DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

[Docket No. FDA–2011–N–0899]

GeneWatch UK comments on: Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Availability

February 2013

GeneWatch UK is a not-for-profit organisation based in the United Kingdom. Our aim is to ensure that genetic science and technologies are used in the public interest. We welcome the opportunity to respond to this consultation.

Wild Atlantic salmon are found in the North Atlantic on both European (Portugal to Russia) and North American (Cape Cod to Labrador) sides, including around North Atlantic islands such as the UK. The Atlantic salmon (*Salmo salmar*) is on the Oslo and Paris Convention (OSPAR) List of Threatened and/or Declining Species and Habitats (covering the North-East Atlantic region) and is also listed in Annexes II and V of the European Union's Habitats Directive as a species of European importance. The issue of the environmental impacts which may be caused by the approval of the application is therefore a matter of international importance. This is especially the case in relation to the failure to secure shipments of GE eyed-eggs, which might lead to widespread dispersal of such eggs in the environment, and the failure to properly describe or account for the United States' and Canada's obligations under the North Atlantic Salmon Conservation Organization (NASCO).

GeneWatch UK disagrees with the FDA's proposal to issue a Finding of No Significant Impact (FONSI) in response to AquaBounty's application, on the following grounds:

(1) The FDA has misinterpreted the national and international obligations of USA and Canada in protecting the marine environment and wild salmon populations, including the obligations under NASCO;
(2) The application is premature in the absence of a decision to authorise production in both Canada and Panama, and risks prejudicing these decisions and undermining the role of US Agencies in the protection of wild salmon, including within NASCO;
(3) The application's scope is wrongly defined since the company does not propose to import eyed-eggs (or any live stage of the fish) into the United States;
(4) Measures for physical containment are inadequate, particularly the failure to secure shipments of eyed-eggs;
(5) There are no measures for traceability, labelling of the final product, or for post-market monitoring;
(6) Measures proposed to achieve single-sex sterile female fish are incorrectly treated purely as a risk reducing ("biological containment") measure, wrongly ignoring concerns that the release of sterile or partially sterile fish can impact adversely on wild salmon populations by altering the population dynamics of these species;
(7) Relevant studies and data are omitted or unavailable, to the extent that it is impossible to determine potential environmental impacts, including impacts on endangered wild salmon populations;
(8) Risks which do not in reality exist have been wrongly attributed to the No Action Alternative, due to a failure to appreciate relevant Conventions, laws and regulations applicable to GMOs in other countries.

The FDA has misinterpreted the international obligations of USA and Canada

Ministerpretation of the US and Canada's legal obligations under the Convention for the Conservation of Salmon in the North Atlantic Ocean

The Convention for the Conservation of Salmon in the North Atlantic Ocean entered into force on 1 October 1983 and created an inter-governmental organization, the North Atlantic Salmon Conservation Organization (NASCO). Both Canada (where the eyed-eggs are to be produced) and the USA (where the final product is to be imported) are Parties to NASCO and are the two members of its North American Commission.

The objective of NASCO is to "*contribute through consultation and co-operation to the conservation, restoration, enhancement and rational management of salmon stocks subject to this Convention, taking into account the best scientific evidence available to it*" (Article 3(2)).[1]

NASCO and its Contracting Parties have agreed to adopt and apply a Precautionary Approach to the conservation, management and exploitation of salmon in order to protect the resource and preserve the environments in which it lives.[2] In this context, NASCO has adopted a Plan of Action for the Application of the Precautionary Approach to the Protection and Restoration of Atlantic Salmon Habitat with the aim of protecting the remaining salmon habitat and restoring as much as possible of the lost and degraded habitat.[3]

NASCO's 'Williamsburg Resolution' is designed to minimise impacts of aquaculture, introductions and transfers and transgenics on the wild stocks.[4] Article 7 of the Williamsburg Declaration states:

"*The Parties should apply the Guidelines for Action on Transgenic Salmon, CNL(97)48 (Annex 5), to protect against potential impacts from transgenic salmonids on wild salmon stocks. In view of the current lack of scientific knowledge on the impact of transgenic salmonids on wild salmon stocks, the use of transgenic salmonids should be considered a high-risk activity. There should be a strong presumption against any such use*." [Emphasis added]

The text of Annex 5 is reproduced below in full:

"*Annex 5*
NASCO Guidelines for Action on Transgenic Salmonids, CNL(04)41
THE PARTIES to NASCO are aware of the development of transgenic salmonids. While there may be benefits from the introduction of such salmonids if, for example, they could not interbreed with wild stocks the Council recognises that there are also risks which may lead to irreversible genetic changes and ecological interactions.
The Council considers that there is an urgent need to take steps to ensure the protection of the wild stocks and has therefore agreed to cooperate to develop means such that transgenic salmonids cannot impact upon wild salmon stocks. The following specific steps are agreed.
The Parties will:
a) advise the NASCO Council of any proposal to permit the rearing of transgenic salmonids and provide details of the proposed method of containment and other measures to safeguard the wild salmon stocks;
b) take all possible actions to ensure that the use of transgenic salmonids, in any part of the NASCO Convention Area, is confined to secure, self-contained, land-based facilities;
*c) inform their salmon producers of the potentially serious risks to wild stocks of this development and consult with the salmon farming industry on this matter through the Liaison Group established between NASCO and the international salmon farming industry;**

d) take steps, as appropriate, to improve knowledge on the potential impacts of transgenic salmonids on the wild salmon stocks and their habitat;
e) examine the trade implications associated with transgenic salmonids in accordance with World Trade Organization Agreements and other instruments of international law.
Furthermore, those Parties to NASCO that are also Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity should take into account the provisions of that Protocol.
**Note: At its Seventeenth General Meeting in Galway, Ireland, in September 1996, the International Salmon Farmers Association (ISFA) adopted its Policy on Transgenic Salmon, which states that "In accordance with sound environmental practices, the ISFA firmly rejects transgenic salmon production*."

Annex 7 of the Williamsburg Declaration covers Research and Development and Data Collection. It notes: "*There remains a need to identify the appropriate factors to be included in a risk assessment in order to evaluate the potential impacts of aquaculture, introductions and transfers, and transgenics on wild salmon stocks*." Identified research needs include, for example, that "*Further work is recommended on biological interactions between wild salmon and salmon of aquaculture origin including competition and behavioural interactions that may affect the viability and success of the wild populations*."

The draft Environmental Assessment (page 11) cites the part of Annex 5 of the Williamsburg Declaration which refers to "*secure, land-based facilities*" but does not cite Article 7 which states there should be a "*strong presumption against*" <u>any</u> use of transgenic salmonids and refers to their introduction as "*high risk*". This is a misrepresentation of the agreement, which is compounded by the claim on page 94 of the draft EA that this resolution calls <u>for</u> rearing of transgenic (i.e., GE) salmon in secure, self-contained, land-based facilities.

In addition, the FDA fails to take account of its full obligations under NASCO and the importance of not prejudicing Canada's decision on such matters (discussed further below) or undermining the role of US Agencies in supporting and implementing the agreement.

