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February 10, 2004

Commissioner Charles Bronson
Florida Department of Agriculture
and Consumer Services
Division of Aquaculture
1203 Governor's Square Boulevard, 5th Floor
Tallahassee, Florida 32301

Dear Commissioner Bronson:

The Center for Food Safety along with the following co-signers, including consumers, fishermen and environmentalists (hereinafter "the undersigned"), submits these comments in response to the Florida Department of Agriculture and Consumer Services (DACS) request for comments regarding the Transgenic Aquatic Species Task Force Draft Policy. The undersigned encourages DACS to establish a regulation requiring a thorough pre-market review of transgenic fish along with specific permitting restrictions. Because transgenic fish species can pose serious human health and environmental risks, the undersigned strongly recommends that DACS adopt the following recommendations.

I. CURRENT REGULATION OF TRANSGENIC AQUATIC SPECIES

Genetic engineering ("GE") is a novel technology that is fundamentally altering our food supply. Biotechnologists now are able to take genetic material from one organism and insert it into the permanent genetic code of another organism. Among these novel creations are fish genetically engineered for human consumption and for pets. Already, over thirty-five species of transgenic aquatic animals are being developed around the world.[1] Despite this rapid development, little, if any, action has been taken by the federal government to establish a regulatory framework for addressing the novel human health and environmental impacts posed by the commercialization of transgenic aquatic animals.

While no federal laws specifically govern the regulation of genetically engineered animals grown for human consumption, the Food and Drug Administration ("FDA") has made the informal decision to regulate transgenic aquatic animals under its authority to review new animal drugs.[2]

[1] Tony Reichhardt, *Will souped up salmon sink or swim?,* 406 Nature 10 (July 6, 2000)[hereinafter "Souped up Salmon"].

[2] FDA/CVM, *Questions and Answers About Transgenic Fish*, *available at*

Under the new animal drug application process, FDA will only provide notice to the public about a transgenic aquatic animal application after the agency has issued a regulation approving commercialization.[3] One company, Aqua Bounty Technologies, is presently requesting FDA approval to market transgenic salmon to the public.[4] Aqua Bounty Technologies' transgenic fish contains a growth hormone gene from a chinook salmon and an antifreeze protein gene promoter from an ocean pout that keeps the growth hormone active.[5] This transgene is injected into fertilized eggs. Due to the continuous production of the growth hormone gene, these transgenic fish grow as much as ten to thirty times faster than normal salmon.[6] In addition to transgenic salmon, there are transgenic tilapia, striped bass, and catfish that are being developed and may soon be on the market. Aqua Bounty Technologies has publicly disclosed information on its transgenic salmon, however, other companies have not. Due to FDA's strict confidentiality requirements all new animal drug applications are kept secret until they are approved. Consequently, it is impossible to know if FDA is reviewing other types of transgenic fish for commercialization.

Another variety of transgenic fish that is already on the market, and is being bred and distributed by two Florida tropical fish wholesalers, is transgenic fluorescent zebra fish.[7] This fish contains a gene from sea anemones that causes the fish to glow red under normal light and fluorescent under ultraviolet light.[8] This is only one of many different types of transgenic pet fish that may soon be sold directly to the public. FDA has recently decided not to regulate transgenic aquarium fish.[9] With no federal oversight over transgenic pet fish, the entire regulatory responsibility over these exotic creatures falls to the states. Thus, the potential impacts to the health of Florida's citizens and to Florida's diverse native species must be considered at the state level.

Due to the lack of a comprehensive federal regulatory framework for transgenic fish, several states have stepped forward to ensure that the wildlife and endangered species in their state waters are protected from the potential impacts of transgenic fish. For example, Maryland and California have legislation and Washington, California, and Oregon have regulations prohibiting transgenic fish from being grown or released in their state waters.[10] This action by the states is consistent with the federal government's position under the international coalition, National Atlantic Salmon

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http://www.fda.gov/cvm/fda/infores/consumer/transgen.htm (last visited Feb. 22, 2000).

[3] 21 U.S.C. § 360b(i); 21 C.F.R. § 514.105(a).

