Aquat. Sci. 66 (2004) 327–341
1015-1621/04/030327-15
DOI 10.1007/s00027-004-0715-8

Aquatic Sciences

Water Policy Article

Risk, regulation and innovation: The case of aquaculture and transgenic fish

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Received: 10 September 2003; revised manuscript accepted: 9 December 2003

Abstract. This paper reviews the public and scientific debates over the risks and benefits of aquaculture and aquatic biotechnology worldwide, and in the United States in particular. The basic argument is that business tends to respond to uncertainty with innovation in management and technology. Technological evolution in the fish business is therefore interpreted as a continuous response to new environmental and socioeconomic uncertainties and subsequent regulation. The use of aquatic biotechnology in fish breeding is just the latest technological response, but also the most controversial. Growth-enhanced transgenic salmon may become the first bioengineered animal product approved for use as food in the United States. The fish may boost future salmon harvests, contribute to productivity increases in aquaculture and lower consumer prices for salmon. But it also faces public opposition, reluctant investors and scientific skepticism due to mainly environmental concerns. The paper argues that even though the regulatory framework in the United States is well-elaborated, it may not be able to reassure public opposition once transgenic salmon should be approved as a 'new animal drug'. Analogous to genetically modified food crops, the consumer market rather than regulation will determine the ultimate fate of transgenic fish.

Key words. Aquaculture business; precautionary principle; transgenic salmon; regulation of animal biotechnology; public perception.

Introduction

In the early 1960s, the capital-intensive high sea fisheries started to face increasing public and scientific concern worldwide. It was expected that global marine fish production may soon reach a harvest ceiling and that overfishing might irreversibly affect the balance of the marine ecosystem and the regeneration capacity of marine fish stocks. As a consequence, it was feared that global marine fish production might not just stagnate but even go into steep decline, while the global demand for fish would continue to increase rapidly.

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Published on Web: August 24, 2004

In the face of growing uncertainty about the future of fish, policy decision makers worldwide eventually agreed to act by adopting precautionary measures[1] in the regulation of marine capture fisheries at the international level and promote new forms of sustainable fish stock management. The general consensus was that fishermen may have to change their role from a 'hunter and gatherer' to a 'homesteader' or 'fish farmer' if they want to stay in business and earn a reasonable income that allows them to be more independent from government support. The intensification of fish production through modern aquaculture was recognized as one answer to these new challenges. In addition to stronger regulatory constraints in high sea fishing, policy incentives to promote fish farming and a constantly growing demand for fish contributed to increasing investments in modern capital-intensive and technology-based aquaculture in the past four decades. Yet, it soon became clear that the rapid expansion of aquaculture was also causing uncertain environmental risks. The Precautionary Principle was therefore applied to regulate aquaculture activities[2]. In view of the ongoing strong demand for fish, business generally responded to such regulation with technology by making aquaculture more productive through stock-improvement techniques such as selective breeding. Selective breeding helped relieve the pressure to colonize further aquatic ecosystems for fish farming (in the face of a rapidly growing consumer demand for fish), and, at the same time, increased pressure to reform state-subsidized deep sea fishery business that continued to be mostly over-mechanized, uncompetitive and unsustainable. Thus, it can be argued that conventional fish breeding and, of late, aquatic biotechnology was adopted by actors in the fish farming business to increase their competitiveness and to take action in the face of uncertainty related to future policy regulation and fish demand.

Yet, bred, and more genetically modified fish, also may pose a risk to fish health (e.g., fish diseases due to high stock densities) and the environment (e.g., the escape of farmed fish into the aquatic environment). In anticipation of uncertain future regulation, the business community is addressing the problems through the use of fish sterilization techniques, more reliable containment and monitoring facilities; and improved management practices. In this context, one may argue that innovation in the private sector is aiming at minimizing existing risks but likely to create new risks that must be addressed again through innovations in technology and management. This innovation-based evolution has brought many benefits to consumers over the last centuries, but has caused increasing public resentment against the resulting increase in complexity and uncertainty. Genetically modified fish, which may be the most controversial technology in the fisheries industry today, will illustrate to what extent the process of technological innovation in fisheries can be interrupted by public perception.

The first part of this paper will give a general overview of the current state of production, consumer demand, technology and regulation in fish farming. It will highlight the major environmental challenges in the history of modern aquaculture and show how they were addressed by policy and business decision makers through regulation and innovation. In the second part, the focus will shift to the modern business of Atlantic salmon and the discussion over the potential risks and benefits of transgenic salmon in the United States. Aqua Bounty Farms, the U.S. firm that developed a growth-enhanced transgenic salmon; expects regulatory approval in the United States in spring 2004. It would be the first transgenic animal officially approved for human consumption worldwide. The regulatory framework designed to regulate transgenic fish in the United States will also be described in detail. The paper closes with a final discussion about the evolution of modern aquaculture, U.S. regulation on transgenic fish, and the uncertain future of transgenic salmon as a commercial product.

The current state of aquaculture

Global aquaculture, or fish farming, produced 45.7 million metric tons of seafood (including aquatic plants) at a value of US$ 56.5 billion in 2000 (FAO, 2002). The contribution of aquaculture to global supplies of fish, crustaceans and molluscs continues to grow, increasing from 3.9 percent of total production by weight in 1970 to 27.3 percent in 2000. Aquaculture is growing more rapidly than all other animal food-producing sectors. Worldwide, the sector has increased at an average compounded rate of 9.2 percent per year since 1970, compared with only 1.4 percent for capture fisheries and 2.8 percent for terrestrial-farmed meat production systems. The growth of inland water aquaculture production has been particularly strong in China, where it averaged 11.5 percent per year between 1970 and 2000 compared with 7.0 percent per year in the rest of the world over the same period. Mariculture production in China increased at an average annual rate of 14 percent, compared with 5.4 percent in the rest of the world (FAO, 2002)[3].

The intensification of aquaculture in the coastal provinces of China is based increasingly on formulated feeds and stock enhancement, whereas traditional integrated systems, based mainly on simple manuring, still predominate in remote rural areas. These traditional forms of aquaculture existed for thousands of years in China. Most of the fishes cultivated are herbivorous or omnivorous, mostly produced in low-intensity systems for local consumption (Li, 1999).

For the last three decades, aquaculture has also become increasingly important to industrialized countries as an emerging economic sector that may contribute to lower consumer prices for fish and economic development in rural areas affected by structural change in agriculture. This modern capital-intensive aquaculture is mainly focusing on high-value carnivorous fish. It involves technically specialized conditions and requires substantial knowledge about habitats and life cycles of fish species.