In summary, the United States' and Canada's international obligations under NASCO include:

- A "strong presumption against" the use of GE salmon (Article 7 of the Williamsburg Declaration);
- The adoption of a precautionary approach;
- The need to restore (not just protect) habitat;
- Implementing <u>all</u> the actions required by Annex 5 of the Williamsburg Declaration;
- Fulfilling the research needs identified in Annex 7.

The FDA's proposal to issue a FONSI considers only some aspects of Annex 5 of the Williamsburg Declaration (the need for physical containment) and ignores all other aspects. Further, it fails to take "all possible steps" to ensure physical containment (discussed further below).

US international obligations under the National Environmental Policy Act

The National Environmental Policy Act (NEPA) sets up procedural requirements for all federal government agencies, including the FDA, to prepare environmental assessments (EAs) and environmental impact statements (EISs).[5] The preliminary FONSI states (page 4) that "*NEPA does not require an analysis of effects in foreign sovereign countries*". However, NEPA does require all agencies of the Federal Government to "*recognize the worldwide and long-range character of environmental problems and, where consistent with the foreign policy of the United States, lend*

appropriate support to initiatives, resolutions, and programs designed to maximize international cooperation in anticipating and preventing a decline in the quality of mankind's world environment" (Section 102 (F)).

The FDA's Environmental Impact Regulations are contained in 21 CFR Part 25.[6,7] Obligations abroad are covered by 21 CFR 25.60 (Environmental effects abroad of major agency actions). Executive Order 12114--Environmental effects abroad of major Federal actions[8] represents the United States government's exclusive and complete determination of the procedural and other actions to be taken by Federal agencies to further the purpose of the NEPA, with respect to the environment outside the United States, its territories and possessions. This states, inter alia:

2-3. Actions Included. Agencies in their procedures under Section 2-1 shall establish procedures by which their officers having ultimate responsibility for authority and approving actions in one of the following categories encompassed by this Order, take into consideration in making decisions concerning such actions, a document described in Section 2-4(a):

(a) major Federal actions significantly affecting the environment of the global commons outside the jurisdiction of any nation (e.g., the oceans or Antarctica);

(b) major Federal actions significantly affecting the environment of a foreign nation not participating with the United States and not otherwise involved in the action;

(c) major Federal actions significantly affecting the environment of a foreign nation which provide to that nation:

(1) a product, or physical project producing a principal product or an emission or effluent, which is prohibited or strictly regulated by Federal law in the United States because its toxic effects on the environment create a serious public health risk; or

(2) a physical project which in the United States is prohibited or strictly regulated by Federal law to protect the environment against radioactive substances.

(d) major Federal actions outside the United States, its territories and possessions which significantly affect natural or ecological resources of global importance designated for protection under this subsection by the President, or, in the case of such a resource protected by international agreement binding on the United States, by the Secretary of State. Recommendations to the President under this subsection shall be accompanied by the views of the Council on Environmental Quality and the Secretary of State.

2-4. Applicable Procedures. (a) There are the following types of documents to be used in connection with actions described in Section 2-3:

(i) environmental impact statements (including generic, program and specific statements);

(ii) bilateral or multilateral environmental studies, relevant or related to the proposed action, by the United States and one or more foreign nations, or by an international body or organization in which the United States is a member or participant; or

(iii) concise reviews of the environmental issues involved, including environmental assessments, summary environmental analyses or other appropriate documents.

(b) Agencies shall in their procedures provide for preparation of documents described in Section 2-4(a), with respect to actions described in Section 2-3, as follows:

(i) for effects described in Section 2-3(a), an environmental impact statement described in Section 2-4(a)(i);

(ii) for effects described in Section 2-3(b), a document described in Section 2-4(a)(ii) or (iii), as determined by the agency;

(iii) for effects described in Section 2-3(c), a document described in Section 2-4(a)(ii) or (iii), as determined by the agency;

(iv) for effects described in Section 2-3(d), a document described in Section 2-4(a)(i), (ii) or (iii), as determined by the agency.

Such procedures may provide that an agency need not prepare a new document when a document described in Section 2-4(a) already exists.

The FDA's proposal to issue a FONSI has failed to pay the necessary attention to these requirements to protect the global commons and the environments of states not participating in the action, including the UK and other members of the NASCO.

Failure to meet obligations under the Endangered Species Act (ESA)

The FDA has made a "no effect" determination under the Endangered Species Act (ESA), 16 USC § 1531 et seq., that approval of the AquAdvantage Salmon NADA will not jeopardize the continued existence of United States populations of threatened or endangered Atlantic salmon, or result in the destruction or adverse modification of their critical habitat, when produced and reared under the conditions described within the draft EA (page 4). This does not appear to be consistent with the legal obligations under the ESA.

The purposes of the Endangered Species Act (ESA) are "*to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes of the treaties and conventions set forth in subsection (a) of this section"* (Section 2(b))[9]. Relevant international agreements include NASCO agreements. The Act provides the legal basis for protective regulations and for recovery plans.

The ESA provides for international cooperation (Section 8): "*In order to carry out further the provisions of this Act, the Secretary, through the Secretary of State shall encourage—*
(1) foreign countries to provide for the conservation of fish or wildlife and plants including endangered species and threatened species listed pursuant to section 4 of this Act;
(2) the entering into of bilateral or multilateral agreements with foreign countries to provide for such conservation; and
(3) foreign persons who directly or indirectly take fish or wildlife or plants in foreign countries or on the high seas for importation into the United States for commercial or other purposes to develop and carry out with such assistance as he may provide, conservation practices designed to enhance such fish or wildlife or plants and their habitat" and allows staff and resources to be appointed to achieve this aim. Further: "*After consultation with the Secretary of State and the Secretary of the Treasury, as appropriate, the Secretary may conduct or cause to be conducted such law enforcement investigations and research abroad as he deems necessary to carry out the purposes of this Act*".

Historically, Atlantic salmon were native to nearly every major river north of the Hudson River, however by the mid-20th Century, the total adult run of Atlantic salmon to U.S. rivers had declined from hundreds of thousands of fish in the early part of the previous century to a probable range of 500 to 2,000 fish, mostly in rivers in eastern Maine.[10] The Gulf of Maine Distinct Population Segment (DPS) of Atlantic Salmon (*Salmo salmar*) is regarded as an endangered species under the ESA[11] and a number of recovery and conservation plans have been put in place.[12] Salmon in this DPS migrate northwards from Maine into Canadian and international waters, including waters in the general vicinity of AquaBounty's Prince Edward Island (PEI) facility.[13]

In 2003, the National Marine Fisheries Service (NMFS) analysed the effects from continued operations of commercial Atlantic salmon aquaculture facilities in Maine. This led to the introduction of protective measures including: 1) use only local North American salmon stocks for production; 2) implementation of containment measures to reduce escapes; 3) audits and reporting requirements; 4) prohibitions on stocking transgenic salmon, and; 5) marking all farmed salmon placed in marine pens within the United States. As a result existing federal and State of Maine permits prohibit rearing transgenic salmon for commercial aquaculture within the United States. These measures

have been reported to NASCO by the USA in its Implementation Plan for the period 2013-18 (Sections 4.4 and 4.5) as demonstrating compliance with the Williamsburg declaration.[14]

In its 2010 Aquaculture Focus Area Review (FAR) submitted to NASCO (Section 2: Implementation of the Williamsburg Declaration), the United States provided more details on the background to the decision to prohibit rearing transgenic salmon in sea pens in the United States, which followed from a 2003 Biological Opinion and consultation with the NMFS. In relation to the AquaBounty application, the FAR reports that the Services (presumably the NMFS and the Fish and Wildlife Service, FWS) have notified the FDA that a consultation is required under the federal ESA to determine the potential impacts of this application on endangered Atlantic salmon.

