

**CITIZEN PETITION BEFORE THE UNITED STATES  
FOOD AND DRUG ADMINISTRATION**

*Dockets Management Branch  
Food and Drug Administration  
Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857*

**CENTER FOR FOOD SAFETY** )  
660 Pennsylvania Ave., S.E. )  
Suite 302 )  
Washington, DC 20003, *et al.*, )

*petitioners,* )

v. )

Docket No. \_\_\_\_\_

**BERNARD A. SCHWETZ, (deputy)** )  
in his official capacity as, )  
Commissioner )  
Food and Drug Administration )  
Room 1-23 )  
12420 Parklawn Dr. )  
Rockville, MD 20857 )

**PETITION SEEKING A MORATORIUM ON THE DOMESTIC MARKETING AND  
IMPORTATION OF TRANSGENIC FISH**

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,<sup>1</sup> the Administrative Procedure Act,<sup>2</sup> and the Food and Drug Administration’s (“FDA”) implementing regulations,<sup>3</sup> petitioners file this petition with the FDA and respectfully request the following:

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<sup>1</sup> “Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances.” U.S. Const., amend. I. The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. United Mine Workers of America, Dist. 12 v. Illinois State Bar Ass’n, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions. Thomas v. Collins, 323 U.S. 516, 530 (1945). “Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger.” Id. The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. United States v. Cruikshank, 92 U.S. (2 Otto) 542, 552 (1875).

<sup>2</sup> 5 U.S.C. § 553(e) (1994).

<sup>3</sup> 21 C.F.R. §§10.20, 10.30 (2001).

- I. A moratorium on the domestic marketing, importation and exportation of transgenic fish,<sup>4</sup> including but not limited to all transgenic fish, transgenic fish eggs, and food products containing any ingredients or material derived from transgenic fish,<sup>5</sup> until the FDA establishes a comprehensive regulatory framework under the mandate of the Federal Food Drug and Cosmetic Act (“FFDCA”) to evaluate and fully address the human health and environmental impacts caused by the commercialization of transgenic fish. Such a regulatory framework shall include:
- (1). Establishment of regulations addressing the safety and efficacy of transgenic fish by requiring all transgenic fish producers to complete a full review of transgenic fish as a new animal drug pursuant to the requirements of 21 U.S.C. § 360b and accompanying implementing regulations;
  - (2). Establishment of regulations addressing the pre-market safety testing of transgenic fish by requiring all transgenic fish to undergo review as a food additive pursuant to the requirements of 21 U.S.C. § 321(s) and accompanying implementing regulations;
  - (3). Establishment of regulations providing for the pre-market monitoring, reporting, and inspecting procedures of transgenic fish by transgenic fish producers pursuant to the FFDCA and accompanying regulations;
  - (4). Establishment of regulations providing for the mandatory labeling of transgenic fish and all food products containing any ingredients or material derived from transgenic fish pursuant to the requirements of 21 U.S.C. § 321(n) and 343(a)(1) and accompanying implementing regulations;
  - (5). Establishment of regulations providing for the post-market monitoring, reporting, and inspecting procedures of transgenic fish by transgenic fish producers pursuant to the FFDCA and accompanying regulations;
  - (6). Establishment of regulations providing that importers must follow the same statutory and regulatory requirements for transgenic fish as domestic producers; and

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<sup>4</sup> Transgenic fish means a genetically engineered fish that (A) has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including, but not limited to, recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture, *and* (B) a fish made through sexual or asexual reproduction (or both) involving a fish described in (A), if possessing any of the altered molecular or cellular characteristics of the fish so described.

<sup>5</sup> Hereinafter, the term “transgenic fish” includes all transgenic fish, transgenic fish eggs, and food products containing any ingredients or material derived from transgenic fish.

- (7). Provide for the permanent prohibition on the domestic marketing, importation and exportation of all transgenic fish should such products fail to be proven safe and efficacious, generally recognized as safe, or otherwise unfit for human consumption.
- II. A moratorium on the domestic marketing, importation and exportation of transgenic fish until the FDA completes a comprehensive environmental impact review as mandated by the National Environmental Policy Act to evaluate and fully address the human health and environmental impacts caused by the commercialization of transgenic fish. Such an environmental review shall include:
    - (1). Completion of an environmental assessment and environmental impact statement as required under the National Environmental Policy Act, 42 U.S.C. § 4332, addressing the effects of the domestic marketing, importation and exportation for each and every transgenic fish application;
    - (2). Completion of a programmatic environmental impact statement as required under the National Environmental Policy Act, 42 U.S.C. § 4332, addressing the effects of the domestic marketing, importation and exportation of all transgenic fish; and
    - (3). Provide for the permanent prohibition should such activities harm the quality of the environment.
  - III. A moratorium on the domestic marketing, importation and exportation of transgenic fish until the FDA reviews the impacts of such activities on endangered species and completes the consultation requirement with the Department of the Interior and Department of Commerce as required under the Endangered Species Act, 15 U.S.C. § 1536.
  - IV. A moratorium on the domestic marketing, importation and exportation of transgenic fish until all other federal agencies comply with the statutory provisions under such agencies' jurisdiction that are triggered by the introduction of transgenic fish into the environment and/or interstate commerce. Such agency action shall include, but not be limited to:
    - (1). Department of the Interior and Department of Commerce compliance with the requisite provisions of the Endangered Species Act, Lacey Act, Aquatic Nuisance Prevention and Control Act, and the National Aquaculture Policy Act;
    - (2). Department of Defense compliance with the requisite provisions of the Rivers and Harbors Act, Endangered Species Act, and the National Environmental Policy Act; and
    - (3). Department of Agriculture compliance with the requisite provisions of the National Aquaculture Policy Act.

## PETITIONERS

Petitioner, *Center for Food Safety* (CFS), is a non-profit, membership organization located at 660 Pennsylvania Ave., SE, Suite 302, Washington, DC 20003. Petitioner was established in 1997 to address the increasing concerns about the impacts of our food production system on human health, animal welfare, and the environment.

Petitioner *American Oceans Campaign* (AOC) is located at 600 Pennsylvania Avenue, Suite 210, Washington DC 20003. AOC is a national organization that works to revitalize the nation's oceans and coastal waters. AOC has two primary goals: restore and protect ocean habitats and ensure clean, safe beach water.

Petitioner *American Lands Alliance* is located at 726 7<sup>th</sup> Street, SE Washington, D.C. 20003. Petitioner works with grassroots activists around the country to protect forests and other ecosystems and the fauna and flora that depend on them.

Petitioner *Atlantic Salmon Federation* (ASF) is located at P.O. Box 5200, St. Andrews, NB E5B 3S8. Petitioner is an international, non-profit organization that promotes the conservation and wise management of the wild Atlantic Salmon and its environment. ASF has a network of seven regional councils (New Brunswick, Nova Scotia, Newfoundland, Prince Edward Island, Quebec, Maine, and New England) which have a membership of more than 150 river associations and 40,000 volunteers. The regional councils cover the freshwater range of the Atlantic Salmon in Canada and the United States.

Petitioner *The Campaign to Label Genetically Engineered Foods* is located at P.O. Box 55699, Seattle, WA 98155. Petitioner seeks to create national grassroots consumer campaign for the purpose of lobbying Congress and the President and to pass legislation that will require the labeling of genetically engineered foods in the United States.

Petitioner *Center for Ethics and Toxics* (CETOS) is located at P.O. Box 673, Gualala, CA 95445. Petitioner is a non-profit organization located on the coast of Northern California which focuses on reducing the amount of chemicals used in the environment and protecting susceptible individuals from exposure to toxic chemicals.

Petitioner *Center for Marine Conservation* (CMC), located at 1725 DeSales Street, N.W. Suite 600 Washington, D.C. 20036, is committed to protecting ocean environments and conserving the global abundance and diversity of marine life. Through science-based advocacy, research and public education, CMC promotes informed citizen participation to reverse the degradation of our oceans.

Petitioner *Council for Responsible Genetics* (CRG) is located at 5 Upland Rd., Suite 3, Cambridge, MA 02140. Founded in 1983, CRG is a national non-profit organization of scientists, environmentalists, public health advocates, physicians, lawyers, and other concerned citizens. CRG encourages informed public debate about the social, ethical, and environmental implications of new genetic technologies.

Petitioner *Cabinet Mountain Market* is located at 14 Old Bull River Rd. Noxon, MT 59853. Petitioner is a grower/consumer co-op dedicated to providing fresh, local, organic foods to the community; and to the members of the community about the impacts of industrial agriculture and its products on human health, animal welfare, rural communities, and the environment.

Petitioner *Earth Island Institute*, located at 300 Broadway, Suite 28, San Francisco, CA 94133, believes that life on earth is imperiled by human degradation of the biosphere. Petitioner develops and supports projects that counteract threats to the biological and cultural diversity that sustains the environment. Through education and activism, these projects promote the conservation, preservation, and restoration of the earth.

Petitioner *Earth Island Journal* (EIJ) is located at 300 Broadway, Suite 28, San Francisco, CA 94133. EIJ was first published in 1982 as a class project at Stanford University. A quarterly magazine since 1987 and currently affiliated with the Earth Island Institute, EIJ has won significant acclaim for its groundbreaking coverage of environmental and social issues.

Petitioner *The Edmonds Institute* is located at 20139 92<sup>nd</sup> Avenue West, Edmonds, WA 98020. Petitioner is a non-profit, public interest organization committed to the health and sustainability of ecosystems and their inhabitants. It seeks to engage in projects that foster respect for and protection of the rights and health of all communities. The Institute focuses its efforts on understanding and sharing information about environmental, human rights and human health, and economic impacts of new technologies and intellectual property policies. The current emphasis of its programs is on: (a) biosafety and the legally-binding international regulation of modern biotechnologies, (b) intellectual property rights and just policies for the maintenance and protection of biodiversity, including policies that foster recognition and sustenance of agricultural biodiversity, and (c) exploration of the ethical implications of new technologies.

Petitioner *Farm Verified Organic, Inc.* (FVO) is located at 5449 45<sup>th</sup> Street SE, Medina, ND 58467. Petitioner is an international organic certification organization established in the early 1980's. Petitioners certify as "organic" over 115 family farms, cooperatives, processors, handlers, and manufacturers around the world.

Petitioner *Friends of the Earth* is located at 1025 Vermont Ave., NW, Suite 300, Washington, DC 20005. Petitioner is a national environmental organization dedicated to preserving the health and diversity of the planet for future generations. As the largest international environmental network in the world with affiliates in 63 countries, Friends of the Earth empowers citizens to have an influential voice in decisions affecting their environment.

Petitioner *Friends of the Presumpscot River* (FOPR) is a non-profit organization located at P.O. Box 223, South Windham, ME 04082. Their mission is to protect and enhance the Presumpscot River and its shore lands through stewardship and advocacy, working on issues such as upgrading the river's classification, discharge permitting processes and development issues along its banks.

Petitioner *Genetically Engineered Food Coalition*, located at 1200 18<sup>th</sup> Street NW, 5<sup>th</sup> Floor, Washington, DC 20036, is a coalition of seven organizations united in their commitment to testing and labeling genetically engineered food.

Petitioner *Georgia Strait Alliance* is a non-profit organization formed in 1990 to protect and restore the marine environment and promote the sustainability of Georgia Strait, and its adjoining waters and communities. Georgia Strait is the 135-mile long inland sea between Vancouver Island and the British Columbia mainland. Georgia Strait adjoins Puget Sound, together making up the area known as Georgia Basin.

Petitioner *Go Wild Consumer Awareness Campaign* is located at 1081 Sudden Valley, Bellingham, WA 98226. The “Go Wild” Campaign educates consumers on sustainable seafood choices, and the health and environmental impacts of gene-altered and feedlot produced salmon and shrimp.

Petitioner *Green Decade Coalition/Newton* (GDC/N) is a non-profit, membership organization located at 474 Center Street, Newton MA 02458. GDC/N was founded in 1990 to create sustainable solutions to environmental problems facing our city and our world.

Petitioner *Greenpeace, Inc.* is located at 1436 U Street NW, Washington, DC, 20009. Petitioner is the U.S. headquarters of one of the world’s major environmental organizations with offices in 33 countries and over 3 million donating supporters worldwide. Petitioner is a non-profit organization devoted to the protection of the environment with an emphasis on global environmental problems such as climate change and the protection of the stratospheric ozone layer, prevention of nuclear, chemical and biological pollution, and defense of biodiversity.

Petitioner *Tim Grussendorf* is a commercial fisherman, fishing vessel *Christi Sea*, and seafood processor located at 9386 River court Way, Juneau, AK 99801.

Petitioner *Half Moon Bay Fisherman’s Marketing Association*, located at P.O. Box 340, El Granada, CA 94018, is a non-profit organization formed in 1960 to advance the interests of commercial fishermen in Pillar Point Harbor, California, with special interests in promoting sustainable fisheries and responsible resource management.

Petitioner *Edward Hansen*, fishing vessel *Ocean Gold*, is a commercial fisherman located at 9369 North Douglas Hwy, Juneau AK 99801.

Petitioner *Humane Society of the United States* (HSUS) is located at 2100 L Street, NW, Washington, DC 20037. Petitioner is the nation’s largest animal-protection organization, with more than 7 million constituents. The HSUS was founded in 1954 to promote the humane treatment of animals and to foster respect, understanding, and compassion for all creatures.

Petitioner *Institute for Agricultural and Trade Policy* (IATP) is located at 2105 1<sup>st</sup> Avenue South, Minneapolis, MN 55404-2505. Petitioner is a research and education organization that acts locally, nationally and internationally to develop and support policies and strategies that expand choices and opportunities to farmers, farm workers and local communities around the world, regenerate the natural resource base, take a precautionary approach to the use of chemicals and genetic manipulation and avoids dependence on purchased inputs and external energy sources, and tackle the causes rather than the consequences of unsustainability, looking for positive, progressive, and proactive ways of solving problems. IATP works with farmers, consumers, unions, environmental organizations, citizens groups and others both in the U.S. and around the world.

Petitioner *Institute for Fisheries Resources*, located at PO Box 11170, Eugene, OR 97440-3370, is a non-profit organization dedicated to the study, protection, and enhancement of both marine and anadromous biological resources on the Pacific Coast of the United States and Canada.

Petitioner *Keta Fisheries* is a commercial fishing company located at 10620 Starlite CT, Juneau, AK 99801 which specializes in wild salmon.

Petitioner *Maine Green Independent Party* is a legitimate political party organized to address problems of democracy, human rights and the environment through political action.

Petitioner *Maine Organic Farmers and Gardeners Association* is located at P.O. Box 2176, Augusta, ME 04338-2176. Petitioner is the oldest and largest organic organization in the USA and seeks to help farmers and gardeners grow organic food, to protect the environment, to promote stewardship of natural resources, to increase local food production, to support sustainable rural communities, and to illuminate for consumers the connections among healthful food, environmentally sound farming practices, and vital local communities.

Petitioner *Maine Toxics Action Coalition* (MTAC) was formed in 1995 to eliminate dioxin from the paper making process in Maine. Petitioner, a coalition of about 20 environmental and health-related organizations statewide, has since expanded their reference to include issues such as education and outreach around toxics and fish consumption, pesticide issues and other public health issues.

Petitioner *The Mangrove Action Project* is a global network dedicated to conserving mangrove forest ecosystems as well as promoting the rights of local coastal communities to sustainably manage their coastal resources, including mangrove forests. MAP was founded in 1992 and now has over 450 NGOs and 250 academics as well as other individual members in 60 nations.