[4] Reportedly, Rex Dunham of Auburn University is seeking FDA approval to market transgenic channel catfish. *See* A. Zitner, *Gene-altered catfish raise environmental, legal issues*. L.A. Times, Jan. 2, 2001. Others may be seeking approval to market transgenic fish but FDA keeps all this information confidential until an order is issued approving commercialization. 21 U.S.C. § 360b(i); 21 C.F.R. § 514.105(a).

[5] Choy L. Hew and Garth Fletcher, *Transgenic fish for aquaculture*, Chemistry & Indus., (Apr. 21, 1997) *available at* http://ci.mond.org/9708/970812.html

[6] *Id.*

[7] Andrew Pollack, *Gene-Altering Revolution Nears the Pet Store: Glow-in-the-Dark Fish*, NY Times (Nov. 22, 2003).

[8] *Id.*

[9] FDA, *FDA Statement Regarding Glofish*, (Dec. 9, 2003), *available at* http://www.fda.gov/bbs/topics/news/2003/new00994.html (last visited Jan. 29, 2004)

[10] 2003 Cal. Adv. Legis. Serv. 871 (Deering); CAL. CODE REGS. tit., 14, § 671.1 (2003); MD. CODE ANN., Nat. Res. § 4-11A-02(a)(3)(2002); OR. ADMIN. R. 635-007-0595 (2003); WASH. ADMIN. CODE § 220-76-100 (2003).

Conservation Organization ("NASCO"). The parties to NASCO have established guidelines on GE fish. These guidelines state that GE fish are only to be grown in secure and confined land based systems.[11] In June 2001, all the parties, including the U.S., agreed to support the guidelines.[12]

The need for strong state regulations was exemplified by recent events in California. Plagued by invasive species, the state of California adopted the most comprehensive regulations over transgenic aquatic animals thus far in the nation. These regulations list transgenic aquatic animals as a restricted species, thus, preventing anyone from possessing, importing, rearing, or researching on transgenic aquatic animals without a permit.[13] Because California is the only state in the nation with these all-inclusive regulations, this state was able to go through a public and analytical decision-marking process on whether to allow the sale of transgenic zebra fish. Due to FDA's decision not to regulate these pet fish, California regulations provide a "backstop" serving as the only mandatory governmental process to review the environmental impacts of transgenic aquarium fish. After reviewing the information about the transgenic zebra fish, the California Fish and Game Commission voted to deny an exemption from the permit process for the sale of transgenic zebra fish.[14]

Rather than going through a review process in Florida, the transgenic zebra fish was allowed to be sold to the public without a risk assessment. Due to this regulatory void, DACS is developing a Transgenic Aquatic Species Task Force to conduct pre-market reviews of transgenic species. The undersigned encourages the task force to adopt the following recommendations.

II. RECOMMENDATIONS TO TASK FORCE

REVIEW PROCESS

1. The Review of Transgenic Aquatic Species Should Be Governed By A Mandatory Regulation Rather Than A Non-binding Policy

The current draft language describing the review of transgenic aquatic species is labeled as a "policy." The undersigned recommends that rather than issuing a policy over the review of transgenic aquatic species, DACS should issue a rule. This is an important distinction because regulations are enforceable and mandatory whereas policies are subject to change and non-binding. The Supreme Court has explained that a substantive rule has the force and effect of law whereas policy statements on the other hand, are "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power."[15] Policy statements do not impose any new rights or obligations on the regulated entity and gives the agency complete discretion.

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[11] North Atlantic Salmon Conservation Organization, *Transgenic Salmon Guidelines*, CNL(01)29 (June 2001).

[12] *Id.*

[13] CAL. CODE REGS. tit., 14 § 671(c)(11), § 671.1 (a)(9).

[14] Kenneth Weiss, *State Takes Dim View of GloFish, Bans Sale*, L.A. Times, Dec. 4, 2003.

[15] *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979).

To demonstrate to Florida citizens that the state is approaching the marketing of transgenic fish species cautiously and even-handedly among transgenic fish producers, DACS should issue a regulation. This rule should require a mandatory review of the potential human health and environmental consequences and issue mandatory permitting restrictions before allowing a transgenic aquatic species to be grown in the state and sold to the public.