The European Union's aquaculture production amounts to 1.1 million tons in volume and represents approximately 3% of the worldwide aquaculture production[4]. For most of the species farmed on its territory, the European Union is a world leader (Fischler, 1999). U.S. aquaculture produced 373,000 tons of seafood in 2001 (compared to 110,000 in Canada) and accounted for a value of almost US$ 1 billion (compared to US$ 680,000 in Canada). Channel catfish, baitfishes, salmons, Rainbow trout and Tilapia were the main fish reared in aquaculture systems (Fisheries Statistics and Economics, 2001). While Europe is the biggest market for farmed fish, North America is the fastest growing market with an annual growth rate of 12-13% in recent years (The Economist, 2003).

The mixed record of aquaculture

In the early 1970s, the intensification of fish production in aquaculture systems was recognized as an appropriate answer to the emerging ecological and economic constraints of capital-intensive marine capture fisheries. At a conference in Kyoto organized by the Food and Agriculture Organization (FAO) in 1976, it was agreed in a joint Declaration on Aquaculture that more fishermen need to become fish farmers to meet the growing demand for fish without depleting the marine fish stocks (Pillay, 2001). It was argued that such a 'Blue Revolution' (analogous to the Green Revolution in agriculture), would convert fish culture from an indigenous art into a science and, subsequently, lead to a rapid increase in fish production in underutilized small ponds and other water bodies. Consequently, many governments started to promote aquaculture as an emerging new sector that helps meet future fish demand and, at the same time, create additional employment and income. However, aquaculture has not just been solving problems but creating new ones through its environmental impact: Most environmental problems are linked to the discharge of polluted water from ponds and net pens. In addition, many coastal ecosystems are sensitive to human intervention in the form of intensive fish and shrimp farming that often causes the destruction of wetlands and mangroves, the dispersion of chemicals and nutrients, and soil salinization. At stake are essential ecosystem services, including the provision of nursery habitats, coastal protection, flood control, sediment trapping and water treatment. Further environmental concerns are the use of wild fish to feed farmed fish, and the introduction of non-native species that places pressure on local fisheries resources. Aquaculture can also affect wild fish populations indirectly through habitat modification, genetic interaction of cultural and wilds stocks, food web interactions, amplification of pathogens that harm wild fish populations, and nutrient pollution (Naylor et al., 2001). The magnitude of the impact of aquaculture on the environment varies considerably between different aquaculture systems and different types of fish.

An extensive evaluation of aquaculture projects in the 1980s (UNDP/NORAD/FAO, 1987)[5] concluded that aquaculture contributed to increasing fish production and food security but often disappointed in terms of sustainability and social equity; especially in developing countries. The report also observed that few developing countries have formulated sustainable policies for aquaculture development. Lack of commitment, weak institutional capacity in developing countries and a top-down strategy in international development assistance were regarded as reasons for the limited success of many aquaculture projects.

Export-oriented aquaculture in Latin America expanded rapidly in the 1980s and 1990s as a new source of income and employment. But these new aquaculture systems (mainly shrimp farming) also created environmental, social and economic problems; and may have caused a negative public attitude towards aquaculture, especially among seafood consumers in developed countries (Aquaculture Magazine, 2000).

Yet, there are also positive examples of sustainable aquaculture, particularly in East Asia, where integrated fish farm management, well-designed aquaculture regulation, community participation in policy formulation, and the consideration and integration of local knowledge systems have contributed to sustainable and productive aquaculture (Henson et al., 2000). Many of these fish farming practices and policies may be successfully adopted and implemented in other regions of the world.

The potential to develop aquaculture in underexploited waterbodies, in paddy fields and artificially created ponds in lowlands and saline-alkali wastelands in developing countries in general, and in Africa in particular, is huge. It could increase fish production and make seafood more affordable to the poor (Henson et al., 2000). Most of the terrestrial plants and animals consumed by humans are cultured. However, the harvest of fish and shellfish is still based mainly on fisheries in wild conditions. A serious evaluation of risks and benefits of this ongoing 'blue revolution' must therefore include a comparison to existing risks and benefits of cattle production as the alternative source of protein.

The Bangkok Declaration (2000), which basically reaffirmed the broad visions set out by the above-mentioned Kyoto Declaration in 1976, pointed out the need to look at the benefits and not just the risks of aquaculture in the developing world. It emphasized the need to continue to develop aquaculture to its full potential in developing countries. Policies and regulation should promote practical and economically viable farming practices that are environmentally responsible and socially acceptable.

Regulatory aspects of aquaculture

By the end of the 1980s, the environmental, socioeconomic and sanitary risks of intensive aquaculture had been recognized and addressed in various regional, national and international agreements on sustainable aquaculture. In the aftermath of the United Nations Conference on Environment and Development (UNCED) in Rio in 1992, initiatives were started to regulate aquaculture in response to the growing concern about unsustainable practices. In 1994, the Holmenkollen Guidelines for Sustainable Industrial Fish Farming were adopted with the purpose to identify environmental hazards generated by aquaculture, to define environmental objectives of the sector, and to outline principles of conduct that may help meet environmental objectives (Svennevig et al., 1999). It set out guidelines for sustainable planning, operation, and conservation of genetic diversity, as well as research and education. The guidelines were reformulated in 1997 and adopted in 1998. In the preamble of the guidelines, three guiding principles are outlined: the Principle of Sustainable Development, the Precautionary Principle and the Principle of Human Equity (Sundli, 1999).

In 1995 FAO established a global Code of Conduct for Responsible Fisheries (CCRF) (FAO, 1995) that asked states to set up, maintain and develop an appropriate legal and administrative framework that facilitates the development of responsible aquaculture. In adopting the Code, FAO member countries requested the Organization to respond to the special requirements of developing countries through an Interregional Assistance Programme for its implementation. The Fish Code was then established as a special programme of global partnerships to promote responsible fisheries.

A Code of Practice for the Products of Aquaculture is provided by the FAO/WHO Codex Alimentarius (FAO/WHO, 1996). The Code cannot be applied to all variations of aquaculture system and practices but deals with individual species and specific aquaculture methods. The coverage of the Code includes: construction and operation establishments, quality and safe use of inputs, fish health and sanitary requirements for harvesting, and storage and transport of live fish.

In 1997, the Codex Alimentarius also incorporated the Hazard Analysis and Critical Control Point Protocol (HACCP) as an approach to ensure food safety of fish (Codex Alimentarius Commission, 2003). This step makes HACCP the basic reference for international trade disputes under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures. HACCP stands for a shift away from traditional food inspection to a system that addresses all the relevant hazards in the food production chain, which covers the harvesting, processing and distribution of fish products.

The growing demand for harmonized food standards in international trade and the supranational importance of aquatic resources may be the principal forces that induced national governments to join such an international regulatory framework.

Apart from these government actions, new initiatives were also started by non-governmental actors: One example is the Marine Stewardship Council that was set up in 1996 by the World Wildlife Fund (WWF), a large environmental NGO, and Unilever, a consumer goods manufacturer and one of the world's largest fish processors. The purpose of this Council is to raise industrial awareness for sustainable fisheries, and aquaculture in particular, and to ensure that the world's fisheries are sustainable, well-managed and able to provide consumers with fish in the long-term. In this context, voluntary eco-labeling is considered to be a cost-effective way of supplying consumers with relevant product information that may influence their purchasing and consumption decisions (Schmidt, 1999).

