

**CITIZEN PETITION BEFORE THE UNITED STATES
DEPARTMENT OF INTERIOR AND THE UNITED STATES
DEPARTMENT OF COMMERCE**

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

petitioners,)

v.)

Docket No. _____

GALE A. NORTON,)
in her official capacity as,)
Secretary)
U.S. Department of Interior)
1849 C St, NW)
Washington, DC 20240)

and)

DONALD L. EVANS,)
in his official capacity as,)
Secretary)
U.S. Department of Commerce)
14th St and Constitution Ave., N.W.)
Room 5854)
Washington, DC 20230)

**PETITION SEEKING A MORATORIUM ON ALLOWING
TRANSGENIC FISH IN THE ENVIRONMENT**

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution¹ and the Administrative Procedure Act,² petitioners file this petition with the U.S. Department of Interior (“DOI”) and the U.S. Department of Commerce (“DOC”) and respectfully request a moratorium on allowing transgenic fish³ in the environment until the DOI/DOC complete the following:

(1) Consult with the Food and Drug Administration (“FDA”), as required by the Endangered Species Act (“ESA”), before FDA approves the marketing of transgenic fish⁴:

- (i) Review the direct, indirect, and cumulative impacts to endangered and threatened species and their designated critical habitats;
- (ii) Prepare a biological opinion;
- (iii) Should the best scientific data available show harm to endangered species and their habitat, issue a finding of jeopardy and adverse modification; and
- (iv) Identify the reasonable and prudent alternative of banning all commercial growing of transgenic fish or in the alternative, ban the growing of transgenic fish in the aquatic environment;

(2) Comply with the requirements of the Lacey Act;

(3) Propose regulations implementing the Aquatic Nuisance Prevention and Control Act to prevent the introduction of transgenic fish into the aquatic environment;

(4) Report to Congress on the environmental damage likely to be caused by growing transgenic fish in the aquatic environment and DOI/DOC’s efforts to prevent and control the introduction of

¹ “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).

² 5 U.S.C. § 553(e) (1994).

³ 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.

⁴ Hereinafter, the term “transgenic fish” includes all transgenic fish and transgenic fish eggs.

transgenic fish; and

(5) Consult with USDA and, should this environmental review show that transgenic fish will harm the environment, amend the National Aquaculture Policy Act by banning the growing of transgenic fish in the aquatic environment.

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 7th 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 92nd 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 45th 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 18th Street NW, 5th 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 1st 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 18th Street, NW, 5th 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 21st 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.⁵ 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. 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.⁶ 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.⁷

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

⁵ Tony Reichhardt, Will souped up salmon sink or swim?, 406 Nature 10 (July 6, 2000)[hereinafter "Souped up Salmon"].

⁶ 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"].

⁷ Id.

currently being researched. The purpose of the petition is to identify the environmental concerns along with the regulatory requirements that must be addressed by DOI and DOC before any and all requests to commercialize transgenic fish are approved.

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. By FDA 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 that may be caused by the accidental release of transgenic fish into the environment.⁸ 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.⁹

Unintended releases of transgenic fish into the world’s waters will likely 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.¹⁰ 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.¹¹ 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

⁸ See *infra* pp. 16-23

⁹ 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.

¹⁰ See *infra* at pp.17-23.

¹¹ 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”].

(“ESA”).¹² Allowing transgenic fish in ocean pens may significantly increase this number of listed species.

DOI/DOC are responsible for conserving and protecting endangered and threatened species under the ESA.¹³ Moreover, the ESA requires every federal agency to “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. . . .”¹⁴ This provision unequivocally states that whenever a federal action may harm an endangered species or adversely modify critical habitat, the consultation requirement of the ESA is triggered. A/F Protein has already admitted that it cannot promise total safety¹⁵ and even FDA recognizes the harmful impact transgenic fish will have on native species.¹⁶ Any doubt about whether FDA should engage in an ESA consultation is removed by the DOI and DOC who acknowledge that transgenic fish may jeopardize the survival of endangered species and who repeatedly state that they need to be involved in deciding whether transgenic fish should be permitted in ocean pens.¹⁷

In addition to the ESA, DOI/DOC are required under the Aquatic Nuisance Prevention and Control Act to prevent the introduction of aquatic nuisance species, such as transgenic fish. Within this Act, Congress devised a Task Force consisting of several environmental agencies, including the DOI and DOC. Recognizing that nonindigenous aquatic species “may compete with or prey upon native species of plants, fish, and wildlife, may carry diseases or parasites that affect native species, and may disrupt the aquatic environment and economy of affected nearshore areas,” Congress authorized this Task Force to prevent and control the introduction of aquatic nuisance species and to annually report its efforts to Congress.¹⁸ Congress emphasizes the importance of *preventing* the establishment of harmful nonindigenous species within this Act because it found that “once nonindigenous species become established, it is nearly impossible to eliminate them from a receiving ecosystem.”¹⁹

¹² 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”].