Wild populations of Atlantic salmon are not the only relevant salmonid populations that need to be considered, because Pacific salmon populations might also be impacted by an escape of GE salmon into the Pacific. According to the Fish and Wildlife Service, the winter-run chinook salmon originating in California's Sacramento River was listed as threatened in 1990, but was reclassified to endangered in 1994. In 1992, the Snake River stock of sockeye salmon was listed as endangered wherever found. The spring-summer and fall runs of chinook originating in Idaho's Snake River were listed as threatened in 1992.[15] The Service now lists endangered and threatened populations for Sockeye salmon (*Oncorhynchus nerka*)[16] in Idaho, Oregon and Washington; Coho salmon (*Oncorhynchus kisutch*)[17] in California, Oregon and Washington; Chinook salmon (*Oncorhynchus tshawytscha*)[18] in Idaho, Oregon, Washington and California; and Chum salmon (*Oncorhynchus keta*)[19] in Oregon and Washington. Populations of steelhead trout (Salmon trout/Rainbow trout) (*Oncorhynchus mykiss*) are also listed as endangered or threatened in Washington, Oregon and California.

Letters from the FWS and NMFS to the FDA, regarding the Endangered Species Act and its application to the endangered Gulf of Maine distinct population segment of Atlantic salmon (*Salmo salar*) have been included in Appendix D of the draft EA. The FWS supports the FDA's "no effect" determination, based on the requirement that the fish would be produced only at the land-based facilities in Canada and Panama named in the application, and the NMFS states that it "better understands" it.

The FDA is proposing issuing a FONSI based on these statements, without (i) prior approvals and assessments of environmental aspects from the proposed facilities in Canada and Panama (discussed further below); (ii) implementing in full the requirements of the NASCO Williamsburg Declaration (and requiring Canada, to do so, see below); (iii) addressing important the gaps in data and scientific understanding (discussed further below) and (iv) obtaining full approval from the NMFS. This does not appear to be consistent with the Agency's legal obligations under the Endangered Species Act.

The application is premature

The application is for import into the United States of fish meat and products and includes no proposal to produce or import any live stage of the fish.

The eyed-eggs referred to as the commercial product, and the other stages of live fish production described in the application, are intended to be produced in Canada and Panama. However, no application for approval of production or export has been published in Canada or Panama, nor has any assessment of health or environmental impacts. No application or approval for import and commercial production (grow out and production of commercial products) been published yet in Panama.

The FDA's proposed FONSI is based on a presumption that the relevant Canadian and Panamanian authorities will consider and approve commercial production of AquaBounty's GE salmon and that these regulatory processes will not materially alter either the information and evidence available or the conditions of production. These are incorrect assumptions which are prejudicial to decisions which have not yet been made in other countries.

The FONSI prejudges Canada's decision under its legal framework and international obligations

Canada is a Party to NASCO and is thus bound by the Williamsburg Declaration. Unlike Panama (discussed below), Canada is not a Party to the Cartagena Protocol on Biosafety (CPB).

Canada has not submitted a 2013 - 2018 Implementation Plan to NASCO, however it did submit 2010 Focus Area Report (FAR) on Fisheries, Habitats and Aquaculture[20] and a 2010 Aquaculture FAR, in which Canada informed NASCO that there was currently no use of transgenic fish in commercial salmonid aquaculture in Canada, although in PEI, there were transgenic fish in land-based closed containment systems for research purposes (Section 2.8).[21]

Canada has made no statement to the effect that it intends to breach the "*strong presumption against*" commercial production of transgenic salmon outlined in the Williamsburg Declaration. The decision by the FDA to issue a FONSI prejudges this important decision and, in addition, undermines the role of US Agencies in supporting the Williamsburg Declaration.

The draft EA not only fails to cite the "strong presumption against" commercial production of GE salmon, it also (Section 6.1.1.3, p.59-60) refers to the loss of Atlantic salmon runs from the area near the Prince Edward Island (PEI) facility, and the degraded local habitat as circumstances that mitigate the risks posed by the potential escape of GM salmon from the productions facility. Yet, under NASCO, Canada (in consultation with the US as the other member of its North American Commission) is obliged to adopt a strategy for restoration of salmon habitat, not merely to assume (as the draft EA does) that salmon will never be re-established there.

In addition, the adoption of the FONSI implies that all the steps required by Annex V of the Williamsburg have been undertaken, and that the research needs included in Annex 7 have been met. Annex V requirements which have not yet been undertaken include, *inter alia*, consulting with the salmon farming industry, improving knowledge through research (e.g. on biological interactions), and examining trade implications.

Should the Canadian authorities choose to consider an application despite Canada's NASCO obligations, the change of use of the PEI facility from R&D to commercial production of AquaBounty's GE salmon eyed-eggs will require the provision of information and assessment specified under Canada's New Substances Notification Regulation (Organisms)[22, 23] This regulatory process will require provision by the applicant of detailed information on, *inter alia*, the GE organism's interactions with other organisms in the environment. Again, the FDA's proposal to issue a FONSI appears to prejudge Canada's approval process and decision, which might lead to the production of new information and data and either the refusal or approval of the application, perhaps on the basis of conditions which differ from those in the company's current application to the FDA.

Other relevant Canadian federal legislation includes the Canadian Environmental Protection Act (CEPA), the Species at Risk Act (SARA), and the Oceans Act.[24]

The Canadian Environmental Protection Act, 1999, requires the Government of Canada, *inter alia*, to exercise its powers in a manner that protects the environment and human health, applying the precautionary principle; endeavour to act in cooperation with governments to protect the environment; encourage the participation of the people of Canada in the making of decisions that affect the environment; protect the environment, including its biological diversity, and human health, by ensuring the safe and effective use of biotechnology; and endeavour to act with regard to the intent of intergovernmental agreements (Article 2).[25]

Canada's Species at Risk Act (SARA) requires that the best available knowledge be used to define long- and short-term objectives in a recovery strategy for endangered and threatened species and it provides for action plans to identify specific actions.[26] It also creates prohibitions to protect listed threatened and endangered species and their critical habitat. The purposes of the SARA are to prevent Canadian indigenous species, subspecies and distinct populations of wildlife from becoming extirpated or extinct, to provide for the recovery of endangered or threatened species, and to encourage the management of other species to prevent them from becoming at risk.

