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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 and improve organisms. Many genetically modified (GM) fish and seafood products are currently under development and offer potential benefits such as increasing aquaculture productivity and improving human health. However, many are concerned that, in this rapidly evolving field, current technological and regulatory safeguards are inadequate to protect the environment and insure public acceptance of these products. This report will be updated as circumstances warrant.

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 trait either from the same species or from an entirely different one and transfer it to create an organism having a unique genetic code (referred to as recombinant DNA).[2] 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.

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[1] The term hybrid is used by breeders to describe the offspring of a cross between different species, subspecies, or strains of animals or plants. The term hybrid is used by geneticists to describe the offspring of two parents differing in any genetic characteristics. An example of a common aquaculture hybrid is a splake, the result of the fertilization of brook trout eggs with lake trout sperm.

[2] For more information about recombinant DNA techniques, see CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*, by Donna U. Vogt and Mickey Parish.

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 transgenic 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 improve the production of human food, to produce pharmaceuticals, to test water contamination, and other uses.[3]

One genetically modified (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.[4] This fish is currently legal to be sold in all states except California. Since Glofish™ are not meant for human consumption, the U.S. Food and Drug Administration (FDA), the agency responsible for regulating GM foods, determined the Glofish™ is not under its jurisdiction.[5]

Another private research company has taken an antifreeze gene from ocean pout (an eel-like, edible fish) to create an Atlantic salmon that grows to market size twice as fast as its non-GM counterparts due to continued growth throughout the cold season, when growth normally slows. 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]

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 into a food

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[3] For a list of genetically engineered organisms under research, see Table 2-2 in National Research Council, *Animal Biotechnology: Science-Based Concerns*, (Washington, D.C.: National Academies Press, 2002) at [http://books.nap.edu/books/0309084393/html/73.html#pagetop], visited Sept. 27, 2004.

[4] Yorktown Technologies, L.P., at [http://www.glofish.com/default.asp], visited Sept. 27, 2004.

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

[6] Aquabounty Technologies, Inc., at [http://www.aquabounty.com/], visited Sept. 27, 2004.

[7] Amitabh Avasthi, "Can Fish Factories Make Cheap Drugs?," New Scientist, v.183, no. 2464, p. 8 (Sept. 11-17, 2004), at [http://www.newscientist.com/news/news.jsp?id=ns99996367], visited Oct. 6, 2004.

[8] See Pew Initiative on Food and Biotechnology, "Harvest on the Horizon, Future Uses of Agricultural Biotechnology," at [http://pewagbiotech.org/research/harvest/], visited Oct. 6, 2004.

[9] National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing*

(continued...)

product, there are concerns that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a "new" food. Within FDA, the Center for Veterinary Medicine regulates 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 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.

States have also taken steps to regulate the use and transport of GM fish. For example, Maryland,[13] Washington,[14] Oregon,[15] and California[16] have passed laws banning the release of GM fish in some or all state waters. No federal law specifically addresses GM fish and seafood.

Environmental Concerns

The FDA is also charged with assessing 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 (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.[17] 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, with the exception of 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.[18]

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[9] (...continued)
Unintended Health Effects, (Washington, D.C.: National Academies Press, 2004) at [http://books.nap.edu/catalog/10977.html], visited Sept. 23, 2004.

[10] The FDA Center for Veterinary Medicine's "Questions and Answers about Transgenic Fish," at [http://www.fda.gov/cvm/index/consumer/transgen.htm], visited Sept. 23, 2004.

[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], visited Nov. 8, 2004.

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

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

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

[16] California Fish & Game Code § 15007 (2003) and Dept. of Fish and Game § 671.1.

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

[18] Union of Concerned Scientists, "Genetically Engineered Salmon," at [http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=327], visited Nov. 8, 2004.

The possible impacts from the escape of GM organisms from aquaculture facilities are of great concern to some scientists and environmental groups. 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."[19] Critics and scientists speculate 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 if modified to improve their ability to withstand wider ranges of salinity or temperature, could be 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[20] and British Columbia[21] have escaped and entered streams, in some cases outnumbering their wild counterparts.