¹³ 16 U.S.C. § 1533(f)(1994).

¹⁴ Id. § 1536(a)(2)(emphasis added).

¹⁵ 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”].

¹⁶ 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”].

¹⁷ See infra pp 23.

¹⁸ 16 U.S.C. §§ 4701(a)(2), 4722(k)(2).

¹⁹ 136 Cong. Rec. 6,455, 6,456 (1990).

After reviewing the potential dangers that may be caused by transgenic fish, the DOI has the authority to list injurious wildlife under the Lacey Act.²⁰ This Act prohibits importation into the U.S. of any wild species determined to be injurious to humans or to wildlife.²¹ In addition, if FDA prohibits the commercialization of transgenic fish, DOI and DOC have the authority under the Lacey Act to prevent the importing, exporting, transporting, selling, receiving, acquiring, or purchasing of transgenic fish.²² If FDA fails to prohibit the commercialization of transgenic fish, then DOI should exercise its authority under the Lacey Act by prohibiting the importation of transgenic fish. Finally, DOI and DOC are responsible under the National Aquaculture Policy Act for developing a plan to promote the development of aquaculture. This plan must be amended to ensure that transgenic fish do not destroy the environment or endangered species. Accordingly, petitioners request the DOI and DOC to immediately take the actions requested herein.

STATEMENT OF LAW

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

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

Aquatic Nuisance Prevention and Control Act, 16 U.S.C. § 4701, *et seq.*

Lacey Act, 16 U.S.C. § 3371, 18 U.S.C. § 42, *et seq.*

All other applicable statutes and regulations.

ARGUMENT

At the same time petitioners filed this petition, petitioners also filed a petition with FDA demanding that FDA comply with the requirements of the ESA by conducting a biological assessment and engaging in a formal consultation with DOI/DOC before approving the commercialization of transgenic fish.²³ As explained below, DOI/DOC are aware of the dangers to marine life if transgenic fish are permitted in ocean pens and have repeatedly warned FDA that they need to be part of the endangered species review process.²⁴

²⁰ 18 U.S.C. § 42; 50 C.F.R. § 16.13.

²¹ Id.

²² 16 U.S.C. § 3372(a)(1).

²³ Petitioners also requested FDA to impose a moratorium on the commercialization of transgenic fish until the agency complies with its responsibilities under the National Environmental Protection Act and enacts regulation under the Federal Food Drug and Cosmetic Act for adequate food safety testing, labeling, and monitoring, reporting and inspecting requirements for domestic producers and importers of transgenic fish.

²⁴ See infra pp 23.

If FDA fails to request DOI/DOC for a formal consultation, then in accordance with the regulatory provisions of the ESA, DOI/DOC should request a formal consultation with FDA.²⁵ After engaging in a formal consultation with FDA, DOI/DOC are required to issue a biological opinion.²⁶ Consistent with the best available scientific evidence, the biological opinion should find that listed species will be in jeopardy if transgenic fish are permitted in ocean pens or any other device within the marine environment. DOI/DOC should then identify the reasonable and prudent alternative of banning the commercialization of transgenic fish or in the alternative, banning the raising of transgenic fish in the marine environment. To adequately enforce this ban, DOI/DOC should propose regulations implementing the Aquatic Nuisance Prevention and Control Act, the National Aquaculture Development Plan, and the Lacey Act. Finally, in order for Congress to understand the dangers of transgenic fish in the environment, DOI/DOC should report its findings and actions to Congress.

I. ENDANGERED SPECIES ACT

As recognized by the Supreme Court, the ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”²⁷ Observing that “man and his technology has [sic] continued at an ever-increasing rate to disrupt the natural ecosystem,”²⁸ Congress intended for the ESA to “halt and reverse the trend toward species extinction, whatever the cost.”²⁹

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.³⁰ 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.”³¹ The DOI and DOC are responsible for taking affirmative steps to protect and recover listed species.³²

Section 7 of the ESA requires every federal agency to conserve species listed as endangered or

²⁵ 50 C.F.R. § 402.14(a). This petition serves as a 60 day notice letter in accordance with the citizen suit provisions of the ESA. 16 U.S.C. § 1540(g).