2. The Definition of Transgenic Should Be Broadly Defined

The proposed draft policy defines transgenic aquatic organisms as "species with introduced genes from a dissimilar species." Due to the continuously developing nature of transgenic aquatic species, it is essential that this definition is broadly drafted. The problem with the current definition is that it excludes at least one type of transgenic fish that has already been developed, a transgenic mud loach. This fish is genetically engineered to contain no extraneous DNA. Instead, a gene and promoter from the mud loach is inserted.[16] This fish grows 35 times faster than the non-genetically engineered fish.[17] Moreover, this fish weighs up to 412g and is as long as 41cm (a normal mud loach is 89g and 28 cm).[18] Even though this fish does not contain genes from a dissimilar species, it has a novel phenotype that is ecologically quite different from a non-transgenic mud loch.[19] The transgenic mud loch example demonstrates that regardless of whether it is a small or large genetic change, there could be a significant environmental consequence that must be reviewed by the task force.[20]

To encompass not only all of the currently known types of transgenic aquatic animals, but also future applications of the technology, the transgenic aquatic species definition needs to be broadened. To extend this definition, it is crucial that the definition include gene addition, deletion, or changing the position of the gene as example of methods of producing transgenic fish yet not limit the technology to these methods. The undersigned recommends that following definition:

> Transgenic aquatic organism means a species that is genetically altered by introducing DNA from (1) another species or (2) through engineered endogenous constructs by means such as but not limited to recombinant DNA and RNA techniques to produce, gene addition, deletion, and doubling, or changing the position of the gene. This definition includes fish eggs and excludes hybridization between closely related species, as in traditional hybridization.[21]

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16 Yoon Kwon Nam, et al*, Dramatically accelerated growth and extraordinary gigantism of transgenic mud loach Misgurnus mizolepis*, 10 Transgenic Research 353 (2001).

17 *Id.*

18 *Id.*

19 National Research Council of the National Academies, *Biological Confinement of Genetically Engineered Organisms,*48 (Jan. 20, 2004)[hereinafter "NAS Bio-Confinement Report"].

20 *See Id.*

21 *See*CAL. CODE REGS. tit. 14, § 1.92.

3. Factors That Should Be Considered In Reviewing Human Health And Environmental Affects From Transgenic Aquatic Species

In reviewing the potential risks posed by transgenic aquatic species, the task force should conduct a thorough review of the potential hazards. Among the issues that need to be analyzed by the task force include the following:

A. Impacts to the environment/endangered species if transgenic aquatic species escape
   - assessment must be specific for each species and genetic manipulation of fish and where the fish will be located in the aquatic system
   - competition for food (aggressiveness to wild fish)
   - competition for mates (impact on wild population numbers)
   - introduced genes into wild population (fitness of species)
   - reliability of sterilization test
   - prey or niche requirements (ecological disruptions)
   - affects on endangered and threatened fish species and marine mammals
   - introduced diseases and parasites

B. Bio-confinement strategies- including, but not limited to, ocean pens, ponds, or indoor enclosed tanks
   - Specific assessment for each species and genetic manipulation of fish and containment facility
   - likelihood of fish escapes and causes (review the number of escapes from facilities containing farmed fish)

C. Impacts to Human Health
   - assess toxicity and unintended effects
   - assess allergenicity
   - review dangers of consuming diseased transgenic fish containing antibiotics

To conduct a meaningful risk analysis, the above considerations are some of the issues that must be rigorously explored and objectively evaluated. Only by fully considering all the potential impacts that may be caused by transgenic aquatic species, can the task force make an informed decision on whether these fish should be available directly to the public.

4. A Risk Analysis Should Be Done For Each Different Transgene Manipulation

Any approval of transgenic aquatic species by this task force must be specific for each organism, protein, and genetic construct. This is necessary to prevent a blanket exemption for a type of transgenic fish that may use different proteins or techniques. Because there a variety of methods for creating transgenic fish, including the use of antibiotic selection markers, viral vectors and/or promoters, that could exhibit different human health and environment impacts, there should be a specific review process for each different transgene manipulation.

