To amend the Federal Food, Drug, and Cosmetic Act to require labeling of genetically engineered fish (HR 205, 115th Congress)

Brief Authors
Jesse Mangold

Brief Editors
Brian Langloss, PhD, [6] Alex Robeson, PhD [7]

Sponsor / Author
Representative Don Young (R-AK-At Large) [10]

Co-Sponsors
Representative Peter DeFazio (D-OR-4) [11]

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Referred to Subcommittee

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Originating Entity
House of Representatives [12]

The Policy

What it does
Amends the Federal Food, Drug, and Cosmetic Act to require labeling of genetically engineered fish.

Synopsis
This bill amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq [13]) to prohibit the sale of genetically engineered fish unless it bears a label. Specifically, HR 205 [14] deems any food that contains genetically engineered fish to be "misbranded food" (21 U.S.C. 343 [15]) unless it bears a label stating that the food contains genetically engineered fish.

Context
On November 19, 2015, the FDA approved [16] the GE AquAdvantage salmon to be the first genetically modified animal cleared for consumption. The labeling of GE salmon is not required by law. However, many consumers are interested in this information. Thus, on November 24, 2015, the FDA posted a draft Guidance for Industry (GFI) for the voluntary labeling of GE salmon by industry manufacturers. Citing the Food, Drug, and Cosmetic Act’s definition of “misbranded articles” (21 U.S.C. 321(n) [18]), the FDA only requires additional labeling of GE foods if there is a material difference between the GE product and non-GE counterpart. According to the draft GFI, potential material differences include “differences in the basic nature of the food, material differences in the consequences of use, material differences in the nutritional properties, or contained any allergens that the consumer would not expect to be in the food.” FDA review found no material differences between AquAdvantage salmon and standard Atlantic salmon, and therefore the FDA cannot require mandatory labeling. The FDA has not yet published a final GFI regarding labeling of GE salmon.

Policy History
HR 4713 [19], titled “Genetically Engineered Salmon Labeling Act,” requires genetically modified salmon to be labeled accordingly and calls for independent scientific review of FDA activities relating to AquAdvantage salmon. The bill was introduced in the House on March 3, 2016, and was referred to the Subcommittee on Health by the Committee on Energy and Commerce on March 4, 2016.

SciPol development brief available at:
The Science

Science Synopsis

Genetic engineering (GE) is a biotechnology that enables the transfer of select individual genes from one organism to another. This process has been widely employed in modern agriculture to give rise to genetically modified (GM) foods, such as insect-resistant crops, where a gene for toxin production found in bacteria is incorporated into the plant genome.

Furthermore, AquaBounty Technologies has used genetic engineering to significantly increase the growth rate of Atlantic salmon and thereby reduce the time required to reach market size compared to non-GE counterparts. This result is accomplished by adding a growth hormone found in Chinook salmon and a gene promoter found in ocean pout to the Atlantic salmon genome to accelerate growth.

Relevant Experts

Alison Van Eenennaam, PhD is a Cooperative Extension Specialist in Animal Biotechnology and Genomics at the University of California, Davis. Her research interests lie in animal genetics, genetic improvement of food animals, agricultural biotechnology, and related public policy.

“The principles of food labeling are the same, whether or not the food is made from a genetically engineered (GE) plant or a GE animal.

1. Labels cannot be false
2. Labels cannot be misleading
3. Label must describe basic nature of the food (e.g. Atlantic salmon)
4. FDA cannot require labels include information about production methods if there is no material difference in the products due solely to the production process
5. Voluntary labeling is allowed if it is not false or misleading

Based on my evaluation of all of the facts in the AquAdvantage briefing packet and relevant scientific literature, and my reading of the applicable principles of food labeling, I do not consider that the data shows that there are “material” differences between food derived from AquAdvantage salmon and foods from other Atlantic salmon. Therefore, in the absence of a material difference, mandatory labeling is not required. Of course, voluntary labeling is allowed if it is not false and misleading.”

Relevant publications:


The Debate

Endorsements & Opposition

Endorsements:

- Food & Water Watch’s Executive Director Wenonah Hauter released a *statement* on November 19, 2015 in support of labeling GE fish in context of broader condemnation of the FDA approval, stating “To add insult to injury, this product will be hitting store shelves without labeling, making it impossible for concerned consumers to distinguish GMO [genetically modified organism] from non-GMO salmon. Not only does this ignore consumers’ fundamental right to know how our food is produced, it is simply bad for business, since many consumers will avoid purchasing any salmon for fear it is genetically engineered.” Food & Water Watch is a Washington, D.C. based NGO, which focuses on corporate and government accountability relating to food, water, and corporate overreach.

- A coalition of groups represented by legal teams from the Center for Food Safety and Earthjustice filed a *lawsuit* on March 31, 2016 against the FDA for their approval of GE salmon. The action calls into question the appropriate regulatory process for GE animals.

Opposition:

- The FDA’s Center for Veterinary Medicine’s Former Director Dr. Bernadette Dunham released a *press announcement* on November 19, 2015, stating “The FDA has thoroughly analyzed and evaluated the data and information submitted by AquaBounty regarding the AquAdvantage Salmon and determined that they have met the regulatory requirements for approval, including that food from the fish is safe to eat.” The Center for Veterinary Medicine is a branch of the FDA that regulates the manufacture and distribution of food, food additives, and drugs that will be given to animals.

Status

HR 205 was introduced in the House on January 3, 2017, and on January 25, 2017 was referred to the *Subcommittee on Health* by the *Committee on Energy and Commerce*.

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