A Consumer Guide to GENETICALLY ENGINEERED Salmon

PENNSTATE

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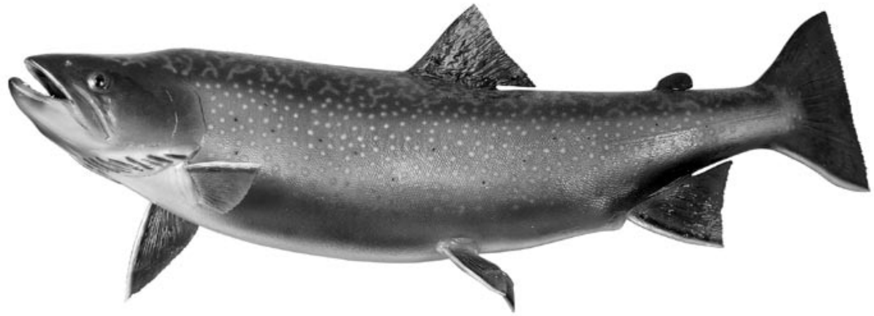
College of Agricultural Sciences

For centuries, humans have used "selective breeding" to improve crops and animals used for food. Certain animals or plants with desirable traits (features) are selected from the current generation to become the parents of the next generation. In the early 1980s, a new selection tool, "genetic engineering," was developed to improve precision and save time. Normally, soybeans are killed by some herbicides (weed killer), and some insects can destroy or damage corn. Genetic engineering has been used to produce herbicide-resistant soybeans (i.e., not killed by herbicides) and pest-resistant corn (i.e., not damaged by insects). These genetically engineered (GE) crops have been grown and processed in the U.S. food system since the 1990s. Work on GE fish, such as GE salmon, began in the mid-1980s. This pamphlet describes how GE salmon is produced and why. It also outlines the possible impacts of producing GE salmon to sell as food.



Comparison of Selective Breeding and Genetic Engineering

All living things contain their reproduction information in units called “genes.” In classic selective breeding, the breeder selects the parents by features, or traits, you can see. These features are the expression of a gene or genes. The parents used must be sexually compatible. During reproduction, each parent passes on an assortment of its genes, which may or may not include the trait desired, to its offspring. Then, the breeder has to find the desired trait among all the possible offspring of this mating. This is a time-consuming process.

Genetic engineering simplifies this process and saves time. Scientists identify and “snip out” the gene they want from a donor organism (living thing). Using a (bacterial) carrier, they insert this gene into the cell of another organism. When these cells are grown into adults, the donated gene might be expressed—the adult would have the trait. This speeds up the process of breeding because the chance of the gene being passed on to the next generation is much higher. However, scientists cannot control in which offspring the donated gene is expressed, so they must still hunt for the desired offspring among all produced.

Genetic engineering allows gene transfer between organisms that do not normally mate. For example, human genes have been put in bacteria to produce insulin, bacterial genes into plants to make them resistant to herbicides, and spider genes into goats to produce spider silk in their milk.

Genetically Engineered Fast-Growing Salmon

Fast-growing GE Atlantic salmon are made as follows. First, a growth hormone gene from a Chinook salmon (one of eight species of Pacific salmon) is linked to a promoter gene from an ocean fish called a pout, which is a saltwater fish living in the deep ocean that people do not regularly eat, making a “trans-gene.” This trans-gene is inserted into fertilized eggs of Atlantic salmon. The fast-growing offspring are identified and mated together with non-GE Atlantic salmon. This is repeated until this fast-growing trait is uniformly expressed in all offspring (i.e., all offspring have the trait).

A promoter gene is an on-off switch for its partner gene. The pout promoter is normally linked to an antifreeze gene. The product of this gene, an antifreeze protein that prevents the tissue in fish from freezing, must be produced all the time by the pout in order to survive. This promoter is “on” all the time because pout live deep in the ocean where it is very cold. In Chinook salmon, growth hormone is produced seasonally, mainly in warmer weather. Linking the pout promoter to the Chinook gene means that growth hormone is produced all the time instead of seasonally in the GE salmon. The resulting GE Atlantic salmon grows 2.5 times faster than non-GE farmed salmon and reaches market weight in 18 months instead of 30 months. This GE salmon would be raised in fish farms that produce fish sold in restaurants and supermarkets.