²⁶ Id. § 402.14(g)(4).

²⁷ Babbitt v. Sweet Home Chapter of Comm. for a Great Or., 515 U.S. 687, 698 (1995).

²⁸ 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., 1st Sess., 202 (1973)(statement of Assistant Secretary of the Interior).

²⁹ Id. at 184.

³⁰ 16 U.S.C. § 1538(a)(1) (1994).

³¹ Id. § 1532(19).

³² Id. § 1533(f).

threatened.³³ It also mandates that “in consultation with and with the Assistance of the Secretary,³⁴” 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 or result in the destruction or adverse modification of habitat of such species. . . .”³⁵

Before going forward with an action that may affect listed species, the federal agency must first prepare a biological assessment. Within the biological assessment, the agency must evaluate the direct and indirect 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.”³⁶ Only if the biological assessment concludes that the agency action will not adversely affect any listed species, and the Secretaries concur in writing, may the agency avoid the formal consultation requirement.³⁷

If an agency action may affect a listed species or critical habitat, then the federal agency must engage in a formal consultation and obtain a biological opinion from the Secretaries of DOI and DOC.³⁸ To adequately review the effects of the action, the federal agency must provide the Secretaries with “the best scientific and commercial data available.”³⁹ 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”⁴⁰ If the federal agency action is likely to jeopardize a listed species or adversely modify critical habitat of the species, then the Secretaries must identify alternatives.⁴¹

³³ Id. § 1536(a)(1); TVA v. Hill, 437 U.S. 153, 173 (1978).

³⁴ 16 U.S.C. § 1532(15) (explaining that Secretary means Secretary of Interior or Secretary of Commerce). See 50 C.F.R. §§ 222-224 (explaining jurisdiction for Secretary of Commerce); See Id. § 17.11 (explaining jurisdiction for Secretary of Interior); See Id. § 400 *et seq* (discussing joint jurisdiction).

³⁵ 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). Federal agencies must also confer with DOI/DOC when an agency action may affect a species proposed to be listed or a critical habitat proposed to be designed for the species. 16 U.S.C. § 1536(a)(4).

³⁶ 50 C.F.R. § 402.12(f).

³⁷ Id. § 402.13.

³⁸ 16 U.S.C. § 1536(b).

³⁹ 50 C.F.R. § 402.14(d).

⁴⁰ Id. § 402.14(g)(1)-(4).

⁴¹ 16 U.S.C. § 1536(b)(3)(A).

(A) Growing transgenic fish in the marine environment will likely threaten the survival of endangered and threatened species.

As explained below, transgenic fish will likely escape ocean pens and harm endangered species. 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.⁴² Based upon the scientific evidence, FDA is required under the ESA to initiate a formal consultation with DOI/DOC before FDA decides whether to approve the commercialization of transgenic salmon.⁴³

(1) Risk of transgenic fish escaping ocean pens.

Most salmon aquaculture is conducted in ocean pens. Although ocean pens may be cost effective for the industry, 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.”⁴⁴

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.⁴⁵ There are also several incidences of mass fish escapes. In 1990, approximately four million fish escaped from a fish farm in Norway.⁴⁶ Recently, over 170,000 farm raised salmon escaped from a net pen after a storm in Maine.⁴⁷ The Fish and Wildlife Service reports that “25-40% of the fish in the North Atlantic Ocean is of aquaculture

⁴² Id. § 1536(a)(2)(stating that an agency must “insure” that its actions will not jeopardize a listed species).

⁴³ Id.; Natural Resources Defense Council, et al. v. Houston, 146 F.3d 118, 1128 n.6 (9th Cir. 1998)(explaining that “the Bureau is not permitted to execute contracts that constitute an irreversible and irretrievable commitment of resources *during* the formal consultation, it also was not permitted to do so *before* it had initiated formal consultation.”); See 16 U.S.C. § 1536(d).

⁴⁴ 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.”).

⁴⁵ 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”].

⁴⁶ Walter Gibbs, Fish-Farm Escapees Threaten Wild Salmon, N.Y. Times, Oct. 1, 1996 at C4.

⁴⁷ 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.”⁴⁸ Weather, human error, and marine mammal and bird attacks⁴⁹ all contribute to the release of fish from ocean pens.⁵⁰ Recognizing that fish repeatedly escape from net pens, CEQ recently stated that it “must be assumed that escapes will occur” from net pens.⁵¹

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.⁵² 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.⁵³ Once transgenic fish are commercialized, there will likely be a great number of transgenic fish in the water. Given the high likelihood that transgenic fish, like other farmed raised fish, will escape from ocean pens in large numbers, endangered species and their habitats will likely be affected by the unprecedented growing of these animals in the wild.