Petitioner *Maryland Conservation Council, Inc.* is a non-profit, volunteer organization incorporated in 1969. It is a statewide coalition of environmental organizations and concerned individuals whose purpose is to provide an effective and continuing coordinating structure to work for the preservation and appreciation of Maryland's rich natural heritage, to sustain the vitality of its biological diversity and of its varied ecological systems, and to ensure the wise use of its resources.

Petitioner *Massachusetts Public Interest Research Group* (MASSPIRG) is located at 29 Temple Place, Boston, MA 02111. Petitioner is a non-profit, nonpartisan organization dedicated to serving as a watchdog for the state's citizens and environment. With tens of thousands of members and a staff of policy specialists, petitioner combines the expertise of professionals with the power of citizens in defense of clean air and water, strong safeguards for consumers, a free and vigorous democracy, and a way of living today that ensures a better quality of life tomorrow.

Petitioner *Alexandra Morton*, is a scientist located at General Delivery, Simoom Sound, British Columbia, Canada. She has been studying killer whales, including their role as top predator in an ecosystem of which salmon are a large part, in a remote archipelago on the coast of British Columbia year-round for 17 years.

Petitioner *Mothers for Natural Law* is a non-profit educational organization founded in 1996 to provide practical information and support to mothers in their attempt to insure and protect the health, well-being and innocence of their children. Though petitioner's goal is to address all challenges facing families today, from child abuse to the abuse of the environment, the primary focus during the first five years has been to raise national public awareness on the dangers of genetically engineered foods and secure mandatory labeling, safety testing, accountability and a moratorium on these foods.

Petitioner *National Environmental Law Center* is located at 29 Temple Place, Boston, MA 02111. Petitioner is a non-profit, non-partisan research and litigation organization working to stop polluters through legal action and pollution prevention techniques.

Petitioner *National Environmental Trust* is located at 1200 18<sup>th</sup> Street, NW, 5<sup>th</sup> Floor, Washington, DC 20036. Petitioner is a non-profit, non-partisan membership group established in 1994 to inform citizens about environmental problems and how they affect our health and quality of life. Through public education, NET helps people understand an issue and express their concerns to public officials.

Petitioner *Native Fish Society* is located at P.O. Box 19570, Portland, OR 97280. Petitioner strives to protect and restore native fish and their habitats, recently securing an administrative rule in Oregon to prevent the release of transgenic fish into state waterways.

Petitioner *Native Forest Network's Eastern North American Resource Center*, located at P.O. Box 57, Burlington, VT 05402, focuses primarily on genetically engineered trees and their threat to global forest ecosystems. Petitioner works to protect native forest, forest communities, and indigenous peoples.

Petitioner *Northwest Ecosystem Alliance* (NWEA) is located at 1421 Cornwall, Suite 201, Bellingham, WA, 98225. NWEA was founded in 1988 to protect and restore wildlands in the Pacific Northwest and support such efforts in British Columbia. NWEA, bridges science and advocacy, working with activists, policy makers and the general public to conserve our national heritage.

Petitioner *Northern Keta Caviar*, located at 2601 Channel Dr. Juneau, AK 99801, is a commercial fishing and caviar production company that processes and sells wild salmon.

Petitioner *Organic Consumers Association* (OCA) is located at 6114 Highway 61, Little Marias, MN 55614. Petitioner is a nationwide grassroots public interest organization dealing with issue of food safety, industrial agriculture, and genetic engineering while promoting organic and sustainable agriculture.

Petitioner *Organic Trade Association* (OTA) is a non-profit business association located at 74 Fairview Street, Greefield, MA 01301. Though OTA does not endorse the organic certification of wild aquatic animals, OTA's mission is to encourage global sustainability through promoting and protecting the growth of diverse organic trade.

Petitioner *Pacific Coast Federation of Fishermen's Association* (PCFFA), located at PO Box 29370, San Francisco, CA 94129-0370, is a federation of 25 different port and fishermen's marketing associations spanning the U.S. west coast from San Diego to Alaska. Since its inception 20 years ago, PCFFA has been leading the industry in assuring the rights of individual fishermen and fighting for the long-term survival of commercial fishing as a productive livelihood and way of life.



Petitioner *Penobscot Bay Watch* is a non-profit, membership organization located at 418 Main Street, Rockland, ME 04841. Petitioner was established in 1995 to respond to concerns about the impact of coastal development and industrial agriculture on the abundance and distribution of natural species in Penobscot Bay and the tidal Penobscot Bay River.

Petitioner *Pesticide Action Network-North America* (PANNA) is located at 49 Powell St., Suite 500 San Francisco, CA 94102. Petitioner has campaigned to replace pesticides with ecologically sound alternatives since 1982. PANNA links over 100 affiliated health, consumer, labor, environment, progressive agriculture and public interest groups in Canada, Mexico, and the United States with thousands of supporters worldwide to promote healthier, more effective pest management through research, policy development, education, media, demonstrations of alternatives and international advocacy campaigns.

Petitioner *Pine Creek Organic* is located at 200 Pine Swamp Road, Danville, PA 17821. Petitioner is a small, certified organic operation growing medicinal and culinary herbs, leafy greens, tomatoes, peppers, and raspberries.

Petitioner *Dean Risley* is a commercial fisherman and processor in Southeast Alaska located at PO Box 1012, Haines, AK, 99827.

Petitioner *Save Our Shores* is located at 2222 East Cliff Drive, #5A, Santa Cruz, CA 95063. Petitioner was formed to protect and promote the ecological integrity of the Monterey Bay National Marine Sanctuary through education, policy research, and citizen action.

Petitioner *Cory Schreiber*, 1221 Northwest 21<sup>st</sup> Avenue, Portland, OR 97209, is a critically acclaimed chef specializing in “cooking from the source,” emphasizing organic produce from the Pacific Northwest. Awarded the James Beard Award in 1998 for the “Best Chef Pacific Northwest,” Mr. Schreiber opened a restaurant, *Wildwood*, in 1994 in his native Portland.

Petitioner *The Sierra Club* is located at 85 Second Street, Second Floor, San Francisco, CA 94105-3441. Petitioner is one of the world’s leading conservation organizations, as well as one of the oldest, with over 600 thousand members. It’s the largest grassroots conservation organization in the United States. The purposes of the Sierra Club include protecting the quality of the natural and human environment and using all lawful means to carry out its objectives.

Petitioner *Southeast Alaska Fishermen’s Alliance, Inc.* is located at 9369 North Douglas Hwy, Juneau, AK 99801. Petitioner is a non-profit, membership organization established in May 2000 to preserve, promote, protect and perpetuate the fishing industry for salmon, crab, shrimp, and longline fisheries in SE Alaska and to further promote legislation, conservation management, safety at sea, and the general welfare of its members.

Petitioner *Sweet Lisa Seafood*, fishing vessel *Salty*, located at PO Box 6464, Ketchikan, AK 99901, produce numerous Alaskan wild salmon products.

Petitioner *The Temple of Ascension* is a learning center dedicated to raising individual consciousness, as well as a healing center dedicated to joining the physical with the spiritual. It is the petitioner's belief that one's birthright (if and when one chooses it) is to ascend from this physical dimension to the next level in spiritual development. One practices ways and means to refine and attune one's body (one's temple) to reach a level of harmony that will activate one's light within, thereby leading to soul development and ascension.

Petitioner *Norman and Karen Thompson*, fishing vessel *Dog Catcher*, is a commercial fisherman in Alaska and Washington, located at 2520 Oakes Ave, Anacortes, WA 98221.

Petitioner *Arthur Thurn*, fishing vessel *Skibo*, operates a 36-foot salmon gill-netter and halibut long-liner that works in Southeast Alaska and is located at 2323 G. Street, Bellingham WA, 98225-3640.

Petitioner *20/20 Vision Education Fund* is a non-profit membership organization located at 1828 Jefferson PL, NW, Washington, DC 20036. Petitioner was established in 1985 to facilitate citizen participation in pending peace and environment issues. This is accomplished by notifying members through a monthly action card that sets out how each member can write a letter or take some action in no more than 20 minutes each month. Priority campaigns include stopping national missile defense, promoting clean vehicle technology and ensuring safe foods.

Petitioner *United States Public Interest Research Group* (U.S. PIRG) is located at 218 D Street, S.E., Washington, DC, 20003. Petitioner is the national office for the State PIRGS, a network of groups with offices around the country working on consumer rights, good government, and environmental issues. For over 25 years the PIRGs have been one of the nation's leading nonprofit, nonpartisan groups acting on behalf of the public.

Petitioner *Washington Public Interest Research Group* (WashPIRG), located at 3240 Eastlake Ave. E., Suite 100, Seattle, WA 98102, is a non-profit, non-partisan environmental and consumer's protection group.

Petitioner *Washington Toxics Coalition* (WTC) is located at 4649 Sunnyside Ave. N., Suite 540, Seattle WA 98103. WTC is a non-profit organization dedicated to protecting public health and preventing pollution in industry, agriculture, and the home. Founded in 1981, WTC has been on the cutting-edge of policy reform efforts ranging from pesticide use reduction in schools to the elimination of persistent bioaccumulative toxics (PBTs) in Washington State. WTC also advocates the adoption of non-toxic alternatives to toxic products and develop high-quality educational materials on alternatives.

Petitioner *Washington Trollers Association* (WTA), located at P.O. Box 7431, Bellevue, WA 98008, strives to preserve and protect the Northwest's salmon stocks as well as represent the people whose livelihoods depend on the salmon. Composed of fishermen who operate out of smaller fishing boats, the WTA promotes sustainable fishing in harmony with nature and selective fishing techniques to ensure that only salmon are harvested.

Petitioner *Washington Trout*, located at PO Box 402, 15629 Main Street NE, Duvall, WA 98019, is a nonprofit science-based organization formed in 1989 to preserve, protect and restore Washington's wild fish and their habitats.

Petitioner *Wild Alaska Smoked Salmon* is a commercial fishing company, fishing vessel *Single O*, located at P.O. Box 2140, Kodiak, AK 99615, which specializes in salmon, halibut, king crab, shrimp, and caviar.

Petitioner *Joe and Erin Willis* are commercial fishermen, fishing vessel *Mariner II*, located at PO Box 43, Petersburg, AK 99833.

## STATEMENT OF GROUNDS

### I. STATEMENT OF FACT

Genetic engineering 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. Among these novel food creations are fish genetically engineered for human consumption. Already, over thirty-five species of transgenic fish are being developed around the world.<sup>6</sup> Despite this rapid development, little, if any, action has been taken by the United States to establish a regulatory framework for addressing the novel human health and environmental impacts posed by the commercialization of transgenic fish.

Currently, the FDA has initiated steps to determine whether or not approval of the first transgenic fish for human consumption is warranted. As far as petitioners are aware, only one company, A/F Protein, is presently requesting FDA approval to market transgenic salmon to the public.<sup>7</sup> A/F Protein's 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.<sup>8</sup> 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.<sup>9</sup>

Although this petition reviews the human health and environmental concerns connected with salmon injected with a growth hormone, it also identifies studies and reports from other types of transgenic fish that are currently being researched. The purpose of the petition is to identify the human health and environmental concerns along with the regulatory requirements that must be addressed by FDA when reviewing any and all requests to market transgenic fish.

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

<sup>7</sup> Reportedly, Rex Dunham of Auburn University is seeking FDA approval to market transgenic channel catfish. 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).

<sup>8</sup> Choy L Hew and Garth Fletcher, Transgenic fish for aquaculture, Chemistry & Indus. (Apr. 21, 1997) available at <http://ci.mond.org/9708/970812.htm>. [hereinafter "Transgenic fish for aquaculture"].

<sup>9</sup> Id.

While no federal laws specifically govern the regulation of genetically engineered animals grown for human consumption, the FDA has made the informal decision to regulate transgenic fish under its authority to review animal drugs. In taking this action, transgenic fish producers must complete a New Animal Drug Application (NADA) and demonstrate the safety and effectiveness of these fish. Any such demonstration of safety must be shown through substantial evidence. Given the potential toxicity, allergenicity, and aquaculture diseases posed by the commercialization of transgenic fish, the FDA must adopt a pre-market regulatory review that does not ignore these potential human health safety concerns.<sup>10</sup> Moreover, the growing consumer concern over genetically engineered foods such as transgenic fish clearly necessitates that the agency act to fully inform consumers about this emerging food safety issue by requiring the mandatory labeling of all transgenic fish approved for human consumption.

In addition to these novel issues of food safety, the commercial introduction of transgenic fish poses significant and unprecedented potential risks to the environment. Although FDA has experience and authority to regulate food and drugs, the agency does not have expertise in areas such as marine ecology. The manner in which transgenic fish will impact the environment must be fully reviewed by the environmental agencies charged by Congress with this responsibility. Taking such action is imperative. Already, scientists are warning about the environmental dangers caused by the accidental release of transgenic fish into the environment.<sup>11</sup> If transgenic fish are permitted to be 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. Even the Council on Environmental Quality (“CEQ”) recently stated that it “must be assumed that escapes will occur” from ocean pens.<sup>12</sup>

Unintended releases of transgenic fish into the world’s waters may cause significant impacts to the environment and endangered species. New studies show that transgenic fish are more aggressive, eat more food, and will attract more mates than wild fish.<sup>13</sup> In addition, these studies show that although transgenic fish will attract more mates, their offspring will be less fit and less likely to survive. As a result, scientists predict that transgenic fish will cause some species to become extinct within only a few generations.<sup>14</sup> Once one species becomes extinct, other species will likely be affected. There are

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<sup>10</sup> See Center for Food Safety, Partial List of Products That Were Recalled From The Market Due To StarLink, A Version Of GE Corn Unfit For Human Consumption, available at, <http://www.centerforfoodsafety.org/cry9contamination.html> (last visited May 2, 2001).

<sup>11</sup> See *infra* at pp. 25-36

<sup>12</sup> 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 Transgenic Salmon Study”]. The leading drafting agency on the growth-enhanced salmon case study was FDA. NMFS and DOI were also part of the drafting team.

<sup>13</sup> *Id.*

<sup>14</sup> 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)[hereinafter “Trojan gene hypothesis”].

already 114 species of fish, including Atlantic salmon, that are listed under the Endangered Species Act (“ESA”).<sup>15</sup> Allowing transgenic fish in ocean pens may significantly increase this number of listed species.

Other unpredictable and egregious environmental consequences are also likely to occur as a result of the accidental introduction of these non-native species into the aquatic environment. Introduction of diseases, increased pollution, and superior competition for wild fish for food and habitat are some of the ecological disruptions likely to be caused by transgenic fish. Acknowledging the potential environmental harm transgenic fish may create, the Department of Interior (“DOI”) and the Department of Commerce (“DOC”) insist that they need to be involved in deciding whether transgenic fish should be permitted in ocean pens.<sup>16</sup> Consistent with FDA’s statutory responsibilities, FDA must consult these environmental agencies in this reviewing process.

Finally, researchers in many countries are interested in the development and marketing of numerous varieties of transgenic fish. Each type of transgenic fish proposed for the market must be thoroughly reviewed by FDA before it is approved. Although FDA is currently reviewing and has not yet approved A/F Protein’s transgenic salmon, this company already has orders for 15 million transgenic salmon eggs and is talking to fish farmers all around the world.<sup>17</sup> Given the immediacy of this situation, it is clear regulatory action must be taken swiftly.

To ensure that any federal action regulating transgenic fish completely and thoroughly provides protection to public health and the environment, for the reasons outlined herein, petitioners request that the agency impose a moratorium on the domestic marketing and importation of transgenic fish unless and until the FDA and other federal agencies with jurisdiction over this subject have established a regulatory framework requiring the mandatory pre-market safety testing, full pre-market environmental review, and (should commercialization occur) mandatory labeling of all transgenic fish.