Under the SARA[27] a number of subpopulations of Atlantic salmon (*Salmo salar*) and other salmon and trout species (that might in theory be impacted by release or escape of GE salmon) have been listed by the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) as of special concern, or endangered[28,29,30,31,32,33,34]. Not all listed populations attain legal status as protected under SARA. However, the Atlantic salmon Inner Bay of Fundy (iBoF) population (on the northeast end of the Gulf of Maine) has legal status under SARA as endangered.[35] Canada's DFO has a recovery strategy in place under the SARA for Inner Bay of Fundy Salmon.[36]

Canada's Oceans Act defines its maritime zones and oceans management strategy, including provisions for the creation of marine protected areas.[37] Federal protected areas include Basin Head Marine Protected Area: a shallow coastal lagoon located on the eastern tip of Prince Edward Island, near the town of Souris.[38]

Fisheries and Oceans Canada's has an R&D programme Regulatory Science for Aquatic Animals with Novel Traits[39] and an R&D development strategy.[40] However, the relevant reports suggest that the building of capacity and knowledge for regulatory assessment is far from complete. Canada will also need to consider the research needs identified in Annex 7 of the NASCO Williamsburg Declaration before making a determination on any AquaBounty application.

In summary, the FDA's proposal to issue a FONSI appears to prejudge the necessary process of environmental assessment within Canada, including its timing, content, outcome and research needs, as well as the need to complete the prior actions required under NASCO. Canada has yet to provide a justification for breaching the strong presumption against commercial production of transgenic salmon under NASCO.

The FONSI prejudges Panama's decision under its own legal framework and international obligations

The proposed decision to issue a FONSI also treats approval of production of AquaBounty's GE salmon in Panama as a foregone conclusion. This is not the case.

Panama is not a Party to NASCO but is a Party to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD). Panama has adopted legislation on the transboundary movement (import/export), contained use, intentional introduction into the environment, transit, risk assessment and management, handling, transport, packaging and identification of genetically

modified organisms (GMOs) consistent with its international obligations under the CPB.[41] It has also established a national biosafety website.[42] Panama has yet to conduct any risk assessments for the open release of GMOs.

In considering any application for the production of AquaBounty's GE salmon in Panama, the Panamanian authorities will have to take account of national legislation and international obligations. If they agree to consider such an application, it is likely that the Panamanian authorities will require further information from the company before making a decision. The proposal by the FDA to issue a FONSI risks prejudicing this process, including the possible publication of new information, and the ultimate decision, which might be to approve or reject the application, or to apply additional or amended conditions which differ from those set out in AquaBounty's current application to the FDA.

In addition, Panama may choose not to consider AquaBounty's application because in doing so it will have to take due account of the CPB's *de facto* moratorium on Genetic Use Restriction Technologies (GURTs). The use of triploidy to create (partially) sterile GE fish falls within the definition of a GURT (or 'Terminator' technology). According to the United Nations Food and Agriculture Organisation (FAO): "*The acronym GURTs stands for genetic use restriction technologies and refers to biotechnology-based switch mechanisms to restrict the unauthorized use of genetic material. Two types of GURTs can be distinguished: variety use restriction (V-GURTs), rendering the subsequent generation sterile (the so-called "terminator" technologies), and use restriction of a specific trait (T-GURTs), requiring the external application of inducers to activate the trait's expression*".[43] GURTs have been discussed extensively by the CBD and FAO and, whilst much research has focused on plants, it has long been recognised that GURTs can be built into any organism, including fish, through mechanisms which include (but are not limited to) triploidy.[44,45] The use of GURTs in animals is an active topic of research and development: for example, AquaBounty has a patent covering maternal sterility mechanisms in animals including fish, arthropods, amphibians, molluscs and crustacea.[46]

The CBD's decision on GURTs, made at the 5th Conference of the Parties (COP)[47] :

Recommends that, in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, inter alia, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated. In order to enhance the capacity of all countries to address these issues, Parties should widely disseminate information on scientific assessments, including through the clearing-house mechanism, and share their expertise in this regard. [Emphasis added]

This decision was reaffirmed at the 8th COP in 2006.

Panama is therefore bound by an international decision which creates a presumption against consideration of AquaBounty's application and in addition obliges it to consider ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health. The FDA's proposal appears to prejudge and undermine Panama's commitment to its international obligations in this regard.

The Decision also requires Parties to take account of:

Potential positive applications of the variety-specific genetic use restriction technologies on limiting gene flow, and possible negative impacts of genetic use restriction technologies on small populations of threatened wild relatives; …

The application's scope is wrongly defined

The draft Environmental Assessment (EA) states (p. 23) that the product being approved is triploid hemizygous, all-female Atlantic salmon (*Salmo salar*) bearing a single copy of the α-form of the opAFP-GHc2 rDNA construct at the α-locus in the EO-1α lineage. It also states that eyed-eggs are the product for commercial sale and distribution (EA, p.4, FONSI, p.2). However, the current application does not allow the commercial product (eyed-eggs) to enter the United States, since it is envisaged that eyed-eggs will be produced only at a facility in Canada and exported to Panama for grow-out (i.e. rearing to market size), harvesting and processing. No live fish would be imported to the United States (only fish fillets and steaks etc.).

The application's scope is therefore wrongly defined: it should be restricted to the import of fish fillets and steaks to the United States (whilst noting this does not remove the need to consider the environmental implications of production and to meet legal obligations to protect the environment and wild salmon populations).

Failure to take all possible steps to ensure physical containment

The Preliminary FONSI states that for the proposed action (i.e. approval of an application for AquAdvantage Salmon), the conditions proposed would limit production of eyed-eggs to a single specific facility on Prince Edward Island (PEI), Canada, for delivery to a single, specific, land-based facility in Panama for grow-out (i.e., rearing to market size), with harvesting and processing (e.g., preparation of fish fillets, steaks, etc.) in Panama prior to retail sale in the United States. These facilities would have various forms of physical and geographical/geophysical containment (described in detail in the Environmental Assessment), which will be subject to inspection by the FDA.

Annex V of the NASCO Williamsburg Declaration requires that Parties that over-rule the strong presumption against production of transgenic salmon should: "*take all possible actions to ensure that the use of transgenic salmonids, in any part of the NASCO Convention Area, is confined to secure, self-contained, land-based facilities*". However, the proposed physical containment does not amount to taking all possible actions, since clearly better contained "closed system aquaculture" facilities are available.[48]

A more serious concern is that no steps have been taken to secure shipments of GE eyed-eggs from Canada to Panama (or to other facilities in the future).

According to the EA p. 23, in the event of an approval, the following warnings would apply to product labelling accompanying all life stages of the AquAdvantage Salmon up to the time of harvest:
• Rear only in a physically-contained freshwater culture facility as specified in an FDA-approved application;
• These fish must not be reared in conventional cages or net-pens; and
• Dispose of morbid or dead fish in a manner consistent with local regulations.
The product label would also contain a statement that eggs and fry are not for resale.

