

**CITIZEN PETITION BEFORE THE  
UNITED STATES DEPARTMENT OF AGRICULTURE**

**CENTER FOR FOOD SAFETY** )  
660 Pennsylvania Ave., S.E. )  
Suite 302 )  
Washington, DC 20003, *et al.*, )  
 )  
*petitioners,* )  
v. )  
**ANN M. VENEMAN** )  
Secretary of Agriculture )  
U.S. Department of Agriculture )  
1400 Independence Ave., S.W. )  
Room 200A )  
Whitten Building )  
Washington, DC 20250 )

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

**PETITION FOR RULEMAKING UNDER THE AQUACULTURE POLICY ACT**  
**SEEKING A MORATORIUM ON THE RAISING OF**  
**TRANSGENIC FISH IN OCEAN PENS**

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 U.S. Department of Agriculture’s (“USDA”) implementing regulations,<sup>3</sup> petitioners respectfully request that the USDA immediately impose a moratorium on the raising of transgenic fish<sup>4</sup> in ocean pens or in any other device

---

<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).

<sup>3</sup> 7 C.F.R. § 1.28.

<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

in the aquatic environment. Consistent with the National Aquaculture Policy Act's mandate of environmental stewardship, USDA should consult with the Department of Interior and the Department of Commerce about the potential environmental and human health impacts caused by transgenic fish. Should a review by these agencies show that transgenic fish will harm the environment, these agencies should amend the National Aquaculture Development Plan by banning the growing of transgenic fish in the aquatic environment. To ensure that transgenic fish do not harm the environment or human health, USDA should then initiate a rulemaking pursuant to the National Aquaculture Policy Act that mandates the following requirements for growing transgenic fish:<sup>5</sup>

- (1) Specific facility design and operation requirements for enclosed land based recirculating systems; and
- (2) Specific requirements for the use of antibiotics;

USDA should also consult with the Environmental Protection Agency ("EPA") and assist EPA in developing specific regulatory requirements for the disposal of waste water from enclosed land based recirculating systems. Finally, before adopting an official policy or regulations addressing transgenic fish, USDA must comply with the requirements of the National Environmental 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.

---

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 and transgenic fish eggs.

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 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.

---

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

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. 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>7</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>8</sup>

Although this petition reviews the 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 USDA before transgenic fish are approved for the market.

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, FDA must adopt a pre-market regulatory review that does not ignore these potential human health safety concerns.

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>9</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>10</sup>

---

<sup>7</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>8</sup> Id.

<sup>9</sup> See infra pp. 13-20

<sup>10</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.

Unintended releases of transgenic fish into the world's waters may cause significant impacts to the environment and endangered species. New studies have shown that transgenic fish are more aggressive, eat more food, and will attract more mates than wild fish.<sup>11</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>12</sup> Once one species becomes extinct, other species will likely be affected. There are already 114 species of fish, including Atlantic salmon, that are listed under the Endangered Species Act ("ESA").<sup>13</sup> Allowing transgenic fish in ocean pens may significantly increase this number of listed species.

Although fish farmers want to use ocean pens to grow transgenic fish, how this activity will affect the aquaculture industry must be thoroughly reviewed. Congress enacted the National Aquaculture Policy Act ("NAPA") in 1980 to prevent the dramatic decline of wild fish and to promote the use, acceptance, and development of aquaculture.<sup>14</sup> Congress found that "many of our traditional stocks of marine resources are declining from overfishing, pollution, and many other pressures"<sup>15</sup> and the "only logical way to counteract such a perilous trend is to learn how to manage living aquatic resources."<sup>16</sup> Congress designated USDA as the lead federal agency responsible for the coordination and dissemination of national aquaculture information and the Secretary of USDA as the permanent chairman of the Joint Subcommittee on Aquaculture of the Federal Coordinating Council on Science, Engineering, and Technology.<sup>17</sup> Along with USDA, Congress specified that the U.S. Department of Interior and the U.S. Department of Commerce are responsible for developing a National Aquaculture Development Plan (hereinafter "Plan") and prescribing regulations that further the purposes of the

---

<sup>11</sup> See *infra* pp. 13-20

<sup>12</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"].

<sup>13</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>14</sup> 16 U.S.C. § 2801, *et seq.*

<sup>15</sup> 126 Cong. Rec. 24,600 (1980). Congress reported that the "National Oceanic and Atmospheric Administration believes that a worldwide shortage of fisheries products can be expected within three to ten years." H.R. Rep. No. 96-198, pt. 1, at 7-8 (1980), *reprinted in* 1980 U.S.C.C.A.N. 2878, 2884-5.