HACCP and Eco-labeling are initiatives that should be welcomed by fish consumers. On the other hand, there remains a certain risk that these tools may also serve as new forms of non-tariff trade barriers because many developing countries do not have the same resources to implement the strict safety standards, and therefore face more rejection of their fish exports (Henson et al., 2000).

Private sector response to stronger environmental regulation in aquaculture

More regulation did not slow productivity growth of commercial aquaculture but made the sector more receptive to innovation in management and technology that may render aquaculture production more sustainable. One response was to improve the sustainable management through precautionary measures, more transparency for other stakeholders such as consumers, and better monitoring facilities. Another response was to increase productivity of aquaculture through the development of new technologies, such as stock enhancement techniques, that may allow the use of natural resources more efficiently and prevent aquaculture from further encroaching on pristine ecosystems.

Technologies for stock enhancement comprise traditional fish breeding as well as genetic engineering. Most animals and plants designed for human consumption have been domesticated for thousands of years, while only 1% of the consumed fish species stems from selectively bred fish. Selective breeding of fish started only in the last century and significant productivity increases have been achieved only with Atlantic salmon, Rainbow trout and Tilapia. In recent years, strong international competition in these fish markets also forced producers to farm other fishes that are more difficult to breed, such as Halibut and Cod in Europe (The Economist, 2003). Yet, Atlantic salmon remains the most important farmed fish in global trade.

As production volumes of Atlantic salmon have increased, costs and prices have been driven down. As a consequence, salmon has become a relatively mid-priced product in international seafood markets (FAO, 2002). Yet, salmon is a carnivorous fish and must be fed with fish meal. To simply use animal protein to produce animal protein is not perceived to be sustainable. The technological response to this concern was to improve the food conversion rates of farmed salmon through breeding, better nutrition, feed development and fish health. This response includes the promotion of several interesting technology-based protein alternatives such as the use of natural gas (methane) for single cell protein (SCP) production as food for fish (Storebakken et al., 2000), yeast-based protein supplements, and plant protein (soy and rapeseed oil, corn gluten). These alternative protein sources already constitute a large share in conventional feed formulations used today. As a consequence, the amount of feed used for growing salmon in 2003 is 44% of what it was in 1972. In addition, fishmeal content of fish feed has been reduced from 70% in 1972 to 35% in 2002 (The Economist, 2003).

Yet, the breeding and farming of Atlantic salmon may pose a serious ecological risk to wild salmon in the North Atlantic region (Europe, United States, Canada and Greenland). Every year hundreds of thousands of farmed salmon escape from net pens and their potential impact on wild salmon is uncertain. Fish may transmit diseases to wild stock and decrease the fitness of wild fish through interbreeding. In Norway, wild Atlantic salmon were increasingly displaced by farmed salmon that escaped net pens. Escaped farmed salmon make up about 30% of the salmon in Norwegian rivers, and outnumber the resident salmon in many inland streams (Svennevig et al., 1999). Again; the private sector responded to these challenges with technological innovation such as:

- Improved containment security and sustainable management (e.g., recirculating systems, more effective cage containment systems, integrated water use, artificial upwelling, and ecosystem food web management).
- Automatic feeding systems with video/computerized control, automated vaccine-based health management to replace antibiotic usage in feeding systems, and various manipulations of environmental variables to adjust biological production cycles (Schmidt, 1999).
- Sterilization techniques through triploidy induction (Agricultural Biotechnology Research Advisory Committee, 1995).

Aquatic biotechnology

Aquatic biotechnology is the latest step in the technological evolution of modern aquaculture. As in many other research areas of the life sciences, modern biotechnology is considered to be a new tool to improve the quality and quantity of fish reared in aquaculture. Finfish and shellfish can be genetically modified through gene transfer, chromosome set manipulation, interspecific hybridization, and other methods. Biotechnology is, however, not only designed for the creation of broodfish with a superior genetic background. Other applications are: The PCR method, considered to be a valuable detection tool for the prevention, control and management of various diseases in aquaculture. For shrimp farmers, for example, it permits fast, widespread, and sensitive screening of potential shrimp virus carriers, and also for early and light infections. Biotechnology can be used for monitoring purposes on the open sea: natural and bred genetic markers could serve as the equivalent of cattle brands. Biofarming is another emerging field of research that could use, for example, Tilapia for the production of insulin (Aquaculture Magazine, 2000)

Several genes have been identified and transferred into different aquatic species (FAO, 2000; Pew Initiative, 2002) designed for human consumption, pharmaceutical production, ornamental purposes, and industrial applications. Some examples are:

- Growth hormones for increased growth and food conversion efficiency
- Anti-freeze protein for increased cold tolerance
- Lysozyme[6], an enzyme that contributes to protection from infection
- Human interferon gene for increased disease resistance
- Prolactin[7] hormones that influence hatching, osmoregulation, behavior and general metabolism
- Human gene for clotting factor VII for its production in fish

Aquatic animals attract more research attention than terrestrial livestock for two primary reasons: First, fish lay eggs in large quantities and those eggs are more easily manipulated, making it easier to insert novel DNA. Cows and pigs produce fewer eggs at a time, and once scientists insert novel DNA, they must re-insert the altered eggs into the animal. Second, fish farming is still a rapidly growing market compared to the meat market (Pew Initiative, 2002).

In several countries such as the United States, Canada, New Zealand, United Kingdom, South Korea, China, India, and Cuba, genetically modified aquatic organisms (GMOs) with the traits listed above are now tested for use in aquaculture (FAO, 2000).

Experiments with transgenic fish have shown that commercially important traits, such as enhanced growth rates (proven to be significant), disease resistance; and increased environmental tolerance (not yet proven to be significant) can be improved. To date, at least 14 species of fish have been genetically modified for enhanced growth. None of these transgenic fish has been approved for commercialization. Government Agencies in the

U.S.A., China, Canada and Cuba are now reviewing proposals for commercialization of genetically modified fish (Pew Initiative, 2002).

Each of these new products will probably trigger a separate debate on potential impacts on human health, biological diversity, and social equity. Transgenic fish may be the first transgenic animal approved for food in the United States and a major concern will be the response of consumers to this new product. In particular, in Europe, surveys have shown that public acceptance of modern biotechnology is lowest where food or animals are involved (Gaskell et al., 2000). Transgenic fish may be seen as a combination of both.

