Prevention of Escapement of Genetically Altered Salmon in the United States Act (HR 206, 115th Congress)

Prohibits interstate and foreign commercial exchange, net pen aquaculture, and release into the wild of genetically modified finfish.

Updated last July 25, 2017
for the 01/03/2017 version of HR 206.

WHAT IT DOES

HR 206 places measures to prevent the sale, movement, or release of finfish (also referred to as true fish, as opposed to shellfish) that are genetically modified or altered using recombinant DNA technologies (collectively referred to in this brief as GM). Based on the text of the bill, this is done out of concern for potential negative impacts on non-GM finfish, the environment, and the economy. Salmon are specifically mentioned in the title of the bill, but, based on the bill’s use and definition of “covered fish” (fish targeted by the bill’s prohibitions), HR 206 imposes regulation on all GM finfish, alive or dead, on a state and national level.

This bill prohibits the sale or movement of GM finfish and products containing GM finfish between states and foreign countries, as well as the intent to do so. However, this bill permits states to self-regulate their own intrastate commercial exchange of GM finfish.

Additionally, HR 206 prohibits the net-penning of GM finfish, and the actual or intended release of these finfish into the wild.

Fish, fish parts, or products are exempted from these prohibitions if:

- Used for land-based scientific research that prevents the GM finfish from coming in contact with and impacting the environment;
- Collected in order to meet this bill’s prohibition; or
- After review of an application to perform one of the proposed prohibited actions, the National Oceanic and Atmospheric Administration (NOAA), in consultation with the United States Fish and Wildlife Service:
  - Prepares a finding of no significant impact on the environment as defined in the Natural Environmental Policy Act 1969 (NEPA) (42 U.S.C. 4321 et seq.); or
  - Finds the application to align with an environmental impact statement prepared by NOAA in accordance with section 102(2)(C) of NEPA (42 U.S.C. 4332(2)(C)).

The bill mandates that NOAA be notified when each agency, department, or other Federal government body comes across the use of GM finfish. It also consolidates under NOAA the authority to prescribe rules and regulations, monitor and enforce compliance, and penalize violations.

RELEVANT SCIENCE

HR 206 defines “covered fish” as “any finfish, live or dead, including the gametes, fertilized eggs, offspring, and descendants thereof, that is modified or produced through the application of recombinant deoxyribonucleic acid (DNA) technologies, using DNA from an organism’s own genome or that of another species, that overcome natural physiological reproductive barriers and that are not techniques used in traditional breeding and selection.” This definition is dense and requires some unpacking.

Finfish, which are also called “true fish” or simply “fish”, are aquatic animals that have a backbone, gills, and fins. Finfish, like all organisms, are made up of microscopic building blocks called cells. Cells are composed of molecules like fats, nucleic acids (DNA and RNA), and proteins. A cell’s genome (total DNA in the cell) contains instructions that tell the cell how to function and how to interact with other cells. These instructions are encoded by a linear sequence of chemical units called nucleotides, strung end-to-end. The basic unit of instruction is called a gene, and each gene encodes information used for the production of other molecules,
namely RNA and proteins, which operate and structure the cell. As an organism grows and its cells replicate, the DNA within the cells is also replicated and passed on. During reproduction, DNA is passed on from both parents to an offspring when a sperm and an egg (gametes) fuse to produce a fertilized egg.

HR 206 refers to genetic modifications produced by recombinant DNA (rDNA) technology, which began to emerge in the 1970’s. Generally speaking, rDNA techniques involve the combination of multiple DNA molecules from different sources to create a novel DNA molecule. This novel DNA molecule can then be introduced into the cells of an organism to add to or modify its genetic makeup and produce a particular trait.

For instance, AquAdvantage® Salmon are Atlantic salmon that have been genetically modified with rDNA technology. Specifically, a growth hormone gene from Chinook salmon (a Pacific species) was combined with a DNA fragment, called a promoter, from ocean pout, another type of fish. The ocean pout promoter keeps the growth hormone gene turned on, even when it normally turns off (during cold months). When inserted into AquAdvantage® Salmon, this elevated growth hormone promotes rapid growth, allowing for increased fishery production.

It is unclear if the definition in HR 206 of genetic modifications would include genome editing, a more nascent technology than rDNA, although it is possible. With genome editing, new technologies like CRISPR-Cas9 allow scientists to make much more precise genetic modifications across an organism’s genome than previously possible, to include adding, removing, or substituting DNA. Genome editing technologies often use rDNA as a tool to produce genome edits, but in this case the rDNA is a means to the modification and not the modification itself. It can be argued that genome editing, by default, involves the recombining of genomic DNA. However, this does not easily fit with the traditional definition of “recombinant DNA technologies” historically held by both the scientific community and the government. It remains to be seen whether this bill, if passed, would cover new technologies like genome editing.

The bill also focuses on preventing the potential escape of GM finfish, in part by prohibiting net-penning of GM fish. Net-penning is a method used in fish farming in which fish are raised in cages located offshore in the ocean or freshwater lakes. In regards to HR 206, the concern with using this aquaculture technique is that the natural environment is exposed to the waste of these GM finfish. Also, these GM finfish could be released in the event of containment failure, caused potentially by a storm or accident, which could result in competition or interbreeding of these fish with wild fish populations. Some opponents of such GM finfish also express concern about the health impact of rDNA-containing fish tissues on the surrounding environment and predators, although the evidence for such impact is disputed.