<sup>16</sup> *Id.* at 9,440.

<sup>17</sup> 16 U.S.C. §§ 2801, 2805.

Plan.<sup>18</sup> In developing this Plan, the agencies are required to address such issues as aquaculture facility design and operation, water quality management, use of waste products, and disease control.<sup>19</sup>

The public's acceptance of the aquaculture industry may soon be threatened by the commercialization of transgenic fish. If FDA approves the commercialization of transgenic fish, then USDA will be responsible for ensuring that the aquaculture industry properly handles the growing and production of transgenic fish. If transgenic fish are permitted to be grown in ocean pens without any oversight or regulation, then the environment and public health may be severely harmed. As a result, the public will question and condemn the practice of aquaculture for not only transgenic fish, but for all farmed fish. Accordingly, petitioners request the USDA to take the actions outlined herein.

### **STATEMENT OF LAW**

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

National Aquaculture Policy Act, 16 U.S.C. 2801, *et seq.*

All other applicable statutes and regulations.

### **ARGUMENT**

At the same time petitioners filed this petition, petitioners also filed a petition with FDA requesting that FDA not approve the commercialization of transgenic fish due to the egregious human health and environmental impacts. If FDA ignores the numerous human health and environmental concerns and approves the commercialization of transgenic fish, USDA will be responsible for determining whether transgenic fish will harm the aquaculture industry. Because USDA is responsible for promoting the aquaculture industry, it must ensure that where transgenic fish are grown and how they are taken care of is regulated in a manner that does not harm the environment and public health.<sup>20</sup> If USDA fails to protect the environment and public safety, the future development of the aquaculture industry will likely be seriously impacted.

---

<sup>18</sup> Id. §§ 2803-4.

<sup>19</sup> Id. § 2803(a)(3).

<sup>20</sup> Under the National Aquaculture Development Plan, the agencies, including USDA, are responsible for ensuring that aquaculture is “compatible with responsible environmental stewardship” and that aquaculture products are safe for consumers. Joint Subcommittee on Aquaculture, Aquaculture Research and Development: Strategic/Implementation Plan, at <http://ag.ansc.purdue.edu/aquanic/jsa/Strategicplan.htm> (last visited Mar. 29, 2000)[hereinafter “Implementation Plan”]; Joint Subcommittee on Aquaculture, Draft National Aquaculture Development Plan of 1996 Joint Subcommittee on Aquaculture National Science and Technology Council, at <http://ag.ansc.purdue.edu/aquanic/publicat/govagen/usda/dnadp.htm> (last visited Mar. 29, 2000).

Consistent with the National Aquaculture Policy Act's mandate of environmental stewardship, USDA should consult with the Department of Interior ("DOI") and the Department of Commerce ("DOC") about the potential environmental and human health impacts caused by transgenic fish. If this review shows that transgenic fish will harm the environment, these agencies should amend the National Aquaculture Development Plan by banning the growing of transgenic fish in the aquatic environment. USDA, DOI, and DOC are directed by Congress to amend the Plan when "projected benefits do not warrant further support."<sup>21</sup> Helping to further the use of transgenic fish in the aquatic environment does not warrant further support. As explained below, there are significant environmental impacts likely to result if transgenic fish are grown in the marine environment. Moreover, to ensure that transgenic fish do not harm the environment or human health, USDA should devise specific regulations addressing facility design, use of antibiotics, and disposal of waste water.

**A. USDA Should Propose Regulations For Specific Facility Design and Operation Requirements For Growing Transgenic Fish In Enclosed Land Based Recirculating Systems.**

If transgenic fish are grown in ocean pens, they may easily escape and then it is likely that they will seriously and permanently harm native aquatic resources. One of NAPA's primary purposes is to alleviate depleting aquatic resources by promoting aquaculture.<sup>22</sup> Allowing transgenic fish to be grown in ocean pens will frustrate this statutory purpose and impede the development of the aquaculture industry. The aquaculture industry will be stigmatized if transgenic fish escape from ocean pens and cause environmental damage. Therefore, instead of growing transgenic fish in ocean pens, transgenic fish should only be grown in enclosed land based recycled tanks with specific USDA requirements for design and operation.

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

Most 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>23</sup>

---

<sup>21</sup> 16 U.S.C. § 2803(d)(3).