## II STATEMENT OF LAW

Administrative Procedure Act, 5 § U.S.C. 551, *et seq.*

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

National Environmental Policy Act, 42 U.S.C. § 4321, *et seq.*

Endangered Species Act, 16 U.S.C. § 1531, *et seq.*

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<sup>15</sup> U.S. Fish and Wildlife Service, U.S. Listed Vertebrate Animal Species Report by Taxonomic Group as of 11/1/2000, available at <http://endangered.fws.gov/wildlife.html> (last visited Nov. 1, 2000) [hereinafter “Listed Vertebrate Species”].

<sup>16</sup> See infra at pp 26-33.

<sup>17</sup> 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](http://dailynews.yahoo.com/h/nm/20000504/sc/biotech_endangered_1.html) [hereinafter “GMOs Pose New Risk”].

All other applicable statutes and regulations.

## ARGUMENT

### **FDA MUST IMPOSE A MORATORIUM ON THE DOMESTIC MARKETING AND IMPORTATION OF TRANSGENIC FISH UNTIL THE AGENCY ADEQUATELY ADDRESSES THE IMPACTS TO HUMAN HEALTH AND THE ENVIRONMENT.**

#### **A. FDA Is Required Under the Federal Food Drug And Cosmetic Act To Review The Human Health Impacts From Consuming Transgenic Fish.**

Petitioners request that all transgenic fish and expression products thereof used in food not be marketed domestically or imported unless and until the agency has formally adopted thorough pre-market safety review procedures for such foods as both a new animal drug and a food additive. This action is necessary to ensure full analysis and review of the potential human health impacts caused by the consumption of transgenic fish. This request is consistent with the new animal drug provisions and Food Additive Amendments of the FFDCFA and, as such, is legally required.

Currently, FDA has informally decided to regulate transgenic fish as animal drugs.<sup>18</sup> Such a determination requires A/F Protein and other producers of transgenic fish to comply with FDA's new animal drug regulations. Consistent with these regulations, transgenic fish producers must complete a new animal drug application prior to the introduction of such products in interstate commerce.<sup>19</sup> Congress has prohibited the FDA from approving any new animal drug created by biotechnology, such as transgenic fish, through an abbreviated application for the approval of a new animal drug.<sup>20</sup> Under these animal drug provisions all new animal drugs are deemed unsafe and cannot be marketed before completing an application and undergoing a pre-market review process to demonstrate efficacy and safety.<sup>21</sup> Thus, a sponsor of the new animal drug application for a transgenic fish has the burden of

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<sup>18</sup> See e.g. Carol Lewis, *A New Kind of Fish Story: The Coming of Biotech Animals*, FDA Consumer, January-February 2001, available at [http://www.fda.gov/fdac/features/2001/101\\_fish.html](http://www.fda.gov/fdac/features/2001/101_fish.html) (last visited January 2, 2001) (quoting Center for Veterinary Medicine director Stephen F. Sundlof stating transgenic animals including fish will be regulated as animal drugs). Petitioners note that the FDA has not adopted this position through the issuance of any regulations, policy, or guidance.

<sup>19</sup> 21 C.F.R. § 514.1.

<sup>20</sup> Animal Drug Availability Act, P.L. 100-670, Title I, § 106, 102 Stat. 3984, provides: "Notwithstanding section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (subsec. (B)(2) of this section), the Secretary of Health and Human Services may not approve an abbreviated application submitted under such section for a new animal drug which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques."

<sup>21</sup> *Id.*; See Margaret Ann Miller, Ph.D., *Food Safety Evaluation of Transgenic Animals*, available at <http://www.fda.gov/cvm/fda/infores/fdavet/1996/396fdavet.html> (last visited Feb. 22, 2000)[hereinafter "FDA, Food Safety Evaluation of Transgenic Animals"] (explaining that "[p]roduct safety includes target animal safety, safety to the environment, and safety for consumers of food derived from treated animals").

coming forward with substantial evidence demonstrating its safety.<sup>22</sup> This requires evidence of an “adequate and well controlled investigation” supporting the safety and effectiveness of a new animal drug.<sup>23</sup> Only when such data is present is the FDA permitted to approve the new drug application.<sup>24</sup>

First, there are significant questions on whether any applicant can meet the NADA requirement of efficacy. The effectiveness of inserting a growth hormone into a fish is already being questioned by scientists. Several scientists recently published a study finding that inserting a growth hormone into a domesticated strain of fish “did not cause further growth enhancement.”<sup>25</sup> As described *supra*, current evidence does not support a finding that transgenic fish are safe and efficacious. Any such FDA finding at this time would be arbitrary and capricious and an abuse of discretion.

Second, questions of food safety for transgenic fish have not been fully analyzed. Although FDA has stated it is regulating transgenic fish as animal drugs, producers of these fish clearly intend to market them as food. The agency itself has stated that transgenic animals such as fish “will no doubt come along that could be viewed as containing food additives, color additives and vaccines.”<sup>26</sup> Accordingly, in addition to regulating the process of transgenic fish as new animal drugs, these products must not be approved for use in food unless or until they are regulated in accordance with FDA’s statutory requirements for regulating food additives.<sup>27</sup> Under the FFDCA, the FDA must regulate all food additives to ensure their safety of use prior to their appearance on the market. For example, a transgenic salmon containing an inserted growth hormone gene that meets the definition of food additive should also be regulated as a food additive.

The FFDCA, as amended by the Food Additive Act of 1958, defines a “food additive” as

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<sup>22</sup> United States v. Undetermined Quantities of Clear Plastic Bags of an Article for Veterinary Use . . . WRM-RID Dog Wormer, 963 F.Supp. 641, 645 (S.D.OH 1997). See also 21 C.F.R. § 514.4 (defining “substantial evidence”).

<sup>23</sup> Id. citing Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 630, 37 L.Ed. 2d 207, 93 S.Ct. 2469 (1972). Petitioners also request that all results and data surrounding such controlled investigations concerning transgenic fish be made available for public scrutiny and review at least 120 days prior to any agency action granting approval of a new animal drug for a transgenic fish.

<sup>24</sup> 21 U.S.C. § 360b(d).

<sup>25</sup> Robert H. Devlin, et al., Growth of domesticated transgenic fish, 409 Nature 781 (Feb. 15, 2001)[hereinafter “Growth of domesticated transgenic fish”](although the study found that wild trout injected with a growth hormone grew faster, the scientists found that the growth of transgenic wild trout did not surpass a fast growing domestic strain of trout grown in aquaculture facilities).

<sup>26</sup> CVM, Questions and Answers About Transgenic Fish, 15 FDA Veterinarian Newsletter, March/April 2000.

<sup>27</sup> Under 21 U.S.C. § 321(s)(5), a new animal drug is excluded from the definition of food additive. However, the agency admits that future transgenic fish could be regulated as a food additive instead of as an animal drug and Petitioners request that the agency immediately take steps to insure that there are no regulatory gaps allowing transgenic fish to allude mandatory pre-market safety review. See generally Office of Technology Assessment, Harmful Non-Indigenous Species in the United States, available at <http://www.wws.princeton.edu/~ota/disk1/1993/9325.html> (last visited May 4, 2001).

follows:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, *in its becoming a component or otherwise affecting the characteristics of any food* (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . . (emphasis added)<sup>28</sup>

In the salmon's case, the transgene and its expression products are additives to a conventional fish that will be present throughout the fish, consumed when eaten, and reasonably affect the characteristic of the food. The growth hormone transgene affects the characteristics of the fish by causing it to grow as much as ten to thirty times faster than wild salmon.<sup>29</sup> Transgenic fish have demonstrated levels of growth hormone more than thirty times that of conventional fish.<sup>30</sup> The transgene "additive" also has been shown to structurally alter many fish by causing deformed heads (overgrowth of cartilage in the head and opercular regions).<sup>31</sup> Moreover, the agency has already conceded that, but for the "generally recognized as safe" exclusion, the transferred genetic material and intended expression products used in plant-based genetically engineered foods meet the statutory definition of "food additive."<sup>32</sup>

The FFDCFA excludes from the definition of "food additive" only substances that are generally recognized as safe "GRAS" either: (1) because they were used in foods before January 12, 1958; or (2) because they have been proven GRAS through scientific procedures. Neither exclusion applies to transgenic fish. First, because genetic engineering (including rDNA) technology was not used in fish prior to 1958, substances used and expressed through this technology cannot be exempted from the definition of food additive on grounds of "prior safe use." Second, transgenic fish have never shown

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<sup>28</sup> 21 U.S.C. § 321(s)(emphasis added).

<sup>29</sup> Transgenic fish for aquaculture, supra note 8.

<sup>30</sup> U.S. Patent No. 5,998,697 (issued Dec. 7, 1999)[hereinafter "Robert H. Devlin patent"].

<sup>31</sup> Transgenic fish for aquaculture, supra note 8.

<sup>32</sup> 57 Fed. Reg. at 22990 (explaining that "in the case of foods derived from new plant varieties, it is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS.").



through scientific procedures to be GRAS.<sup>33</sup> To the contrary, as demonstrated herein, there remains substantial disagreement within the scientific community as to the safety of transgenic fish. Therefore, before transgenic fish are permitted to be marketed as a food, FDA should require producers to undergo FDA's petition process to demonstrate the safety of the food additive.

Under the statutory requirements for both new animal drugs and food additives, FDA must review the human health impacts of consuming transgenic fish by requiring adequate human food safety tests.<sup>34</sup> A/F Protein admits that their transgenic salmon are developed through a “juggling of the genes” of wild salmon yet refutes the need for toxicology tests.<sup>35</sup> This attempt to circumvent pre-market safety testing is unacceptable. Under the FFDCA, FDA cannot allow A/F Protein or any other company developing transgenic fish for human consumption to avoid presenting substantial evidence of human food safety testing. Transgenic animals have never been approved for human consumption and therefore, FDA must ensure adoption of a stringent regulatory framework that mandatorily analyzes all potentially harmful human health impacts of transgenic fish.<sup>36</sup> In accordance with FDA's new animal drug and food additive regulations, FDA must require long-term studies to address the following uncertainties:

(1) Toxicity and Unintended Effects

To ensure that toxicity and other unintended effects do not occur as a result of consuming transgenic fish, FDA must require that sufficient tests are conducted. FDA has excluded human food safety toxicology tests from the required testing requirements because it found that “[t]he standard battery of toxicology studies used to establish the safety of ‘traditional’ animal drugs are not appropriate

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<sup>33</sup> The proponent of a GRAS exemption bears the full burden to prove that the use of a substance is GRAS. Fmali Herb, Inc. v. Heckler, 715 F.2d 1385, 1391 (9<sup>th</sup> Cir. 1983). Specifically, the FFDCA imposes on the GRAS proponent a two part legal standard requiring: (1) technical evidence that a particular use is safe and (2) a finding that this technical evidence of safe use is “generally known and accepted” among qualified scientists in the field. 21 U.S.C. § 321(s). In the case of transgenic fish, neither of these legal burdens have been met.

<sup>34</sup> See CVM Guideline No. 3, General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals available at [www.fda.gov/cvm/guidance/guideline3toc.html](http://www.fda.gov/cvm/guidance/guideline3toc.html) (Revised July 1994)(explaining that “Although sections 409, 512, and 706 of the [FFDCA] and their implementing regulation vary slightly in wording, they have a common purpose - assuring the safety of the residues that people will consume from tissues of treated animals. Therefore the FDA believes that the same testing requirements should apply to a new animal drug or a food or color additive used in food-producing animals.”)

<sup>35</sup> Paul Majendie, Environmentalists alarmed over giant GM fish, Reuters (Apr. 11, 2000), at <http://www.connectotel.com/gmfood/re110400.txt>; Scott Allen, Some Aren't Hooked on Superfish Revolution, Boston Globe (Aug. 23, 1999), available at [www.biotech-info.net/hooked\\_on\\_superfish.html](http://www.biotech-info.net/hooked_on_superfish.html) [hereinafter “Superfish Revolution”].

<sup>36</sup> American Cyanamid Co. v. FDA, 770 F.2d 1213, 1216 (D.C. Cir. 1985)(explaining that the “FDA's broad mandate to safeguard the public health thus affords it the flexibility to shape its administrative actions when it has reason to doubt the safety of a new animal drug.”).

for assessing the safety of transgenes in genetically modified animals.”<sup>37</sup> If toxicology tests are inadequate for assessing the safety of transgenic animals, then FDA must develop and mandate specific testing protocols to determine whether there are toxicity and other unintended effects within transgenic fish that may impact human health. Any approval of a transgenic fish application prior to the agency requiring such testing data would be inconsistent with the intent and scope of the FFDCAs which places the legal burden upon the applicant to establish safety.

Furthermore, such FDA action would be ignoring significant human health concerns raised by the agency itself. Already, there are concerns that the foreign growth hormone may increase production of other compounds such as insulin in the fish.<sup>38</sup> Additionally, FDA recognizes that the transgene cannot be “turned off” once it is inserted in the organism, and this could lead to uncontrolled expression.<sup>39</sup> Depending on where transgenes are inserted, they could also “affect the expression of other genes by disabling them or turning them on at an inappropriate time.”<sup>40</sup> Furthermore, FDA acknowledges that “[t]he incidental insertion of drug resistance genes from bacterial plasmids introduces further uncertainties as to food safety.”<sup>41</sup> These uncertainties and unique food safety concerns must be assessed in appropriate scientific studies and mandatory pre-market safety review.<sup>42</sup>

## (2) Allergenicity

In the United States, about a quarter of the population reports some adverse reaction to food.<sup>43</sup> The incidence of all allergic diseases appear to be on the increase in industrialized societies.<sup>44</sup> The

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<sup>37</sup> FDA, Food Safety Evaluation of Transgenic, *supra* note 21, at 16.

<sup>38</sup> Carol Kaesuk Yook, Altered Salmon Leading Way To Dinner Plates, but Rules Lag, N.Y. Times, May 1, 2000, at A1, A20 [hereinafter “Altered Salmon”]; See FDA Food Safety Evaluation of Transgenic Animals, *supra* note 21. (explaining that the FDA interprets the FFDC as requiring an examination of food safety implications of secondary metabolic changes resulting from drug treatment, including an assessment of pleiotrophic changes for transgenic animals). See Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 89 (Jan. 2001)(explaining that the growth hormone can affect the production of insulin and catecholamines and the size of the pituitary gland of transgenic coho salmon is reported to be reduced by 50- 83%). [hereinafter “Elements of Precaution”].

<sup>39</sup> FDA, 14 FDA Veterinarian, 1, 11 (May/June 1999), *available at* <http://www.fda.gov/cvm/fda/infores/fdavet/1999/may.htm>.

<sup>40</sup> Id.; Elements of Precaution, *supra* note 38, at 87-89 (explaining that unintended genetic changes in fish is the rule rather than the exception and includes changes in enzyme activity, gross anatomy, behavior and hormonal activity).

<sup>41</sup> Id.

<sup>42</sup> See 40 C.F.R. § 1508.27(b)(2)(5).

<sup>43</sup> Nestle, Marion, Ph.D., M.P.H., Allergies to Transgenic Foods – Questions of Policy, 334 New Eng. J. Med. 688-692 (1996).

<sup>44</sup> Burks, A. Wesley, Stranley, J.S., Food Allergy, 10 Current Opinion In Pediatrics, 588-593 (1998).

prevalence of a food allergy is much higher for infants and children than adults. The true prevalence of a food allergy is believed to be between 2% and 8% for infants and children and approximately 1% for the adult population.<sup>45</sup> 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 recent 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.<sup>46</sup> At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem.<sup>47</sup>

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.<sup>48</sup> Moreover, the recent analysis over the potential allergenicity of StarLink™ genetically engineered corn has shown a need for federal agencies to develop adequate testing protocols to analyze the allergenicity of transgenic organisms.