A 2009 report by the U.S. Government Accountability Office (GAO) on seafood fraud exposed the inadequacies in the detection and prevention of seafood fraud by federal agencies.[49] The

international conservation group, Oceana, subsequently found that a third of fish samples from retail outlets across the US were mislabeled.[50] The FDA's apparent confidence that adding a label to GE fish eggs in transit will prevent supplies being diverted or re-sold for rearing in conventional cages or net-pens, or release into rivers or seas, is seriously misplaced. It is difficult to believe that the FDA is prepared to issue a FONSI on such an inadequate basis.

In addition, there are doubts about the legal powers of the FDA to impose the stated conditions and conduct inspections on overseas facilities.

Whilst food safety measures are routinely imposed by inspection of facilities in other countries, there is less precedent for imposing environmental protection measures such as physical containment or restriction of production sites. In the aquaculture industry, regulations with regard to quality control, such as the Hazard Analysis Critical Control Point (HACCP), have been adopted by most major importing countries, and have been made compulsory for many fish processing industries. These measures make the exporting processor or trader fully responsible for the quality of the product in terms of food safety and may require inspections. However, these measures must comply with the World Trade Organisation (WTO) Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT) adopted in 1995.[51] The SPS Agreement applies only to measures associated with the protection of human, animal and plant health and attempts to ensure they are applied in such a way that they are not a disguised restriction on international trade, so to prevent such measures from being used as unjustified trade barriers, primarily through reliance on standards established by set by international bodies such as the Codex Alimentarius Commission.

The TBT Agreement recognises "*that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement*".[52] Thus the TBT Agreement does allow environmental protection measures, not merely safety measures. However, the scope of such measures is strictly limited and must be applied in a non-discriminatory way. The TBT Agreement tries to balance the trade-facilitating aspects of standards against their trade -distorting potential by obligating countries to ensure that technical regulations do not create unnecessary obstacles to international trade discriminate in favour of domestic producers or goods of different origin. For the purpose of protecting the environment, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Mandatory labelling of GM food, for example by the European Union, has not been found to breach the WTO agreements, and various forms of voluntary eco-labeling and social certification for fisheries are also widespread. However, mandatory environmental conditions placed on a case-by-case on production facilities in other countries, such as the requirements for physical containment and associated inspection of facilities proposed in the draft FONSI appear to be likely to be vulnerable to challenge under WTO rules, unless they are based on relevant international standards applied in a non-discriminatory way. The legal basis for the FDA's claim that it can apply production conditions on a case-by-case basis to the product overseas via labelling requirements and inspections is therefore questionable.

This view is reinforced by examination of the FDA's Compliance Program Guidance Manual for approval evaluation of animal drugs.[53] The draft EA cites this manual as the basis under which the FDA's inspections of the proposed production facilities in Canada and Panama were conducted (see

e.g. Section 7.2.1.1.2 and F.1). Yet this Guidance provides no legal basis for inspections designed to prevent environmental harm (such as the physical containment barriers relied on heavily in the draft EA); all matters for inspection outlined in the Guidance are directed at product quality and safety (i.e. ensuring product identity, quality, purity and safety), consistent with the SPS Agreement. This is hardly surprising, because the Federal Food, Drug and Cosmetic Act allows approval to be refused if "*the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity*" i.e. if production is inadequate in relation to product safety issues (§ 360b. New animal drugs (d)(1)(C) page 228[54]) but specifies no legal powers under which conditions can be attached to animal drug production for the purpose of protection of the environment. The FDA appears to be arguing in the draft FONSI that the requirement that it complies with NEPA, as outlined in the Code of Federal Regulations Title 21[55], allows it to attach environmental conditions to animal drug production facilities. Yet NEPA appears to provide no powers to impose production conditions on facilities outside of the United States.

A secondary issue relates to enforcement of physical and geographical production conditions, even supposing they can be lawfully applied. Imports of fish and fishery products into the USA are regulated under the Federal Regulations, 21 CFR 123. These regulations apply to domestically produced products and imports and require that processors of fish and fishery products operate preventive control systems that incorporate the seven principles of HACCP. To enforce these food safety requirements overseas the FDA uses two mechanisms: (1) Memoranda of Understanding with seafood trading partners which put the burden of foreign processors' HACCP verification and other quality assurance means with the foreign government; and (2) a system in which importers take their own "affirmative steps" to ensure that their suppliers are processing in accordance with the regulations. The former process requires inter-governmental agreement, not mere labelling, and the latter process is likely to add burdens to importers who, if approval is granted, will be obliged to verify that imported salmon products either do not contain AquaAdvantage salmon, or contain only AquaAdvantage salmon grown under the FDA's specified conditions.

Finally, conditions are normally applied to guarantee standards of end product (i.e. fish and fish products for human consumption) which can then be enforced by monitoring of the food chain. Conditions applied to large numbers of eyed-eggs, which are easily shipped and not readily monitored or traced, are much less likely to be enforceable, even when applied to facilities within the United States.

In reality, if the envisaged physical and geographical containment conditions cannot be applied and/or enforced, broodstock development, broodstock maintenance, product manufacture and production of the final Aquabounty adult salmon may all take place in areas, either inside or outside the United States, which may impact on wild salmon populations and/or other species. Thus, the exposure routes for the United States considered in Section 6.1 of the EA are seriously inadequate. Impacts on the United States environment may occur via any of the production phases taking place within or outside the United States, at any location and under a wide variety of production conditions because physical containment requirements are only likely to be legally enforceable on facilities within the United States. Even in such cases, the potential for accidental or deliberate onward transport or selling of eyed-eggs elsewhere is likely to be high, because traceability of large numbers of eyed-eggs is likely to be poor.

Section 7.1 of the EA, purporting to answer the question "What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?" is therefore based on a false premise, since neither restriction of production to particular sites, nor the physical containment measures applied at those sites, can be guaranteed via the proposed mechanism of the FDA attaching conditions to

production sites and labels to live products. The claim on page 74 of the EA that "*both the production of eyed-eggs and the grow-out of the fish is to be conducted only in land-based facilities with redundant physical containment measures and with point-to-point control of shipping and land-based materials transfer*" is dubious because there it is doubtful whether there is any existing legal mechanism through which the FDA can impose the claimed conditions.

The FDA has placed great weight on the proposed physical containment measures in its determination, but has failed to address the secure the weakest point in the chain (the shipment of eyed-eggs); to take "all possible steps" to ensure containment as required by NASCO; or to provide convincing evidence that it has sufficient powers to apply or enforce conditions on the relevant facilities, or conduct inspections.

Failure to consider labelling and traceability of final product, and lack of monitoring

The entire system of physical containment, beginning in Canada and including the shipment of eyed-eggs and grow-out and production in Panama depends on no one breaking the rules or ignoring the labels on the GE eyed-eggs. And yet it is proposed that the final product (fish fillets and steaks etc.) will be marketed without labelling in the United States so there is no prospect of tracing whether it was in fact produced lawfully in conformity with the approval, or at some other facility elsewhere. Further there is no monitoring (DNA testing) proposed to check whether unlawfully produced AquaBounty GE fish are entering the United States. This is a major omission from the EA document which risks rendering it entirely meaningless.

