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Genetically Engineered Fish and Seafood

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Summary

Genetic engineering techniques allow the manipulation of inherited traits to modify organisms. Genetically modified (GM) fish and seafood products are currently under development and may offer potential benefits such as increasing aquaculture productivity and addressing human health concerns. However, some critics of this rapidly evolving field are concerned that current technological and regulatory safeguards are inadequate to protect the environment and ensure public acceptance of these products.

To date, there has been little legislative activity in Congress on GM fish and seafood issues, but as commercialization moves closer, pressures may build for oversight of industry developments and the appropriate role of federal regulation. This report will be updated as circumstances warrant.

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Through selective breeding, farmers and scientists have a history of modifying animals to maximize desirable traits. In the broadest sense, genetic modification refers to changes in an organism's genetic makeup not occurring in nature, including the production of conventional hybrids.[1] With the advent of modern biotechnology (e.g., genetic engineering or bioengineering), it is now possible to take the gene (or genes) for a specific protein either from the same species or from an entirely different one and transfer it to create an organism expressing a novel trait or a trait outside the normal range of variation for the species. This technique can add both speed and efficiency to the development of new foods and products. Genetically engineered plant varieties, such as herbicide-resistant corn and soybeans, have already been widely adopted by U.S. farmers, and genetically engineered fish or seafood may similarly be adopted by the aquaculture industry.

Background

Potential issues include the impacts of genetically modified (GM) fish and seafood on the environment and food safety, and whether GM foods should be specially labeled. Underlying these issues is the question of whether U.S. regulation and oversight of biotechnology — with responsibilities spread primarily among the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) — remain appropriate, particularly as newer applications emerge that did not exist when the current regulatory regime was established. For additional background on broader concerns, see CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*.

Scientists are seeking ways to genetically engineer fish and other seafood species to introduce or amplify economically valuable traits. Fish are of particular interest to researchers since many fish produce large quantities of eggs; those eggs, being external to the animal (as opposed to mammals that produce fewer eggs internally), make it relatively simple to insert novel DNA.

Research on GM strains is currently under development for at least 35 species of fish worldwide, as well as for a variety of mollusks, crustaceans, plants, and marine microorganisms, for various purposes. Fish are being modified to increase food for human consumption, to produce pharmaceuticals, to test water contamination, and for other uses.[2]

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[1]The term hybrid is used by geneticists to describe the offspring of two parents differing in any genetic characteristics, such as the offspring of a cross between different species, subspecies, strains, or inbred lines of animals or plants. An example of a common aquaculture hybrid is the sunshine bass, the result of the fertilization of white bass eggs with striped bass sperm.

[2]For a list of genetically engineered organisms under research, see Table 2-2 in National

(continued...)

One GM fish has been marketed to date. Glofish™, a genetically altered version of the popular aquaria zebrafish (*Danio rerio*), fluoresce after the insertion of a sea anemone gene into the zebrafish egg.[3] This fish is currently legal to be sold in all states except California. Since Glofish™ were determined not to "pose any more threat to the environment than their unmodified counterparts," and because they are not meant for human consumption, the U.S. Food and Drug Administration (FDA), which is responsible for regulating GM foods, determined the Glofish™ posed no clear risk to human health or the environment and should not be formally regulated by the FDA.[4] However, the FDA made clear that this decision applied only to this specific line of fish, and that the FDA maintained jurisdiction over these and any other GM fish.

Another private research company has taken the promoter[5] from an antifreeze protein gene found in ocean pout (an eel-like, edible fish) to regulate expression of a salmon growth hormone gene and drive its expression throughout the cold season, when growth normally slows, to create an Atlantic salmon that grows to market size twice as fast as its non-GM counterparts. The company is currently seeking regulatory approval from the Food and Drug Administration to sell its fish in the United States for human consumption.[6] Other examples of GM fish that have been developed, but for which regulatory approval is not yet being sought, include fish that would produce a blood-clotting factor to treat hemophiliacs[7] and disease-resistant channel catfish.[8]

Domestic Regulation

A National Research Council study maintains there is a low to moderate food safety risk from GM seafood.[9] Since genetic engineering can introduce new protein

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[2](...continued)
Research Council, *Animal Biotechnology: Science-Based Concerns*, (Washington, DC: National Academies Press, 2002), at [http://books.nap.edu/books/0309084393/html/73.html#pagetop], visited Sept. 27, 2004.