The emerging debates are likely to include questions such as:

– What, if any, additional regulations, safeguards, testing or monitoring are needed to manage transgenic fish?
– Are genetically modified fish substantially different from non-genetically modified fish for human consumption?
– What will be the impact of transgenic fish if they escape into the aquatic environment?
– How will these potential risks be addressed by regulators and operators?
– Are there social, environmental and health benefits of having transgenic fish, and who will benefit?
– Must these products be labeled in supermarkets?
– Who will be in possession of this technology (intellectual property rights), and how will this change the fish market structure)?
– Do we have a right to create transgenic animals at all?

Many of these questions cannot be answered by experts but need to be open for public discussion, although experts can provide important information to guide public debates. Expert information will also be required to create an effective and robust regulatory framework that is strict enough to prevent abuse and well-known potential hazards, yet flexible enough to respond quickly to unanticipated new challenges. The crucial questions are how to address scientific uncertainty best in the regulation of transgenic fish, and to what extent the public accepts this uncertainty as the necessary price of technological development in aquaculture.

The following section deals with these issues by investigating the case study of growth-enhanced Atlantic salmon, the first transgenic animal that is likely to be approved for consumption in the United States.

The case of transgenic Atlantic salmon

There are two companies in the United States that officially[8] deal with transgenic fish, while there are around 30 to 40 laboratories that are doing research on biotechnology in aquaculture.

One of these two companies, Aqua Bounty Farms in Waltham, MA, with its subsidiary Aqua Bounty Farms Canada on Prince Edward Island in Canada, has created an Atlantic salmon engineered to grow faster and to use feed more efficiently. It is currently waiting for the regulatory approval of its product in the United States.

Description of the organism

Aqua Bounty Farms's Atlantic salmon of Canadian origin contains a gene construct consisting of a Chinook salmon growth hormone gene and a regulatory sequence for the control and expression (a promoter sequence derived from another fish, called the ocean pout[9]). The expression of the introduced structural gene elicits the phenotype of enhanced growth rate and feed efficiency[10]. It can then be multiplied through backcrossing and selection.

The growth rate of this farmed fish can be increased by 400% to 600%, while simultaneously reducing feed input by up to 25% per unit of output (Hew et al., 1992). However, the ultimate size of the fish at maturity remains the same as other farmed salmon. The company has 10,000 to 20,000 transgenic salmon in indoor tanks at three facilities in Canadian Maritime provinces (Entis, 2003).

In culture conditions such as sea cages, several measures to minimize the reproductive impact were developed by making the transgenic fish sterile using chromosomal manipulation. It involves masculinizing females with hormones to allow the reliable production of fertile eggs that produce all-female offspring. All-female eggs can then be treated with temperature and pressure to yield triploid sterile offspring (offspring with three sets of chromosomes and incapable of sexual reproduction). The first step is reliable; the second step (induction of triploidy) varies from fish species to species and with the personnel conducting the work. One screening method removes those fish that failed to become triploid. Unfortunately, this method requires manual checking of every individual. It can, therefore, not be applied for the screening of fertilized eggs that the developer of transgenic fish wants to sell to his costumers (Pew Initiative, 2002). The developer would hatch salmon in freshwater facilities. After 9-16 months (compared to 24-84 in the wild), the young salmon undergo smoltification (acclimation to salt water), after which they survive in a marine environment (on sea farms). Triploid, all-female eggs, fry and fingerlings would then be sold or contracted out to fish farmers to grow to market size for food, in net pens or other facilities (Entis, 1999).

The impact on the salmon industry

Worldwide, approximately 2.3 million tons of wild and farmed salmon, smelts and sea trout were harvested in 2000 (compared to 625,000 tons in 1975) (FAOSTAT, 2002). International trade in farmed salmon has increased from virtually zero to about 1 million tons (in 2001) in less than two decades. The traded salmon species in 2001 were mainly Atlantic salmon (88%) and, to a far lesser extent, coho salmon (10%) (FAO, 2002). Growth in trade has followed the growth in salmon production, as the bulk of production is concentrated in a few countries with limited domestic markets such as Norway, Chile and the United Kingdom. In 2001, the United States accounted for 342,556 tons of which approximately 50,000 tons stem from farmed salmon and sea trout (Fisheries Statistics and Economics, 2001).

In the U.S.A., only 25,000 tons of salmon were sold in 1990; in 2000, it was estimated to be 200,000 tons (Sebulonsen, 2000). The United States imported most of its farmed salmon from Canada and Chile, with a market value of US$ 622 million in 1999. Completely new salmon markets have evolved, for example, in South East Asia and Eastern Europe. The most important market is the European market where about 550,000 tons of salmon are sold. Growth stems almost solely from Atlantic farmed salmon (except in Japan where farmed Pacific coho from Chile is a significant product).

With plunging consumer prices driven by massive scale economies and overproduction, the salmon farming industry is rapidly consolidating. Nutreco, a vertically integrated Dutch agribusiness giant became the world's biggest farmed salmon producer after buying the two largest salmon farming companies in 1999 and 2000. It accounts for more than 20% of the world's farmed salmon production (Ellis, 2000).

A company that produces a new growth-enhanced salmon may not just face skepticism from consumers, but may also be shunned by the fishery industry itself, especially by large firms such as Nutreco, that are already under attack for their salmon farming practices in Chile by NGOs such as Friends of Earth. Established local fish producers might fear new competition from transgenic fish and a radical change in the market structure of the sector. In turn, supermarkets and restaurant chains who value consumer concerns more strongly than producers' innovative strategies may be unwilling to buy transgenic fish and run the risk of being ostracized by their customers. Consequently, large salmon trading companies may refrain from buying transgenic salmon or entering into strategic alliances with a company that produces transgenic salmon. Though the average consumer may only be driven by price incentives and would not hesitate to buy cheaper transgenic salmon, companies may nevertheless be afraid of anti-GMO campaigns performed by activist groups which might negatively affect the public image of the brand.

The producers of increasingly sophisticated land-based water recirculating systems belong to those companies that are potentially interested in the aquatic biotechnology business because it would make these facilities more competitive and cost-effective, considering that they cost 40% more to build and 60% more to operate than sea cages (Li, 1999). A faster growing and more disease-resistant salmon can make these expensive new systems more profitable due to the rapid production cycle and improved feed conversion ratios. Recent improvements in the design and engineering of these modern plants allow for higher stocking densities, less disease exposure, fewer breakdowns and lower operating costs. Moreover, transgenic salmon could be kept from open waters and, therefore, make it acceptable from an environmental point of view. However, producers of such systems are also reluctant to produce fish that might not find buyers in the market.