**RELEVANT EXPERTS**

Alison L. Van Eenennaam, PhD, is an Animal Genomics and Biotechnology Cooperative Extension Specialist in the Department of Animal Science at the University of California, Davis. Her research generally focuses on the application of DNA-based biotechnology in animal agricultural systems.

“[HR 206] does not precisely outline which “recombinant deoxyribonucleic acid (DNA) technologies” are covered, nor what is actually meant by this term. Does it specifically refer only to genetically engineered fish carrying rDNA constructs? Does it include fish with gene edits that result in genetic alterations that are identical and indistinguishable from natural alleles found in the population (i.e. which could be obtained using traditional selection and breeding)? Does it include genome edits that result in deletions[,] meaning the absence of a specific DNA sequence[?]... Does it preclude the existing interstate commerce of genetically engineered fluorescent aquarium species (e.g. Glofish®) that are currently being sold in all 50 states? It [is] also unclear which traditional breeding techniques are exempt because there is no precise definition of the term "traditional". For example, fish breeders often manipulate ploidy [copies of parts or whole of genome] using pressure, chemicals or temperature to increase entire sets of chromosomes [more info] to make polyploid fish.”

Relevant publications:
BACKGROUND

AquAdvantage® Salmon were approved by the FDA for commercial production and human consumption on November 19, 2015. The FDA regulates the genetic modifications engineered in AquAdvantage® Salmon as new animal drugs (NADs) under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301).

According to a report from the Congressional Research Service (CRS), AquAdvantage® Salmon will not be farmed using net-pens:

“Environmental concerns related to the development of GE salmon include the potential for competition and interbreeding with wild fish. According to some, escaped GE salmon could spawn with wild Atlantic salmon and introduce the modified genetic material to the wild population. To address these concerns, AquaBounty will produce salmon eggs (all sterile females) in Canada, ship these eggs to Panama, grow and process fish in Panama, and ship table-ready, processed fish to the United States for retail sale. Aquabounty will limit production to land-based facilities to isolate GE salmon from the environment and minimize the likelihood of harm to wild fish populations. Production from these facilities is limited to approximately 100 metric tons, which is a small fraction of the current U.S. fresh and frozen salmon supply of 700,000 metric tons.”

ENDORSEMENTS & OPPOSITION

Endorsements:

- Representative Don Young, the sponsor of HR 206, proposed a similar bill (HR 394) to the 114th Congress with the same title and content. In a press release posted on his website, Mr. Young stated:

  “The FDA is reviewing GE salmon as if it were a new animal drug, but this type of review process is obviously dead wrong for a product destined for our dinner plates. Furthermore, it fails to consider the possible threat GE fish pose to natural salmon fisheries in this nation... The PEGASUS [Prevention of Escapement of Genetically Altered Salmon in the United States] Act’s message is unmistakable, it tells federal regulators to rethink their approach before a monumental mistake is made that cannot be undone. As lawmakers, we must do everything in our power to protect the public and one of the finest products in the world.”

Opposition:

At present, there has not been any publicly reported opposition to this bill.

STATUS

HR 206 was introduced in the House on January 3, 2017, and was referred to the House Committee on Natural Resources. It was then referred to the Subcommittee on Water, Power and Oceans on February 10, 2017.

RELATED POLICIES

Natural Environmental Policy Act 1969 (NEPA) (42 U.S.C. 4321 et seq.)

2017 Update to the Coordinated Framework for the Regulation of Biotechnology (final version)
Environmental Assessment: AquAdvantage Salmon (FDA, Nov 2015)


Regulation of Intentionally Altered Genomic DNA in Animals (FDA draft guidance, Jan 2017). The FDA felt that rDNA technologies, which it previously referred to as genetic engineering (GE) technologies in its 2009 Final Guidance for Industry #187, were categorically different than newer genome editing technologies. Thus, when the FDA released its draft revision to the Final Guidance for Industry #187 in January 2017, it proposed dropping the term “genetic engineering” in favor of “intentionally altered genomic DNA” to encompass both rDNA/GE and genome editing technologies. The comment period for this regulation has officially closed.

POLICY HISTORY

Previous versions of this bill were introduced in 2015 (HR 394) to the 114th Congress and in 2013 (HR 1667) to the 113th Congress. The texts of those previous bills match HR 206 word-for-word. Both bills died in committee.

Similar bills were introduced in the Senate in 2011 (S 1717) to the 112th Congress and in 2013 (S 246) to the 113th Congress. These bills were sponsored by Senator Mark Begich [D-AK] and differed from the House bills in that they prohibited to a narrower category of GM fish (marine and anadromous fish) and did not explicitly prohibit net-penning GM fish.

SPONSORS

Sponsor: Representative Don Young (R-AK-At Large)

Cosponsor:

- Representative Peter A. DeFazio (D-OR-4)

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