Fish Farming

One-third of the salmon sold in the United States now comes from fish farms. Most is imported from Canada and Chile since the United States produces mainly wild salmon (i.e., caught by fishermen). North American–farmed salmon is produced in the northern oceans on both the east and west coasts. Salmon are hatched and raised in fresh-water pens for 12 to 18 months, when they go through a natural process called "smoltification." This allows them to survive in salt water. Then they are moved to sea farms along the coast where they are grown in cages called ocean net pens. Once at market weight, they are harvested and processed for shipment and sale. The Atlantic salmon used now in fish farming is the result of inbreeding with European stocks. They are not genetically identical to native Atlantic salmon.

Fish can escape from ocean net pens and breed with closely related species. Escape can be caused by human error or damage to pens from weather or ships or predators such as sea lions. Some escaped Atlantic salmon have spawned in nearby rivers, although how long they will survive in the wild is not clear.

Use of sterile females can reduce the risk of escaped salmon breeding with native fish. Treating fertilized fish eggs that are female with heat or pressure shock produces triploid fish. Triploids have three sets of genetic information instead of the usual two and are sterile. However, the efficiency of triploid production is not 100 percent. It can be at least 99 percent so that maybe one out of a hundred females could breed with wild fish. Heat- or pressure-treated eggs and the resulting immature triploid female fish would be sold to fish farmers.

Fish farms produce concentrated wastes (i.e., fecal matter and excess feed). They can spread bacteria, viruses, and parasites to wild fish and introduce chemicals, including antibiotics, used to treat fish diseases into the environment. However, farms have taken steps to reduce these impacts.

Current Situation

Aqua Bounty Technologies, a Canadian company with a U.S. partner, has petitioned the Food and Drug Administration (FDA) to approve sale of this GE salmon in the United States. The company produced this GE fish to shorten the time to harvest and thereby reduce production costs. It will also lower time exposed to risks such as disease and predators, as well as losses due to storm damage.

FDA is conducting the safety review of introducing GE fish. Because of current laws, FDA is assuming that GE salmon contains a new animal drug (the inserted trans-gene pair). It is up to Aqua Bounty to provide data that the "drug" is safe for human and animal food as well as safe for the GE fish. Based on the 1986 Coordinated Framework for Biotechnology, FDA can consult with other federal agencies that regulate the actual locations and facilities where the salmon would be raised in the United States. ("Coordinated framework" is the plan for how current federal agencies can interact to regulate GE organisms using existing laws. "Biotechnology" is any process that uses living things to produce an outcome we desire. It is a whole set of tools or techniques used by scientists who work with living organisms.) FDA will evaluate the environmental impact of the new animal drug contained in the GE fish through an environmental impact statement prepared largely by Aqua Bounty. FDA must also evaluate whether environmental consequences of using the new animal drug will adversely affect humans or animals. Unforeseen or unlikely hazards can be managed through monitoring by the company and FDA after approval.

To date, FDA has not ruled on this petition.

Possible Consequences of FDA Approval of GE Atlantic Salmon

Impact of Review of GE Salmon on the Current Regulatory Framework

The 1986 Coordinated Framework (CF) provides guidance for safety and environmental risk assessment of GE products. The framework is based on legislation in existence in 1986. It allows the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the FDA to work together in reviewing products.

FDA is the lead agency for review of GE fish. FDA has chosen to regulate this GE fish as an animal drug. This review process is most likely to detect problems for human safety. Currently, companies that produce GE products are not required to seek an FDA ruling about safety. However, companies must notify FDA when introducing GE products into the food system. Aqua Bounty is voluntarily seeking an FDA ruling about safety issues through its submitted petition.