As a result of these potential human health effects, FDA must develop and mandate specific testing protocols to determine whether there are allergens within transgenic fish that may impact human health prior to any regulatory approval of such products.<sup>49</sup>

### (3) Aquaculture Disease and Antibiotics

The FDA must also develop and mandate specific testing protocols to determine whether the use of antibiotics to control aquaculture diseases in transgenic fish may impact human health. Transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities

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<sup>45</sup> Id.; See also, Bock, S. Allan, Prospective Appraisal of Complaints of Adverse Reactions to Foods in Children During the First 3 Years of Life, 79 *Pediatrics* 683-688 (1987).

<sup>46</sup> Nordlee, Julie A., MS; *et al.* Identification Of A Brazil-Nut Allergen in Transgenic Soybeans, 334 *New Eng. J. Med.* 726-728 (1996).

<sup>47</sup> Hansen, Dr. Michael & Jean Halloran, Why We Need Labeling of Genetically Engineered Food, Consumers Int'l, Consumer Policy Institute, April 1998.

<sup>48</sup> Hansen, Michael, Ph.D. & Jean Halloran, Jeopardizing the Future? Genetic Engineering, Food and the Environment, PAN AP Safe Food Campaign (1998).

<sup>49</sup> See Center for Food Safety, *et al.*, Legal Petition Seeking the Establishment of a Mandatory Pre-Market Safety Testing, Pre-Market Environmental Review & Labeling for All Genetically Engineered Foods, FDA Docket No. 00P-1211 (filed March 21, 2000)[hereinafter “CFS Petition”].

because transgenic fish are identified as “macromutants” with a reduced ability to survive.<sup>50</sup> Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish.

The most common method of distributing antibiotics to farmed fish is through fish feed. As a result, antibiotics enter the environment through uneaten fish feed and feces. It is predicted that 75% of most antibiotics are lost in the environment.<sup>51</sup> Consequently, these antibiotics accumulate in wild fish and shellfish that feed on the food and feces of farmed fish.<sup>52</sup> By eating farmed fish treated with antibiotics or even wild fish exposed to the antibiotics, humans will be ingesting antibiotics that may be harmful.<sup>53</sup> Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.<sup>54</sup>

The use of antibiotics in aquaculture also exacerbates the significant problem of antibiotic resistant bacteria. Bacteria that are resistant to antibiotics can harm human health by preventing the effective treatment of illness. The American Society of Microbiology warns that the use of antibiotics in aquaculture is potentially one of the most important factors creating the evolution of antibiotic-resistant bacteria.<sup>55</sup>

The Centers for Disease Control (“CDC”) found that bacteria from aquaculture ecosystems can be transferred directly to humans by handling the fish.<sup>56</sup> Even if someone is not exposed to the aquaculture operation, FDA acknowledges that “[b]acteria on fish may also be transmitted to humans when the aquaculture fish are eaten, or when other foods, which have been cross-contaminated by bacteria from fish, are eaten.”<sup>57</sup> Accordingly, the potential human health concerns connected with the use of antibiotics in aquaculture, including the unique role transgenic fish may play in exacerbating such use, must be fully assessed by FDA.

In conclusion, FDA must require A/F Protein, or any other sponsor of transgenic fish, including

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<sup>50</sup> See Trojan gene hypothesis, *supra* note 14, at 13853 (explaining that “[r]educed viability is assumed to be common because transgenic individuals are best viewed as macromutants that lack any history of selection that could reduce negative fitness effects.”).

<sup>51</sup> Rebecca Goldberg and Tracy Triplett, *Murky Waters: Environmental Effects of Aquaculture in the U.S.*, Environmental Defense Fund at 44 (1997) [hereinafter “Murky Waters”].

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* (explaining that newborns can be harmed by chloramphenicol and betalactam compounds can cause fatal allergic reactions).

<sup>55</sup> *Id.* at 45.

<sup>56</sup> Memorandum from Frederick Angulo, D.V.M., Ph.D. to the record (Oct. 18, 1999) [hereinafter “Antimicrobial resistance”].

<sup>57</sup> *Id.*

importers, to demonstrate by substantial evidence that their fish are as safe as non-transgenic fish before they are allowed to enter the food supply. Given the uncertain and potentially dangerous human health effects of transgenic fish, FDA must mandate a comprehensive pre-market safety review of such products under both the animal drug and food additive requirements. *Therefore, as required by the FFDCFA and FDA's own regulations, Petitioners request that FDA fully and completely mandate the regulatory review of the human health concerns presented by transgenic fish before approving the applications to commercialize transgenic fish by domestic producers and importers.*

**B. The FDA Must Establish Full Transparency and Public Involvement in Any Established Regulatory Approval Process for Transgenic Fish.**

As the FDA is well aware, the introduction of transgenic fish into the food supply is a major issue of interest and concern among the American public. Petitioners request that any FDA regulatory process addressing approvals of transgenic fish engage public comment prior to decision making. In announcing use of the new animal drug application procedures, FDA has taken actions that will prevent adequate public participation in this regulatory process. Under the new animal drug application process notice to the public about a transgenic fish will only be made after an order is issued by the FDA establishing a regulation approving commercialization.<sup>58</sup> Such limited public involvement is inconsistent with the spirit of recent federal pronouncements on democratic governance and will only serve to sap the public's confidence in the FDA's oversight processes.

Under Executive Order No. 12,866, each federal agency is directed "to provide the public with meaningful participation in the regulatory process."<sup>59</sup> This meaningful opportunity to comment on regulatory proposals in most cases "should include a comment period of not less than 60 days."<sup>60</sup> A regulatory process that fails to provide a comment period prior to the approval of transgenic fish will prevent any public participation.

Petitioners request the FDA to amend its public notice procedures for any regulatory action taken on transgenic fish to be consistent with the Food Additive Petition public notice provisions. Under such requirements, the public would be notified in the Federal Register of any receipt of a transgenic fish application<sup>61</sup> and of any order approving commercialization.<sup>62</sup> The public would also be able to object to any approval of transgenic fish and request a public hearing concerning the approval order.<sup>63</sup>

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<sup>58</sup> 21 U.S.C. § 360b(i); 21 C.F.R. § 514.105(a).

<sup>59</sup> Exec. Order No. 12,866, 58 Fed. Reg. 51735 (1993).

<sup>60</sup> *Id.*

<sup>61</sup> 21 U.S.C. § 348(b)(5); 21 C.F.R. §§ 171.1(i)(2), 571(i)(2).

<sup>62</sup> 21 U.S.C. § 348(e); 21 C.F.R. §§ 171.100(a), 571.102(a).

<sup>63</sup> 21 U.S.C. § 348(f)(1); 21 C.F.R. §§ 171.110, 571.110. Any objections and request for hearings are governed by 21 C.F.R. Part 12.

The agency should grant the requests outlined above, otherwise the validity of any FDA decision on matters concerning transgenic fish could be subject to challenge because of potential violations of the APA.<sup>64</sup> Courts have repeatedly recognized the laudable goals of the APA's notice and comment requirement to increase public participation and fairness in agency decision making. The law is well settled that the APA requires the FDA

to provide notice of its proposed rulemaking adequate to afford 'interested parties a reasonable opportunity to participate in the rulemaking process.' Such notice must not only give adequate time for comments, but also must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.<sup>65</sup>

*Therefore, Petitions request that the FDA adopt regulatory procedures ensuring full public involvement prior to any agency action taken concerning transgenic animals, including but not limited to transgenic fish.*

### **C. FDA Is Required Under The National Environmental Policy Act To Review The Impacts To Human Health And The Environment.**

The National Environmental Policy Act ("NEPA") is the "basic national charter for protection for the environment."<sup>66</sup> NEPA is intended to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man."<sup>67</sup> The duties under this section are not "inherently flexible."<sup>68</sup> In fact, "[c]onsideration of administrative difficulty, delay or economic cost will not suffice to strip the section of its fundamental importance."<sup>69</sup> The purpose behind NEPA is to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken."<sup>70</sup>

Recognizing the affects of new technologies on the environment, Congress explicitly states in NEPA that "new and expanding technological advances" are activities that could threaten the

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<sup>64</sup> 5 U.S.C. § 553.

<sup>65</sup> Florida Power & Light Company, et al. v. NRC, 846 F.2d 765, 771 (D.C. Cir. 1988). See also Connecticut Light & Power Co. v. NRC, 673 F.2d 525, 530-31 (D.C. Cir.1982); Home Box Office, Inc. v. FCC, 567 F.2d 9, 35 (D.C. Cir. 1977).

<sup>66</sup> 40 C.F.R. § 1500.1.

<sup>67</sup> 42 U.S.C. § 4321.

<sup>68</sup> Calvert Cliffs Coordinating Comm. Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109 (D.C. Cir. 1971).

<sup>69</sup> Id.

<sup>70</sup> 40 C.F.R. § 1500.1(b),(c).

environment.<sup>71</sup> In the legislative history, Congress expressed its concern with “[a] growing technological power \* \* \* far outstripping man’s capacity to understand and ability to control its impact on the environment.”<sup>72</sup> Thus, in order to understand and control the effects of this new technology, Congress requires federal agencies to consider the environmental effects of new technology by complying with the requirements of NEPA. In addition to environmental concerns, the proposed action’s possible direct, indirect, and cumulative impacts on public health must be reviewed.<sup>73</sup>

As mandated by Congress, FDA must comply with NEPA before approving the commercialization of transgenic fish and allowing transgenic fish to be grown in ocean pens. FDA’s decision on whether or not to approve transgenic fish as an animal drug and a food additive is a major federal action that may significantly affect the environment. Therefore, before this decision is reached, FDA is required to fully and completely consider the human health and environmental impacts as part of the NEPA process.

(1) FDA’s responsibilities under the National Environmental Policy Act.

To accomplish NEPA’s purposes, all federal agencies are required to prepare a “detailed statement” regarding all “major federal actions significantly affecting the quality of the human environment . . .”<sup>74</sup> This statement - - known as an Environmental Impact Statement (“EIS”) - - must describe (1) the “environmental impact of the proposed action,” (2) any “adverse environmental effects which cannot be avoided should the proposal be implemented,” (3) “alternatives to the proposed action,” (4) “the relationship between local short-term uses of man’s environment and the maintenance and enhancement of long-term productivity,” and (5) any “irreversible or irretrievable commitment of resources which would be involved in the proposed action should it be implemented.”<sup>75</sup>

To determine whether an EIS is required, federal agencies must prepare an Environmental Assessment (“EA”), that provides sufficient evidence and analysis to support the agency’s determination on whether a proposed action will significantly affect the environment. The Council on Environmental Quality (“CEQ”) factors for determining the “significance” of an action include: (1) “the degree to which the proposed action affects public health or safety,” (2) “the degree to which the effects on the quality of the human environment are likely to be highly controversial,” (3) “the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks,” (4) “[t]he degree to which the action may establish a precedent for future actions with significant effects

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<sup>71</sup> 42 U.S.C. § 4331(a).

<sup>72</sup> Found. on Economic Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1985) quoting S. Rep. No. 91-296 (1969).

<sup>73</sup> 40 C.F.R. § 1508.8(b); Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 106 (1983)(explaining that “NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action.”).

<sup>74</sup> 42 U.S.C. § 4332 (C).

<sup>75</sup> Id.

or represents a decision in principle about a future consideration,” or (5) “the degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.”<sup>76</sup> The “presence of one or more of these factors should result in an agency decision to prepare an EIS.”<sup>77</sup>

As a limited exception to NEPA’s requirements, agencies may categorically exclude a class of actions. However, if the proposed action may “significantly affect the quality of the human environment,” then the agency must prepare an EA/EIS.<sup>78</sup> Furthermore, FDA’s own regulations require an EA/EIS when the action may seriously harm the environment or an endangered species.<sup>79</sup>

- (2) FDA must conduct an Environmental Assessment/Environmental Impact Statement and review the impacts to human health.

FDA must comply with NEPA before transgenic fish are approved as a safe food product.<sup>80</sup> If FDA allows transgenic fish to be consumed by the public, this will represent the first time that a transgenic animal will be part of the food supply. Due to this significant unprecedented action, FDA must perform an EA/EIS for each fish proposed for market in order to adequately review the affects of transgenic fish on human health.<sup>81</sup> As explained *supra*, there are numerous public health and safety issues that should be reviewed in an EA/EIS. Even the Supreme Court has recognized that NEPA requires an EIS to disclose the significant health impacts of a proposed action.<sup>82</sup>

- (3) FDA must conduct an Environmental Assessment/Environmental Impact Statement and review the impacts to the environment.

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<sup>76</sup> 40 C.F.R. § 1508.27(b)(2)(4)(5)(6)(9). The CEQ issued regulations implementing NEPA in response to President Carter’s Executive Order No. 11991 (1977). See *Andrus v. Sierra Club*, 442 U.S. 347, 357 (1979). The Executive Order directs federal agencies to “comply with the regulations issued by the Council.” See *id.*, quoting Exec. Order 11991. The Supreme Court has held that these regulations are entitled to substantial deference by the courts. *Id.* at 358; *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 372 (1989).

<sup>77</sup> *Public Service Co. of Colo. v. Andrus*, 825 F. Supp. 1483, 1495 (D. Idaho 1993); See *Friends of the Earth, Inc. v. U.S. Army Corp of Eng’rs*, 2000 U.S. Dist. LEXIS 11755 (D.D.C. 2000).

<sup>78</sup> 40 C.F.R. § 1508.4.

<sup>79</sup> 21 C.F.R. § 25.21 (stating that FDA requires an EA when the “available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment” and the action may adversely affect a species or habitat of a species protected by the Endangered Species Act).

<sup>80</sup> See 42 U.S.C. § 4332 (C).

<sup>81</sup> 40 C.F.R. § 1508.27(b)(2),(6).

<sup>82</sup> *Baltimore Gas & Electric Co. v. NRDC*, 462 U.S. 87, 106 (1983).



Although A/F Protein stated that they have not conducted *any* environmental tests,<sup>83</sup> FDA is responsible for reviewing the environmental risks.<sup>84</sup> NEPA requires FDA to conduct an individual EA/EIS for each transgenic fish proposed for marketing. FDA is required to conduct an EA/EIS before any action on the Investigational New Animal Drug (“INAD”) is conducted and before approving a New Animal Drug Application (“NADA”).<sup>85</sup> In addition, approvals of food additive petitions requires an EA/EIS.<sup>86</sup> Any decision to categorically exclude these actions from NEPA should be rejected because the CEQ factors for identifying the “significance” of this action on the environment, requiring an EA/EIS, are repeatedly demonstrated. Additionally, FDA’s own regulations require an EA/EIS because the scientific evidence and agency admissions discussed below indicate that transgenic fish will likely escape ocean pens and harm endangered species and the environment.

(a) *Risk of transgenic fish escaping ocean pens.*

Most salmon aquaculture 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. Even A/F Protein admits that “unless the aquaculture operation is entirely land-based with rigid containment methods in place, there is always the possibility of sterile transgenic fish escaping into the wild.”<sup>87</sup>

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.<sup>88</sup> There are also several incidences of mass fish escapes. In 1990, approximately four million fish escaped from a fish farm in Norway.<sup>89</sup> Recently, over 170,000 farm raised salmon escaped from a net pen after a storm in Maine.<sup>90</sup> The Fish and Wildlife Service reports that “25-40% of the fish in the North Atlantic Ocean is of aquaculture

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<sup>83</sup> Altered Salmon, *supra* note 38, at A20.

<sup>84</sup> See 42 U.S.C. § 4332 (C), 21 C.F.R. § 25.40(b)(stating that although FDA may require an applicant to prepare an EA, FDA is responsible for the scope and content).