In this context, it is not the individual consumer perception or consumer choice in front of a labeled genetically modified fish in the supermarket that counts most for the food, retailing and gastronomy business (the potential wholesale buyers of such fish), but the vulnerability of their reputation when it comes to organized consumer campaigns against GMO products found labeled or unlabeled on their shelves[11]. Public perception is often related to affective rather than cognitive judgments (Finucane et al., 2000), and therefore it may be significantly influenced by such protest events if these are widely and repeatedly covered by the mass media in a frame of good (concerned citizens) and evil (irresponsible companies). As a consequence, a company that sells GMO fish to consumers may become publicly stigmatized as an irresponsible company (Gregory et al., 1995), and the decision of consumers to shop in a GMO-free supermarket chain becomes a political or worldview-oriented choice (Aerni, 2002) rather than a choice of taste or price. This trend toward the politicization of food in affluent societies makes the retailing and gastronomy business more alert to public perception that is believed to strongly influence consumer perception. This is especially the case in Europe, the biggest market for fish products, where the current attitude of consumers towards transgenic food continues to be predominantely negative (Gaskell et al., 2002). This attitude may change in the mid- or long-term if companies and regulatory agencies are able to properly respond to public concerns, and if trust in the long-term safety of genetically modified food is not undermined by a serious scandal related to such food. In addition, the potential benefits to human health, the environment and animal well-being as well as to global food security and improved nutrition for people in developing countries will have to become more obvious, and the potential risks better manageable. The positive aspect of transgenic salmon is that its feed conversion rate is 25% better than that of conventional salmon with a shortened production time. It would consequently produce less waste because of its reduced demand for fishmeal and lead to a more efficient use of resources in fish production. Genetic engineering may also make it possible to convert carnivorous into herbivorous fish, for example by introducing a gene that expresses a biochemical pathway for synthesizing Omega-3 fatty acids, now required nutrients in fish feeds (Entis, 1999; Fletcher et al., 2000).

Potential environmental risks of transgenic salmon

The particular environmental concerns regarding transgenic fish include: competition of transgenic stocks with wild populations, introgression of the transgene into wild gene pools and heightened predation of transgenics on prey populations. Exact probabilities of risk might, however, be difficult or impossible to determine for all categories of possible harm because of the many unknown factors involved in such a risk assessment. The focus of environmental risk assessment is therefore on the likelihood of a genetically modified organism to destabilize a natural community, considering the following variables: (1) the effect of the transgene on the 'fitness' of fish within the ecosystem, (2) the ability of the genetically modified fish to escape and disperse into diverse communities, and (3) the stability and resilience of the receiving community (National Research Council, 2002).

Once a transgene is introduced into a community, whether by vertical or horizontal gene transfer, natural selection for fitness (survival and reproductive success relative to other individuals in the population) will determine the ultimate fate of the transgene. A study conducted by Muir and Howard (1999) showed that the introduction of Human Growth Hormone (HGH) into the model species, Japanese Medaka (*Oryzias latipes*), was observed to increase size, hasten sexual maturity and produce more eggs. All three factors enhance the mating success of modified fish and are seen as a strong indication that transgenic fish species will displace their wild counterparts once they are released into the environment. Sensitivity analyses developed and conducted by the same authors (Muir and Howard, 2001; 2002 a, b) showed that transgene effects on age at sexual maturity should have the greatest effect on net fitness of transgenic fish. Moreover, growth-enhanced transgenic fish were found to have a reduced juvenile viability (Dunham, 1994; Muir and Howard, 2001; Devlin et al., 2001; Abrahams and Sutterlin, 1999). The major concern derived from these findings is that the assumed enhanced mating success of growth-enhanced transgenic fish (Groot and Margolis, 1991), combined with its reduced juvenile viability, might lead to the gradual spiraling down of population size of local fish populations[12]. Even though transgenic Atlantic salmon with a growth hormone also showed effects similar to the ones observed with Japanese Medaka, the migratory nature of the breeding process of Atlantic salmon makes interbreeding in nature much more difficult[13]. The experience with farmed salmon shows a low survival rate. Lifetime reproductive success, measured from spawning to adult return, is only 16% achieved by wild salmon (Fleming et al., 2000). These findings seem to indicate that genetically modified fish developed for production traits have a low probability of establishment, even though the environmental concerns cannot be dismissed due to the many possible scenarios that might contribute to increased viability of the fish over time and the magnitude of possible phenotypic change due to transgenesis. There is also widespread concern about possible increased adaptability of transgenic fish in a wide range of environmental conditions through features such as cold resistance (Fletcher et al., 1992) and disease resistance (Dunham et al., 2002) and that the numbers of escaped transgenics may dwarf those of native fish in many ecosystems, so that the probability of surviving and spawning with wild stock becomes large.

On the other hand, there are scholars who question the assumption made in many studies on the environmental impact of transgenic fish that the wild is an environment devoid of new and substantial selection pressures created by man (Knibb, 1997); the argument is that very often environments have already been disturbed by man, and new selection pressures operate on new existing genetic variance from either the wild or the laboratory, in accordance with relative abundance, extent of genetic variance, and probability of new mutation. As a consequence, Knibb (1997) submits that natural selection can be expected to remove deleterious laboratory genetic changes from wild populations. This view is, however, again questioned by other experts believing it would not reflect the range of theory and empirical knowledge of fish ecology, fish management, and fish population (Hallerman, forthcoming).

Many other studies on fitness of different transgenic fish species have been conducted such as the effects of an introduced growth hormone gene in both, domestic and wild-strain trout (Devlin et al., 2001), and its impact on social interactions (Jönsson et al., 2001) and physiological behavior (Stevens et al., 1998).

Based on current knowledge, it is not possible to predict the evolutionary consequences of potential introgression of transgenes on the evolutionary future of a natural population. Experience gathered from the impact of conventionally-bred farmed salmon on the aquatic environment also remains inconclusive[14].

Aqua Bounty Farms addresses this uncertainty by its intention to sell only sterile eggs of transgenic salmon.

But, as mentioned earlier, 100% sterility cannot be ensured.

The use of sterile eggs is not favored by fish farmers of conventional Atlantic salmon stocks, as it is demonstrated to reduce productivity and resistance to stress. In the case of transgenic salmon, productivity enhancements produced by transgenesis are significantly greater than productivity losses from triploidy (Entis, 2003).

Potential health risks of transgenic salmon

So far, no possible adverse impacts of transgenic salmon on human health have been reported. However, the common public and scientific concerns about the possible long-term risks of genetic modification techniques for food production will remain.

It is expected that the possible risks inherent in current fish populations, such as toxic compounds, allergens, and hormones, may be more complex in aquatic biotechnology. There are some concerns that gene transfer could inadvertently cause tolerance in transgenic fish to a toxin, such as mercury, and consequently lead to its accumulation in their tissues – or that the gene transfer could cause the production of a new toxin. However, these assumptions are hypothetical and it is unlikely that gene transfer would cause such effects (Berkowitz and Krypsin-Sorensen, 1994; Pew Initiative, 2002).

Another hypothetical assumption is that the process of genetic engineering of aquatic organisms could accidentally increase the allergic potential of that organism (by inducing it to produce a protein that was previously not produced or to change the composition of a particular protein. Finally, there are concerns about the impact of genetic engineering on hormones in fish. Most hormones do not act independently, but rather affect and are affected by a number of others. In fish, an increase in growth hormone may raise the levels of other growth hormones (Moriyama, 1995). However, the US Food and Drug Administration (FDA) investigated this potential risk of altered hormones on human health from the use of recombinant bovine growth hormone (rbGH) in dairy cattle in the 1980s and found no evidence of an increased risk to human health (Pew Initiative, 2002).