The 1986 framework uses various laws and regulations made before the use of genetic engineering. These laws and regulations were designed to check the safety of chemicals and drugs. It is not clear how rules to assess drug safety can assess the possible effects of GE fish on the environment. FDA's choice of "new animal drug" approval requires Aqua Bounty to show "reasonable certainty of no harm" to human or animal health. However, FDA may not have the authority to prevent or reduce environmental impacts that have no health risks to humans. The new animal drug application process is confidential (called "closed") to protect business information from competitors. Monitoring (looking for problems over time) and reporting needed after approval are also not clearly defined. FDA monitors for drugs after approval, but it has no experience monitoring for adverse environmental events.

GE animals raise new regulatory and environmental issues. Inserting growth hormone into salmon has effects throughout the salmon body. This might affect animal health. If trans-genes show up in different tissues, changes in nutrients, allergens, or toxins could result. So, full safety review is desirable. Raising GE salmon could mean fish farms use less feed and make less waste. But the salmon can escape from ocean-based pens and edge out their natural cousins for food and mates. Their effect on native species is not known. The ability of regulatory agencies to control all of the environmental and human health hazards has not been tested yet.

Some organizations believe that the regulatory system governing GE animals and fish must be stronger. The risks and benefits must be carefully evaluated on a case-by-case basis prior to these animals entering the market (pre-market). These organizations feel that the current regulatory system is weak because formal safety review by FDA is not required. They seek a mandatory pre-market approval process for all GE foods with clear safety standards, greater public access to information used in making decisions, and more public participation in decisions. They are critical of FDA's approval process for engineered animals because the company looking for approval provides the environmental impact assessments and the process is completely closed. Such secrecy does not inspire public trust.

Some feel approval of GE fish for commercial sale should require evidence of ecological safety as well as food safety. One government report recommended that the potential risks of GE fish to the environment be reviewed individually for each application (a case-by-case approach). Another report recommends that the approval process for GE animals include a look at the impact of the genetic modifications on animal health.

Other groups believe that FDA is adequately prepared to judge both the human and environmental safety of this fish using the 1986 Coordinated Framework. They argue that companies producing GE products have voluntarily sought out FDA safety review and that it has occurred on a case-by-case basis. Some government reports show that important benefits could result from developing GE animals, although the uses of genetic engineering have to be carefully chosen and regulated.

Regardless, the gaps identified in handling of this case may highlight the need for new regulations for GE animals or alterations in current regulations.

Impact on Research Examining and Controlling the Environmental Effects of GE Fish

Various groups point out that the environmental impacts of GE salmon are not well understood. Some groups urge more research on possible effects of escaped fish on the environment and the impacts of GE fish on wild fish. Better ways to prevent escape are also needed. Near escapes due to human error or flaws in safety systems have even been reported in land locked facilities. This indicates how difficult it is to design 100% effective safety measures. Thus demand for such research may increase.

Impact on Regulation of Fish Farming

Fish farmers acknowledge that salmon do escape from ocean pens, and some escapees have spawned in nearby rivers and interbred with wild salmon. However, fish farmers are improving containment systems. Fish farms produce waste, but farmers must protect the local marine environment from pollution or their fish will die. Advancements in technology have reduced the amount of salmon waste discharge. Areas around fish farms are routinely monitored for pollution effects. Fish farmers keep the use of therapeutics (antibiotics) to treat salmon diseases as low as possible.

Other groups feel that aquaculture (fish farming) must be done in a more environmentally sustainable manner. They recommend that EPA strengthen its oversight of fish farms and improve salmon farming practices. Monitoring and enforcement actions to detect noncompliance should be increased to provide stronger environmental regulation of fish farming. This is especially important if GE salmon production is approved since more fish could be raised within a given time period. Regulation of fish farming may change.

Impact on Fish Farming Yields

GE salmon produce normal levels of growth hormone all year round, rather than seasonally, and grow to the same size as regular salmon. GE salmon does reach mature size faster using less feed (perhaps 10 to 25 percent less). Fish farms have submitted orders for GE fish eggs that would be processed quickly upon FDA approval. If approved, fish farmers will likely have to adopt GE salmon in order to stay competitive. Cost of GE fish eggs may require them to produce more fish to ensure a profit. Farming yields may increase dramatically. Sometimes this results in fish flooding the market, which could depress prices and possibly profits. The level of consumer demand for fish and the yields needed to meet that demand pose challenges for fish farmers.