5. Any Transgenic Aquatic Species Already Being Sold To The Public Should Go Through The Task Force Review Process

Although the transgenic fluorescent zebra fish did not go through a pre-market review process, the undersigned are encouraged to hear that the task force is reviewing this fish now.[22] In addition to the transgenic zebra fish, there may be other transgenic pet fish that are currently being sold in pet shops that have not gone through the task force review process. For example, there are reports that transgenic medaka are being sold in pet stores in Chicago; and it is reported that these fish are being grown by Segrest Farms in Florida. Medaka and other types of transgenic pet fish could be currently growing in Florida fish farms and presently being sold in Florida pet stores without any regulatory review. Because there is no mandatory federal review process and the task force is only presently being developed, it is possible that there are several types of transgenic pet fish that quietly entered the market unnoticed by state regulators. Therefore, the undersigned recommends that an investigation by DACS be conducted to determine if there are any transgenic aquatic species currently being sold in Florida. If there are, these exotic fish must go through the task force review process.

6. A Pre-Market Review Process For Transgenic Aquatic Species Should Be Open To Public Review And Comment

Each transgenic aquatic species that goes through the task force review process should be open to public review and comment. Adequate public notice should be given indicating that the task force is reviewing a new type of transgenic fish species. Moreover, clear information should be given setting forth the date public comments are due. Only through a transparent public process, will the public be confident that the Florida government is adequately protecting consumers and the environment from the potential risks posed by transgenic aquatic species.

PERMITTING RESTRICTIONS

7. No Transgenic Aquatic Species Should Be Grown Or Released Intentionally Or Unintentionally Into Open Waters

The intent of the legislator under the Florida Aquaculture Policy Act, is to "enhance the growth of aquaculture in this state, while protecting Florida's environment."[23] To adequately protect Florida's environment, it is crucial that transgenic fish are not grown or released into open waterways. The scientific evidence demonstrates that if bio-confinement measures fail and transgenic fish are released into the environment, then these exotic creatures will compete with native fish populations and disrupt the ecological balance. The importance of bio-confinement is discussed in a report recently released by the National Academy of Sciences.[24] Without strong bio-confinement measures, the transgene could escape and wreck havoc on the environment.[25]

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[22] The Center for Food Safety submitted comments to the task force regarding our concerns with the commercialization of this fish on January 14, 2004.

[23] FLA. STAT. ch. 597.0021(1)(emphasis added)

[24] NAS Bio-Confinement Report,*supra* note 19.

[25] *See id.* at 47-48.

Therefore, the undersigned recommend that the task force employ the most effective methods of bio-confinement. This includes not growing transgenic fish in open waters and physically preventing the transgenic organism from intentionally or unintentionally entering an open waterway.[26] Preventing exotic species from entering Florida's ecosystem is critical because as stated by the Florida Fish and Wildlife Conservation Commission, "it is impractical, if not impossible for man to eliminate an exotic fish once it is reproducing in Florida's open waterways."[27]

A. Risk of transgenic fish escaping into the wild

If transgenic aquatic species are grown in ocean pens, it is inevitable that these fish will escape. Examples from fish farmers throughout the world demonstrate that farmed fish are repeatedly escaping from ocean pens, outdoor ponds in flood-prone areas, and flow-through raceways.[28]

Most marine aquaculture in the U.S. is conducted in ocean pens. Although ocean pens may be cost effective, this method of aquaculture is highly susceptible to breakage and thus, there is a substantial likelihood that transgenic fish will escape from ocean pens and mix with wild fish. As demonstrated by the current use of ocean pens for aquaculture, the accidental release of fish is considerable. Indeed, on average, 15% of farmed fish escape.[29] There are also several incidences of mass fish escapes. In 1990, approximately four million fish escaped from a fish farm in Norway.[30] In the U.S., over 170,000 farm raised salmon escaped from a net pen after a storm in Maine.[31] The Fish and Wildlife Service reports that "25-40% of the fish in the North Atlantic Ocean is of aquaculture origin."[32] Weather, human error, and marine mammal and bird attacks[33] all contribute to the release of fish from ocean pens.[34] Recognizing that fish repeatedly escape from net pens, CEQ stated that it "must be assumed that escapes will occur" from net pens.[35]

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[26] This tactic is already being used by the National Marine Fisheries Service and Fish and Wildlife Service who prevent transgenic salmon from being grown in net pens in Maine due to the impacts to endangered Atlantic salmon.

[27] Florida Fish and Wildlife Conservation Commission, *Exotic Freshwater Fishes*, *available at,* http://www.floridaconservation.org/fishing/Fishes/non-native.html (last visited Jan 23. 2004)[hereinafter "Exotic fish"].