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.[22] Biotechnology proponents argue that GM fish would be unlikely to survive in the wild since they would likely be less adept at avoiding predators.

Another study postulated a "Trojan gene hypothesis" 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.[23] Even if fast-growing GM fish do not spread their genes among their wild counterparts, critics fear they might disrupt the ecology of streams by competing with native fish for scarce resources. The consequences of such competition would depend on many factors, including the health of the wild population, the number and specific genetic strain of the escaped fish, and local environmental conditions.

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[19] 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.

[20] Washington Dept. of Fish and Wildlife, "Atlantic Salmon in Washington State," at [http://wdfw.wa.gov/fish/atlantic/toc.htm], visited Nov. 1, 2004.

[21] 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], visited Nov. 10, 2004

[22] 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*, vol. 101, no. 25, pp. 9303-9308, (June 22,2004) at [http://www.pnas.org/cgi/content/abstract/101/25/9303], visited Oct. 6, 2004.

[23] 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*, vol. 101, no. 9, pp. 2934-2938 (March 2, 2004) at [http://www.pnas.org/cgi/reprint/101/9/2934.pdf], visited Oct. 6. 2004.

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 develop normal sexual characteristics and, in general, the degree of sterility in triploid females is greater than males.[24] Thus, all-female lines of triploid fish are the best current method to insure non-breeding populations of GM fish. Nonetheless, there are batch-to-batch variations and it is uncertain whether this method could be effective for all species of fish; it has not been successful for shrimp.[25] Also, critics question whether escaped 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. The ecological risks of stocking GM shellfish in the wild have not yet been thoroughly considered, but confinement of these organisms is likely to be even more difficult than confinement of fish, due to their methods of reproduction and dispersal.[26] 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[27] plan. 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.

Possible Benefits and Disadvantages of Genetically Engineered Fish and Seafood

Biotechnology proponents maintain that genetic modification techniques have many advantages over traditional breeding methods, including faster and more specific selection of beneficial traits. Because scientists are able to directly select traits they wish to create or amplify, the desired change can be achieved in very few generations, making it faster and lower in cost than traditional methods, which may require many generations of selective breeding. Genetic modification techniques allow scientists to precisely select

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[24] Gary H. Thorgaad 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.

[25] National Research Council, *Bioconfinement of Genetically Engineered Organisms*, (Washington D.C.: Nat. Academies Press 2004), at [http://books.nap.edu/catalog/10880.html], visited Oct. 6, 2004.

[26] 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.

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

traits for improvement, enabling them to create an organism that is not just larger and faster growing, but potentially improved, such as by increasing 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 improve disease resistance, could reduce the use of antibiotics. Increased cold resistance in fish could lead to the ability to grow seafood in previously inhospitable environments, allowing aquaculture to expand into previously unsuitable areas. Research efforts are also under way to improve human health by genetically modifying fish to produce human drugs like a blood clotting factor and to create 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,[28] it is uncertain whether consumers will be as accepting of GM fish. Although such fish may taste the same and are expected, like their traditionally bred counterparts, to be less expensive than wild-caught fish, ethical concerns over the appropriate use of animals, in addition to environmental concerns, may affect public acceptance of GM fish as food. 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.[29]

In addition, the commercial fishing industry says that it has successfully educated the public to discriminate among fish from different sources, such wild and farmed salmon. It is possible that a publicized escape of GM fish could lead to reduced public acceptance of their wild product. 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.[30]

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[28] Thomas Hoban, "Trends in Consumer Attitude About Agricultural Biotechnology," AgBioForum, vol. 1, is. 1, pp. 3-7 at [http://www.agbioforum.org/v1n1/v1n1a02-hoban.htm], visited Oct. 6, 2004.

[29] See the Center for Food Safety's "Genetically Engineered Fish Campaign," at [http://www.centerforfoodsafety.org/page241.cfm], visited Oct. 4, 2004.

[30] See CRS Issue Brief IB10131, *Agricultural Biotechnology: Overview and Selected Issues*, by Barbara Johnson.