported that the majority (66%) think the EU should immediately end all animal testing.[183] A 2018 Accenture Strategy Global Consumer Pulse Research survey of nearly 30,000 consumers from around the world reported that the vast majority (74%) of consumers "crave greater transparency in how companies source their products . . . and their stance on important issues such as animal testing."[184]

Consumers have publicly opposed animal testing conducted to promote agricultural commodities under the Orders for years. After more than 85,000 consumers contacted the Hass Avocado Board and asked it to end its animal testing, it adopted a new public policy stating that it "does not support, fund, or conduct animal research."[185] Over 100,000 consumers have contacted other R&P boards and the USDA, requesting them to prohibit assessment fees that fund animal testing.[186]

2. Farmers Oppose Animal Testing.

Advocacy groups for farmers have urged the USDA to use its authority to establish controls to curb waste that contributes to farmers' financial burden associated with federally mandated assessment fees used to fund animal testing. The AMS "provides oversight, paid for by industry

[181] Cary Funk & Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals that Benefits Human Health, but Many Oppose Other Uses*, PEW RSCH. CTR. (Aug. 16, 2018), https://www.pewresearch.org/science/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses/.
[182] Rebecca Riffkin, *In U.S., More Say Animals Should Have Same Rights as People*, GALLUP (May 18, 2015), https://news.gallup.com/poll/183275/say-animals-rights-people.aspx.
[183] *Cruelty Free Europe—Animal Testing in the EU*, SAVANTA (July 17, 2020), https://savanta.com/eu/knowledge-centre/poll/cruelty-free-europe-animal-testing-in-the-eu/.
[184] Press Release, Majority of Consumers Buying from Companies that Take a Stand on Issues They Care About and Ditching Those That Don't, Accenture Study Finds, ACCENTURE (Dec. 5, 2018), https://newsroom.accenture.com/news/2018/majority-of-consumers-buying-from-companies-that-take-a-stand-on-issues-they-care-about-and-ditching-those-that-dont-accenture-study-finds.
[185] *See Hass Avocado Board Bans Animal Experiments*, *supra* note 4.; Research Opportunities, *supra* note 4 ("The [Avocado Nutrition Center] does not support animal research.").
[186] *Animals Beheaded for Blueberries? USDA Farmer 'Tax' Funds Cruel Tests*, PETA, https://support.peta.org/page/22117/action/1 (last visited Mar. 1, 2024).

assessments, which helps *ensure fiscal accountability* and program integrity."[187] Funding for worthless and deadly experiments on animals comes from a portion of the hundreds of millions of dollars in annual fees that farmers are required to pay to agricultural commodity R&P boards. According to the U.S. Government Accountability Office, these fees totaled $885 million in 2016 alone.[188] Between 2016 and 2019, the Soybean Board assessed farmers more than $3.2 million to fund experiments on animals.[189] Between 2017 and 2020, more than $448,000 of assessments from sorghum farmers funded experiments on animals.[190] Between 2017 and 2019, the Watermelon Board spent more than $177,000 from assessments to fund experiments on animals.[191] Animal testing wastes these farmer-paid assessment funds because animals are scientifically unfit "models" for human food research, regulatory agencies do not require such experiments, and consumers shun the activity.

Family Agriculture Resource Management Services (F.A.R.M.S.), a national advocacy group for Black farmers and leading nonprofit dedicated to reversing small farmland loss in low-income rural areas,[192] wrote to the USDA and various boards, stating that "[m]any farmers in today's economy are struggling. They don't need barbaric tests on animals to sell their agricultural commodities. Rather, they need economic relief from inflated assessment fees that are wasted on worthless experiments on animals."[193] Likewise, Farms to Grow, Inc., a national advocacy group for Black and other underserved minority farmers,[194] wrote to the same audience, stating it "defies logic that these tests—in which animals have been beheaded for blueberries, mutilated for mangoes, and suffocated for soybeans—would purport to help promote those agricultural products, since the majority of consumers don't support animal cruelty."[195]