[3]Yorktown Technologies, L.P., at [http://www.glofish.com/default.asp].

[4]For the FDA statement regarding Glofish, see [http://www.fda.gov/bbs/topics/NEWS/2003/NEW00994.html], visited Oct. 6, 2004.

[5]The DNA region, usually upstream to the coding sequence of a gene or operon, which binds and directs RNA polymerase to the correct transcriptional start site and thus permits the initiation of transcription.

[6]Aquabounty Technologies, Inc., at [http://www.aquabounty.com/].

[7]Amitabh Avasthi, "Can Fish Factories Make Cheap Drugs?" *New Scientist*, v. 183, no. 2464 (Sept. 11-17, 2004): 8, at [http://www.newscientist.com/news/news.jsp?id=ns99996367].

[8]See Pew Initiative on Food and Biotechnology, *Harvest on the Horizon, Future Uses of Agricultural Biotechnology*, at [http://pewagbiotech.org/research/harvest/].

[9]National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, (Washington, DC: National Academies Press, 2004) at [http://books.nap.edu/catalog/10977.html].

into a food product, there are concerns that this technique could introduce an allergen, known or previously unknown, into the food supply.

Within FDA, the Center for Veterinary Medicine (CVM) regulates GM (i.e., transgenic) animals intended for human consumption under the same authority it uses to regulate new animal drugs.[10] In addition, GM fish must adhere to the same standards of safety under the Federal Food, Drug, and Cosmetics Act (FFDCA)[11] and the seafood inspection program overseen by FDA's Center for Food Safety and Applied Nutrition[12] that apply to conventionally bred fish. Under the adulteration provisions in §402(a)(1) of the FFDCA, the FDA has the power to remove a food from the market or sanction those marketing the food if that food poses a risk to public health. In addition, other laws might elicit federal oversight of GM fish and seafood by federal fisheries management agencies — the Fish and Wildlife Service and the National Marine Fisheries Service, whose expertise and credibility could address multiple concerns and issues.[13] No federal law specifically addresses GM fish and seafood.

Since states have the primary authority for fishery resources within their boundaries and offshore to the outer limit of state waters (generally 3 miles), several states have taken steps to regulate the use and transport of GM fish.[14] For example, Maryland,[15] Washington,[16] Oregon,[17] and California[18] have passed laws banning the release of GM fish in some or all state waters.

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[10]FDA Center for Veterinary Medicine, "Questions and Answers about Transgenic Fish," at [http://www.fda.gov/cvm/transgen.htm].

[11]21 U.S.C. §§301, et seq.

[12]FDA's Center for Food Safety and Applied Nutrition administers the agency's seafood inspection program; see [http://www.cfsan.fda.gov/seafood1.html].

[13]Eric M. Hallerman and A.R. Kapuscinski, "Transgenic Fish and Public Policy: Regulatory Concerns," *Fisheries*, v. 15, no. 1 (1990): 12-20; Council on Environmental Quality and Office of Science and Technology Policy, "Case Study No. 1: Growth-Enhanced Salmon," *Case Studies of Environmental Regulation for Biotechnology*, 2001 (available at [http://ostp.gov/html/ceq_ostp_study1.pdf], visited Mar. 8, 2005); Pew Initiative on Food and Biotechnology, *Future Fish: Issues in Science and Regulation of Transgenic Fish*, 2003 (available at [http://pewagbiotech.org/research/fish/fish.pdf]).

[14]S. Stenquist, "Federal and State Regulations Relevant to Uncontained Applications of Genetically Engineered Marine Organisms," in *Genetically Engineered Marine Organisms: Environmental and Economic Risks and Benefits* by R. A. Zilinskas and P.J. Balint, eds. (Boston, MA: Kluwer Academic Publishers, 1998), p. 139-180.

[15]Maryland Natural Resources Code Ann. §4-11A-02 (2003).

[16]Washington Administrative Code 220-76-100 (2003).

[17]Oregon Administrative Code 220-76-100 (2003).

[18]California Fish & Game Code § 15007 (2003) and Dept. of Fish and Game § 671.1. This law prohibits all "unpermitted" import, possession, transport, and sale of GM fish. Because permit requirements are extremely stringent — permits can essentially only be issued for bona fide research use — this law essentially bans any commercial GM fish.