<sup>85</sup> 21 C.F.R. § 25.20(m).

<sup>86</sup> *Id.* § 25.20(i).

<sup>87</sup> Arnold Sutterlin, *et al.*, Environmental Risks In Using GH Transgenic Atlantic Salmon And Rainbow Trout For Commercial Marine Production In Canada, available at <http://www.nbiap.vt.edu/brarg/brasym96/sutterlin96.htm> (last visited Sept. 9, 1999); A/F Protein Inc., The Blue Revolution, available at <http://webhost.avint.net/afprotein/blue.htm> (last visited May 24, 2000)(admitting that “an ocean pen facility may well represent the most cost effective method of production, it is also the riskiest with storms, disease, predation, and changes in water temperature having severe impacts on harvest.”).

<sup>88</sup> 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”].

<sup>89</sup> Walter Gibbs, Fish-Farm Escapees Threaten Wild Salmon, N.Y. Times, Oct. 1, 1996 at C4.

<sup>90</sup> 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).

origin.”<sup>91</sup> Weather, human error, and marine mammal and bird attacks<sup>92</sup> all contribute to the release of fish from ocean pens.<sup>93</sup> Recognizing that fish repeatedly escape from net pens, CEQ recently stated that it “must be assumed that escapes will occur” from net pens.<sup>94</sup>

If FDA approves A/F Protein’s application to market transgenic fish and allows the use of ocean pens, then this will be the first time that a transgenic animal will be grown in ocean pens for human consumption.<sup>95</sup> A/F Protein, who intends to license these fish eggs to fish farmers, reports that they have had discussions about transgenic salmon with almost every salmon company in the world.<sup>96</sup> Once transgenic fish are commercialized, there will likely be a great number of transgenic fish in the water. Recognizing the harm that transgenic fish may cause, a DOI official cautioned that rare wildlife may be impacted by transgenic fish.<sup>97</sup> An EA/EIS must be prepared for unprecedented actions with significant effects.<sup>98</sup> Given the high likelihood that transgenic fish, like other farmed raised fish, will escape from ocean pens in large numbers, the environment, including endangered species will likely be affected by the unprecedented growing of these animals in the wild. Therefore, FDA must comply with NEPA.<sup>99</sup>

*(b) Risks of transgenic fish harming endangered species*

An EA/EIS must also be prepared for any action that may affect an endangered or threatened species or its habitat.<sup>100</sup> Once transgenic fish escape from ocean pens, endangered species and species approaching “endangered species” status will likely be severely impacted. The rapidly decreasing fish population levels are evident in a recent study showing that there are 82 species of fresh water fish in

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<sup>91</sup> 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).

<sup>92</sup> 62 species of birds and 13 species of mammals are potential predators of transgenic fish in ocean pens. Murky Waters, supra note 51, at 57.

<sup>93</sup> 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).

<sup>94</sup> CEQ Transgenic Salmon Study, supra note 12, at 23.

<sup>95</sup> FDA, Center for Veterinary Medicine, Questions and Answers about Transgenic Fish, available at <http://www.fda.gov/cvm/fda/infores/consumer/transgen.htm> (last visited Feb. 22, 2000) [hereinafter “Questions and Answers”] (stating that “No transgenic fish have been approved for producing food in the U.S.).

<sup>96</sup> Altered Salmon, supra note 38.

<sup>97</sup> GMOs Pose New Risk, supra note 17.

<sup>98</sup> 40 C.F.R. § 1508.27(b)(6).

<sup>99</sup> See Edmonds Inst. v. Babbitt, 42 F. Supp. 2d 1, 18-19 (D.D.C. 1999).

<sup>100</sup> 40 C.F.R. § 1508.27(b)(9); 21 C.F.R. § 25.21.

North American waters that are near extinction.<sup>101</sup> Moreover, the number on the endangered species list has reached 114 and includes populations of the chinook, chum, coho, and sockeye salmon.<sup>102</sup> Even the number of Atlantic salmon have dramatically decreased leading the DOI and DOC to recently list this species as endangered under the ESA.<sup>103</sup> These agencies stated that one of the reasons for the decline of this species is due to aquaculture because farmed fish can spread diseases to wild Atlantic salmon and when farmed fish escape they can affect the genetic integrity and compete with Atlantic salmon for habitat and food.<sup>104</sup>

Given the fragile state of fish populations and aquatic ecosystems, allowing transgenic fish in ocean pens will likely result in further devastating the Atlantic salmon and other fish populations. Already, introduced non-native fish from aquaculture facilities are believed to have contributed to the decline of eight fish species listed under the ESA.<sup>105</sup> Concerned about the depleting numbers of Atlantic salmon, the Department of Interior warned that this species could be “quickly wiped out if transgenic fish grown in nearby aquaculture farms escape their pens.”<sup>106</sup> The Department of Interior recognizes the harm that transgenic fish may cause endangered 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 transgenic fish may have a greater mating advantage due to their larger size.<sup>107</sup> 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.”<sup>108</sup> 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

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<sup>101</sup> J.A. Musick, et al, Marine, Estuarine, and Diadromous Fish Stocks at Risk of Extinction in North America, 25 Fisheries 6, 19 (Nov. 2000)[hereinafter “Musick”].

<sup>102</sup> Listed Vertebrate Species, supra note 15.

<sup>103</sup> 65 Fed. Reg. 69459 (2000).

<sup>104</sup> See DOI and DOC, Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered (Nov. 2000).

<sup>105</sup> See Murky Waters, supra note 51 at 51 - 52; DOI and DOC, Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered (Nov. 2000).

<sup>106</sup> GMOs Pose New Risk, supra note 17.

<sup>107</sup> Trojan Gene Hypothesis, supra note 14, at 13853 - 13856.

<sup>108</sup> Id.

within only 40 generations.<sup>109</sup> They refer to these disturbing results as the “Trojan gene effect.”<sup>110</sup>

A/F Protein does not believe that transgenic fish could cause a Trojan gene effect but acknowledges that the company has not done any experiments to determine whether transgenic fish are larger at sexual maturity or have a mating advantage.<sup>111</sup> However, one scientist who has conducted experiments with transgenic fish discovered that growth-enhanced transgenic coho salmon are 50% larger at sexual maturity than wild fish.<sup>112</sup> Additionally, William Muir, the same Purdue researcher who discovered the “Trojan gene effect,” recently expanded his prior research. This time, instead of assuming that transgenic fish would be bigger, he tested this hypothesis. He found that a salmon growth hormone caused adult medaka to grow 50% larger than normal but their viability to sexual maturity is as low as 78%.<sup>113</sup> These results suggest that transgenic fish may be bigger and could cause the Trojan gene effect at a very quick rate.

Other studies also demonstrate that transgenic fish may be less fit than wild fish. Research conducted by Robert Devlin and others indicates that transgenic fish are less careful about avoiding predators and may not be able to endure the arduous migratory process.<sup>114</sup> The best current scientific evidence available shows that species extinction may occur as a result of transgenic fish that slip out of ocean pens into the wild. Therefore, it is imperative that an EA/EIS be prepared.

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<sup>109</sup> Id.

<sup>110</sup> 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.”). Researcher Hedrick further explained that his findings “should serve to alert researchers of the inherent risks of accidental releases of GM organisms into natural populations.” Id. at 843.

<sup>111</sup> Altered Salmon, supra note 38, at A20.

<sup>112</sup> Souped up Salmon, supra note 6, at 11.

<sup>113</sup> Id. Although the chinook salmon, the largest species of salmon, can grow up to 100 pounds in the wild, a New Zealand Company reported that its transgenic salmon could grow up to 550 pounds. Les Blumenthal, Genetically Altered Salmon Cause Debate Among U.S. Officials, News Tribune (Aug 21, 2000) (hereinafter “Salmon Cause Debate”).

<sup>114</sup> RH Devlin, et al. Increased ability to compete for food by growth hormone-transgenic coho salmon *Oncorhynchus kisutch*, 30 Aquaculture Research 479-482 (1999) [hereinafter “Increased ability to compete”] (explaining that transgenic salmon have a reduced ability to avoid predators and complete migration for spawning due to their inferior swimming ability); Mark Abrahams & Arnold Sutterlin, The foraging and antipredator behavior of growth-enhanced transgenic Atlantic salmon, 58 Animal Behaviour 933-942 (June 22, 1999) [hereinafter “Foraging behavior”]; R.A. Dunham & R.H. Devlin, Comparison of Traditional Breeding and Transgenesis in Farmed Fish with Implications for Growth and Enhancement and Fitness, 6 Transgenic Animals in Agriculture 209, 210, 222 (1999). As for the studies that show no problems with predator avoidance or swimming ability, FDA must comply with NEPA because these conflicting studies demonstrate a controversy about the effect of introducing transgenic fish. See e.g. Rex A. Dunham, Predator Avoidance of Transgenic Cannel Catfish Containing Salmonid Growth Hormone Genes, 1 Marine Biotech. 545 (1999).

The FDA is also required to conduct an EA/EIS when the effects of an action are likely to be highly controversial.<sup>115</sup> Here, FDA cannot simply rely upon A/F Protein’s scientifically unsupported statements that transgenic fish are safe when several studies reveal that transgenic fish are less fit and will likely cause species extinction. In light of this dispute concerning the effect of transgenic fish on endangered species, FDA must comply with its statutory responsibilities by conducting its own EA/EIS.

In response to the concerns that transgenic fish may lead to species extinction, A/F Protein states that they will only sell transgenic fish that are sterile to be grown in net pens.<sup>116</sup> 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.<sup>117</sup>

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.<sup>118</sup> 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.”<sup>119</sup> Recently, CEQ released a study on transgenic fish.<sup>120</sup> This study revealed that 100% sterilization cannot be guaranteed.<sup>121</sup> FDA, who was part of the CEQ study, recognizes the uncertainty in sterilization.<sup>122</sup> Therefore, FDA must conduct an EA/EIS when the effect of an action is highly uncertain and involves unique risks. Due to the uncertainty in producing sterile fish 100% of the time, and the risks of extinction if sterilization is not always 100% effective, FDA must conduct an EA/EIS.

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<sup>115</sup> 40 C.F.R. § 1508.27(b)(4). See Found. for North American Wild Sheep v. U.S. Dep’t of Agric., 681 F.2d 1172, 1182 (9<sup>th</sup> Cir. 1982)(explaining that the term “controversial” refers to the existence of a “substantial dispute . . . as to the size, nature, or effect” of the proposed action.); See Coalition on Sensible Transp. Inc. v. Dole, 642 F. Supp. 573, 587 (D.C. Cir. 1986).

<sup>116</sup> Altered Salmon, supra note 38, at A20.

<sup>117</sup> Souped up salmon, supra note 6, at 11.

<sup>118</sup> CEQ Transgenic Salmon Study, supra note 12.

<sup>119</sup> 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).

<sup>120</sup> CEQ Transgenic Salmon Study, supra note 12, at 8. The leading drafting agency on the growth-enhanced salmon case study was FDA. NMFS and DOI were also part of the drafting team.

<sup>121</sup> Id. at 1, 31 (admitting that none of the sterilization techniques are 100% effective); See Elements of Precaution, supra note 38, at 166 (explaining that the working group of the International Council for the Exploration of the Sea, including scientists from the U.S., found that 100% sterilization of transgenic fish cannot be ensured).

<sup>122</sup> See CEQ Transgenic Salmon Study, supra note 12, at 8 (explaining that even when transgenic fish are rendered sterile, “males exhibit spawning behavior with fertile diploid females, leading to decreased reproductive success of the fertile diploid females.”).

(c) *Risks of transgenic fish harming the environment.*

Even if A/F Protein could guarantee that sterilization of transgenic fish will be 100% effective, transgenic fish that escape ocean pens will likely disrupt and harm the environment requiring FDA to conduct an EA/EIS.<sup>123</sup> Repeatedly, non-native organisms have caused harmful ecological disruptions. Recognizing the serious environmental damage caused by non-native organisms, President Clinton issued an Executive Order in 1999 aimed at preventing the introduction of invasive species.<sup>124</sup> Transgenic fish are non-native organisms that may cause serious environmental damage. Therefore, FDA must review the ecological impacts that may be caused by transgenic fish.

Transgenic fish are different from wild salmon and will likely seriously disrupt the ecosystem. Studies show that growth-enhanced transgenic salmon are more aggressive and eat as much as five times as much food as wild species.<sup>125</sup> Even A/F Protein admits that its transgenic salmon consume more food than wild salmon.<sup>126</sup> One researcher observed that transgenic fish have “a revved-up metabolism. They’re hungry all the time.”<sup>127</sup> As a result, these transgenic fish could be foraging ravenously when food availability in an area is low out competing native fish.<sup>128</sup>

Moreover, the fish being consumed by these aggressive hungry transgenic salmon predators will likely be impacted.<sup>129</sup> One scientist warned that “[t]hey’re creating very, very large fish that will become predators of other fish.”<sup>130</sup> These transgenic predators could further disrupt the ecosystem by expanding their geographic habitat by entering colder waters. Considering that some transgenic fish may contain a gene for tolerance to temperature, these fish may enter colder waters resulting in

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<sup>123</sup> 21 C.F.R. § 25.21. 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 fertile diploid females, leading to decreased reproductive success of the fertile diploid females.” CEQ Transgenic Salmon Study, supra note 12, at 8.

<sup>124</sup> Exec. Order No. 13,112, 64 Fed. Reg. 6,183 (Feb. 8, 1999).

<sup>125</sup> Foraging behavior, supra note 114; Increased ability to compete, supra note 114, at 479 - 482 (explaining that transgenic coho salmon consumed almost three times the food of wild fish); CEQ Transgenic Salmon Study, supra note 12, 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.”).

<sup>126</sup> A/F Protein, Inc., News From the Farm, available at <http://www.afprotein.com/news2.htm> (last visited 3/1/00) [hereinafter “News From the Farm”] (stating that transgenic fish “require more food on a daily basis.”).

<sup>127</sup> Sarah Schmidt, Frankenfish or Salmon Savior, National 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.”).

<sup>128</sup> Souped up salmon, supra note 6, at 11.

<sup>129</sup> Genetic engineering creates supersalmon and controversy, Seattle Times, Nov. 30, 1999.

<sup>130</sup> Id.

competition with different species.<sup>131</sup> By out competing salmon and other endangered species for resources and habitat, transgenic fish will likely seriously disrupt the ecosystem.<sup>132</sup>

As for the fish that do not escape ocean pens, the practice of raising transgenic fish in ocean pens will likely disrupt the ecosystem. Raising transgenic fish in ocean pens may contribute to water pollution and harm wetlands.<sup>133</sup> Aquaculture waste can deplete the oxygen in the water,<sup>134</sup> exacerbates toxic algae blooms, and accumulates below and around the net pens.<sup>135</sup> Moreover, aquaculture waste can harm sensitive wetland areas that provide food and habitat and are vital to the survival of many species of birds and fish.<sup>136</sup>

Aquaculture also introduces diseases and parasites that can affect wild populations.<sup>137</sup> Indeed, the primary cause of salmon mortality in Norwegian rivers is the monogenean fluke introduced by aquaculture.<sup>138</sup> In addition, because many transgenic fish are “macromutants” with a reduced ability to survive, transgenic fish may be susceptible to more diseases and introduce more diseases than fish currently grown in aquaculture facilities. As a result, the amount of antibiotics used to treat transgenic fish will most likely be higher than the amount of antibiotics currently used for farmed fish. However, not all of the antibiotics are absorbed by the fish and consequently, antibiotics enter the environment

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<sup>131</sup> Rebecca Goldberg, Something Fishy, <http://www.environmentaldefense.org/pubs/reports/aquaculture/transgenic.html> (last modified May 2000); See CEQ Transgenic Salmon Study, supra note 12, at 22 (explaining that phenotypic changes that should be examined include tolerance to temperature).