Wrong definition of "biological containment" and failure to consider risks associated with sterility and partial-sterility in fish

The draft EA (page ix) defines "*Biological containment (bioconfinement)*" as the "*Use of biological methods, such as induced sterilization (e.g., triploidy), to prevent gene flow and reproduction in the environment*". This definition is incorrect and misleading because it confuses two different terms (containment and confinement), wrongly implies that sterile or partially sterile organisms are in some way contained or confined (i.e. have no contact with the environment) and fails to recognise that most sterilisation methods are partial. Further, the use of this term has underpinned a misleading framing of the risk assessment, which focuses only on gene flow and the issue of whether the GE salmon will reproduce and establish in the environment, not on other mechanisms (competition and impact on population dynamics) which could harm wild salmon populations. Far from being mitigated, competitive risks (risks of population suppression of wild populations) can be exacerbated by the introduction of methods which limit reproduction in genetically engineered organisms.

This poor definition has important consequences for the risk assessment and approvals process.

In its 2004 report, the National Research Council's (NRC's) Committee on the Biological Confinement of Genetically Engineered Organisms states that biological confinement (bioconfinement) includes the use of biological barriers, such as induced sterilization, that prevent GEOs or transgenes from surviving or reproducing in the natural environment (page 15).[56]

In colloquial use, biological containment may refer to any number of methods to contain genetically engineered organisms by creating biochemical barriers to prevent them from growing outside the laboratory.[57] It refers, in normal scientific use, to genetically engineered micro-organisms that have been disabled in some way to seek to prevent their survival outside the laboratory. In this sense of the term, biological containment aims to prevent survival and spread (including, but not limited to,

reproduction) of genetically engineered organisms, whereas biological confinement as described by the NRC is a narrower term which aims to prevent reproduction and gene flow, without necessarily having any effect on the survival and spread of the parent organism. "Biological containment" is also often used to describe secure facilities for the study of infectious organisms: therefore there is also potential for confusion with the concept of physical containment for biological organisms. Thus, the term "biological containment" as defined and used in the draft EA and preliminary FONSI clearly does not fit with either of its normal uses (or the normal English understanding of the term "containment"): therefore this term should not be used.

However, the term "biological confinement" as introduced by the NRC is also potentially confusing because it conflicts with legal definitions already in use in some other countries. For example, Canada's New Substances Notification Regulations (Organisms) states (Article 1): "*"confinement procedures" means any physical, chemical, biological or operational control, or combination of those controls, to restrict the exit or dispersal of a micro-organism*"[emphasis added]. This regulatory definition is again focused on limiting dispersal, not merely reproduction. A better term for limiting reproductive capacity is "*reproductive confinement*" which has been used, for example, in research grants to AquaBounty in the USA[58]; and Canada[59].

A more widely used term, is Genetic Use Restriction Technologies (GURTs), which is the term adopted by the Cartegena Protocol on Biosafety (CPB) to the Convention on Biological Diversity and by the Food and Agriculture Organisation to the United Nations (FAO), as described above.

In the context of the current application (and in many other situations), the term "biological containment" is highly misleading since GE salmon, in the absence of physical containment, may survive a number of years and travel long distances. Even sterile fish will interact with the environment and members of their own and other species, including predators and prey. Importantly, the introduction of sterile and/or partially sterile organisms into the environment may introduce new risks or increase some risks. These risks relate to competition effects (for mates or other resources) which can create a population suppression effect on the wild native species (and perhaps other species) when combined with limited reproductive capacity, with knock-on effects on other species and ecosystems more broadly. Such risks can occur even if there is no risk of establishment of the introduced organism in the wild and are increased, not reduced, by the introduction of sterile or partially sterile traits (i.e. traits which limit reproductive capacity).

Population suppression effects are well known in insects where the Sterile Insect Technique (SIT), involving the mass release of sterile insects, has been used to suppress and even eradicate some pest populations. A similar approach has been applied experimentally in carp in Australia, illustrating, at least in theory, how methods of limiting reproduction in released fish could be used deliberately to reduce or even wipe out wild relatives. [60] In another example, chemically sterilised male lampreys are being released in Lake Superior in an attempt to suppress the lamprey population.[61] Five different "autocidal" genetic methods of controlling invasive pests have been investigated in the literature. These are sex- or stage-specific lethality/sterility, gender distortion i.e. daughterless or sonless, inducible mortality using an environmental or artificial trigger, pleitropy – the "Trojan gene" effect – e.g. increasing mating advantage whilst decreasing viability of offspring, and 'selfish genes' which spread within the genome. Population suppression effects are discussed in more detail below in relation to GE salmon, but the key point here is that they cannot be neglected in favour of focusing only on the benefits of partial sterilisation in terms of reducing gene flow, because there are also risks associated with introducing sterile or semi-sterile organisms into the environment.

This issue is highlighted in the NRC (2004) report on Biological Confinement, when it describes weaknesses in biological confinement methods for fish on page 135. It states: "*The incomplete success in producing triploids is a major problem, particularly for treating large batches of newly fertilized eggs. Several limitations to screening and detection affect success with culling individuals that fail to become triploid. The degree of functional sterility in triploids varies, depending on the species and sex of the fish. A small percentage of mosaic individuals (bearing a mix of diploid and triploid cells) also can compromise sterility if their gonads are diploid and thus develop into normal, fertile gametes. Sterile individuals that still enter into courtship behavior could disrupt successful reproduction of wild relatives, and recurring large escapes of sterile individuals could heighten competition with or predation on wild species*". [Emphasis added].

As noted above, the use of triploidy in GE fish falls within the definition of GURTs adopted by the FAO. In 2000, the fifth meeting of the Conference of the Parties to the CPB adopted a resolution on Genetic Use Restriction Technologies (GURTs), cited above. The decision refers to the need to assess (and make available) information including: "*Potential positive applications of the variety-specific genetic use restriction technologies on limiting gene flow, and possible negative impacts of genetic use restriction technologies on small populations of threatened wild relatives*" [Emphasis added] and recommends a precautionary approach.

These possible negative impacts (population suppression effects) are not properly considered in the draft EA or preliminary FONSI because the definition and treatment of "biological containment" as a risk reduction measure (rather than as a measure which can both reduce and increase risks) means that the framing of the risk assessment is incorrect. The preliminary FONSI refers to "*biological containment*", along with physical and geographical/geophysical containment, as a "*mitigation measure*" (page 3) without any reference to the possible adverse effects of sterility or partial sterility on wild relatives. The draft EA also repeatedly refers to "biological containment" as a mitigation measure. Following from this, the current questions considered by the FDA are:
"*1. What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?*
2. What is the likelihood that AquAdvantage Salmon will survive and disperse if they escape the conditions of confinement?
3. What is the likelihood that AquAdvantage Salmon will reproduce and establish if they escape the conditions of confinement?
4. What are the likely consequences to, or effects on, the environment of the United States should AquAdvantage Salmon escape the conditions of confinement?"
Yet the possible existence of population suppression effects means that there could be adverse effects on the environment (including wild and endangered salmon populations) in the United States (and/or elsewhere) even if AquaAdvantage Salmon do not reproduce and establish at all. (By analogy, the Sterile Insect Technique does not lead to any establishment of the released insects, but in some circumstances can crash and even eliminate wild populations of the target species). This means the risk assessment has been wrongly framed so that important questions about potential adverse impacts have not been included.