Environmental Concerns

Under the National Environmental Policy Act of 1969 (P.L. 91-190; 42 U.S.C. §§4321-4347), the FDA must assess the potential environmental impacts of newly engineered fish. To fully assess these potential impacts, FDA consults with the Fish and Wildlife Service and the National Marine Fisheries Service (popularly called "NOAA Fisheries"). However, critics question whether the FDA has the mandate and sufficient expertise to identify and protect against all potential ecological effects of transgenic fish.[19] Under the FFDCA's provisions on new animal drugs (21 U.S.C. §321), the FDA must keep all information about a pending drug application confidential, except for information publicly disclosed by the manufacturer. This approach limits the opportunity for public comment before approval. Consumer advocates are calling for more transparency in this process and for more authority to be given to environmental and wildlife agencies.[20]

The possible impacts from the escape of GM organisms from aquaculture facilities are of great concern to some scientists and environmental groups.[21] A National Research Council report states that transgenic fish pose the "greatest science-based concerns associated with animal biotechnology, in large part due to the uncertainty inherent in identifying environmental problems early on and the difficulty of remediation once a problem has been identified."[22] Critics and scientists predict that GM fish could breed with wild populations of the same species and potentially spread undesirable genes. In addition, they argue that transgenic fish, especially organisms that have been modified so as to enable them to withstand wider ranges of salinity or temperature, could be more difficult or impossible to eradicate, similar to an invasive species. Escaped transgenic fish could harm wild fish through increased competition or predation. Critics maintain that an indication of this potential problem may be noted where non-GM salmon from nearshore net pens in the northwest United States,[23] British Columbia,[24] Norway, and Scotland[25] have escaped and entered streams, in some cases outnumbering their wild counterparts.

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[19] Andrew Martin, "One Fish, Two Fish, Genetically New Fish; Firm Seeks OK for Altered Salmon," *Chicago Tribune*, Nov. 13, 2003.

[20] Union of Concerned Scientists, "Genetically Engineered Salmon," at [http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=327].

[21] Pew Initiative on Food and Biotechnology, *Future Fish* (see note 13, above).

[22] National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2004) at [http://books.nap.edu/books/0309084393/html/73.html#pagetop], visited Sept. 27, 2004.

[23] Washington Dept. of Fish and Wildlife, "*Atlantic Salmon in Washington State: A Fish Management Perspective*," at [http://wdfw.wa.gov/fish/atlantic/toc.htm].

[24] The Alaska Fish and Game Dept. reports statistics on escaped and recovered Atlantic Salmon in Washington State, British Columbia, and Alaska at [http://www.adfg.state.ak.us/special/as/docs/esc_rec87-01.pdf].

[25] Eric M. Hallerman and A.R. Kapuscinski, "Ecological Implications of Using Transgenic Fishes in Aquaculture," *ICES Marine Science Symposia*, v. 194 (1992): 56-66.

However, it is not known whether GM fish could survive in the wild in sufficient numbers to inflict permanent population damage. One study indicated that, when food supplies were low, GM fish might have the ability to harm a wild population, although the authors caution that laboratory experiments may not reflect what would happen in the wild.[26] Biotechnology proponents argue that GM fish would be unlikely to survive in the wild since they would likely be less adept at avoiding predators.

A predictive model — popularly termed the Trojan gene model — was put forward after observing that GM Japanese medaka, a fish commonly used as an experimental model, were able to out-compete non-altered fish for mates. The resulting offspring were less fit, resulting in the eventual demise of the modified population.[27] Even if fast-growing GM fish do not spread their genes among their wild counterparts, critics fear they might disrupt the ecology by competing with native fish for scarce resources. The consequences of such competition would depend on many factors, including the size of the wild population, the number and specific genetic strain of the escaped fish, and local environmental conditions.