(2) Risks of transgenic fish harming the genetic integrity of endangered species

Once transgenic fish escape from ocean pens, endangered species and species approaching “endangered species” status are likely to be severely impacted. Currently, there are many fish population levels that are rapidly decreasing. A recent study shows that there are already 82 species of fresh water fish in North American waters near extinction.⁵⁴ Moreover, the number on the endangered species list has reached 114 and includes populations of the chinook, chum, coho, and sockeye salmon.⁵⁵ Even the number of Atlantic salmon have dramatically decreased leading the DOI and DOC to recently list this species as endangered under the Endangered Species Act.⁵⁶ DOI/DOC stated that one of the reasons

⁴⁸ 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).

⁴⁹ 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”].

⁵⁰ 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).

⁵¹ CEQ Transgenic Salmon Study, supra note 9, at 23.

⁵² Questions and Answers, supra note 16 (stating that “No transgenic fish have been approved for producing food in the U.S.”).

⁵³ Altered Salmon, supra note 15.

⁵⁴ 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”].

⁵⁵ Listed Vertebrate Species, supra note 12.

⁵⁶ 65 Fed. Reg. 69459 (2000).

for the decline of this species is due to aquaculture. The agencies explained that 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.⁵⁷ Given the fragile state of fish populations and the aquatic ecosystems, allowing transgenic fish in ocean pens will likely result in further devastation of Atlantic salmon and other fish populations.

Additionally, impacts on predator species who consume transgenic fish must be considered.⁵⁸ Recognizing the importance of this environmental review, CEQ recently stated that how the growth hormone in certain transgenic fish will impact predator species should be considered.⁵⁹ There are 93 bird species and 13 marine mammal species that could be adversely affected by transgenic fish.⁶⁰

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.⁶¹ 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.”⁶² 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.⁶³ They refer to these disturbing results as the “Trojan gene effect.”⁶⁴

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.⁶⁵ However, one scientist who has conducted

⁵⁷ DOI and DOC, Guide to the Listing of a Distinct Population Segment of Atlantic Salmon as Endangered, 5,12-13 (Nov 2000).

⁵⁸ See CEQ Transgenic Salmon Study, supra note 9, at 23.

⁵⁹ Id.

⁶⁰ Listed Vertebrate Species supra note 12.

⁶¹ Trojan Gene Hypothesis, supra note 11, at 13853 - 13856.

⁶² Id.

⁶³ Id.

⁶⁴ 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.

⁶⁵ Altered Salmon, supra note 15, at A20.

experiments with transgenic fish discovered that growth-enhanced transgenic coho salmon are 50% larger at sexual maturity than wild fish.⁶⁶ 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%.⁶⁷ 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 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.⁶⁸ 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 FDA initiate a formal consultation with DOI/DOC.

In response to the concerns that transgenic fish may lead to species extinction, A/F Protein states that it will only sell transgenic fish that are sterile to be grown in net pens.⁶⁹ To sterilize fish, fertilized eggs receive heat or 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.⁷⁰

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.⁷¹ 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

⁶⁶ Souped up Salmon, supra note 5, at 11.

⁶⁷ 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”).

⁶⁸ R.H. 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).

⁶⁹ Altered Salmon, supra note 15, at A20.

⁷⁰ Souped up salmon, supra note 5, at 11

⁷¹ CEQ Transgenic Salmon Study, supra note 9.

variation.”⁷² Recently, CEQ released a study on transgenic fish.⁷³ This study revealed that 100% sterilization cannot be guaranteed.⁷⁴ FDA, DOI, and DOC who were part of the CEQ study, clearly recognize the uncertainty in sterilization.⁷⁵ 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 engage in a formal consultation with DOI/DOC before FDA approves the public commercialization of transgenic fish.

(3) Risk of transgenic fish harming the ecosystem of endangered species

Even if A/F Protein or any other producer of transgenic fish could guarantee that sterilization of transgenic fish will be 100% effective, transgenic fish that escape ocean pens will likely disrupt the ecosystem and as a result, harm endangered species and their critical habitats. 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.⁷⁶ Transgenic fish are non-native organisms that may cause serious environmental damage, including disrupting the habitat of endangered species. To prevent the introduction of an invasive species, FDA must review the ecological impacts that may be caused by transgenic fish by consulting with DOI/DOC.