<sup>22</sup> H.R. Rep. No. 96-198, pt.1, at 14, *reprinted in* 1980 U.S.C.C.A.N. at 2891.

<sup>23</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://acbi.ca/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.").

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>24</sup> There are also several incidences of mass fish escapes. In 1990, approximately four million fish escaped from a fish farm in Norway. Recently, over 170,000 farm raised salmon escaped from a net pen after a storm in Maine.<sup>25</sup> The Fish and Wildlife Service reports that “25-40% of the fish in the North Atlantic Ocean is of aquaculture origin.”<sup>26</sup> Weather, human error, and marine mammal and bird attacks<sup>27</sup> all contribute to the release of fish from ocean pens.<sup>28</sup> Recognizing that fish repeatedly escape from ocean pens, CEQ recently stated that it “must be assumed that escapes will occur” from net pens.<sup>29</sup>

If USDA allows transgenic fish to be grown in ocean pens, then this will be the first time that a transgenic animal will be raised in the ocean for human consumption.<sup>30</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>31</sup> Once transgenic fish are commercialized, there will likely be a great number of transgenic fish in the water.<sup>32</sup> Recognizing the harm that transgenic fish may cause, a DOI official cautioned that rare wildlife may be impacted by transgenic fish. Given the high

---

<sup>24</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>25</sup> Walter Gibbs, Fish-Farm Escapees Threaten Wild Salmon, N.Y. Times, Oct. 1, 1996 at C4; 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).

<sup>26</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>27</sup> 62 species of birds and 13 species of mammals are potential predators of transgenic fish in ocean pens. Rebecca Goldberg and Tracy Triplett, Murky Waters: Environmental Effects of Aquaculture in the U.S., Environmental Defense Fund at 57 (1997) [hereinafter “Murky Waters”].

<sup>28</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>29</sup> CEQ Transgenic Salmon Study, supra note 10, at 23.

<sup>30</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>31</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”].

<sup>32</sup> Les Blumenthal, Genetically Altered Salmon Cause Debate Among U.S. Officials, News Tribune (Aug 21, 2000) [hereinafter “Salmon Cause Debate”].

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.

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

Once transgenic fish escape from ocean pens, endangered species and species approaching “endangered species” status will be severely impacted. The rapidly decreasing fish population levels are evident in a recent study showing that there are already 82 species of fresh water fish in North American waters that are near extinction.<sup>33</sup> Moreover, the number on the endangered species list has reached 114 and includes populations of the chinook, chum, coho, and sockeye salmon.<sup>34</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>35</sup> These agencies stated that one of the reasons for the decline of this species is due to aquaculture because farmed fish spread diseases to wild Atlantic salmon and when farmed fish escape they affect the genetic integrity and compete with Atlantic salmon for habitat and food.<sup>36</sup>

Given the fragile state of fish populations and the 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>37</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>38</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

---

<sup>33</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>34</sup> Listed Vertebrate Species, supra note 13.

<sup>35</sup> 65 Fed. Reg. 69459 (2000).

<sup>36</sup> DOI and DOC, Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered (Nov 2000).

<sup>37</sup> See Murky Waters, supra note 27 at 51 - 52; DOI and DOC, Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered (Nov 2000).

<sup>38</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).

fish will have a greater mating advantage due to their larger size.<sup>39</sup> However, their offspring will have a reduced ability to survive because transgenic fish are “macromutants that lack any history of selection that could reduce negative fitness effects.”<sup>40</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 within only 40 generations.<sup>41</sup> They refer to these disturbing results as the “Trojan gene effect.”<sup>42</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>43</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>44</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>45</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>46</sup> The best current scientific

---

<sup>39</sup> Trojan Gene Hypothesis, supra note 12, at 13853 - 13856.

<sup>40</sup> Id.

<sup>41</sup> Id.

<sup>42</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>43</sup> Altered Salmon, supra note 31, at A20.

<sup>44</sup> Souped up Salmon, supra note 6, at 11.

<sup>45</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. Salmon Cause Debate, supra note 32.

<sup>46</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



evidence available shows that species extinction may occur as a result of transgenic fish that slip out of ocean pens into the wild.

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>47</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>48</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 strains of fish and the ability of the personnel.<sup>49</sup> Anne Kapuscinski, Ph.D., professor and expert 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>50</sup> Recently, CEQ released a study on transgenic fish.<sup>51</sup> This study revealed that 100% sterilization cannot be guaranteed.<sup>52</sup> Due to the uncertainty in producing sterile fish 100% of the time, there is a risk of extinction if sterilization is not always 100% effective.