Other potential safeguards also exist. For example, FDA could require that only sterile GM fish be approved for culture in ocean pens. Fertilized fish eggs that are subjected to a heat or pressure shock retain an extra set of chromosomes. The resulting *triploid* fish do not produce normal eggs or sperm, and females do not exhibit maturation of the ovary or reproductive behaviors.[28] Thus, all-female lines of triploid fish are the best current method to ensure non-breeding populations of GM fish. Nonetheless, there are batch-to-batch variations in the efficacy of triploidy induction, and it is uncertain whether this method could be effective for all species of fish; it has not been successful for shrimp.[29] Also, critics question whether escaped male triploid fish, which in some species have sufficient sex hormone levels to enable normal courtship behavior, could mate with wild individuals, lowering reproductive success of the wild population.[30] The ecological risks of stocking GM shellfish in the wild have not yet been thoroughly considered, but confinement of

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[26]Robert H. Devlin, et al., "Population Effects of Growth Hormone Transgenic Coho Salmon Depend on Food Availability and Genotype by Environment Interactions," *Proceedings of the National Academy of Sciences*, v. 101, no. 25 (June 22, 2004): 9303-9308, at [http://www.pnas.org/cgi/content/abstract/101/25/9303].

[27]Richard D. Howard, et al., "Transgenic Male Mating Advantage Provides Opportunity for Trojan Gene Effect in a Fish," *Proceedings of the National Academy of Sciences*, v. 101, no. 9 (March 2, 2004): 2934-2938, at [http://www.pnas.org/cgi/reprint/101/9/2934.pdf].

[28]Gary H. Thorgaard and Standish K. Allen, "Environmental Impacts of Inbred, Hybrid and Polyploid Aquatic Species,"in *Dispersal of Living Organisms into Aquatic Ecosystems*, (Univ. of Maryland Sea Grant, 1992), pp. 281-288.

[29]National Research Council, *Bioconfinement of Genetically Engineered Organisms*, (Washington DC: Nat. Academies Press, 2004), at [http://books.nap.edu/catalog/10880.html].

[30]Eric M. Hallerman and A. R. Kapuscinski, "Potential Impacts of Transgenic and Genetically Manipulated Fish on Wild Populations: Addressing the Uncertainties Through Field Testing," in *Genetic Conservation of Salmonid Fishes*, by J. G. Cloud and G. H. Thorgaard, eds. (New York, NY: Plenum Press, 1993), pp. 93-112.

these organisms is likely to be even more difficult than confinement of fish, due to their methods of reproduction and dispersal.[31] Other sterilization methods are currently under study, and it is likely that research in this area will increase options for containment. Critics of GM fish speculate that the risks to native fish populations, however small, may outweigh the potential benefits of this technology, especially where native fish populations are already threatened or endangered.

To be most effective in reducing ecological risk, the National Research Council report on the *Bioconfinement of Genetically Engineered Organisms* recommends that each individual organism have its own bioconfinement[32] plan. Guidelines for designing and implementing confinement of a GM aquatic species have been developed by a U.S. Department of Agriculture-sanctioned working group.[33] Also, since no single method is likely to be 100% certain, bioconfinement redundancy is crucial, especially if it will not be combined with physical confinement. Growing GM fish in isolated onshore tanks rather than in offshore or nearshore pens may minimize the risk of escape into the wild.

International Developments

Many countries and international institutions have promulgated policies for oversight of GM organisms, including aquatic species.[34] Notably, Canada — where development of GM salmon is progressing — has regulations that are more prescriptive and restrictive than those in the United States. Nations that are party to the United Nations Convention on Environment and Development adhere to the Cartegena Protocol regarding international transfer of GM organisms; each such nation has designated an oversight authority and a permitting process. Cuba is such a nation; it has regulations, and seems poised to approve commercial production of transgenic tilapia. Cuba, like much of the world, seems to be waiting to see whether the United States will approve commercialization of the GM salmon. This decision may prove to be a tipping point in commercialization of GM fish and GM farm animals, more generally. Alternatively, should Chile, a major producer of Atlantic salmon, approve production of GM salmon, this could provide the tipping point. The Organization for Economic Cooperation and Development and the Food and Agriculture Organization-World Health Organization have held several workshops on GM fish, and published working papers. The international dimension of issues

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[31]Many shellfish, such as oysters, broadcast their eggs and sperm into the water column and have larvae that have a planktonic or swimming form, making them very difficult to contain in an open water pen.

[32]Bioconfinement refers to biological methods, such as induced sterilization, used to confine GM organisms and their transgenes to their designated release setting.