Transgenic fish are different from wild salmon and may 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.⁷⁷ Even A/F Protein admits that its transgenic salmon consume more food

⁷² 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).

⁷³ CEQ Transgenic Salmon Study, supra note 9.

⁷⁴ Id. at 1, 31 (admitting that none of the sterilization techniques are 100% effective); 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).

⁷⁵ See CEQ Transgenic Salmon Study, supra note 9, 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.”).

⁷⁶ Exec. Order No. 13,112, 64 Fed. Reg. 6,183 (Feb. 8, 1999).

⁷⁷ Foraging behavior, supra note 68; Increased ability to compete, supra note 68, at 479 - 482 (explaining that transgenic coho salmon consumed almost three times the food of wild fish); CEQ Transgenic Salmon Study, supra note 9, 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.”).

than wild salmon.⁷⁸ One researcher observed that transgenic fish have “a revved-up metabolism. They’re hungry all the time.”⁷⁹ As a result, these transgenic fish could be foraging ravenously when food availability in an area is low out competing native fish.⁸⁰ Moreover, the fish being consumed by these aggressive hungry transgenic salmon predators may be impacted.⁸¹ One scientist warned that “[t]hey’re creating very, very large fish that will become predators of other fish.”⁸² 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.⁸³ As demonstrated by these scientific studies, transgenic fish will likely seriously disrupt the ecosystem and jeopardize endangered species by out competing wild fish for resources and habitat.⁸⁴

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.⁸⁵ Aquaculture waste accumulates below and around net pens and can deplete the oxygen in the water harming marine life.⁸⁶ Moreover, aquaculture waste can harm sensitive wetland areas that provide food and habitat and are vital to the

⁷⁸ 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.”).

⁷⁹ 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.”).

⁸⁰ Souped up salmon, supra note 5, at 11.

⁸¹ Genetic engineering creates supersalmon- and controversy, Seattle Times, Nov. 30, 1999.

⁸² Id.

⁸³ Rebecca Goldberg, Something Fishy, <http://www.environmentaldefense.org/pubs/reports/aquaculture/transgenic.html> (last modified May 2000); See CEQ Transgenic Salmon Study, supra note 9, at 22 (explaining that phenotypic changes that should be examined include tolerance to temperature).

⁸⁴ Ecological implications, supra note 45, at 60 - 61.

⁸⁵ 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.”).

⁸⁶ Murky Waters, supra note -, 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 78. 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).

survival of many species of birds and fish.⁸⁷

Aquaculture also introduces diseases and parasites that can affect wild populations.⁸⁸ Indeed, the primary cause of salmon mortality in Norwegian rivers is the monogenean fluke introduced by aquaculture.⁸⁹ 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. 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.⁹⁰ Pesticides are also used to control parasites.⁹¹ The effect of antibiotics and 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, including endangered species, will likely 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.”⁹² Taking this many fish will likely affect the balance of the ecosystem and impact many endangered species requiring FDA to consult with DOI/DOC. Although some of the ecological disruptions caused by transgenic fish are described above, the full extent of the harm that may be caused by these fish must be thoroughly reviewed by DOI/DOC before FDA approves the commercialization of transgenic fish.

(B) Before FDA can approve the commercialization of transgenic fish, a formal consultation must be initiated and a biological opinion prepared.

⁸⁷ Murky Waters, *supra* note 49, 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).

⁸⁸ 64 Fed. Reg. 62627, 62635 (Nov. 17, 1999); 65 Fed. Reg. at 69476-7.

⁸⁹ Ecological implications, *supra* note 45, 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.”).

⁹⁰ 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> (last modified July 14, 1998) (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 (Oct. 18, 1999) [hereinafter “Antimicrobial resistance”] (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.”).

⁹¹ Murky Waters, *supra* note 49, at 46-7 (explaining that the environmental effects from pesticides are not completely understood).

⁹² Nature’s Subsidies, *supra* note 85, at 884; *See* Farmed Fish Fed On Wild Caught Fish Products, Environment News Service, June 29, 2000, <http://ens.lycos.com/ens/jun200/2000I-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.”).