[28] NAS Bio-Confinement Report,*supra* note 19, at 114.

[29] Eric M. Hallerman & Anne R. Kapuscinski, *Ecological implications of using transgenic fishes in aquaculture*, 194 ICES Mar. Sci. Symp. 56, 59 (1992) [hereinafter "Ecological implications"].

[30] Walter Gibbs, *Fish-Farm Escapees Threaten Wild Salmon*, N.Y. Times, Oct. 1, 1996 at C4.

[31] *Catastrophic Salmon Escape Prompts Calls for Moratorium on the Aquaculture Industry*, *available at* http://www.clf.org/hot/20010223.htm (last visited Apr. 2, 2001).

[32] Fish and Wildlife Service, *Biological Report on the Status of Atlantic Salmon: Threats to Wild Salmon*, *available at* http://news.fws.gov/salmon/asalmon75.html. (last visited Apr. 10, 2000).

[33] Rebecca Goldberg and Tracy Triplett, *Murky Waters: Environmental Effects of Aquaculture in the U.S.*, Environmental Defense Fund at 57 (1997) [hereinafter "Murky Waters"](stating that 62 species of birds and 13 species of mammals are potential predators of transgenic fish in ocean pens).

[34] Environmental Assessment Office, British Columbia, *The Salmon Aquaculture Review: Escaped Farm Salmon*, *available at* http://www.eao.gov.bc.ca/PROJECT/AQUACULT/SALMON/report/v1chp5.htm (last modified July 14, 1998).

[35] *Case Study No. I, Growth-Enhanced Salmon, in CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology*, 23, *available at* http://www.ostp.gov/html/012201.html (last visited Apr. 19, 2001)[hereinafter "CEQ

Florida is already experiencing the affects from fish farm escapes. Spotted tilapia, Orinoco Sailfin Catfish, and Oscar are some of the non-native fish that have escaped from Florida fish farms and established themselves in Florida's waters.[36] A total of 127 non-indigenous fish have been recorded in Florida's open waters and 32 exotic freshwater fish are reproducing in the freshwaters of Florida – more than any other place in the world.[37] The majority of these introductions are due to releases from tropical fish farms or owners of pet fish.[38] These non-native tropical fish are able to survive because of Florida's tropical climate.[39] Given the high likelihood that transgenic fish will escape or be released, the environment, including endangered species will likely be affected by these transgenic organisms.

B. Risks of transgenic fish harming the genetic integrity of native species

Once transgenic fish escape into the marine environment, native species, including endangered species will likely be severely impacted. Fish populations are already rapidly decreasing.[40] One of the causes for this decline is the introduction of non-native fish. Non-native fish species from aquaculture facilities are believed to have contributed to the decline of eight fish species listed under the ESA.[41] Concerned about the depleting numbers of Atlantic salmon, the Department of Interior ("DOI") warned that this species could be "quickly wiped out if transgenic fish grown in nearby aquaculture farms escape their pens."[42] To protect this endangered species, DOI and the Department of Commerce ("DOC") prohibit transgenic salmon from being grown in net pens in Maine.[43] DOI/DOC recognize that transgenic fish may harm native species and the scientific studies support this assertion.

Recent studies suggest that reproductive problems in transgenic fish could also severely harm existing fish populations. Studies conducted by two scientists at Purdue University show that

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Transgenic Salmon Study"].

[36] USGS, *Nonindigenous Fishes of Florida*, *available at* http://sofia.usgs.gov/sfrsf/rooms/species/invasive/focus/ (last visited Dec. 9, 2003)[hereinafter "USGS"].

[37] Pam L. Fuller, et al., NONINDIGENOUS FISHES INTRODUCED INTO INLAND WATERS OF THE UNITED STATES, 2, U.S. Geological Survey (1999); Exotic Fish, *supra* note 27.

[38] USGS, *supra* note 36.

[39] *Id.*

[40] J.A. Musick, et al, *Marine, Estuarine, and Diadromous Fish Stocks at Risk of Extinction in North America*, 25 Fisheries 6, 19 (Nov. 2000).

[41] *See*Murky Waters, *supra* note 33 at 51 - 52; DOI and DOC, *Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered* (Nov. 2000).