[33]Agricultural Biotechnology Research Advisory Committee, *Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish* (U.S. Dept. of Agriculture, 1995), available at [http://www.isb.vt.edu/perfstands/psmain.cfm].

[34]Eric M. Hallerman, *Public Policies Regulating the Use of Genetically Modified Aquatic Organisms: Current and Future Needs Internationally*, VSG-94-168R (Charlottesville, VA: Virginia Sea Grant College Program, 1994); D. M. Bartley and Eric M. Hallerman, "A Global Perspective on the Utilization of Genetically Modified Fishes in Aquaculture and Fisheries," *Aquaculture*, v. 137 (1995): 1-7.

pertaining to GM aquatic organisms has important bearing on how technical and policy issues may be resolved.

Possible Benefits and Disadvantages of GM Fish and Seafood

Biotechnology proponents maintain that genetic modification has many advantages over traditional breeding methods, including faster and more specific improvement of beneficial traits. Because scientists are able to directly manipulate the traits they wish to create or amplify, the desired change can be achieved in very few generations, frequently making it faster and cheaper than traditional methods, which may require many generations of selective breeding. Genetic modification allows scientists to precisely select traits for alteration, enabling them to create an organism that, for example, grows larger or faster or has a different nutritional content. Proponents claim that faster-growing fish could make fish farming more productive, increasing yields while reducing the amount of feed needed, which in turn could reduce waste. Shellfish and finfish, genetically modified to enhance disease resistance, could reduce the use of antibiotics. Increased freeze resistance in fish could lead to the ability to grow freeze-resistant species in previously inhospitable environments, allowing aquaculture to expand into previously unsuitable areas. Research efforts are also under way to address selected human health concerns, such as genetically modifying fish to produce human drugs like a blood clotting factor and creating shellfish that will not provoke allergic reactions. Biotechnology proponents claim these advantages could translate into a number of potential benefits, such as reduced costs to producers, lower prices for consumers for edible fish and pharmaceuticals, and environmental benefits, such as reduced water pollution from wastes. Food scientists and the aquaculture industry may support the introduction of genetic engineering, provided that issues of product safety, environmental concerns, ethics, and information are satisfactorily addressed.

On the other hand, while the majority of consumers in the United States appear to have accepted GM food and feed crops,[35] it is uncertain whether consumers will be as accepting of GM fish. Although such fish may taste the same and some are expected to be less expensive than other farmed fish,[36] ethical concerns over the appropriate use of animals, in addition to environmental concerns, may affect public acceptance of GM fish as food.[37] Ongoing campaigns by environmental and consumer groups have asked grocers, restaurants, and distributors to sign a pledge to not sell GM fish products, even if approved by the FDA.[38]

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[35]Thomas Hoban, "Trends in Consumer Attitude About Agricultural Biotechnology," *AgBioForum*, v. 1, no. 1 (1998): 3-7, at [http://www.agbioforum.org/v1n1/v1n1a02-hoban.htm], visited Oct. 6, 2004.

[36]GM fish with traits to enhance efficiency of production would be expected to be less expensive. However, GM fish that offer added nutritional benefits or some other consumer-oriented trait might actually command a premium price in the marketplace.

[37]National Research Council, *Animal Biotechnology* (see note 22, above).

[38]The Center for Food Safety, "Genetically Engineered Fish Campaign," at [http://www.

In addition, the commercial fishing industry says that it has successfully educated the public to discriminate among fish from different sources, such as wild and farmed salmon. It is possible that a publicized escape of GM fish could lead to reduced public acceptance of both the wild and the non-GM aquacultured products. Many environmental and consumer groups are asking that genetically engineered products be specially labeled. However, industry groups are concerned that such labeling might lead consumers to believe that their products are unsafe for consumption.[39]

To date, there has been little legislative activity in Congress on GM fish and seafood issues,[40] but as commercialization moves closer, pressures may build for oversight of industry developments and the appropriate role of federal regulation.

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[38](...continued)
centerforfoodsafety.org/page241.cfm].

[39]See CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*.

[40]In the 109th Congress, an amendment was offered to an agriculture appropriations bill, and subsequently withdrawn, that would have prohibited the use of FY2006 funds for the approval or process of approval of an application for an animal drug for creating transgenic salmon or any other transgenic fish.