Impact on the Environment

Some claim GE salmon that escape are unlikely to compete with native fish because they are less fit. They do not have the swimming speed to pursue prey. GE salmon use up their energy reserves more quickly and may be eaten by predators more often than native fish. Supporters of GE salmon claim they can produce batches of female fish that are 100 percent triploid and, therefore, are 100 percent sterile. This would eliminate some of the problems caused by escaping GE fish.

Others point out that while production of triploids is fairly successful, 100 percent sterility is not guaranteed. Thorough testing of triploid females would be necessary to ensure sterility close to 100 percent. Multiple confinement methods should be used to reduce risk of escape. However, most confinement methods have not previously been used with GE fish. Better methods to detect escape must be developed. The release of sterile GE fish with reduced fitness could still threaten local diversity of marine life.

The environmental risk from GE fish is probably greater for ocean pens than for facilities on land. The environmental effects will depend on how fish farmers use the GE fish. For instance, if current levels of fish production are maintained, this might actually reduce the pollution associated with fish farms. But if farmers run two to four production cycles in the time originally needed for one cycle (because the fish mature faster), then the increased output of pollution could be a serious problem.

Some people feel that escape makes raising GE fish a potential international problem. Several international studies have recommended that a moratorium (a waiting period set by an authority) be placed on rearing GE fish in ocean net pens. Some feel approval of GE fish for commercial purposes should only allow fish to be raised in facilities on land, not in the ocean.

The ultimate impact on the environment is unknown.

Impact on Wild Salmon Populations

Farming Atlantic salmon helps conserve wild salmon populations by replacing a diminishing natural resource. Farming salmon produces protein efficiently. It take less than 2 pounds of feed to produce 1 pound of farmed salmon compared to 5 pounds of wild feed to produce 1 pound of wild salmon. Use of GE salmon may increase fish farm yields and reduce the demand for wild salmon, which may help wild salmon runs recover.

Alternatively, if consumers are uncomfortable with GE salmon, demand for wild fish may not drop that much. The continued reduction in wild salmon due to destruction of spawning routes in major rivers and disease may not be counterbalanced by GE salmon.

Impact on Particular Economic Groups

If GE salmon production reduces the demand for wild salmon, commercial salmon fishermen may suffer. Demand for wild salmon sport fishing may still be strong. If wild salmon populations recover, commercial fishing may come back. If GE salmon makes fish farming more successful, this may improve the economic conditions in places where fish farming workers live.

GE salmon eggs and fry could be sold worldwide. If fish farmers in other countries adopt this fish, their labor costs may allow production of GE salmon at a much lower cost. This low-cost GE salmon could drive down prices needed by fish farmers in North America to recover costs of using GE salmon. This would reduce long-term economic benefits to the North American fish farmer industry.

Impact on Consumer Access to Salmon

Fish is an important part of human diets all over the world. As marine fish capture is declining from overfishing, aquaculture is replacing this loss. Fish is a major source of animal protein in most developing countries. Demand for fish is growing in developed countries due to the reported health benefits. Use of GE salmon could reduce production costs and thus produce cheaper salmon for consumers, making it more available to those who now cannot afford it.

However, this assumes that the supermarket price of GE salmon will be as low as or lower than the price of regular farmed salmon. The actual price of GE salmon is unknown. This price must reflect the cost to the fish farmer of purchasing GE salmon eggs and fry and of raising these fish. Aqua Bounty must also recover its development costs.

Impact on the Demand for Labeling

FDA will not require labeling on GE salmon sold to consumers unless the GE salmon is found to differ in nutrient content, allergen, or toxicant level from non-GE farmed salmon. However, FDA has released guidelines for voluntary GE labeling that fish suppliers may use. USDA has proposed voluntary guidelines that would require all fish to be labeled as wild-caught or farm-raised and by country of origin. These guidelines may become mandatory in the future.

Many groups support mandatory labeling of GE fish sold for human consumption. Some feel that mandatory labeling would allow consumers to influence industry reliance on genetic engineering. Tying regulation and labeling together, a number of groups have consistently urged government regulators to require labeling of GE foods, a more comprehensive regulatory framework, and a full safety assessment of the implications of releasing GE animals (including fish) into the environment and the food supply. Some feel that religious, ethical, and right-to-know values are also reasons that GE foods should be labeled.