[42] Julie Vorman, *GMOs may pose new risk to endangered plants, animals*, Yahoo News, May 4, 2000 *available at* http://dailynews.yahoo.com/h/nm/20000504/sc/biotech_endangered_1.html

[43] Letter to Stephen Silva, Maine State Program, Environmental Protection Agency from Michael Bartlett, U.S. Dept. of Interior, Fish and Wildlife Service and Patricia Kurkul, U.S. Dept. of Commerce, Nat. Marine Fisheries Service (Jan. 12, 2001)(stating that transgenic salmonids are prohibited).

transgenic fish may have a greater mating advantage due to their larger size.[44] However, their offspring may have a reduced ability to survive because transgenic fish are "macromutants that lack any history of selection that could reduce negative fitness effects."[45] As a result of transgenic fish producing the least fit offspring yet obtaining a disproportionate share of the mates, the Purdue scientists predict that if 60 transgenic fish were introduced into a population of 60,000 wild fish, the species would become extinct within only 40 generations – an effect referred to as the "Trojan gene effect."[46] The theory was verified in another study performed by Phillip Hederick who states that his findings "should serve to alert researchers of the inherent risks of accidental releases of GM organisms into natural populations."[47]

In response to the concerns that transgenic fish may lead to species extinction, Aqua Bounty Technologies states that they will only sell transgenic fish that are sterile to be grown in net pens.[48] To sterilize fish, fertilized eggs receive heat and pressure shock which results in adding an extra set of chromosomes. Instead of the fish having the normal two sets of chromosomes, the fish has three sets. As a result, this "triploid" fish does not develop normal sexual characteristics.[49] Even if transgenic fish are required to be sterile, the reliability of the sterilization is not guaranteed for every fish. Sterilization is variable because it is affected by different fish strains and the ability of the personnel performing the technique.[50] Anne Kapuscinski, a specialist in biotechnology and aquaculture at the University of Minnesota in St. Paul, is concerned about the unpredictability of sterilization and stated that "[e]ven when you're pretty good at it, you get a lot of batch to batch variation."[51] A CEQ study warns that 100% sterilization cannot be guaranteed and a NAS bio-confinement study demonstrates the problems with triploidy.[52] Without a complete guarantee that transgenic fish will be sterile, these exotic fish will invade and impact native fish populations.

In 2002, the National Academy of Sciences (NAS) issued a report cautioning that the "ability of certain GE organisms to escape, disperse, and to become feral in diverse communities is of high concern."[53] The NAS report goes on to warn that the "GE organism might eventually replace its relative or become established in the community if the GE organism is more fit than its wild

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[44] William M. Muir and Richard D. Howard, *Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis*, 96 PNAS 13853-13856 (Nov. 23, 1999).

[45] *Id.*

[46] *Id. See* Phillip W. Hedrick, *Invasion of transgenes from salmon or other genetically modified organisms into natural populations*, 58 Can. J. Fish Aquatic Science, 841-844 (stating that "there are very broad conditions in which a transgene with a large mating advantage and a pleiotropic viability disadvantage may invade natural populations, reduce their fitness, and potentially cause their extinction.").

[47] *Id.* at 843.

[48] Carol Kaesuk Yook, *Altered Salmon Leading Way To Dinner Plates, but Rules Lag*, N.Y. Times, May 1, 2000, at A1, A20.

[49] Souped up salmon, *supra* note 1, at 11.

[50] CEQ Transgenic Salmon Study, *supra* note 35.

[51] *Id*; *See generally*, Anne Kapuscinski and Eric Hallerman, *Transgenic Fish and Public Policy: Anticipating Environmental Impacts of Transgenic Fish*, 15 Fisheries 2-11 (Jan - Feb 1990)(discussing issues associated with sterilization).

[52] CEQ Transgenic Salmon Study, *supra* note 35, at 8, 31 (admitting that none of the sterilization techniques are 100% effective); NAS Bio-Confinement Report,*supra* note 19, at 117-125.