---

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).

<sup>47</sup> Altered Salmon, supra note 31, at A20.

<sup>48</sup> Souped up salmon, supra note 6, at 11

<sup>49</sup> CEQ Transgenic Salmon Study, supra note 10

<sup>50</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>51</sup> CEQ Transgenic Salmon Study, supra note 10. The leading drafting agency on the growth-enhanced salmon case study was FDA. NMFS and DOI were also part of the drafting team.

<sup>52</sup> Id. at 1, 31 (admitting that none of the sterilization techniques are 100% effective and explained that even when transgenic fish are rendered sterile, “the males may exhibit spawning behavior with fertile deploid females, leading to decreased reproductive success of the fertile diploid females.”); See Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 166 (Jan. 2001) (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).

*(3) 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.<sup>53</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>54</sup> Transgenic fish are non-native organisms that may cause serious environmental damage. Therefore, USDA 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>55</sup> Even A/F Protein admits that its transgenic salmon consume more food than wild salmon.<sup>56</sup> One researcher observed that transgenic fish have “a revved-up metabolism. They’re hungry all the time.”<sup>57</sup> As a result, these transgenic fish could be foraging ravenously when food availability in an area is low out competing native fish.<sup>58</sup>

Moreover, the fish being consumed by these aggressive hungry transgenic salmon predators may be impacted.<sup>59</sup> One scientist warned that “[t]hey’re creating very, very large fish that will become

---

<sup>53</sup> See CEQ Transgenic Salmon Study, supra note 10, 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”).

<sup>54</sup> Exec. Order No. 13,112, 64 Fed. Reg. 6,183 (Feb. 8, 1999).

<sup>55</sup> Foraging behavior, supra note 46; Increased ability to compete, supra note 46, at 479 - 482 (explaining that transgenic coho salmon consumed almost three times the food of wild fish); CEQ Transgenic Salmon Study, supra note 10, at 8 (explaining that released sterile triploids may “pose heightened competition with diploid conspecifics (i.e., fish of the same species), perhaps including in some cases, predation on juvenile conspecifics.”).

<sup>56</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>57</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>58</sup> Souped up salmon, supra note 6, at 11.

<sup>59</sup> Genetic engineering creates supersalmon- and controversy, Seattle Times, Nov. 30, 1999.

predators of other fish.”<sup>60</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 competition with different species.<sup>61</sup> By out competing salmon and other endangered species for resources and habitat, transgenic fish will likely seriously disrupt the ecosystem.<sup>62</sup>

As for the fish that do not escape ocean pens, the practice of raising transgenic fish in ocean pens will likely also disrupt the ecosystem and jeopardize endangered species. Raising transgenic fish in ocean pens may contribute to water pollution and harm wetlands.<sup>63</sup> Aquaculture waste accumulates below and around net pens and can deplete the oxygen in the water and harm aquatic life.<sup>64</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>65</sup>

Aquaculture also introduces diseases and parasites that affect wild populations.<sup>66</sup> Indeed, the primary cause of salmon mortality in Norwegian rivers is the monogenean fluke introduced by aquaculture.<sup>67</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

---

<sup>60</sup> Id.

<sup>61</sup> See Rebecca Goldberg, Something Fishy, <http://www.environmentaldefense.org/pubs/reports/aquaculture/transgenic.html> (last modified May 2000); See CEQ Transgenic Salmon Study, supra note—, at 22 (explaining that phenotypic changes that should be examined include tolerance to temperature).

<sup>62</sup> Ecological implications, supra note 24, at 60 - 61.

<sup>63</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>64</sup> Murky Waters, supra note 27, at 35-48. A/F Protein admits that transgenic fish consume 70 to 80% more oxygen than wild fish. News From the Farm, supra note 56. See 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>65</sup> Murky Waters, supra note 27, 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>66</sup> 64 Fed. Reg. at 62635 (Nov, 17, 1999).

<sup>67</sup> Ecological implications, supra note 24, 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.”).

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 through uneaten feed and feces.<sup>68</sup> Pesticides are also used to control parasites.<sup>69</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>70</sup> Taking this many fish will likely effect the balance of the ecosystem.