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[187] Research & Promotion Programs, *supra* note 9 (emphasis added).
[188] U.S. Gov't Accountability Off., GAO-18-54, Agricultural Promotion Programs: USDA Could Build on Existing Efforts to Further Strengthen Its Oversight 1 (2017), https://www.gao.gov/assets/gao-18-54.pdf.
[189] *See* Exhibit 1 (Soybean Board) (describing data obtained through FOIA request 2020-AMS-00248-F).
[190] *See* Exhibit 2 (United Sorghum Checkoff Program) (describing data obtained through FOIA request 2020-AMS-00248-F).
[191] *See* Exhibit 3 (Watermelon Board) (describing data obtained through FOIA request 2020-AMS-00248-F).
[192] *See About Us*, FARMS, https://30000acres.org/about-us/ (last visited Mar. 1, 2024).
[193] Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Thomas J. Vilsack, Sec'y of Agric., USDA (July 7, 2021), https://www.peta.org/wp-content/uploads/2021/07/FARMS-to-USDA-and-checkoffs-re-animal-testing-1.pdf; Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Bart Minor, President and CEO, Mushroom Council (July 7, 2021); Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Manual Michel, Exec. Dir., Nat'l Mango Board (July 7, 2021); Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Mark Arney, Exec. Dir./CEO, Nat'l Watermelon Promotion Board (July 7, 2021); Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Polly Ruhland, CEO, United Soybean Board (July 7, 2021); Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Tim Lust, CEO, United Sorghum Checkoff Program (July 7, 2021); Letter from Jillian Hishaw, F.A.R.M.S. Founding Dir., to Kasey Cronquist, President, U.S. Highbush Blueberry Council (July 7, 2021).
[194] *See* About Us, FARMS TO GROW, https://www.farmstogrow.com/about (last visited Mar. 1, 2024).
[195] Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Thomas J. Vilsack, Sec'y of Agric., USDA (Oct. 28, 2021), https://www.peta.org/wp-content/uploads/2021/10/2021-10-28-FTG-to-USDA-and-checkoffs-re-animal-testing.pdf; Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Kasey Cronquist, President, U.S. Highbush Blueberry Council (Oct. 28, 2021); Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Tim Lust, CEO, United Sorghum Checkoff Program (Oct. 28, 2021); Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Polly Ruhland, CEO, United Soybean Board (Oct. 28, 2021); Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Bart Minor, President and CEO, Mushroom Council (Oct. 28, 2021); Letter from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Manuel Michel, Exec. Dir., Nat'l Mango Board (Oct. 28, 2021); Letter

Congress intended activities promoted under the Orders to serve a vital purpose for farmers and consumers. However, both groups have opposed animal testing because this activity does not advance Congress' objective. Just as the Orders prohibit other activities that may undermine their purpose (e.g., actions that would be a conflict of interest),[196] AMS must prohibit R&P boards from using assessments to fund tests on animals because this activity also compromises "fiscal accountability and program integrity."[197]

C. Animal Testing Funded by R&P Boards Is Not in Accord with Federal Guiding Principles Related to the Use of Animals in Experimentation.

The absence of any human toxicity concern associated with the agricultural commodities in this petition means that researchers could safely conduct their studies on humans, which would yield clinically relevant results, unlike experiments on mice, rats, and other animals. Also, researchers widely use advanced *in vitro* and computational models for researching the mechanisms and safety of the effects of food on human health. Proceeding in this manner (i.e., funding only non-animal, human-relevant experiments) would adhere to research guidelines described in U.S. government-issued publications. For example, the *U.S. Public Health Service's Guide for the Care and Use of Laboratory Animals* includes the principle of "consideration of alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals."[198] The "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" states that "animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results."[199] Adhering to these standards would reduce the number of animals used in experiments funded by R&P boards from thousands to zero because the law does not require testing on animals and experimenters can safely conduct all experiments using exclusively non-animal methods.

VI. PROPOSED RULE CHANGE

Petitioner requests the United States Department of Agriculture, through its component agency, the Agricultural Marketing Service, amend the following orders/rules and regulations of the respective commodity research and promotion programs overseen by AMS as described, including defining "animal testing" and prohibiting the use of assessments for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing, except as explicitly required by law.

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from Gail P. Myers, Cofounder, Farms to Grow, Inc., to Mark Arney, Exec. Dir./CEO, Nat'l Watermelon Promotion Board (Oct. 28, 2021).

[196] *See, e.g.*, 7 U.S.C. § 1221.111(a).

[197] Research & Promotion Programs, *supra* note 9.

[198] GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS 12 (Nat'l Rsch. Council, 8th ed. 2011), https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf.

[199] *Id*. at 199.

- **Blueberry Order**

  Add 7 C.F.R. § 1218.24 (new):

  > Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

  Amend 7 C.F.R. § 1218.48 to add:

  > (c) Using funds collected by the Council under the Order to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing. This prohibition shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Council and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Hass Avocado Order**

  Add 7 C.F.R. § 1219.27 (new):

  > Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

  Amend 7 C.F.R. § 1219.42 to add:

  > (e) Using funds collected under this subpart for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing. This prohibition shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Board and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Mango Order**

  Add 7 C.F.R. § 1206.25 (new):

Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

Amend 7 C.F.R. § 1206.37 to add:

(c) Using funds collected by the Board under the Order to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing. This prohibition shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Board and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Mushroom Order**

Add 7 C.F.R. § 1209.22 (new):

Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

Amend 7 C.F.R. § 1209.50 to add:

(h) The Council shall not engage in, and shall prohibit the employees and agents of the Council from engaging in, using funds collected by the Council under this subpart to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing. This prohibition shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Council and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Sorghum Order**

Add 7 C.F.R. § 1221.33 (new):

Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

Amend 7 C.F.R. § 1221.111 to add:

> (d) Using funds collected by the Board under the Order to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing. This prohibition shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Board and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Soybean Order**

Add 7 C.F.R. § 1220.131 (new):

> Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

Add 7 C.F.R. § 1220.231 (new):

Animal testing.