In summary, the term "biological containment" has been wrongly defined and used in the draft EA. Since triploidy (or any other mechanism of sterility or partial-sterility) does not provide "containment" this term should be avoided. Drawing on the NRC 2004 report, the term "biological confinement" might be used instead, but this would conflict with the definition in Canada's New Substances Notification Regulations (Organisms) and hence give rise to unnecessary confusion about the meaning of this term: methods of sterility or partial sterility do not restrict the exit or dispersal of an organism, they only limit its reproduction. The term "reproductive confinement" could perhaps be used with an amended definition which recognises that sterility is unlikely to be 100%: "*Use of biological methods, such as induced sterilization or partial sterilization (e.g., triploidy), to limit gene*

flow and reproduction in the environment"; and/or the more specific terms sterilisation/partial sterilisation or triploidy could be used as and when needed in the document, without defining a broader group of potential mechanisms. Alternatively, the internationally recognised term Genetic Use Restriction Technology (GURT) could be used instead.

Following on from this, the conceptual risk assessment model and the series of risk-related questions also need to be redefined in order to reflect the objective of the risk assessment, which is to protect wild salmon populations (including endangered populations) and the environment more broadly. This requires a change of focus so that mechanisms which could adversely impact wild salmon populations (population suppression effects), without necessarily leading to the reproduction and establishment of an AquaBounty salmon population in the wild, are properly included.

Changing the definition and risk assessment questions would remain important even if subsequent analysis were to conclude that population suppression effects are unimportant for the particular product under consideration in the application. This is because: (1) the risk assessment will not be complete and cannot meet the relevant legal requirements if these issues are not properly considered; and (2) poor definitions and conceptual risk assessment models will set a bad precedent for future applications.

Impossibility of determining environmental impacts, including impacts on wild salmon populations

The various stages of production of AquaBounty's GE salmon include are shown in Figures 4 ad 5 on pages 36 and 38 of the draft EA. Production and maintenance of broodstock will take place in Canada, using female GE salmon to produce neo-male GE salmon broodstock. The GE neo-males will be mated with non-GE females and heat-shock treatment will be used to produce all-female triploid GE eyed-eggs. This is the product that will be shipped to Panama for grow out. Any environmental assessment in Canada must therefore consider both the GE females used in production and GE neo-males, maintained as broodstock. In Panama, any environmental assessment will focus on triploid GE females.

However, there is little if any information about the environmental behaviours or impacts of any of these fish provided in the draft EA.

Independent studies have mainly been conducted in other species (such as coho salmon). AquaBounty's own (limited) research does not appear to have included any studies of GE neo-males or GE female triploids.[62,63] This makes it impossible to draw any conclusions about the effects of the actual product or broodstock on the environment, in the event of an escape.

This is important because e.g. triploid fish may differ from diploids in many respects which can be important for an environmental assessment, for example they may be more susceptible to infection.[64]

As noted above, population suppression effects have been neglected. However, it is difficult to extrapolate existing models to the actual product.[65] It should be noted, however, that sterile triploid female fish can migrate to fresh water and that competition effects can potentially exist.[66,67] Competitive effects are likely to be complex and vary by life-stage.[68]

The Ecological Society of America has noted the importance of including effects on non-target species in any environmental assessment of Genetically Engineered Organisms (GEOs).[69] A first step is the identification of species of concern such endangered species or economically or culturally

important species.[70] This work does not appear to have been undertaken. For example, if GE salmon were to escape into the Pacific (most likely due to failure to secure the transport of GE eyed-eggs, see above) they might have impacts on other salmon species, since inter-competition effects occur between different salmon species.[71,72]

Numerous research needs have been identified which have yet to be addressed.[73] Salmonoid survival rates and behaviour in marine environments are extremely variable spatially and temporally and poorly understood.[74] More work to establish baseline conditions and behaviours is therefore needed before impacts of GE salmon can be properly evaluated.

In summary, relevant studies and data are omitted or unavailable, to the extent that it is impossible to determine potential environmental impacts of the application, including impacts on endangered or threatened wild salmon populations

Misleading claims in relation to the No Action Alternative

A decision to refuse the application is clearly less harmful to the environment because it would not breach the NASCO Williamsburg Declaration's strong presumption against the production of transgenic salmon. However, the FDA appears to be trying to avoid this obvious conclusion by claiming that if it refuses the application AquaBounty's GE salmon will be produced under less stringent environmental conditions elsewhere. It is hard to see how refusal of the application (and thus restriction of the potential market for fish fillets and steaks etc.) will make production anywhere more likely. This claim is also based on an incorrect understanding of the relevant legislation, regulations and conventions that would apply to GE salmon production elsewhere.

The draft EA states that the No Action Alternative (denial of approval) might lead to production and marketing of AquAdvantage Salmon at locations outside the United States, including (page 24) "*in any of the marine locations where Atlantic salmon are currently commercially grown (e.g., Canada, Chile, China, Norway, and Scotland) in net pens or cages, but also non-traditional freshwater locations where adequate water conditions occur naturally (e.g., temperatures are low enough and dissolved oxygen (DO) concentrations are high enough), or have been physically altered, to support Atlantic salmon survival and growth. Grow-out in freshwater locations could potentially occur in net pens or cages in ponds and lakes, in flow-through tanks and/or raceways, or in recirculating systems*".

The preliminary FONSI recognises that refusal of the application might lead to no production (with no environmental impact) but states: "*However, to the extent that production would occur with less restrictive containment conditions than those proposed (e.g., fish might not be triploid, might not be reared in land-based facilities, or might not be subjected to multiple and redundant forms of physical containment), it is expected that adverse environmental impacts to the United States might be more likely to occur than under the conditions of production and grow-out for the proposed action*".

This is completely wrong because:

(1) There is no evidence that any country is planning production of GE salmon and many countries are bound by the NASCO Williamsburg Declaration (including Canada, Norway and Scotland) and other international agreements such as the CPB (including China, Norway and Scotland) and the OSPAR/HELCOM Conventions (including Norway and Scotland) which include strong presumptions against any such production;
(2) Refusal of the product in the United States would restrict the market and provide a strong disincentive to producers, thus reducing, not increasing, the likelihood of production elsewhere;

(3) The risk of production elsewhere on refusal of the application is further reduced by the opposition to it by the salmon farming industry globally; a mandatory labelling requirement for GM foods in many countries (combined with poor consumer acceptability); and the poor quality of the final product (e.g. high moisture content);
(4) It is not clear that production elsewhere could in any case proceed with inadequate controls or whether, if it did so, it would in reality pose greater risks to the United States than the facilities in the current application;
(5) The proposal to require FDA inspections for production facilities exporting the GE fish to the United States (assuming this can be applied and enforced, see above) does not in any case prevent other (uninspected or open sea) facilities being built to produce or export GE salmon elsewhere: what prevents this happening is the regulatory restrictions and market conditions which exist in other countries, including via international agreements (see point (1)).