Based upon the scientific evidence demonstrating that endangered species are likely to be severely impacted by transgenic fish, FDA should engage in a formal consultation with DOI/DOC before approving the commercialization of transgenic fish. Additionally, FDA has already admitted several concerns about the impact of transgenic fish on marine life, 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.”⁹³ If FDA disregards the scientific evidence and its own concerns by failing to initiate a formal consultation, then in accordance with the regulatory requirements of the ESA, DOI/DOC should demand a formal consultation.⁹⁴

DOI/DOC have already repeatedly expressed their concerns about growing transgenic fish in the marine environment. For example, the National Marine Fisheries Service (“NMFS”), part of the DOC, warned FDA that it must be part of the environmental review, “We have to have absolute certainty that transgenic fish do not interact with wild stocks.”⁹⁵ NMFS explained further that FDA did not have the expertise to consider the environmental impacts of transgenic fish, including whether transgenic fish should be grown in ocean pens and that NMFS would need to be part of the review.⁹⁶ As for the DOI, it does not believe that “the potential impacts on nature have been thought through as well as they should be”⁹⁷ and fears that rare wildlife may be impacted by transgenic fish.⁹⁸ Concerned about the depleting numbers of Atlantic salmon, the DOI warned that this species could be “quickly wiped out if transgenic fish grown in nearby aquaculture farms escape their pens.”⁹⁹

Consistent with the scientific evidence and DOI/DOC’s concerns, the agencies should engage in a formal consultation and then issue a biological opinion finding that transgenic fish will jeopardize the continual existence of endangered and threatened species. In addition, DOI/DOC should recommend the “reasonable and prudent alternative” of banning the commercialization of all transgenic fish. DOI already stated that it wants “to ban all genetically modified salmon for now” in order to protect the declining Atlantic salmon population.¹⁰⁰ This action should be taken. In the alternative, DOI/DOC should recommend the alternative of banning the raising of transgenic fish in net pens or

⁹³ Questions and Answers, supra note 16.

⁹⁴ 50 C.F.R. § 402.14(a).

⁹⁵ Altered Salmon, supra note, at A20.

⁹⁶ Id.

⁹⁷ Id.; See Ecological Implications, supra, note 45, at 56-64.

⁹⁸ 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 [hereinafter “GMOs Pose New Risk”].

⁹⁹ Id.

¹⁰⁰ Marc Kaufman, Atlantic Salmon Placed on Endangered Species List, Wash. Post, Nov. 14, 2000.

in any other device in the aquatic environment. If the agency finds the use of transgenic fish acceptable, then it should limit such use only to the reasonable alternative of 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.¹⁰¹ Already, several aquaculture companies are successfully using this type of system for a variety of fish.¹⁰²

*Therefore, in accordance with the ESA, petitioners request that DOI/DOC review the direct, indirect, and cumulative impacts to endangered and threatened species and their critical habitat that may occur from the commercialization of transgenic fish. Consistent with the best available scientific data, DOI/DOC's biological opinion should find that transgenic fish will significantly jeopardize the population levels of species listed under the ESA. Due to this finding, DOI/DOC should recommend the reasonable and prudent alternative of banning the commercialization of transgenic fish or in the alternative banning the raising of transgenic fish in ocean pens or in any other device in the aquatic environment.*¹⁰³

II LACEY ACT

If FDA acts consistently with the best available scientific evidence and its responsibilities under the ESA by banning the commercialization of transgenic fish, then petitioners request that DOI and DOC enforce this ban under the Lacey Act. The Lacey Act authorizes DOI and DOC to prohibit the importing, exporting, transporting, selling, receiving, acquiring, or purchasing of fish that is taken, possessed, transported or sold in violation of a U.S. law.¹⁰⁴ To ensure that transgenic fish or transgenic fish eggs are not illegally grown and sold to consumers in violation of FDA's decision making authority, DOI and DOC should exercise its authority.¹⁰⁵

If, however, FDA fails to prohibit the commercialization of transgenic fish, then DOI should exercise its authority under the Lacey Act by prohibiting the importation of transgenic fish. The Lacey Act prohibits importation into the U.S. of any species of wild animal found by the Secretary of Interior to be "injurious to human beings, to the interests of agriculture, horticulture, forestry, or to wildlife or

¹⁰¹ *Id.* at 80-83. 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. 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.*

¹⁰² *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 recirculating systems.

¹⁰³ If DOI/DOC issue a biological opinion finding that endangered species will be in jeopardy by growing transgenic fish in ocean pens, then FDA must adopt an alternative action. As explained by the Supreme Court in Bennett v. Spear, this opinion has "powerful coercive effect." 520 U.S. 154, 169 (1997).

¹⁰⁴ 16 U.S.C. § 3372(a)(1).