### *Conclusion*

By allowing transgenic fish to be grown in ocean pens, it will likely lead to species extinction and disrupt the balance of the environment. As a result, the entire aquaculture industry will be permanently scarred and the public will question the further development of the aquaculture industry. To ensure that USDA meets its mandate under the NAPA, USDA should propose design and operation regulations for growing transgenic fish 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>71</sup> Already, several aquaculture companies are successfully using this type of system for a variety of fish.<sup>72</sup> *Therefore, petitioners request a rulemaking banning the growing of transgenic fish in ocean pens and requiring specific design and operation requirements for enclosed land based recirculating systems.*

---

<sup>68</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); Memorandum from Frederick Angulo, D.V.M., Ph.D. to the record, 1-3 (Oct. 18, 1999) (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.”) [hereinafter “Antimicrobial resistance”].

<sup>69</sup> Murky Waters, *supra* note 27, at 46-7(explaining that the environmental effects from pesticides are not completely understood).

<sup>70</sup> Nature’s Subsidies, *supra* note 63, 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>71</sup> Murky Waters, *supra* note 27 at 80-83.

<sup>72</sup> *Id.* at 83.

**B. USDA Should Propose Regulations Specifying The Amount Of Antibiotics That May Safely Be Used In Treating Transgenic Fish.**

In order to protect human health, USDA should specify the amount of antibiotics permitted to be used in treating diseased transgenic fish.<sup>73</sup> As stated supra, because transgenic fish are “macromutants,” transgenic fish may be susceptible to more diseases and introduce more diseases than fish currently grown in aquaculture facilities. As a result of these diseases, the amount of antibiotics used to treat transgenic fish will most likely be higher than the amount of antibiotics currently used for farmed fish. The most common method of distributing antibiotics to farmed fish is through fish feed. However, , not all of the antibiotics are absorbed by the fish and consequently, antibiotics enter the environment through uneaten feed and feces.<sup>74</sup> It is predicted that 75% of most antibiotics are lost in the environment.<sup>75</sup> Consequently, these antibiotics accumulate in wild fish and shellfish that feed on the food and feces of farmed fish.<sup>76</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>77</sup> Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.<sup>78</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>79</sup>

The Centers for Disease Control (“CDC”) found that bacteria from aquaculture ecosystems can

---

<sup>73</sup> See Implementation Plan, supra note 20 (requiring safe food from aquaculture facilities).

<sup>74</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 68 , 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>75</sup> Id. at 44.

<sup>76</sup> Id.

<sup>77</sup> Id.

<sup>78</sup> Id. (explaining that newborns can be harmed by chloramphenicol and betalactam compounds can cause fatal allergic reactions).

<sup>79</sup> Id. at 45.

be transferred directly to humans by handling the fish.<sup>80</sup> Even if someone is not exposed to the aquaculture operation, FDA explained 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>81</sup>

Allowing the unlimited use of antibiotics for treating diseased transgenic fish will likely harm human health. If consumers become ill after eating transgenic fish, the result will likely be a lack of consumer satisfaction and confidence with the aquaculture industry. If USDA does not regulate the use of antibiotics, the growth and development of the entire aquaculture industry may suffer.

To alleviate human health concerns, transgenic fish should only be grown in enclosed land based recirculating systems. Because these systems recirculate the water in the tanks, the amount of parasites and diseases are reduced and therefore, the need to administer antibiotics is significantly decreased.<sup>82</sup> *In addition, petitioners request that USDA propose regulations specifying the type and amount of antibiotics permitted to be used to treat diseased transgenic fish in order to prevent harm to human health.*

**C. USDA Should Consult with EPA Regarding An Environmentally Safe Method For The Disposal Of Waste Water From Transgenic Fish Facilities.**

As explained above, allowing transgenic fish to be grown in ocean pens will likely harm the environment and human health. In order to prevent the public from condemning the aquaculture industry, USDA should require that transgenic fish only be grown in enclosed land based recirculating systems. To further prevent environmental harm from growing transgenic fish, USDA should consult with EPA and assist EPA in developing a regulation regarding the proper disposal of waste water from transgenic fish facilities. Although recirculating systems continuously treats and returns the water, this water must be disposed of properly because aquaculture waste contains high concentrations of nutrients.<sup>83</sup> The companies currently using enclosed land based recirculating systems are treating the effluent and using the sludge to fertilize farms.<sup>84</sup> This practice should be required by all facilities. *Therefore, petitioners recommend that USDA consult with EPA and assist EPA in developing a regulation addressing the environmentally safe methods of disposing of waste water.*

---

<sup>80</sup> Antimicrobial resistance, *supra* note 68. at 1-3.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> Murky Waters, *supra* note 27, at 80-83.