Regulation of transgenic salmon in the United States

There remains some uncertainty about how transgenic salmon will be regulated in the United States as the first transgenic animal designed for human consumption. However, a first case study on growth-enhanced salmon directed by the Council on Environmental Quality (CEQ) and the Office of Science and Technology Policy (OSTP) (CEQ and OSTP, 2001) indicates that transgenic salmon will most probably be regulated by means of existing regulatory agencies, acts, orders and guidelines. Not all aspects of aquatic biotechnology regulation may be adequately addressed within the Coordinated Framework outlined in the CEQ/OSTP study. But regulatory policy is regarded as a process that evolves through formal and informal understandings between agencies of how a particular organism is supposed to be regulated. In the case of transgenic fish, the lead agency will be the Food and Drug Administration (FDA). Transgenic Atlantic salmon is subject to FDA oversight because it is treated as a 'new animal drug', which is defined in the Federal Food, Drug and Cosmetic Act (FFDCA) 21 U.S.C §§ 371–379. Since the growth hormone protein of transgenic salmon is encoded by the inserted genetic construct, it also affects the structure and function of the salmon, and therefore, it is considered as a new animal drug.

Any conditions that the FDA imposes on the new animal drug's use will apply to all fish derived from that original transgenic line. The FFDCA also provides FDA with authority to take action based on environmental impacts that may also affect the health of humans and animals indirectly (e.g., if transgenic salmon were to affect a plant population that is a significant food source for another aquatic animal population).

To protect competitively sensitive proprietary information, the agency is not permitted to disclose the existence of an Investigational New Animal Drug, or INAD, unless the sponsor has publicly disclosed it (which Aqua Bounty Farms has to a considerable extent).

When research conducted by the FDA Center for Veterinary Medicine is completed, it will serve as the basis of transgenic salmon as a New Animal Drug Application (NADA). The burden of proof that the drug meets safety and effectiveness standards is entirely with the sponsor.

Granting an INAD and approving a NADA are federal actions under the National Environmental Policy Act (NEPA) 42 U.S.C. §§ 4321-4370. Therefore, submission of a categorical exclusion or an environmental assessment (EA) are required. NEPA provides a structure for environmental assessment that is well known and provides a mechanism for coordination with other federal agencies.

The Agricultural Biotechnology Research Advisory Committee (ABRAC, 1995) developed Performance Standards for safely conducting research with genetically modified fish and shellfish. These standards were adopted by the U.S. Department of Agriculture (USDA) and serve as a guide in risk assessment and management for proposed experiments with aquatic transgenic organisms and offer practical support in the form of a decision support software program (Hallerman et al., 1999). Such a decision making framework will help researchers identify risks as well as culture methods, facilities, and operational safeguards to help minimize the risks by appropriate containment. It is also based on an adaptive biosafety approach that provides flexibility, accommodates dynamic circumstances and emphasizes the importance of learning (Hallerman et al., 1999). Such an approach might also be adopted at the international level. USDA also developed an assessment of a research program, called 'Environmental Assessment and Finding of No Significant Impact', related to a USDA funded research program on transgenic carp (55 Fed. Reg. 46661). These are believed to be the first federal National Environmental Policy Act (NEPA) documents to address environmental impacts of transgenic fish.

For transgenic fish, the EA will facilitate the development of the environmental component of FDA's 'safety' review under the FFDCA (directly or indirectly affecting health).

If a NADA is approved, the assessment, monitoring plans and mitigations will be available for public review. If the use of a new animal drug does not conform to its FDA-approved application (e.g., environmental mitigation measures), it is considered unsafe (21 U.S.C.§ 360b(a)(1)(B)).

In this context, FDA is asking for more quantitative models to analyse uncertainty. Uncertainty is increasingly addressed by gathering more empirical data, and by taking various conservative assumptions (safety factors that compensate for the unknown). Professional judgment and statistical data (confidence limits, percentiles, Monte Carlo simulations, fuzzy mathematics, Bayesian methodologies) are used in estimating the degree of uncertainty (US EPA, 1998; Suter, 1993).

Atlantic salmon farming is also subject to a number of federal and state environmental controls that apply whether or not the fish being farmed are transgenic. Coastal zone management authorities of the states, the Army Corps of Engineers (ACE), the Fish and Wildlife Service (FWS) of the Department of Interior, and the National Marine Fisheries Service (NMFS) of the Department of Commerce, are involved with the selection and permitting of net pens and hatcheries. The permit application must include a description of the purpose, proposed activities, location, character of the area and potentially conflicting use. The federal review process entails evaluations by FWS and NMFS, and several federal acts may indirectly be affected[15]. The Environmental Protection Agency (EPA) and the states together enforce the Clean Water Act (CWA) (33 U.S.C. §§ 251–1387), regulating the potential harm that may be caused by fish wastes and disposal of new animal drugs used on fish. EPA also issues discharge permits, applying the National Pollution Discharge Elimination System (NPDES).

Under current regulation, labeling of transgenic fish will most probably be on a voluntary basis. However, Elliot Entis, CEO of Aqua Bounty Farms (Entis, 2003) confirmed that growth-enhanced salmon would be labeled at any rate.

As in the case of transgenic crops, the United States government decided to regulate transgenic fish by means of existing policies. It was argued that a coordinated framework would be more cost-effective and enable the lead agency to consult with experts of the different agencies involved. This approach is, however, not praised by everybody: Canadian regulatory agencies, which followed hitherto the U.S.A. approach in risk assessment, have been criticized in a report of an Expert Panel of the Royal Society of Canada for being too lenient on genetically modified food (The Royal Society of Canada, 2001). The expert panel advocated a more vigorous and independently reviewed testing of genetically modified food, and would impose a moratorium on GM fish grown in farms on Canada's coasts as a measure of precaution.