<sup>132</sup> Ecological implications, supra note 88, at 60 - 61.

<sup>133</sup> Rosamond L. Naylor, et al, Nature's Subsidies to Shrimp and Salmon Farming, 282 Science 883 (Oct. 20, 1998) [“hereinafter “Nature’s Subsidies”] (explaining that the “Nordic salmon farming industry discharges quantities of nitrogen and phosphorous equivalent to the amounts in untreated sewage from a population of 3.9 and 1.7 million people, respectively.”).

<sup>134</sup> A/F Protein admits that transgenic fish consume 70 to 80% more oxygen than wild fish. News From the Farm, supra note 126. Don Stevens, et al, Respiratory metabolism and swimming performance in growth hormone transgenic Atlantic salmon, 55 Can. J. Fish. Aquatic Science 2028-2035 (1998).

<sup>135</sup> Murky Waters, supra note 51, at 35-48.

<sup>136</sup> Id. at 79; EPA, Consequences of Losing or Degrading Wetlands, available at <http://www.epa.gov/owow/wetlands/facts/fact3.html> (last visited Nov. 30, 2000).

<sup>137</sup> 64 Fed. Reg. at 62635 (Nov, 17, 1999).

<sup>138</sup> Ecological implications, supra note 88, at 60; See 65 Fed. Reg. 69459, 69469 (in listing Atlantic salmon under the ESA, the Services explained that the “possible establishment of ISA in and around U.S. pen sites . . . pose a risk to wild salmon.”).

through uneaten feed and feces.<sup>139</sup> Pesticides are also used to control parasites.<sup>140</sup> The effect of antibiotics and other drugs, such as pesticides, on the environment needs to be thoroughly reviewed, particularly the impact to nontarget organisms. Due to the introduced diseases, parasites, antibiotics, and pesticides, the entire ecosystem may be affected and is at risk of harm.

Finally, feeding transgenic fish will require the taking of wild fish. Researchers revealed that in 1997, approximately “1.8 million tons of wild fish for feed were required to produce 644,000 metric tons of Atlantic salmon - a 2.8:1 ratio.”<sup>141</sup> Taking this many fish will likely affect the balance of the ecosystem.

Some of the environmental risks involved with transgenic fish are described above but the full extent of the harm that may be caused by these fish are unknown. Ecologists currently analyzing the risks associated with transgenic fish repeatedly warn that the current scientific knowledge is inadequate to provide an adequate assessment of the risks, “[t]here’s just so much speculation compared to the amount of data.”<sup>142</sup> Similarly, a Department of Interior official stated, “I don’t think the potential impacts on nature have been thought through as well as they should be.”<sup>143</sup> Thus, in light of the current evidence showing that transgenic fish that escape ocean pens and transgenic fish contained in ocean pens may disrupt the ecosystem and due to the lack of complete scientific information analyzing all of the environmental risks, allowing the commercialization of transgenic fish is a significant environmental action requiring FDA to complete an EA/EIS.<sup>144</sup>

### *Conclusion*

FDA must conduct an EA/EIS if the proposed action may significantly affect the environment. Here, the factors identifying the “significance” of the action are repeatedly demonstrated. Due to the

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<sup>139</sup> Environmental Assessment Office, British Columbia, The Salmon Aquaculture Review Final Report available at <http://www.eao.gov.bc.ca/project/AQUACULT/SALMON/report/V1chp7.htm>, supra note —, (explaining that more studies need to review the impacts of antibiotics on the marine environment); Antimicrobial resistance, supra note 56, at 1-3 (explaining that “bacteria resistant to antimicrobial agents used on specific fish farms have been isolated from sediment beneath the fish “net pens” on those fish farms.”).

<sup>140</sup> Murky Waters, supra note 51, at 46-7 (explaining that the environmental effects from pesticides are not completely understood).

<sup>141</sup> Nature’s Subsidies, supra note 133, at 884; See Farmed Fish Fed On Wild Caught Fish Products, Environment News Service, June 29, 200, <http://ens.lycos.com/ens/jun200/2000L-06-29-09.html> (explaining that “producing one pound of carnivorous farmed salmon or shrimp requires about three pounds of wild fish in the form of fish meal.”).

<sup>142</sup> Souped up Salmon, supra note 6, at 10 (Dr. Devlin warns about the lack of data analyzing the risks of transgenic fish).

<sup>143</sup> Altered Salmon, supra note 38, at A20; See Ecological Implications, supra, note 88, at 56-64.

<sup>144</sup> 40 C.F.R. § 1508.27 (b)(5)(9); 21 C.F.R. § 25.21.



unprecedented action of allowing a transgenic animal in the environment, the potential harm to endangered species, the controversial effects of transgenic fish harming endangered species and the environment, and the large amount of unknown information concerning the unique environmental risk from transgenic fish, FDA must comply with the CEQ regulations by conducting an EA. Furthermore, due to the potential harm to the environment and endangered species, FDA is required under its own regulations to comply with NEPA.

Additionally, “[i]f substantial questions are raised whether a project may have a significant effect upon the human environment, an EIS must be prepared.”<sup>145</sup> FDA has already admitted several environmental concerns about transgenic fish including, “competition with wild populations, movement of the transgene into the wild gene pool, and ecological disruptions due to changes in prey and other niche requirements in the transgenic variety versus the wild populations.”<sup>146</sup> Considering the agency’s own concerns and the large amount of evidence demonstrating the potential harm of transgenic fish on the environment, FDA must fully and completely review the environmental impact by conducting not only an EA, but also an EIS.

(4) Scope and Content of FDA’s Environmental Assessment and Environmental Impact Statement

When conducting an EA/EIS, FDA must take a “hard look” at the human health and environmental consequences.<sup>147</sup> “An environmental assessment must offer something more than a “checklist” of assurances and alternatives. It must indicate, in some fashion, that the agency has taken a searching, realistic look at the potential hazards and, with reasoned thought and analysis, candidly and methodically addressed those concerns.”<sup>148</sup> Among the issues that FDA needs to address in an EA/EIS are the following:

- A. Impacts to Human Health
  - (1) assess toxicity and unintended effects
  - (2) assess allergenicity
  - (3) review dangers of consuming diseased farmed fish
  - (4) review dangers of consuming fish containing antibiotics
  
- B. Biocontainment strategies -types of holding facilities, including ocean pens, ponds, or indoor enclosed tanks
  - (1) assessment must be specific for each species of fish and where the fish will be located in the aquatic system
  - (2) likelihood of fish escapes (review the number of escapes from ocean pens containing farmed fish)

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<sup>145</sup> Found for North American Wild Sheep v. USDA, 681 F.2d 1172, 1178 (9<sup>th</sup> Cir. 1982).

<sup>146</sup> Questions and Answers, supra note 95.

<sup>147</sup> Kleppe v. Sierra Club, 427 U.S. 390, 410 n.21 (1976).

<sup>148</sup> Found on Economic Trends v. Weinberger, 610, F. Supp. 829, 841 (D.D.C. 1985).

- (3) assess the impacts on the facility from storms, seal and bird attacks, and human error
- C. Impacts to the environment/endangered species if transgenic fish escape
- (1) assessment must be specific for each species of fish and where the fish will be located in the aquatic system
  - (2) competition for food (aggressiveness to wild fish)
  - (3) competition for mates (impact on wild population numbers)
  - (4) introduced genes into wild population (fitness of species)
  - (5) reliability of sterilization test
  - (6) prey or niche requirements (ecological disruptions)
  - (7) affects on endangered and threatened fish species (including the listing of Atlantic salmon) and marine mammals
  - (8) oxygen depletion levels
  - (9) introduced diseases and parasites
  - (10) introduced antibiotics and other drugs
  - (11) algae blooms and pollution resulting from aquaculture facilities
- D. Impact on wild fish numbers and the ecosystem due to the number of fish taken to produce transgenic fish.
- (1) number of wild fish needed to develop the anti-freeze protein
  - (2) number of fish needed to feed transgenic fish.
- E. Impact on transgenic fish due to rapid growth
- (1) abnormalities in development
- F. Socio-economic impacts
- (1) impacts to fishermen dependent upon selling wild-caught fish

The omission of any of these considerations will preclude a meaningful type of informed decision-making mandated by NEPA.<sup>149</sup> In addition to the above issues, FDA must consider the availability of alternatives.<sup>150</sup> The agency is responsible for rigorously exploring and objectively evaluating all reasonable alternatives.<sup>151</sup> The human health and environmental impacts of the proposed action and alternatives should be listed in comparative form in order for the agency and the public to review the information.<sup>152</sup>

Consistent with CEQ's regulations, the alternative of "no action" must be included within the

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<sup>149</sup> See Found for North American Wild Sheep, 681 F.2d at 1178.

<sup>150</sup> 42 U.S.C. § 4332(C)(iii), 40 C.F.R. § 1508.9(b).

<sup>151</sup> 40 C.F.R. § 1502.14(a).

<sup>152</sup> Id.

review.<sup>153</sup> Not approving the commercialization of transgenic fish is a viable alternative due to the potentially harmful human health impacts and due the egregious impacts to endangered species and the environment.<sup>154</sup> Moreover, even FDA stated that “improvements offered by transgenic fish, and any other transgenic animals, must be dramatic when compared to what is possible by other, better-accepted, approached” such as selective breeding and improving nutrition and management of aquaculture species.<sup>155</sup> One FDA official stated “[u]ntil those [alternative] options are exhausted, the effort of launching a transgenic food animal product could be questioned.”<sup>156</sup> Approving transgenic fish should be highly questioned and the alternatives available should be explored. Within the draft EIS, FDA must thoroughly review the “no action” alternative and consider public comment.

Although not approving transgenic fish is the preferred alternative, if the agency approves transgenic fish, then a reasonable alternative is to ban the use of net pens. Even Canada’s expert panel on biotechnology has recommended a moratorium on the raising of transgenic fish in aquatic net pens.<sup>157</sup> The U.S. and Canada share aquatic resources. Therefore, transgenic fish that escape from net pens in the U.S. could severely harm Canadian marine life. Pursuant to Executive Order 12114, FDA should consider this impact and then ban the use of net pens in the U.S. for raising transgenic fish.<sup>158</sup>

Instead of using net pens, these fish should be grown in enclosed land based recirculating systems. These systems are highly controllable and because these systems are enclosed and on land, the concerns that transgenic fish will escape or cause environmental damage is virtually eliminated.<sup>159</sup> Rather than discharging the water after one use, recirculating systems continuously treats and returns the water. Along with conserving water, these systems reduce parasites and diseases.<sup>160</sup> Already, several

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<sup>153</sup> Id. §1502.14(d). Bob Marshall Alliance v. Hodel, 852 F.2d 1223 (9<sup>th</sup> Cir. 1988)(explaining that “[i]nformed and meaningful consideration of alternatives – including the no action alternative – is thus an integral part of the [NEPA] statutory scheme”).

<sup>154</sup> Similar to ocean pens, ponds will also allow transgenic fish to escape and adversely impact endangered species and the environment. See Murky Waters, supra note 51, at 76-77.

<sup>155</sup> John Matheson, Will Transgenic Fish Be The First Ag-Biotech Food-Producing Animals?, 14 FDA Veterinarian 12 (May/June 1999).

<sup>156</sup> Will consumers buy transgenic foods?, available at [http://www.seafoodbusiness.com/99may/issue\\_top.html](http://www.seafoodbusiness.com/99may/issue_top.html) (May 1999).

<sup>157</sup> Elements of Precaution, supra note 38, at 170.

<sup>158</sup> See 21 C.F.R. § 25.60. Recognizing the dangers transgenic fish may inflict upon the marine environment, Maryland recently passed a bill imposing a moratorium on the raising of transgenic fish in water that connects to another body of water. H.R. 189, 415<sup>th</sup> Sess. (Md. 2001).

<sup>159</sup> Murky Waters, supra note 51 at 80-83.

<sup>160</sup> As for the discharge of waste containing high concentrations of nutrients, this waste must be disposed of properly. Companies using these systems are treating the effluent and using the sludge to fertilize farms. Id.

aquaculture companies are successfully using this type of system for a variety of fish.<sup>161</sup> If FDA excludes this alternative from consideration, then the agency must fully and completely state why this alternative was eliminated.<sup>162</sup>

After reviewing all alternatives, FDA should present the alternatives in a draft EIS for the public to review.<sup>163</sup> *In light of the dangers to human health, endangered species, and the environment, petitioners recommend that FDA's final decision, based upon the EIS, prohibit the commercialization of transgenic fish. At a minimum, FDA should ban the use of net pens for raising transgenic fish and require that transgenic fish only be raised in enclosed land based recirculating systems.*

- (5). FDA must conduct a Programmatic Environmental Impact Statement and review the impacts to human health and the environment.

If FDA decides to adopt regulations governing the commercialization of transgenic fish, then in addition to the statutory mandate to complete an EA/EIS for each transgenic fish proposed for the market, FDA is required to conduct a comprehensive environmental impact statement called a programmatic environmental impact statement ("PEIS"). NEPA requires FDA to conduct a PEIS before adopting new regulations.<sup>164</sup> Thus, before FDA adopts any regulations governing the commercialization of transgenic fish, it must review the broad cumulative impacts of this action.<sup>165</sup> Although petitioners are only aware of one application before FDA to approve transgenic fish, there are over thirty-five species of transgenic fish currently being developed around the world.<sup>166</sup> How regulations governing a variety of transgenic fish will impact human health and the environment must be thoroughly assessed by FDA in a PEIS.<sup>167</sup> *Therefore, petitioners recommend that FDA address the cumulative impacts of transgenic fish on human health and the environment in a PEIS prior to proposing any new regulations for transgenic fish.*

#### **D. FDA Is Required Under The Endangered Species Act To Consult With The DOI and**

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<sup>161</sup> *Id.* at 83. Although these systems are more expensive, the more environmental restrictions placed upon aquaculture will encourage the use and development of cost-effective enclosed recirculation systems.

<sup>162</sup> 40 C.F.R. § 1502.14(a).

<sup>163</sup> *Id.* § 1503.1.

<sup>164</sup> *Id.* §§ 1502.4(b)(3), 1508.18(b)(1).

<sup>165</sup> *Churchhill County v. Babbitt*, 150 F.3d 1072, 1076 (9th Cir. 1998)(explaining that "[w]hen there is a regional plan or when multiple federal programs will have a 'cumulative or synergistic environmental impact upon a region' the relevant agency must prepare a programmatic environmental impact statement ('PEIS') on the regional plan or on the programs' combined impact)(citing *Kleppe v. Sierra Club*, 427 U.S. 390, 400-2,10 (1976)).

<sup>166</sup> Souped up Salmon, *supra* note 6, at 10.

<sup>167</sup> 40 C.F.R. § 1502.4(b)(c)(3).