[53] National Academy of Sciences, *Animal Biotechnology: Science-Based Concerns*, 10 (Aug. 11, 2002)[hereinafter "NAS Report"].

relatives in that environment."[54] Thus, according to the NAS, the release of transgenic fish into the environment may threaten the survival of wild fish species.[55]

C. Risks of transgenic fish harming the marine ecosystem

Even if it could be guaranteed that the sterilization of transgenic fish will be 100% effective, transgenic fish that escape into the ocean will likely disrupt and harm the environment.[56] Repeatedly, non-native organisms have caused harmful ecological disruptions. If transgenic fish are permitted in Florida, the evidence demonstrates that these creatures will seriously disrupt Florida's ecosystems.

The difference between transgenic and nontransgenic fish is significant. Studies show that growth enhanced transgenic salmon are more aggressive and eat as much as five times as much food as wild species.[57] One researcher observed that transgenic fish have "a revved-up metabolism. They're hungry all the time."[58] As a result, these transgenic fish could be foraging ravenously when food availability in an area is low, thereby, out competing native fish.[59] Moreover, the fish being consumed by these aggressive hungry transgenic salmon predators will likely be impacted.[60] One scientist warned that "[t]hey're creating very, very large fish that will become predators of other fish."[61] By out competing native species for resources and habitat, transgenic fish will likely seriously disrupt the ecosystem.[62]

Conclusion

These are some of the environmental risks involved with transgenic fish but the full extent of the harm that may be caused by these fish are unknown. Rather than allowing transgenic fish into the state's waters and risk biological pollution, the task force should require strict bio-confinement measures to prevent transgenic fish from being grown or released intentionally or unintentionally into Florida's open waters.

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54 *Id.* at 9.

55 *Id.* at 11.

56 CEQ warns that the use of triploidy does not eliminate all environmental risks. Even if a transgenic male fish is rendered sterile, "the males may exhibit spawning behavior with fertilie diploid females, leading to decreased reproductive success of the fertile diploid females." CEQ Transgenic Salmon Study, *supra* note 35, at 8.

57 Mark Abrahams & Arnold Sutterlin, *The foraging and antipredator behavior of growth-enhanced transgenic Atlantic salmon*, 58 Animal Behavior 933-942 (June 22, 1999); RH Devlin, *et al*, *Increased ability to compete for food by growth hormone-transgenic coho salmon Oncorhynchus kisutch*, 30 Aquaculture Research 479-482 (1999)(explaining that transgenic coho salmon consumed almost three times the food of wild fish); CEQ Transgenic Salmon Study, *supra* note 35, at 8 (explaining that released sterile triplids may "pose heightened competition with diploid conspecifics (i.e., fish of the same species), perhaps including in some cases, predation on juvenile conspecifics.").

58 Sarah Schmidt, *Frankenfish or Salmon Savior*, Nat'l Post (Sept. 4, 1999)(observing the abnormal behavior in transgenic fish, Dr. Devlin discovered that transgenic fish are much more aggressive. "It's one of the things that made me wake up.").

59 Souped up salmon, *supra* note 1 at 11.

60 *Genetic engineering creates supersalmon and controversy*, Seattle Times, Nov. 30, 1999.

61 *Id.*

62 Ecological implications, *supra* note 29, at 60 - 61.

8. If Transgenic Aquatic Species Are Permitted To Be Sold To The Public, The Transgenic Aquatic Species Should Be Labeled

Poll after poll demonstrates that consumers want to know whether the food they are consuming is genetically altered.[63] In addition to being a right to know issue, Florida consumers should know whether the fish they are consuming is transgenic because of the potential human health risks.

The genetic engineering of food, including transgenic fish, creates two separate and serious health risks involving allergenicity. The first is that genetic engineering can transfer allergens from foods to which people know they are allergic, to foods that they think are safe. This risk is not simply hypothetical. A study by the *New England Journal of Medicine* showed that when a gene from a Brazil nut was engineered into soybeans, people allergic to nuts had serious reactions to the engineered product.[64] At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem.[65]

There is yet another potential allergy risk associated with transgenic fish. These foods could be creating new allergic responses. Each genetic "cassette" being engineered into a fish species may contain a number of novel proteins (in the form of altered genes, genes from bacteria and viruses, marker systems, and vectors) which may have never been part of the human diet. Each of these numerous novel proteins could create an allergic response in some consumers.[66] The NAS identified as a great concern the "unintended and unanticipated effects and byproducts of the genetic engineering of a food animal, including but not limited to these novel proteins."[67] The novel proteins in genetically engineered foods raise serious questions regarding toxicity and allergenicity. NAS reports that these novel genes may trigger allergencity or hypersensitivity responses and could cause severe reactions in some people.[68]