The Report of the Pew Initiative on Food and Biotechnology (Pew Initiative, 2002) also criticizes the FDA-led regulatory procedures. The authors of the report doubt the FDA's competence for judging environmental risks (even in a coordinated effort with other agencies). Issues not associated with conventional animal drugs (e.g., concerns arising from gene flow from generation to generation) should also be considered. The report also complains that public disclosure is not provided before the approval of NADA. This would prevent the public from participating in an informed debate on the risks and benefits of transgenic fish. Even though the report is right to complain about the lack of transparency and clarity of current regulatory procedures, it ignores that FDA is carrying out its evaluation in a coordinated effort with EPA (bound by acts such as NEPA and the Clean Water Act) and USDA. Moreover, a positive FDA decision does not imply that states would have to allow the farming of transgenic fish in their territory since this belongs partly to state jurisdiction (aquaculture permits). The sponsor of the application (in this case Aqua Bounty Farms) has also voluntarily disclosed the necessary information about its transgenic salmon (as an INAD) (Entis, 2003). A public debate on the risks and benefits of transgenic fish should therefore not be hampered by the lack of information prior to approval. Even though there have been various public protest actions against transgenic fish and numerous major articles in leading newspapers, there seems to be a lack of interest among the general public to participate in a debate on that particular issue in advance of the pending FDA approval decision. It indicates that people first need to perceive the technology not just as another science fiction scenario but as a real fact in daily life (e.g., when transgenic salmon would show up on supermarket shelves) in order to become enthusiastic or concerned about it. Since the fish would be labeled, it will be interesting to see how organized protest responds to it and to what extent consumers care. The worst case scenario for Aqua Bounty Farms would be an effective public media campaign by anti-biotechnology activists against supermarket chains that offer labeled transgenic fish that would subsequently induce them to withdraw the product altogether. Experience with genetically modified food products in Europe showed that supermarkets are afraid to be exposed by campaigners as suppliers of genetically modified organisms (GMOs). The consequence was that they removed GM food from their shelves; no matter whether these products were labeled or not.

While many countries have created bio- and health safety regulations for transgenic plant varieties, regulations for transgenic animals are still largely unregulated outside the United States. On the international level, the Working group on the Application of Genetics in Fisheries and Marine culture (WGAGFM) advocated a policy based on a few recommendations under the auspices of the International Council for the Exploration of the Sea (ICES). The most important demand is a 100% effectiveness in the reproductive sterilization of GMOs to prevent genetic impacts on wild populations due to the release of GMOs into the environment.

Discussion

The overall development of the fish industry since the second half of the 20th century shows a shift from small-scale fish catching to large-scale fish catching to fish farming and fish breeding. This development is mainly a result of environmental and socioeconomic constraints, changing national and international fishery policies, and technological and managerial innovation in industry.

Worldwide aquaculture fish production has tripled in the past 15 years and is assumed to grow fast in the future. This fast growth of aquaculture has created benefits in terms of additional employment, lower consumer prices for fish, and less pressure on marine aquatic resources, but also caused environmental and fish health problems. Subsequently, the aquaculture industry was subjected to more national and international scrutiny and regulation. It also started to address its problem through self-regulation and quality labeling. Another consequence was an accelerated path of technological change to make capital-intensive aquaculture safer for the aquatic environment and fish health. The use of genetic engineering in fish breeding is the latest development of this technological transformation of the aquaculture industry; but also the most contentious, since it may not just minimize existing risks and provide additional benefits but create new risks that will be unknown and hard to manage.

The case of transgenic Atlantic salmon, which contains a growth hormone gene from another fish, triggers all the fears and hopes that arise from such a controversial innovation. This is particularly so because of the uncertain impact of such fish in case of escape into the aquatic environment. A zero risk cannot be guaranteed in spite of improved containment facilities and fish sterilization techniques.

Transgenic Atlantic salmon in the United States will be regulated like an animal drug with the Federal Food and Drug Administration (FDA) as the lead agency. Ultimately, permission to farm such fish is in the jurisdiction of the states as well as federal agencies that oversee marine resource use, the environment and wildlife.

The adaptive approach to biosafety risk assessment developed in the United States Department of Agriculture (USDA) is a very helpful tool to gather more information about the uncertainties concerning the impact of an unintended release of transgenic fish into the aquatic environment. In this regard, U.S.A. regulations are not about general decisions in favor or against a technology but aim to break down the issue to informed decisions on a case by case basis, assisted by experts from other government agencies, industry and academia. Yet, the federal regulation does not take into consideration aspects such as the potential scale of adoption and local socioeconomic and natural environments (which are considered to be in the realm of state regulation). There will always be a remaining degree of uncertainty in such decisions, but uncertainty can be reduced and new uncertainties can be managed more effectively over time through the process of trial and error in risk assessment that is based on learning. Since unanticipated side-effects may always occur, precaution must be the overall guiding principle in regulating aquatic biotechnology.

Yet, ultimately, it is the public and not science that decides about the acceptability of certain risks. The public and science only coincide in their risk perception if the public entirely trusts science to act in the public interest. If public trust in the responsible institutions (science, industry and government) decreases then the ultimate policy decisions tends to become more influenced by shared interests, values and worldviews (Beck, 2000), and less by the careful balancing of the risks and benefits of a new technology. This politicization or democratization of risk may make it unlikely that transgenic fish will show up on the mass consumer market any time soon. In case FDA will approve transgenic salmon for human consumption, it may not be the end but the beginning of a worldwide controversy over genetically modified animals as food. In the face of the political risks involved, it is therefore understandable that policy decision makers in the United States prefer to postpone the decision every year (a positive approval decision was already expected in spring 2002).

But even if transgenic fish will be approved by FDA eventually, it is not very likely that this innovation will be welcomed in the established fish industry or the fish retail business. Assuming that there would be no public acceptance problem, transgenic salmon would certainly be a successful business innovation because it would increase productivity significantly and force competitors to adopt the technology unless they want to drop out of business. After all, genetically modified fish follows the evolutionary logic of modern fish farming that is characterized by risk, regulation and innovation. Yet, in an increasingly demand-driven food economy, it is consumer perception that matters. Life styles, worldviews and health concerns tend to have more influence on consumer behavior in affluent Western societies. The companies that are closest to the consumers, the retailers, send this message to the wholesalers and the wholesalers demand from producers to consider the desires and concerns of these affluent consumers. The producers again send the message to their input providers and, ultimately, the input providers, which are the main force of revolutionary technological innovation in the primary sector, are affected by such consumer perception and preferences[16].

The U.S.A. firm that developed transgenic salmon is potentially such an input provider. It would sell (or contract out) eggs, fry and fingerlings to fish farmers, where they would grow to market size for food, in net pens or other facilities. The producers, in this case the fish farming business, may however be reluctant to adopt the technology unless wholesalers (e.g., salmon trading companies) and retailers (e.g., supermarket chains) signal their willingness to buy such fish. The retail business, which wields most market power in the food business, is closest to the consumer and, therefore, most worried about its public image. A retail company may not offer labeled transgenic fish on its shelves if it is likely to be negatively exposed by the anti-biotech campaigners and the mass media, because such media coverage is likely to influence consumers and their choice of supermarkets as well.

The difficulty to predict activist, mass media and consumer response after an eventual positive regulatory approval decision of transgenic salmon in the United States makes it very difficult to tell something about its future.

Acknowledgments

I am very grateful to Thomas Bernauer, Elliot Entis, Eric Hallerman, Calestous Juma and Peter Rieder for their very valuable support.