<sup>84</sup> *Id.* at 83.

#### D. USDA Must Comply With The Requirements Of The National Environmental Policy Act

The National Environmental Policy Act (“NEPA”) is the “basic national charter for protection for the environment.”<sup>85</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>86</sup> The duties under this section are not “inherently flexible.”<sup>87</sup> In fact, “[c]onsideration of administrative difficulty, delay or economic cost will not suffice to strip the section of its fundamental importance.”<sup>88</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>89</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 environment.<sup>90</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>91</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>92</sup>

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>93</sup> This statement - - known as an Environmental Impact Statement (“EIS”) - - must

---

<sup>85</sup> 40 C.F.R. § 1500.1.

<sup>86</sup> 42 U.S.C. § 4321.

<sup>87</sup> Calvert Cliffs Coordinating Comm. Inc. v. U.S. Atomic Energy Comm’n, 449 F.2d 1109 (D.C. Cir. 1971).

<sup>88</sup> Id.

<sup>89</sup> 40 C.F.R. § 1500.1(b),(c).

<sup>90</sup> 42 U.S.C. § 4331(a).

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

<sup>92</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>93</sup> 42 U.S.C. § 4332 (C).

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>94</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 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>95</sup> The “presence of one or more of these factors should result in an agency decision to prepare an EIS.”<sup>96</sup>

As mandated by Congress, USDA must comply with NEPA by preparing an EA/EIS before adopting any new policy or regulation involving the growing and commercialization of transgenic fish.<sup>97</sup> By adopting a new policy or regulation, USDA will be expending an “irreversible and irretrievable commitment of resources to an action that will affect the environment.”<sup>98</sup> This major federal action triggers NEPA review. *Therefore, petitioners request that USDA fully comply with the NEPA process prior to taking any action involving transgenic fish.*

---

<sup>94</sup> Id.

<sup>95</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 11991 (1977). See Andrus v. Sierra Club, 442 U.S. 347, 357 (1979). The Executive Order directed federal agencies to “comply with the regulations issued by the Council.” See id., quoting Executive 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>96</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>97</sup> “Major federal action” includes “[a]doption of official policy, such as rules, regulations, and interpretations,” “[a]doption of formal plans,” and “[a]doption of programs.” 40 C.F.R. § 1508.18(b)(1)-(3).

<sup>98</sup> Wyoming Outdoor Council v. U.S. Forest Service, 165 F.3d 43, 49 (D.C. Cir. 1999)(quoting Mobil Oil Corp. v. FTC, 562 F.2d 170, 173 (2d Cir. 1977)).



## CONCLUSION

For the reasons contained herein, the petitioners respectfully request that the USDA immediately impose a moratorium on the raising of transgenic fish in ocean pens or in any other device in the aquatic environment. Consistent with the National Aquaculture Policy Act's mandate of environmental stewardship, USDA should consult with the Department of Interior and the Department of Commerce about the potential environmental and human health impacts caused by transgenic fish. Should a review by these agencies show that transgenic fish will harm the environment, these agencies should amend the National Aquaculture Development Plan by banning the growing of transgenic fish in the aquatic environment. To ensure that transgenic fish do not harm the environment or human health, USDA should then initiate a rulemaking pursuant to the National Aquaculture Policy Act that mandates the following requirement for growing transgenic fish:

- (1) Specific facility design and operation requirements for enclosed land based recirculating systems; and
- (2) Specific requirements for the use of antibiotics

USDA should also consult with the Environmental Protection Agency ("EPA") and assist EPA in developing specific regulatory requirements for the disposal of waste water from enclosed land based recirculating systems. Finally, before adopting an official policy or regulation addressing transgenic fish, USDA must comply with the requirements of the National Environmental Policy Act. Petitioners request that the agency provide an answer to this citizen petition within 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,

---

Andrew Kimbrell  
Executive Director

---

Joseph Mendelson, III  
Legal Director

---

Tracie Letterman  
Staff Attorney

Center for Food Safety  
660 Pennsylvania Ave., S.E.  
Suite 302  
Washington, DC 20003  
(202) 547-9359

CC: Gale Norton  
Secretary  
U.S. Department of Interior  
1849 C St, NW  
Washington, DC 20240

Donald Evans  
Secretary  
U.S. Department of Commerce  
14<sup>th</sup> St. and Constitution Ave., N.W.  
Room 5854  
Washington, DC 20230

Christie Whitman  
Administrator  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460