¹⁰⁵ *Id.*

the wildlife resources of the United States.”¹⁰⁶ After conducting an ESA consultation and reviewing the best scientific data available, DOI will likely find that transgenic fish pose a risk to humans and/or ecological systems if they are permitted to be marketed to consumers. Consequently, DOI is authorized under the Lacey Act to prohibit the importation of transgenic fish into the U.S. *Therefore, petitioners request that DOI/DOC act in accordance with their statutory mandate under the Lacey Act.*

III. AQUATIC NUISANCE PREVENTION AND CONTROL ACT

If FDA allows the commercialization of transgenic fish but prohibits the growing of transgenic fish in net pens, then petitioners request that DOI/DOC enforce a ban on growing transgenic fish in the marine environment by utilizing the Aquatic Nuisance Prevention and Control Act of 1990 (“ANPCA”).¹⁰⁷ Congress enacted the ANPCA after finding that nonindigenous aquatic species “may compete with or prey upon native species of plants, fish, and wildlife, may carry diseases or parasites that affect native species, and may disrupt the aquatic environment and economy of affected nearshore areas.”¹⁰⁸ The ANPCA establishes the first national program to control the unintentional introduction of “aquatic nuisance species.”¹⁰⁹ An “aquatic nuisance species” is defined as “a nonindigenous species that threatens the diversity or abundance of native species or the ecological stability of infested waters, or commercial, agricultural, aquacultural or recreational activities dependent on such waters.”¹¹⁰ This Act seeks to prevent and control aquatic nuisance species because Congress found that “once nonindigenous species become established, it is nearly impossible to eliminate them from a receiving ecosystem.”¹¹¹

Within the ANPCA, Congress devised a Task Force consisting of several environmental agencies, including the DOI and DOC. This Task Force is responsible for preventing, monitoring, controlling, and researching the introduction of aquatic nuisance species.¹¹² If the Task Force determines that there is “a substantial risk of unintentional introduction of an aquatic nuisance species by an identified pathway and that the adverse consequences of such an introduction are likely to be substantial,” then the Task Force is responsible for minimizing the risk of an introduction by

¹⁰⁶ 18 U.S.C. § 42(a)(1); 50 C.F.R. § 16.13. Congress intended the Lacey Act to broadly apply to any species of wild fish that the Secretary of Interior finds to be injurious. See 18 U.S.C. § 42(a)(1); See Id. § 42(a)(2)(defining the term “wild” to include any creature normally found in a wild state even if the animal is raised in captivity).

¹⁰⁷ Pub. L. No. 101-646, 104 Stat. 4761 (1990), *amended by* The National Invasive Species Act of 1996, Pub. L. No. 104-332, 110 Stat. 4073 (1996).

¹⁰⁸ 16 U.S.C. § 4701(a)(2).

¹⁰⁹ 136 Cong. Rec. 6,455, 6,457 (1990).

¹¹⁰ 16 U.S.C. § 4702(1); See 136 Cong. Rec. at 6459.

¹¹¹ 136 Cong Rec. 6,455, 6,456 (1990)

¹¹² 16 U.S.C. § 4722.

coordinating “environmentally sound efforts with regional, State and local entities.”¹¹³ In order to effectively prevent and control aquatic nuisance species, Congress authorizes DOI and DOC with the authority to implement regulations.¹¹⁴

(A) Implementation of the Aquatic Nuisance Prevention and Control Act

As explained above, transgenic fish will easily escape ocean pens and when they do, they will likely weaken the genetic integrity of the species and severely disrupt the ecosystem. As a result, native salmon populations will face possible extinction. Additionally, by reducing biodiversity and the abundance of fish species, commercial and recreational interests will be impeded. Due to the potential impact to the survival of native species and to commercial and recreational interests, transgenic fish are precisely the type of “aquatic nuisance species” that Congress intended to prevent from entering the nation’s waters.¹¹⁵

The Task Force should first find that ocean pens are highly susceptible to breakage and therefore, ocean pens are an “identifiable pathway” leading to the unintentional introduction of the aquatic nuisance species, transgenic fish.¹¹⁶ In order to further the purposes of the ANPCA, the Task Force must devise cooperative and environmentally sound monitoring measures with regional, state, and local entities to ensure that transgenic fish are not grown in ocean pens.¹¹⁷ Moreover, if transgenic fish are approved to be grown in land based systems, then the Task Force should also monitor these facilities to ensure that there are not accidental releases of transgenic fish into the aquatic environment. Utilizing the ANPCA is essential for preventing the introduction of transgenic fish into the aquatic environment.

Therefore, petitioners request that DOI and DOC implement the ANPCA by proposing monitoring regulations, reviewable and subject to public comment, to ensure that transgenic fish are not grown in ocean pens or accidentally released from land based systems.