In summary, the alternative action of refusing the application is clearly less harmful to the environment.

In more detail:

The salmon farming industry and restricted market
A footnote to Annex 5 of the NASCO Williamsburg Declaration (cited above) notes that at its Seventeenth General Meeting in Galway, Ireland, in September 1996, the International Salmon Farmers Association (ISFA) adopted its Policy on Transgenic Salmon, which states that, in accordance with sound environmental practices, the ISFA firmly rejects transgenic salmon production. IFSA has confirmed to NASCO that this remains its position.[75] Individual companies and some national aquaculture organisations have made similar statements or adopted resolutions.

AquaBounty's own studies show its GE salmon is a low quality product, high in water content.[76] Hence, demand for GE salmon is likely to be low.

Compulsory labelling of genetically modified organisms (GMOs) used in food and feed is not required in any of the countries covered by the current application (USA, Canada, Panama) but is common elsewhere.[77] It is likely that consumer concerns about GE salmon would further restrict the market for the product in these countries.

Other NASCO Parties
In 2011, NASCO reported that most Focus Area Reviews (FAR) submitted by Parties to the Convention indicate that there is no rearing of transgenic salmonids in these countries.[78] Only the FAR for Canada indicated that research has been approved to rear transgenic salmonids in contained facilities and the US FAR indicated that an application has been made FDA for approval to sell transgenic salmon in the US. All NASCO Parties are committed to the Williamsburg Declaration, which includes a strong presumption against the use of transgenic salmonids and a series of requirements, including ensuring that any such use is confined to secure, self-contained, land-based facilities.

Parties to HELCOM AND OSPAR
The 2003 Declaration of the First Joint Ministerial Meeting of The Helsinki and OSPAR Commissions, states (paragraph 19)[79]:

"*Recognising that the release of genetically modified marine organisms presents an inherent threat of potentially severe, irreversible and transboundary effects, and the need to apply the precautionary*

principle, we agree to take all possible actions, in accordance with the requirements of the Directive 2001/18/EC and comparable national legislation, to ensure that the culture of genetically modified marine organisms is confined to secure, self-contained, land-based facilities in order to prevent their release to the marine environment".

The Helsinki (HELCOM) and Oslo and Paris (OSPAR) Conventions cover the marine environments of the Baltic Seas and North-East Atlantic respectively. Parties to HELCOM are: Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden.[80] Parties to OSPAR are: are Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the European Community.[81]

The Atlantic salmon (*Salmo salmar*) is on the OSPAR List of Threatened and/or Declining Species and Habitats (Reference Number: 2008-6).[82] The species is found in OSPAR regions I (the Arctic), II (the Greater North Sea), II (the Celtic Seas) and IV (the Bay of Biscay/Golfe de Gascogne and Iberian coasts).

Atlantic Salmon is also listed in Annexes II and V of the European Union's Habitats Directive as a species of European importance.

Parties to the Cartegena Protocol on Biosafety
The US is not a Party to the Cartegena Protocol on Biosafety, but 166 other countries are.[83,84] These countries have adopted a precautionary approach to the release of living modified organisms (LMOs) and a series of decisions on GURTs, which include triploidy in fish within the definition (see above).

Salmon producing countries and potential use of GE salmon
As noted in the draft EA (page 125) the greatest salmon farming production currently occurs in Norway, Chile, Scotland and Canada where smolts are typically grown to market size (generally 2 - 5 kg) in ocean net pens or cages. Other countries with significant production of Atlantic salmon include Australia, China, New Zealand, the Faroe Islands, and the United States. More detail is provided by the FAO.[85] The most rapidly growing supplier is Chile, which has low labour and materials costs and can therefore effectively compete with traditional producing countries in distant markets.

The UNEP-WCMC species database[86] lists Atlantic Salmon (*Salmo salmar*) as a native species in: Belgium, Canada, Czech Republic, Denmark, Estonia, Faeroe Islands, Finland, France, Germany, Greenland, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Russian Federation, Slovakia, Spain, Sweden, United Kingdom of Great Britain and Northern Ireland, United States of America; and as an extinct species in Switzerland. All these countries are parties to at least one of the NASCO or OSPAR/HELCOM agreements which adopt a presumption against the use of GE salmon and require restriction of production to secure, on-land, contained facilities, as well as a precautionary approach and some are, in addition, parties to the CBP.

Atlantic salmon is also listed in the UNEP-WCMC species database as an introduced species in: Argentina, Australia, Chile and New Zealand. New Zealand is a Party to the CPB, Argentina and Chile have signed but not ratified, and Australia has not signed.[87] China (the only other country mentioned in the draft EA) is a Party to the CPB. Australia, New Zealand and China are amongst the countries that require compulsory labelling of GE foods, where a market for GE salmon therefore appears unlikely to develop.

Of the countries listed in the draft EA, it is therefore only Chile that might theoretically proceed to approval of production of GE salmon with weaker controls than proposed by the FDA, including

possible production in net pens or cages. In Chile, there is an Advisory Committee for the Release of Transgenics (CALT) in the agriculture and livestock ministry and a biosafety law which remains in draft: the approval process for GE salmon production therefore remains somewhat unclear. However, it is by no means obvious that Chile would ignore the requirements of the CBD (which it has signed but not ratified), including the agreed position on the use of GURTs. Nor is Chile likely to proceed with an approval in the absence of a biosafety law. In addition, salmon exports are vital to the Chilean salmon aquaculture industry.[88] Major export countries include Japan, US, Brazil, China and Spain: of these countries, only the USA would not require mandatory labelling of AquaBounty's GE salmon as a genetically modified organism (GMO). Therefore, the possibility of an export market for unlabelled GE salmon in the United States – which would be created by approval of the application - is more likely to act as an incentive than a disincentive to poorly regulated production, with potential adverse environmental impacts.

Conclusion

The FDA should not issue the FONSI because:
(1) It conflicts with the USA's international obligations under NASCO and fails to take account of its obligations under NEPA to protect the global commons and environments of other states, and the requirements of the ESA to protect wild salmon populations;
(2) The application is premature and a FONSI would prejudice other national and international decisions in Canada, Panama and NASCO;
(3) The application's scope is wrongly defined since the company does not propose to import eyed-eggs (or any live stage of the fish) into the United States;
(4) Measures for physical containment are inadequate, particularly the failure to secure shipments of eyed-eggs;
(5) There are no measures for traceability and labelling of the final product, or for post-market monitoring;
(6) "Biological containment" has been wrongly defined and the risk assessment has been wrongly framed to exclude adverse impacts that sterile or semi-sterile GE salmon can have on wild salmon populations by altering the population dynamics of these species;
(7) Relevant studies and data are omitted or unavailable, to the extent that it is impossible to determine potential environmental impacts, including impacts on endangered wild salmon populations;
(8) The No Action Alternative is clearly the environmentally preferable option.

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