## DOC Before Approving An Activity That May Affect An Endangered Or Threatened Species.

As recognized by the Supreme Court, the Endangered Species Act (“ESA”) is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”<sup>168</sup> Observing that “man and his technology has [sic] continued at an ever-increasing rate to disrupt the natural ecosystem,”<sup>169</sup> Congress intended for the ESA to “halt and reverse the trend toward species extinction, whatever the cost.”<sup>170</sup>

Once species are listed as endangered or threatened under the ESA, they receive a number of statutory protections. For example, Section 9 prohibits any person to “take” a listed species.<sup>171</sup> The term “take” is broadly defined to include “harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.”<sup>172</sup> The DOI and DOC are responsible for taking affirmative steps to protect and recover listed species.<sup>173</sup>

Section 7 of the ESA requires every federal agency to conserve species listed as endangered or threatened.<sup>174</sup> It also mandates that “in consultation with and with the Assistance of the Secretary,” each federal agency shall “insure that any action authorized, funded or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species. . . .”<sup>175</sup>

Before going forward with an action that may affect listed species, the federal agency must first prepare a biological assessment. The biological assessment must evaluate the effects of the action on listed species “including consideration of cumulative effects,” and consideration of “alternate actions considered by the Federal agency for the proposed action.”<sup>176</sup> Only if the biological assessment concludes that the agency action will not adversely affect any listed species, and the Secretaries concur

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<sup>168</sup> Babbitt v. Sweet Home Chapter of Comm. for a Great Or., 515 U.S. 687, 698 (1995).

<sup>169</sup> TVA v. Hill, 437 U.S. 153, 176 (1978) (quoting hearings on Endangered Species before the Subcommittee of the House Committee on Merchant Marine and Fisheries, 93d Cong., 1<sup>st</sup> Sess., 202 (1973)(statement of Assistant Secretary of the Interior).

<sup>170</sup> Id. at 184.

<sup>171</sup> 16 U.S.C. § 1538(a)(1).

<sup>172</sup> Id. § 1532(19).

<sup>173</sup> Id. § 1533(f).

<sup>174</sup> Id. § 1536(a)(1); TVA v. Hill, 437 U.S. 153, 173 (1978).

<sup>175</sup> 16 U.S.C. § 1536(a)(2). If the Director of the FWS or NMFS determines that any action by the federal agency may affect a listed species, the Director may request a consultation if the federal agency fails to do so. 50 C.F.R. § 402.14(a).

<sup>176</sup> 50 C.F.R. § 402.12(f).

in writing, may the agency avoid the formal consultation requirement.<sup>177</sup>

If an agency action may affect a listed species, then the federal agency must engage in a formal consultation and obtain a biological opinion from the Secretaries of DOI and DOC.<sup>178</sup> To adequately review the effects of the action, the federal agency must provide the Secretaries with “the best scientific and commercial data available.”<sup>179</sup> Then, the Secretaries must review this information, evaluate the status of impacted species, determine the cumulative effects of the action, and issue a biological opinion as to “whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species . . .”<sup>180</sup> If the federal agency action is likely to jeopardize a listed species, then the Secretaries must identify alternatives.<sup>181</sup>

The ESA prohibits an agency from proceeding with an action that may impact a listed species before the analysis required by Section 7 is complete.<sup>182</sup> Here, FDA must complete the ESA Section 7 requirement before FDA decides whether to approve transgenic salmon as an animal drug or as a food additive.<sup>183</sup> As explained above, the scientific evidence shows that transgenic fish are more aggressive, eat more, and produce less viable offspring that may result in wild species becoming extinct within only a few generations.<sup>184</sup> A/F Protein also recognizes the dangers to endangered species and states “Lord knows we can’t promise total safety for anything.”<sup>185</sup> Even FDA is aware that the transgene could move into the wild populations.<sup>186</sup>

There are 114 listed endangered and threatened fish species and 82 species nearing extinction that could be impacted by transgenic fish.<sup>187</sup> Additionally, impacts on predator species who consume

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<sup>177</sup> Id. § 402.13.

<sup>178</sup> 16 U.S.C. § 1536(b).

<sup>179</sup> 50 C.F.R. § 402.14(d).

<sup>180</sup> Id. § 402.14(g)(1)-(4).

<sup>181</sup> 16 U.S.C. § 1536(b)(3)(A).

<sup>182</sup> Id. § 1536(a)(2)(stating that an agency must “insure” that its actions will not jeopardize a listed species).

<sup>183</sup> As explained supra, transgenic fish should also be regulated as a food additive and therefore, FDA should complete the Section 7 ESA requirement before approving a food additive petition for transgenic fish.

<sup>184</sup> See supra 25-36. See also S.C.R. 71, 2000 Leg., 1999-2000 Sess. (CA 2000) (discussing environmental concerns with transgenic fish, especially impact on endangered or threatened species of salmon).

<sup>185</sup> Altered Salmon, supra note 38, at A20.

<sup>186</sup> Questions and Answers, supra note 95.

<sup>187</sup> Listed Vertebrate Species, supra note 15; Musick, supra note 101.

transgenic fish must be considered.<sup>188</sup> There are 93 bird species and 13 marine mammal species that could be adversely affected by transgenic fish.<sup>189</sup> Due to the listed species that could be harmed by transgenic fish, FDA must complete a biological assessment and engage in formal consultations.

It would be arbitrary and capricious and an abuse of discretion if FDA fails to engage in formal consultations. The DOI and DOC have already indicated their concerns over transgenic fish. The National Marine Fisheries Service (“NMFS”), part of the DOC, warned FDA that it must be part of this review, “[w]e have to have absolute certainty that transgenic fish do not interact with wild stocks.”<sup>190</sup> The NMFS further explained that the FDA did not have the expertise to consider the environmental impacts of transgenic fish, including whether transgenic fish should be grown in net pens and that NMFS would need to be involved in the review.<sup>191</sup> Finally, the DOI fears that Atlantic salmon, recently listed under the ESA, could be “quickly wiped out” by transgenic salmon<sup>192</sup> and wants “to ban all genetically modified salmon for now.”<sup>193</sup>

In light of the scientific evidence and agency concerns that endangered species will be harmed if transgenic fish are permitted to be grown in ocean pens, FDA must fully identify the effects of this action on listed species and identify alternative actions. *Therefore, petitioners request that FDA prepare a biological assessment and initiate formal consultations with DOI and DOC before taking any action in approving the commercialization of transgenic fish.*<sup>194</sup>

#### **E. FDA Is Required Under The Federal Food Drug And Cosmetic Act To Mandate The Labeling Of All Transgenic Fish.**

Should the FDA approve the domestic marketing or importation of any transgenic fish, Petitioners request that the FDA, under FFDCFA §§ 321(n), 343(a)(1) and 352(a), require the labeling of any and all transgenic fish, or products derived from such transgenic fish, because of the reasonable expectation of consumers and admitted performance and organoleptic changes in such products. Consistent with the regulatory requests contained in this petition, the agency should initiate a rulemaking requiring all producers of transgenic fish to comply with mandatory labeling requirements for transgenic fish as both drugs and foods.

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<sup>188</sup> See CEQ Transgenic Salmon Study, supra note 12, at 23 (stating that how the growth hormone affects predators of transgenic fish should be considered).

<sup>189</sup> Listed Vertebrate Species supra note 15.

<sup>190</sup> Altered Salmon, supra note 38, at A20.

<sup>191</sup> Id.

<sup>192</sup> GMOs Pose New Risk, supra note 17.

<sup>193</sup> Marc Kaufman, Atlantic Salmon Placed on Endangered Species List, Wash. Post, Nov. 14, 2000.

<sup>194</sup> If DOI/DOC issue a biological opinion finding that endangered species will be in jeopardy if transgenic fish are grown in net pens, then FDA must adopt an alternative action. As explained by the Supreme Court in Bennett v. Spear, this opinion has a “powerful coercive effect.” 520 U.S. 154, 169 (1997).

Under the FFDCA, a food or drug is deemed misbranded if its labeling is “false or misleading in any particular.”<sup>195</sup> Further, in accordance with Section 201(n), the FFDCA provides that:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary. (emphasis added).<sup>196</sup>

In accordance with these sections of the FFDCA, FDA should mandate the labeling of transgenic fish.<sup>197</sup>

(1). Transgenic Fish Are Required To Be Labeled Under The Drug Provisions Of The Federal Food Drug And Cosmetic Act

The FDA’s classification of transgenic fish as new animal drugs triggers the requirement for mandatory labeling of all transgenic fish.<sup>198</sup> A new animal drug applicant seeking approval of a transgenic fish must submit a new animal application providing specimens of the labeling proposed to be used for such drug.<sup>199</sup> Under the FFDCA, an animal drug is deemed to be misbranded unless its

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<sup>195</sup> 21 U.S.C. §§ 343 (a), 352(a).

<sup>196</sup> 21 U.S.C. § 321(n)(emphasis added)

<sup>197</sup> The legislative history of the FFDCA suggests, at a minimum, that a material fact would be an omission on a food label that a reasonable person would view as important and would thus trigger a finding of misbranding under 21 U.S.C. § 343(a). Although the FFDCA legislative history is quiet as to what type of fact is “material” stating only the “purpose is obvious,” H.R. Conf. Rep. No. 2139 at 3, the drafters explicitly connected the language of § 201(n) with the Wheeler-Lea Act language regarding false advertising. S.5, H.R. Conf. Rep. No. 2139, 75<sup>th</sup> Cong., 3<sup>rd</sup> Sess. 3 (April 14, 1938) *reprinted in* FDA, A Legislative History of the Food, Drug & Cosmetic Act, Vol. 6 at 302 (1979); *See also*, S.1077, H.R. Conf. Rep. No. 1774, 75<sup>th</sup> Cong. 3d Sess. § 15 (February 8, 1938) *reprinted in* Charles Wesley Dunn, Wheeler-Lea Act: A Statement of Legislative History (1938) at 163. In that context the language has been traced back to the 1938 Restatement of Torts §538 which defined a fact to be material “if its existence or nonexistence is a matter to which a reasonable man would attach importance in determining his choice of action in a transaction in question.” (*See also*, 1977 Restatement of Torts 2d. § 538(2)(a), retaining identical language.) Milton Handler, The Control of False Advertising under the Wheeler-Lea Act, 6 Law & Contemp. Probs. 91, 97-98 (1939).

<sup>198</sup> *See* 21 U.S.C. § 352.

<sup>199</sup> 21 U.S.C. § 360b(b)(1)(F).



label bears specific information. Among these requirements are directions for use and warnings necessary for the protection of public health.<sup>200</sup>

As stated *infra*, the introduction of transgenic fish into the food supply raises many potential human health concerns, including the introduction of novel allergens, new food toxicity, and other unintended effects. These new potential risks to consumer safety presented by the consumption of a new animal drug are material facts that mandates labeling.<sup>201</sup> Omitting labeling requirements for transgenic fish may result in increased consumer exposure to health risks without the requisite notice of encountering such risks. This outcome would be contrary to the FFDCA's overriding purpose of protecting public health.

Furthermore, the FDA has consistently required potentially allergenic foods to be labeled.<sup>202</sup> For example, when regulating foods named by a nutrient content claim (such as "fat free") in conjunction with a traditional standardized name (for example "reduced fat sour cream"), the agency stated:

The highlighting of ingredients that are not part of the traditional standard of identity, or that are added in excess of what is permitted by that standard, is appropriate to ensure continued consumer confidence in standardized foods. FDA believes under section 201(n) and 403(d) of the act, consumers are entitled to know how the new standardized food differs from traditional standardized food. In some cases, consumers may have allergies to certain ingredients that may not be normally encountered in the standardized food. Therefore, FDA finds that these ingredients must be highlighted.<sup>203</sup>

Thus, the combination of the FFDCA's requirements for animal drug labeling and the agency's past precedents concerning food allergens mandates that the labeling of transgenic fish provide consumers with the material fact that the fish is transgenic.

(2). Transgenic Fish Are Required To Be Labeled Under The Food Provisions Of The Federal Food Drug And Cosmetic Act.

The food labeling provisions of the FFDCA also mandate the labeling of all transgenic fish. Labeling is required **either** (1) where it is found that where there are changes in a performance

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<sup>200</sup> 21 U.S.C. § 352(f).

<sup>201</sup> FDA has explained that the presence of an increased risk to consumer safety constitutes a "material change." See 49 Fed. Reg. 13679 (explaining that a special warning label is on protein products intended for weight loss because of the health risks associated with low calorie diets).

<sup>202</sup> The agency has noted that fish proteins are often common food allergens that may illicit allergenic response and the use of such proteins in genetically engineered foods would be material under the FFDCA's labeling provisions. See 57 Fed. Reg. 22984 (May 29, 1992).

<sup>203</sup> 58 Fed. Reg. 2431, 2443 (Jan. 6, 1993).

characteristic of a food; or (2) where it is found that there are organoleptic changes to the food.<sup>204</sup> For example, in addressing regulatory changes for food nutrient content claims, the agency has stated:

Under section 201(n) (21 U.S.C. § 321(n)) and 403 (a) of the act, the label or labeling of food must disclose to consumers what they are buying when they purchase these modified foods. Information disclosing differences in performance characteristics (e.g. physical properties, flavor characteristics, functional properties and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading and the product would be misbranded under section 403(a) of the act.<sup>205</sup>

Thus, the interpretation of § 321(n) adopted by the FDA and recognized by the courts establishes that performance changes such as alterations in food characteristics such as physical properties, flavor characteristics, functional properties and changes in shelf life must be communicated to the consumer via labeling; otherwise, such food is misleading and misbranded under § 343(a).<sup>206</sup> At a minimum, this agency interpretation of § 321(n) must be implemented and applied consistently and predictably.<sup>207</sup>

Transgenic fish have numerous performance characteristics that make them materially different from wild or non-transgenic farm raised fish. First, transgenic fish grow faster and weigh more than other fish of the same age. For example, at eight months old, transgenic salmon are as much as eight times larger than wild fish.<sup>208</sup> At twelve months old, these transgenic fish are eleven times heavier than wild fish.<sup>209</sup> As a result of this performance change, transgenic salmon would reach market size one year earlier than non-transgenic salmon. The rapid maturity of transgenic fish raises questions about altered internal physical and metabolic changes within such fish that may not be readily apparent to consumers but may affect the food quality of the fish.

Even more striking, performance changes such as the potential for physical abnormalities in transgenic fish highlight the “material” nature of genetically engineering fish. Transgenic salmon contain thirty (30) times higher levels of growth hormone than non-transgenic salmon. This difference

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<sup>204</sup> Stauber v. Shalala, 895 F.Supp. 1178, 1193 (W.D. Wis. 1995).

<sup>205</sup> 58 Fed. Reg. 2431, 2437 (June 6, 1993).

<sup>206</sup> If the agency now claims to depart from this existing interpretation, it must set forth a reasoned explanation from its departure of prior norms. Western States Petroleum Assoc. v. EPA, 87 F.3d 280, 284-285 (9<sup>th</sup> Cir. 1996); Telecommunications Research and Action Center v. FCC, 800 F.2d 1181, 1184 (D.C. Cir. 1986).

<sup>207</sup> See Morton v. Ruiz, 415 U.S. 199, 232 (1974).

<sup>208</sup> U.S. Patent No. 5,545,808 (issued Aug. 13, 1996)[hereinafter “Choy L. Hew and Garth L. Fletcher patent”].

<sup>209</sup> Robert H. Devlin patent, supra note 30.

often results in physical deformities in the head and jaw of transgenic fish.<sup>210</sup> The performance changes in transgenic fish are so evident that even the FDA itself has decided to regulate transgenic fish not like other fish, but rather as an animal drug. This regulatory decision requiring evidence demonstrating safety and effectiveness demonstrates that transgenic fish are fundamentally different from non-transgenic fish. Given the evidence that genetic engineering directly alters the performance characteristics of fish, including their physical and functional properties, the failure of the FDA to mandate labeling apprising consumers of such a material fact would be contrary to past agency precedent and arbitrary and capricious.

Additionally, transgenic fish also exhibit organoleptic changes that are a material fact and mandate labeling. Organoleptic changes include changes in taste, color, smell, and texture.<sup>211</sup> In transgenic salmon the increased growth hormone levels cause the salmon to lose their dark vertical bars and develop a silver coloration six months earlier than non-transgenic salmon.<sup>212</sup> Thus, if commercialized, consumers will be confronted with fish marketed as salmon that have different coloration than non-transgenic salmon. Other organoleptic changes affecting taste, smell, and consistency of transgenic fish may be present, however, the FDA refuses to release any of this information.<sup>213</sup> Nonetheless, the intended and unintended changes in the organoleptic properties of transgenic fish already demonstrated mandate labeling under section 321(n).