(B) Report to Congress on the efforts to prevent and control the introduction of transgenic fish into the marine environment.

Also within the ANPCA, the Task Force is required to annually report to Congress describing

¹¹³ Id. § 4722(c)(2).

¹¹⁴ Id. § 4722(j). Congress also authorizes the Secretary of Transportation to implement regulations. Id.

¹¹⁵ See Id. § 4702(1).

¹¹⁶ See Id. § 4722(c)(A).

¹¹⁷ See 16 U.S.C. § 4722(c).

its efforts in preventing and controlling aquatic nuisance species.¹¹⁸ Congress should be provided with the information showing that transgenic fish are likely to significantly harm endangered species and the environment if introduced into the aquatic environment. In addition, DOI/DOC's utilization of the ANPCA to prevent and control the introduction of transgenic fish should be thoroughly explained.

Therefore, petitioners request that DOI/DOC issue a report to Congress describing the environmental damage likely caused by transgenic fish if these fish were permitted in the aquatic environment and DOI/DOC's efforts to prevent and control this aquatic nuisance species.

IV. National Aquaculture Policy Act

Petitioners also request that DOI/DOC exercise their statutory authority by prohibiting the growing of transgenic fish in net pens under the National Aquaculture Policy Act ("NAPA"). Congress enacted the NAPA in 1980 to prevent the dramatic decline of wild fish and to promote the use, acceptance, and development of aquaculture.¹¹⁹ Congress found that "many of our traditional stocks of marine resources are declining from overfishing, pollution, and many other pressures"¹²⁰ and the "only logical way to counteract such a perilous trend is to learn how to manage living aquatic resources."¹²¹ Congress designated DOI, DOC, and the U.S. Department of Agriculture ("USDA") as the agencies responsible for developing a National Aquaculture Development Plan (hereinafter "Plan").¹²²

Consistent with the National Aquaculture Policy Act's mandate of environmental stewardship,¹²³ DOI and DOC should consult with USDA and based upon this review and the best scientific evidence available amend the 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

¹¹⁸ Id. § 4722(k)(2). See Id. § 2804(d)(explaining that USDA, DOI, and DOC are responsible for issuing biennial reports on the status of aquaculture).

¹¹⁹ 16 U.S.C. § 2801, *et seq.* (1994).

¹²⁰ 126 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.

¹²¹ at 9,440.Id.

¹²² Id. §§ 2803-4.

¹²³ 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, <http://ag.ansc.purdue.edu/aquanic/jsa/Strategicplan.htm> (last visited Mar. 29, 2000); Joint Subcommittee on Aquaculture, Draft National Aquaculture Development Plan of 1996 Joint Subcommittee on Aquaculture National Science and Technology Council, <http://ag.ansc.purdue.edu/aquanic/publicat/govagen/usda/dnadp.htm> (last visited Mar. 29, 2000).

further support.”¹²⁴ As explained in detail above, furthering the use of transgenic fish in the aquatic environment does not warrant any support. *Therefore, petitioners request that DOI/DOC consult USDA and amend the Plan by banning the growing of transgenic fish in the aquatic environment.*

CONCLUSION

For the reasons contained herein, the petitioners respectfully request that FDA impose a moratorium on allowing transgenic fish in the environment and initiate the following actions:

(1) Consult with the Food and Drug Administration (“FDA”), as required by the Endangered Species Act (“ESA”), before FDA approves the marketing of transgenic fish;

- (i) Review the effects of the action and the cumulative impacts to endangered and threatened species;
- (ii) Prepare a biological opinion;
- (iii) Should the best scientific data available show harm to endangered species and their habitat, issue a finding of jeopardy and adverse modification; and
- (iv) Identify the reasonable and prudent alternative of banning all commercial growing of transgenic fish or in the alternative, ban the growing of transgenic fish in the aquatic environment;

(2) Comply with the requirements of the Lacey Act;

(3) Propose regulations implementing the Aquatic Nuisance Prevention and Control Act to prevent the introduction of transgenic fish into the aquatic environment;

(4) Report to Congress on the environmental damage likely to be caused by growing transgenic fish in the aquatic environment and DOI/DOC’s efforts to prevent and control the introduction of transgenic fish; and

(5) Consult with USDA and should this environmental review show that transgenic fish will harm the environment, amend the National Aquaculture Policy Act by banning the growing of transgenic fish in the aquatic environment.

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,

¹²⁴ 16 U.S.C. § 2803(d)(3).

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