(a) Except as otherwise provided in paragraph (b) of this section, the Board shall not engage in, and shall prohibit the employees and agents of the Board from engaging in, using funds collected by the Board under this subpart to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing.

(b) The prohibition in paragraph (a) of this section shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Board and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

- **Watermelon Plan**

Add 7 C.F.R. § 1210.316 (new):

> Animal testing means using living and/or dead animals as test subjects, in whole or in part, including, without limitation, amphibians, birds, fish, invertebrates, mammals other than humans, and reptiles to perform tests.

Add 7 C.F.R. § 1210.368 (new):

Animal testing.

(a) Except as otherwise provided in paragraph (b) of this section, the Board shall not engage in, and shall prohibit the employees and agents of the Board from engaging in, using funds collected by the Board under this Plan to undertake any action for the purpose of engaging in, entering into a contract for, conducting, funding, or commissioning any study, test, experiment, research, laboratory procedure, or promotion activity that uses animal testing.

(b) The prohibition in paragraph (a) of this section shall not apply where explicitly required by law. If animal testing is explicitly required by law, prior to engaging in animal testing, both the Board and the Secretary must publicly issue findings that such animal testing is explicitly required by law. Such determinations are non-delegable.

Exhibit 1

United Soybean Board
FY2017 Research Projects

Start Date	End date	Project Name	Project Number	Fiscal Year Spending
10/1/2016	9/30/2017	Modify Soluble Carbs 09/19	1720-152-0101	610,649.38

United Soybean Board
FY2018 Research Projects

Start Date	End date	Project Name	Project Number	Fiscal Year Spending
10/1/2017	9/30/2018	Modify Soluble Carbs 09/20	1720-152-0101	187,366.33
10/1/2017	9/30/2018	Modify Carbs in Soy Seed 09/20	1820-152-0101	429,861.59
10/1/2017	9/30/2018	Global Soy in Aqua Research 09/19	1830-352-0501	569,921.58
10/1/2017	9/30/2018	New US Soy Utilization in Aqua 09/19	1830-352-0502	66,284.68
10/1/2017	9/30/2018	New Utilization Research 09/19	1830-352-0509	81,640.00
10/1/2017	9/30/2018	Industrial Uses Meal Biorefinery 09/19	1840-352-0707	832,824.53
				2,167,898.71

United Soybean Board
FY2019 Research Projects

Start Date	End Date	Project Name	Project	Fiscal Year Spending
10/1/2018	9/30/2019	Global Soy in Aqua Research 09/19	1830-352-0501	14,467.52
10/1/2018	9/30/2019	US Soy Meal in Animal Agriculture 09/20	1930-352-0509	363,391.13
10/1/2018	9/30/2019	HO Soy Oil in Animal Ag 09/21	1930-362-0602	37,757.38
10/1/2018	9/30/2019	Rodent Gnawing of Rubber Compounds 09/20	1940-362-0727	30,940.00
				446,556.03

Exhibit 2

United Sorghum Checkoff Program

Code	Title	Entity	Start Date	Budget Total
RG004-16	Sorghum as a feedstuff for gamebirds and broilers in the Southeast	Clemson University	7/1/2017	$ 99,868.00
RN002-18	Colon Cancer Chemoprevention with Sorghum - Impact of Cooking	Michigan State University	8/16/2018	$ 88,242.59
MD004-19	Supplementation of gluten-free sorghum flour based pet treat with animal protein sources; effects on dough and product quality and animal acceptance	Kansas State University	3/1/2019	$ 49,092.00
RG001-20	Enhancing Sorghum Opportunities in Domestic and Export Aquafeed Sectors	Virginia Polytechnic Institute & State University	1/10/2020	$211,246.00

Exhibit 3

National Watermelon Promotion Board

Year	Vertebrate Research	Total Research Funds
2017	$39,900	$304,752
2018	$95,000	$330,540
2019	$42,500	$315,813

2017

Oregon State University - Defining the Metabolic Benefits of Watermelon and Watermelon By-Product Consumption During Consumption of an Unhealthy Western-Style Diet $39,900

2018

Oregon State University – Investigating the Differential Effects on Metabolism with Consumption of Watermelon and Watermelon By-Product During Intake of an Unhealthy Western-Style Diet $45,000

Oklahoma State University – Watermelon and the Bioactive Compounds Promote the Digestive Health in Diabetes $50,000

2019

Oregon State University – Understanding the Healthy Components of Watermelon Flesh and V Value-Added Products $42,500