(3). Patenting of Transgenic Fish Indicates A Material Fact Requiring Labeling.

In the past, FDA has justified its failure to require labeling by claiming genetically engineered food are substantially equivalent to conventionally produced foods and thus need not be labeled.<sup>214</sup> Such a position is inconsistent with the unique legal recognition granted to these food producers by the United States Patent and Trademark Office (PTO).

Under United States patent law, a patent cannot be granted unless the patent applicant can fulfill the requirements that the subject matter for which the applicant seeks protection is useful, novel, and non-obviousness.<sup>215</sup> Such a legal prerequisite necessitates that any object “substantially equivalent” to

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<sup>210</sup> Id. See Growth of domesticated transgenic fish, supra note 25, at 781-82 (explaining that a stronger gene construct may increase growth in domestic fish but these fish may experience a higher incidence of abnormalities such as cranial abnormalities); See Elements of Precaution, supra note 38, at 88 (explaining that transgenic coho salmon exhibit morphological abnormalities in the cranial, jaw and opercular regions.).

<sup>211</sup> Stauber, 895 F. Supp. at 1193 (explaining that an “organoleptic difference is one capable of being detected by a human sense organ.”).

<sup>212</sup> Robert H. Devlin patent, supra note 30.

<sup>213</sup> The Center for Food Safety submitted a FOIA request on December 7, 1999. FDA responded on April 6, 2000, stating that all the information involving transgenic fish is confidential until transgenic fish are approved for the market.

<sup>214</sup> Petitioners disagree with such a legal interpretation. See CFS Petition, supra note 49.

<sup>215</sup> 35 U.S.C. §§ 101, 102, 103.

an existing object<sup>216</sup> would not be patentable subject matter. In the case of transgenic fish, the PTO has clearly recognized that they are not legally “substantially equivalent” to non-transgenic fish. A/F Protein’s transgenic salmon is patented<sup>217</sup> and so are other transgenic fish.<sup>218</sup> This legal determination clearly dictates that novel physical, organoleptic and other changes that have occur in transgenic fish are “material” fact requiring the FDA to mandate labeling.

(4). Consumer Demand Necessitates Labeling.

Whether transgenic fish are regulated as animal drugs or food additives, consumers also have a reasonable expectation that changes in their food of the magnitude created by genetic engineering will trigger labeling. Consumer demand for the labeling of a food bolsters a finding of “material fact” under the FFDCA. As the FDA has stated previously:

[T]he large number of consumer comments requesting retail labeling attest to the significance placed upon such information by consumers. Moreover, several comments argued irradiation of food altered the organoleptic properties of food thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act.<sup>219</sup>

In addressing the role of public concern as it relates to labeling, the agency has further elaborated that:

In determining whether labeling is misleading, the agency must take into account the extent to which labeling fails to reveal material facts in light of representations made about the food or consequences that many result from the use of such food [section 201(n) of the act]. Therefore, the agency must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if the organoleptic changes were not significant.<sup>220</sup>

FDA acknowledges that the public is demanding the labeling of all genetically engineered foods,

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<sup>216</sup> A naturally occurring product, such as a fish, is not patentable subject matter under the “products of nature” doctrine. See e.g. Ex parte Grayson, 51 U.S.P.Q. 413 (Pat. Off. Bd. App. 1941)(shrimp with head and digestive organs removed not patentable).

<sup>217</sup> Choy L Hew and Garth L. Fletcher patent, supra note 208.

<sup>218</sup> Devlin, Robert H. patent no. 5,998,697 (Dec. 7, 1999).

<sup>219</sup> 51 Fed. Reg. 13376, 13388 (April 18, 1986).

<sup>220</sup> Id. at 13390.

including transgenic fish. FDA states “Not surprisingly, most consumers believed that genetically engineered foods should be labeled.”<sup>221</sup> In response to its 1992 Policy Statement requesting labeling of genetically engineered foods, many people said that labels should be “clear, prominent, and not restricted to fine print.”<sup>222</sup> Moreover, poll after poll repeatedly shows consumer demand for the labeling of all genetically engineered foods.<sup>223</sup> Recognizing the importance of not misleading consumers, A/F Protein has stated that they intend to voluntarily comply with the labeling requirements.<sup>224</sup> Although A/F Protein intends to comply with established labeling requirements, a failure to create such requirements would render A/F Protein’s promise insignificant.

The differences between transgenic and non-transgenic fish combined with consumers’ interest in knowing these differences are material fact under § 321(n), the FFDCA requires that consumers are given this information through labeling. A failure to require such labeling would be arbitrary, capricious, an abuse of discretion and contrary to law.

*Therefore, petitioners request FDA to initiate a rulemaking that clarifies the animal drug and food labeling responsibilities for transgenic fish producers. In order to adequately inform consumers that the fish they are purchasing are genetically engineered, the labeling must be used uniformly by all transgenic fish producers.*<sup>225</sup>

#### **F. Before Transgenic Fish Are Marketed, FDA Must Enact Monitoring, Reporting, and Inspecting Procedures That Adequately Address Human Food Safety Concerns.**

If transgenic fish are approved for the market, then regulations must be adopted to address the unique food safety concerns that may develop during the production and processing of transgenic fish. Under the FFDCA, an “adulterated” food cannot enter interstate commerce.<sup>226</sup> An “adulterated” food includes food that contain poisonous or deleterious substances or food that has been “prepared, packed, or held under insanitary conditions.”<sup>227</sup> To prevent contamination, FDA must require adequate monitoring, reporting, and inspecting of potential food safety hazards by domestic producers and importers before transgenic fish enter the market. Furthermore, FDA must conduct its own inspections to ensure that the public does not consume seafood harmful to their health.

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<sup>221</sup> Memorandum from Alan Heaton to James Maryanski (Nov. 3, 1993).

<sup>222</sup> Id.

<sup>223</sup> See Compilation of Public Opinion Polls at <http://www.centerforfoodsafety.org/facts&issues/polls.html>.

<sup>224</sup> A/F Protein, Biotech Acceptance: A Label Goes A Long Way, available at <http://acbi.ca/afprotein/label.htm> (last visited Nov. 2, 2000)(explaining that Aqua Bounty Farms intends to require all licensees growing their transgenic fish to comply with a labeling requirement).

<sup>225</sup> Petitioners request that the labeling requirements for genetically engineered food requested in Citizens’ Petition 00-1211 be applied to this petition and incorporated to cover transgenic fish.

<sup>226</sup> 21 U.S.C. § 331.

<sup>227</sup> Id. § 342(a).

(1). Domestically

FDA's regulations require producers of fish to monitor food safety hazards that are reasonably likely to occur and to maintain records of their observations.<sup>228</sup> FDA reports that only 24% of seafood producers fully comply with the agency's safety regulations.<sup>229</sup> Furthermore, the FDA only conducts unannounced inspections for each plant once or even less a year.<sup>230</sup> This is a significant safety hazard because seafood causes more food-poisoning outbreaks than any other food source.<sup>231</sup> Some of the food safety hazards that transgenic fish could contain include, allergens, bacteria, viruses, antibiotics, toxins, parasites, pesticides, and heavy metals. Also, due to the "juggling of the genes," physical abnormalities, such as deformed heads are likely.<sup>232</sup> These abnormalities may harm human health.

Due to the unique food safety hazards that may occur with the marketing of transgenic fish, approving transgenic fish without mandating and enforcing an adequate system for insuring food safety is unacceptable. To insure that these fish are safe for human consumption, FDA must require comprehensive monitoring, reporting, and inspecting by both transgenic fish producers and FDA inspectors. *Therefore, petitioners request FDA to propose a rulemaking to inform producers of transgenic fish on adequate human safety procedures including, but not limited to, use of antibiotics, reporting abnormalities, and inspecting/testing methods.*<sup>233</sup>

(2). Importation

Currently, 35 species of transgenic fish are being developed in countries around the world.<sup>234</sup> In China, it is reported that transgenic carp are already in commercial production.<sup>235</sup> Considering that over 55% of the fish consumed in the U.S. is imported, it is highly likely that a significant number of

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<sup>228</sup> 21 C.F.R. §§123.6, 123.8.

<sup>229</sup> CSPI, U.S. Seafood-Safety System "Unworthy of Public Support", available at [http://www.cspinet.org/new/seafood\\_safety.html](http://www.cspinet.org/new/seafood_safety.html) (last visited Sept. 28, 2000).

<sup>230</sup> Id.

<sup>231</sup> Id.

<sup>232</sup> Salmon Cause Debate, supra note 113 (explaining that a New Zealand company breed transgenic fish that developed deformed heads and other abnormalities).

<sup>233</sup> In addition to pre-marketing requirements, post-marketing safety requirements must be established. It is necessary for FDA to establish regulations providing for the recall of transgenic fish if these fish are later found to be unsafe. See 21 C.F.R. §§ 7.1-7.87.

<sup>234</sup> Souped up salmon, supra note 6, at 10.

<sup>235</sup> Eric M. Hallerman, Ecological and Evolutionary Issues Posed by Genetically Modified Fishes; Altered Salmon, supra note 38, at A21 (stating that transgenic fish in Cuba may already be in commercial use).

transgenic fish will be imported into this country.<sup>236</sup> Without reviewing the importing country's processing procedures for transgenic fish, FDA is exposing the public to various safety hazards.

Under current U.S. law, fish importers must verify that their inspection system is equivalent to the FDA's regulations.<sup>237</sup> Importers who cannot demonstrate that their fish were processed under similar conditions as domestic producers will not be allowed into the U.S. When FDA first considered whether or not to regulate importers, the agency received many comments stating that "the safety of seafood cannot be adequately ensured if the majority of products (that is, imports) are not subject to the same controls as domestic products."<sup>238</sup>

As with other types of fish, FDA must require transgenic fish importers to verify that the transgenic fish are safe, regularly inspected, and processed under sanitary conditions that are similar to FDA's own regulations.<sup>239</sup> This oversight by FDA is essential because transgenic fish from other countries may be processed and inspected differently. For example, imported transgenic fish may be treated for illness with antibiotics that have never been approved as safe by the FDA. FDA must be aware of any processing differences.

FDA should also not approve transgenic fish imports if the fish were grown in ocean pens. After complying with NEPA and the ESA, FDA will be aware of the potential environmental impacts resulting from the escape of transgenic fish from ocean pens. The potential extinction of an entire population of fish is so egregious that FDA must require that not only domestic producers, but also importers only grow transgenic fish in enclosed facilities. Furthermore, enclosed land based recycling systems are highly controllable and can eliminate many human safety concerns by reducing parasites and diseases in fish. The importing country must verify that the facilities used to produce and process transgenic fish are equivalent to domestic facilities.

*In order to adequately address the unique food safety concerns that may arise during the production and processing of transgenic fish, petitioners request that FDA implement a rulemaking mandating that importers of transgenic fish satisfy the same safety, inspection, and environmental containment requirements as domestic producers.*

## **ENVIRONMENTAL IMPACT**

The specific actions requested by petitioners are not categorically excluded under 21 C.F.R. § 25.30(h) and therefore do not require the preparation of an EA or EIS.

## **CERTIFICATION**

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representation data

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<sup>236</sup> 60 Fed. Reg. 65096, 65097 (1995).

<sup>237</sup> 21 U.S.C. § 381, 21 C.F.R. § 123.12.

<sup>238</sup> 60 Fed. Reg. at 65152.

<sup>239</sup> 21 U.S.C. § 123.12.

known to the petition which are unfavorable to the petition.

### CONCLUSION

For the reasons contained herein, the petitioners respectfully request that FDA initiate the following actions:

I. A moratorium on the domestic marketing, importation and exportation of transgenic fish, including but not limited to all transgenic fish, transgenic fish eggs, and food products containing any ingredients or material derived from transgenic fish, until the FDA establishes a comprehensive regulatory framework under the mandate of the Federal Food Drug and Cosmetic Act (“FFDCA”) to evaluate and fully address the human health and environmental impacts caused by the commercialization of transgenic fish. Such a regulatory framework shall include:

- (1). Establishment of regulations addressing the safety and efficacy of transgenic fish by requiring all transgenic fish producers to complete a full review of transgenic fish as a new animal drug pursuant to the requirements of 21 U.S.C. § 360b and accompanying implementing regulations;
- (2). Establishment of regulations addressing the pre-market safety testing of transgenic fish by requiring all transgenic fish to undergo review as a food additive pursuant to the requirements of 21 U.S.C. § 321(s) and accompanying implementing regulations;
- (3). Establishment of regulations providing for the pre-market monitoring, reporting, and inspecting procedures of transgenic fish by transgenic fish producers pursuant to the FFDCA and accompanying regulations;
- (4). Establishment of regulations providing for the mandatory labeling of transgenic fish and all food products containing any ingredients or material derived from transgenic fish pursuant to the requirements of 21 U.S.C. § 321(n) and 343(a)(1) and accompanying implementing regulations;
- (5). Establishment of regulations providing for the post-market monitoring, reporting, and inspecting procedures of transgenic fish by transgenic fish producers pursuant to the FFDCA and accompanying regulations;
- (6). Establishment of regulations providing that importers must follow the same statutory and regulatory requirements for transgenic fish as domestic producers; and
- (7). Provide for the permanent prohibition on the domestic marketing, importation and exportation of all transgenic fish should such products fail to be proven safe and



efficacious, generally recognized as safe, or otherwise unfit for human consumption.

- II. A moratorium on the domestic marketing, importation and exportation of transgenic fish until the FDA completes a comprehensive environmental impact review as mandated by the National Environmental Policy Act to evaluate and fully address the human health and environmental impacts caused by the commercialization of transgenic fish. Such an environmental review shall include:
- (1). Completion of an environmental assessment and environmental impact statement as required under the National Environmental Policy Act, 42 U.S.C. § 4332, addressing the effects of the domestic marketing, importation and exportation for each and every transgenic fish application;
  - (2). Completion of a programmatic environmental impact statement as required under the National Environmental Policy Act, 42 U.S.C. § 4332, addressing the effects of the domestic marketing, importation and exportation of all transgenic fish; and
  - (3). Provide for the permanent prohibition should such activities harm the quality of the environment.
- III. A moratorium on the domestic marketing, importation and exportation of transgenic fish until the FDA reviews the impacts of such activities on endangered species and completes the consultation requirement with the Department of the Interior and Department of Commerce as required under the Endangered Species Act, 15 U.S.C. § 1536.
- IV. A moratorium on the domestic marketing, importation and exportation of transgenic fish until all other federal agencies comply with the statutory provisions under such agencies' jurisdiction that are triggered by the introduction of transgenic fish into the environment and/or interstate commerce. Such agency action shall include, but not be limited to:
- (1). Department of the Interior and Department of Commerce compliance with the requisite provisions of the Endangered Species Act, Lacey Act, Aquatic Nuisance Prevention and Control Act, and the National Aquaculture Policy Act;
  - (2). Department of Defense compliance with the requisite provisions of the National Environmental Policy Act, Endangered Species Act, and Rivers and Harbors Act; and
  - (3). Department of Agriculture compliance with the requisite provisions of the National

Aquaculture Policy Act.

As established in 21 C.F.R. § 10.30(e)(2), petitioners request that the agency provide an answer to this citizen petition with 180 days. In the absence of an affirmative response, petitioners will be compelled to consider litigation in order to achieve the agency action requested.

Respectfully submitted,

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