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APPENDIX: Listing of Acronyms

ACE	Army Corps of Engineers
ABRAC	Agricultural Biotechnology Research Advisory Committee
CCRF	Code of Conduct for Responsible Fisheries
CEQ	Council on Environmental Quality
CIFA	Central Institute for Freshwater Aquaculture
CWA	Clean Water Act
EA	Environmental Assessment
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Federal Food and Drug Administration
FFDCA	Federal Food Drug, and Cosmetic Act
FWS	Fish and Wildlife Service
GM	Genetically Modified
HACCP	Hazard Analysis and Critical Control Point
HGH	Human Growth Hormone
ICES	International Council for the Exploration of the Sea
INAD	Investigational New Animal Drug
NADA	New Animal Drug Application
NEPA	National Environmental Policy Act
NGOs	Nongovernmental Organizations
NMFS	National Marine Fisheries Services
NORAD	Norwegian Agency for Development Cooperation
NPDES	National Pollution Discharge Elimination System
OECD	Organization for Economic Co-operation and Development
OSTP	Office of Science and Technology Policy
SCP	Single Cell Protein
UNCED	United Nations Conference on Environment and Development
USDA	United States Department of Agriculture
U.S.C.	United States Code
WGAGFM	Working Group on the Application of Genetics in Fisheries and Marine Culture
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wild Life Foundation

ENDNOTES

[1] The 1982 Law of the Sea Convention recognizes in its preamble the obligation of all states to protect and preserve the marine environment as the common heritage of mankind. Yet, it is up to the signatory states how to apply this measure of precaution in law or regulation; this flexibility is often associated with the Principle of Proportionality, which takes into account the wide range of individual, national and official attitudes to resilience, vulnerability and periodical irreversible thresholds in the weighting of the costs and benefits of precautionary measures (O'Riordan and Cameron, 1994). Though the Precautionary Principle lacks a specific and widely recognized definition, it is probably most adequately expressed in Principal 15 in UNCED Rio Declaration 1992 which says '…where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.

[2] The General Principles of the FAO Code of Conduct for Responsible Fisheries recommends the adoption of a precautionary approach to conservation, management and exploitation of living aquatic resources emphasizing that '..the absence of adequate scientific information should not be used as a reason for postponing or failing to take measures to conserve target species, associated or dependent species and non-target species and their environment' (FAO, 1995).

[3] There is however a strong likelihood that China's aquaculture production, particularly its growth since the early 1990s, has been overestimated in the statistics (The Economist, 2001; Watson and Pauly, 2001).

[4] Norway, which is the largest salmon producer worldwide and the leading technological innovator in the salmon business, is not part of the EU and therefore not included in EU statistics.

[5] For full names of the abbreviated organizations see appendix

[6] Lysozyme catalyzes the breakdown of certain carbohydrates found in the cell walls of certain bacteria (e.g., cocci). It thus functions, in the case of lacrimal fluid, to protect the cornea of the eye from infection

[7] Prolactin is a protein hormone produced by the pituitary gland of mammals that acts with other hormones to initiate secretion of milk by the mammary glands. It also acts to maintain the corpus luteum of the ovary, which is the source of the female sex hormone progesterone. Its function in males is not known. In humans prolactin is similar to human growth hormone.

[8] Aquabounty Farms is the only company that is working openly with fish as food, but there are others working in the biomedical area.

[9] The key to stimulating dramatically faster growth rates is not necessarily the changing of the growth hormone gene, but rather the promoter DNA sequence that controls it (MacLean and Laight, 2000). Selecting the right promoter allows developers to 'trick' the fish's cells into making growth hormone when it otherwise would not, so they grow faster at different times in the fish's development (Pew Initiative, 2002)

[10] Aquabounty Farms transferred also an antifreeze polypeptide gene from flounder into Atlantic salmon in order to increase its freeze resistance, and research is done on improved resistance to diseases.

[11] Currently most of the consumers in the United States and Europe are denied to choose between GM and non-GM food because labeling of such food is either not mandatory (as it is the case in the Unites States) or labeling is mandatory but as a result of protest campaigns against retailers with labeled GM food, it was mostly removed from the supermarket shelves altogether (as it is the case in Europe).

[12] According to this Trojan Gene Hypothesis, less fit individuals would then obtain the majority of matings, while the resulting transgenic offspring would not survive as well as nontransgenic genotypes.

[13] Atlantic salmon breed annually (more than 90% only once in a lifetime) not continuously like Japanese Medaka. The growth hormone may hasten age at maturity in transgenic Atlantic salmon, but because of the annual and migratory nature of the breeding process, the effect would be to only mimic the behavior of a "grilse" salmon (a fish that matures after one winter at sea), which account for about half of all wild salmon worldwide (and up to 80% in some regions) (Joseph McGonigle, Aqua Bounty Farms, personal communication in 2001).

[14] In 2000, the US government listed wild Atlantic salmon in eight Maine rivers as endangered. There exist more than 60 theories for the causes of the decline in native salmon abundance throughout North America. These theories include increased predation, disease, changes in ocean temperatures and currents and impacts from aquaculture. The impact of salmon farming on native salmon in eastern Maine focuses on the concern that farm-raised fish will interbreed with wild Atlantic salmon and leading to a gene introgression into the wild stock. Moreover, disturbance of habitat or displacement of wild stock as a consequence of competition for resources, predation, or miss-mating is a major concern. The fact, that 100'000 farmed salmons managed to escape after a storm in Maine in February 2001, the largest known escape of aquaculture fish in the eastern United States (Daley, 2001), increased public concern about farmed salmon in the U.S. even more. However, to date, farmed Atlantic salmon has not been proven to establish successfully in new habitats in North America, though this is currently subject to intense study and debate. At least in the case of Maine, stocking records and accounts of adult salmon returns to Maine rivers have been demonstrated that in most instances few stocked salmon survived from most of the historical salmon stocking that has occurred in Maine Rivers (Baum, 1997). In turn, Hindar (1993) and Kapuscinski and Hallerman (1991) point out that introductions of non-native organisms have significantly contributed to extinctions of North American fish species during the past century. Evidence of the first successful spawning of Atlantic salmon that escaped from net pen aquaculture in rivers of British Columbia has been reported by Rimmer (1998).

[15] The following Acts may directly or indirectly play a role surrounding the issues of transgenic fish. The detailed content of the different Acts can be found on the website 'Code of Federal Regulation' http://www.gpoaccess.gov/cfr/index.html):
- Fish and Wildlife Coordination Act
- Rivers and Harbors Act (Section 10)
- Marine Mammal Protection Act
- Coastal Zone Management Act
- The Lacey Act
- Endangered Species Act
- Nonindigenous Aquatic Nuisance Prevention and Control Act
- Magnuson-Stevens Act
- National Aquaculture Act
- National Aquaculture Improvement Act

[16] The increased importance of consumer perception has also increased the competition among political stakeholders to influence consumer perception through advertising, PR or protest campaigns (Aerni, 2002; Luhmann, 1991).