In addition, transgenic fish are "macromutants" and thus likely subject to more diseases than non-transgenic fish. Consequently, the use of antibiotics in these fish may lead to antibiotic resistance in humans. Although FDA has asserted responsibility for reviewing the human health impacts of transgenic food fish, Florida should pro-actively protect the health of its citizens by requiring labeling of transgenic fish. Some people may have a reaction to consuming transgenic fish

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[63] *See*Center for Food Safety Compilation of Public Opinion Polls on Genetically Engineered Foods at http://www.centerforfoodsafety.org/facts&issues/polls.html.

[64] Nordlee, Julie A., MS; *et al. Identification Of A Brazil-Nut Allergen in Transgenic Soybeans*, 334 New Eng. J. Med. 726-728 (1996).

[65] Hansen, Dr. Michael & Jean Halloran, *Why We Need Labeling of Genetically Engineered Food*, Consumers Int'l, Consumer Policy Institute, April 1998.

[66] Hansen, Michael, Ph.D. & Jean Halloran, *Jeopardizing the Future? Genetic Engineering, Food and the Environment*, PAN AP Safe Food Campaign (1998).

[67] NAS Report, *supra* note 53, at 72.

[68] *Id.* at 70.

and therefore, to protect and alert Florida consumers, transgenic aquatic species should be clearly labeled.

9. If A Transgenic Aquatic Species Is Allowed On The Market, It Should Be Re-evaluated If New Scientific Information Demonstrates New Risks

The scientific information predicting the risks associated with transgenic fish is still developing. The technology is developing so rapidly that long-term scientific studies have not been conducted. Risks that do not seem possible now, could appear later. Therefore, if a transgenic aquatic species is allowed on the market, it should be re-evaluated if new scientific information reveals new ecological or human health risks.

III. CONCLUSION

The undersigned encourages DACS to conduct a thorough review process and adopt permit requirements to fully protect public health and the environment. Therefore, the undersigned recommends the adoption of a regulation that includes the following language:

(1) A Transgenic Aquatic Species Is Defined As:

a species that is genetically altered by introducing DNA from (1) another species or (2) through engineered endogenous constructs by means such as, but not limited to, recombinant DNA and RNA techniques to produce, gene addition, deletion, and doubling, or changing the position of the gene. This definition includes fish eggs and excludes hybridization between closely related species, as in traditional hybridization.

(2) Factors That Must Be Considered In Reviewing Human Health And Environmental Affects From Transgenic Aquatic Species Include The Following:

A. Impacts to the environment/endangered species if transgenic aquatic species escape
- assessment must be specific for each species and genetic manipulation of fish and where the fish will be located in the aquatic system
- competition for food (aggressiveness to wild fish)
- competition for mates (impact on wild population numbers)
- introduced genes into wild population (fitness of species)
- reliability of sterilization test
- prey or niche requirements (ecological disruptions)
- affects on endangered and threatened fish species and marine mammals
- oxygen depletion levels
- introduced diseases and parasites

B. Bio-confinement Strategies - including, but not limited to, ocean pens, ponds, or indoor enclosed tanks
- specific assessment for each species and genetic manipulation of fish and containment facility
- likelihood of fish escapes and causes (review the number of escapes from facilities containing farmed fish)

C. Impacts to Human Health

- assess toxicity and unintended effects
- assess allergenicity
- review dangers of consuming diseased farmed fish containing antibiotics

(3) A Risk Analysis Must Be Done For Each Different Transgene Manipulation

(4) Any Transgenic Aquatic Species Already Being Sold To The Public Must Go Through The Task Force Review Process

(5) No Transgenic Aquatic Species May Be Grown Or Released Intentionally Or Unintentionally Into Open Waters

(6) If Transgenic Aquatic Species Are Permitted To Be Sold To The Public, The Transgenic Aquatic Species Must Be Labeled

(7) If A Transgenic Aquatic Species Is Allowed On The Market, It Must Be Re-evaluated If New Scientific Information Demonstrates New Risks

Thank you for the opportunity to comment. Please let us know if we can provide you with any further information.

Respectfully,

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