Impact on World Aquaculture Yields

Aquaculture is one of the fastest-growing food production sectors. China, India, and Japan lead the world in fish (all types) production through aquaculture. This technology can provide economic benefits to the farmers raising them, especially those living in less-developed countries. A doubling of income can have a substantial benefit as long as GE fry are affordable. Supporters of aquaculture feel there is little risk to human health. If the best containment measures are taken and decisions are made on a case-by-case basis, GE fish, including salmon, can potentially do much good. However, worldwide production could increase competition with North American fish farm output.

Impact on Human Health

Taste, texture, and nutrient content affect consumer food choice if the price is affordable. No information is available on the taste, texture, or nutrient content of GE salmon. It is not clear how taste and texture of GE salmon will compare with that of regular farmed salmon or wild salmon. If there is a major difference in nutrient content between GE and regular farmed salmon, FDA will require this to be reported on the food label. However, no statement of omega-3 fatty acid content is now required on food labels. Omega-3 fatty acid content of fatty fish such as salmon is one of the major reasons for recommending increased consumption.

The mercury and chemical [polychlorinatedbiphenyls (PCBs), dioxin, and Polybromenateddiphenyl ethers (PBDEs)] content of fatty fish, including salmon, and its effects are being debated. Some studies find that farmed salmon has higher levels of these chemicals than wild salmon. Other scientists and industry supporters claim the levels found in either type of fish are too low to cause alarm. They quote studies reporting that farmed and wild salmon do not differ in levels of these chemicals. They state that consumers are exposed to much higher levels of these same chemicals in their nonfood environment. FDA and EPA must evaluate these studies as they consider recommendations for consumers on how often to eat salmon.

FDA safety review only promises “reasonable certainty of no harm” based usually on animal studies. FDA cannot guarantee long-term (e.g., over ten years or more) safety of eating GE salmon. FDA cannot guarantee there will be no unexpected health effects due to the genetic changes produced in GE salmon. For instance, some may wonder about the year-round production of growth hormone in the fish. This does not affect the amount of growth hormone in the fish at harvest. Scientists assume that cooking the fish will destroy that growth hormone as it is a protein and proteins are broken down by heat. Stomach acid also destroys protein. Other possible effects of the gene transfer are not known.

Impact on Use of Genetic Engineering in the Food System

Scientists have been working on producing GE fish for decades. Scientists all over the world investigate ways to improve production of salmon, tilapia, carp, catfish, and trout. Most of this effort is aimed at increasing growth rate. Currently, only GE plant crops are allowed in the U.S. food system. Approval of GE salmon can increase the likelihood that other GE fish will be approved for food production.

Some scientists feel that production of GE fish crosses an important dividing line between plants and animals. They also feel that approval of GE fish opens doors to approval of other GE animals in the food system. For some, this is a moral question rather than a scientific question. They worry that once genetic engineering is commonly used in animals, it becomes more acceptable to use in humans. Others feel that genetic engineering is just the latest advance in science that can be used to benefit humans and ensure a sufficient food supply. They view approval of GE salmon as a scientific safety decision, not a moral decision.

Conclusion

Introducing products of any new technology into the food system has consequences. Some will be known, others will be unknown or unexpected. This creates a high degree of uncertainty about the overall impact of the technology. Regulatory agencies are learning how current regulations can address all of the issues surrounding the use of GE animals. Consumers need to consider all possible consequences or impacts in forming an opinion. One's personal values also influence opinions of these products. We hope this information booklet helps you assess GE salmon and its role in your food choices.

The following Web sites offer information and various perspectives on approval of GE salmon:

- Consumers Union: http://www.consumersunion.org/food/gef2-802.htm
- Pew Initiative on Food and Biotechnology: http://pewagbiotech.org/research/fish/
- Salmon Nation: http://www.salmonnation.com/fish/gefish.html
- Union of Concerned Scientists: http://www.ucsusa.org/food_and_environment/genetic_engineering/

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