



Agenda item 6.9
For decision

Council

CNL(02)25

Transgenic Salmon

Transgenic Salmon

1. It seems very likely that the first transgenic animal available as food might be the Atlantic salmon. In response to concerns about the risks posed by transgenic salmon the Council has adopted Guidelines for Action on Transgenic Salmon. Under these guidelines the Parties agree, *inter alia*, to:
 - i) advise the 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 stocks;
 - ii) take all possible actions to ensure that the use of transgenic salmon, in any part of the NASCO Convention area, is confined to secure, self-contained, land-based facilities.

The President will invite the Parties to report to the Council on any proposal to permit the rearing of transgenic salmon.

2. At the 2001 Annual Meeting, Canada had advised the Council that a company, Aqua Bounty, with a research facility on Prince Edward Island is producing transgenic Atlantic salmon and rainbow trout broodstock in a secure land-based facility. The Department of Fisheries and Oceans had not received any formal proposal for commercial rearing but had confirmed that if this should occur then the proposal would be thoroughly examined and a risk analysis performed in accordance with the Fisheries Act and the Canadian Environment Protection Act. The USA had informed the Council of preliminary discussions between a company and the US Food and Drug Administration (FDA). The permitting process, which includes environmental analysis, was briefly described.
3. Last year a report on a visit by the Secretary and President to the Aqua Bounty facility on Prince Edward Island was presented. The hatchery manager had indicated that he foresaw the use of sterile transgenic salmon in sea cages rather than land-based facilities. The Council had noted that such an approach would not be consistent with its guidelines. The US had committed to alert the President and Secretary when there was a possibility to make NASCO's views on this matter known to the relevant authorities in the USA. On 30 October the US Department of Interior Fish and Wildlife Service and the US Department of Commerce National Marine Fisheries Service wrote to the FDA expressing concern that the introduction and use of genetically modified salmon by the salmon farming industry has the potential to adversely affect endangered wild salmon (Annex 1). NASCO's concerns about the use of transgenic salmon in aquaculture were conveyed to the FDA in a letter dated 11 December 2001 (Annex 2). To date we have received no response to this correspondence.

4. Last year the Parties all indicated that they support the present NASCO Guidelines for Action on Transgenic Salmon although it was noted that they do not necessarily have legal force. The Council had previously agreed that when the Standing Committee on the Precautionary Approach considers the issue of introductions and transfers it should also consider how the Precautionary Approach would apply to transgenic salmon. Terms of Reference for a meeting of the SCPA on application of the Precautionary Approach to introductions and transfers, aquaculture and transgenics are contained in document CNL(02)17. These refer to the need to review the measures contained *inter alia* in the Guidelines for Action on Transgenic Salmon to ensure their consistency with the Precautionary Approach.
5. The Council had previously agreed that there might be benefits from a Special Session on transgenic salmon at a future meeting and may, therefore, wish to consider if this Special Session should be held at the Twentieth Annual Meeting when the recommendations of the SCPA should be available.

Secretary
Edinburgh
12 April, 2002



United States Department of Interior
Fish and Wildlife Service
22 Bridge Street, Unit #1
Concord, NH 03301



United States Department of Commerce
National Oceanic and Atmospheric Administration
National Marine Fisheries Service
One Blackburn Drive
Gloucester, MA 01930-2298

OCT 30 2001

Mr. Charles Eirkson
U.S. Food and Drug Administration
Center for Veterinary Medicine
1750 Standish Place
Rockville, MD 20855

Dear Mr. Eirkson:

We are contacting you regarding the application of Aqua Bounty Farms of Massachusetts for U.S. Food and Drug Administration (FDA) approval for production and marketing of genetically modified Atlantic salmon. The interest of the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife (the Services) in this application is based upon the agencies' responsibilities and authority pursuant to the Endangered Species Act (ESA) of 1973 (as amended).

In November 2001, the Services jointly listed the Gulf of Maine Distinct Population Segment of Atlantic salmon as an endangered species under the ESA. The final rule listing the Gulf of Maine Distinct Population Segment of Atlantic salmon and a recent status review (1999) of the species conclude that the potential for interactions between wild salmon and aquaculture escapees represents a significant threat to the continued existence of endangered salmon in Maine. There is a large body of scientific evidence that clearly indicates genetic and ecological interactions between wild and aquaculture salmon can adversely affect wild populations.

We are confident that the FDA is aware of its responsibility under the ESA to consult with the Services under section 7(a)(2) of the Act. Section 7(a)(2) directs all federal agencies to, in consultation with the NMFS, "insure that any action authorized, funded, or carried out by such agency will not jeopardize the continued existence of an endangered species." The introduction and use of genetically modified salmon by the salmon farming industry has the potential to adversely affect endangered wild salmon and thus, is of concern to the Services.

We urge the FDA to keep the Services fully informed of the status of the Aqua Bounty Farm's application and your agency's review. Moreover, we strongly encourage the FDA to initiate consultation with the Services early in its deliberations on this permit application as it will help ensure that any decision by the FDA addresses any potential adverse impact the decision may have on endangered Atlantic salmon. The Services stand ready to work with the FDA to ensure any outcome of your review of this application is sufficiently protective of endangered wild Atlantic salmon.

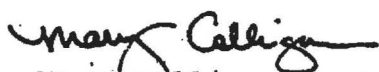
In addition to the ESA, the North Atlantic Salmon Conservation Organization (NASCO), the international organization responsible for



the implementation of the Convention for the Conservation of Salmon in the North Atlantic Ocean, an international treaty to which the United States is a contracting party, has adopted guidelines that obligate the U.S. to keep NASCO informed of any proposal to use genetically modified fish within the U.S.

We appreciate your consideration of these issues and look forward to your response. Please do not hesitate to contact Mary Colligan of NMFS staff at (978) 281-9116 if you wish to discuss this matter further or need any additional information regarding the potential impacts of transgenic fish to endangered Atlantic salmon or how best to initiate consultation on this federal action.

Sincerely,



Mary Colligan
NER, ARA Protected Resources
National Marine Fisheries Service



Michael J. Bartlett
Supervisor, N.E. Field Office
U.S. Fish and Wildlife Service

Cc: Stephen F. Sundlof, Director, CVM
Rollie Schmitten, NOAA-Fisheries
Malcolm Windsor, NASCO
Gordon Russell, FWS

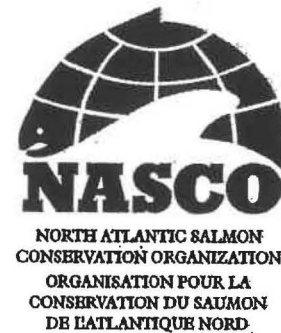
NASCO, 11 Rutland Square Edinburgh EH1 2AS Scotland UK
Telephone: (Int+44) 131 228 2551 Fax: (Int+44) 131 228 4384
e-mail: hq@nasco.int website: www.nasco.int

Annex 2

CNL30.076

11 December, 2001

Mr Charles Eirkson
US Food and Drug Administration
Center for Veterinary Medicine
1750 Standish Place
Rockville, MD 20855
USA



Dear Mr Eirkson

The 30 October letter from Ms Mary Colligan (of the National Marine Fisheries Service) and Mr Michael J Bartlett (of the US Fish and Wildlife Service) has been copied to me. It concerns the application by Aqua Bounty Farms for approval for production and marketing of genetically modified salmon.

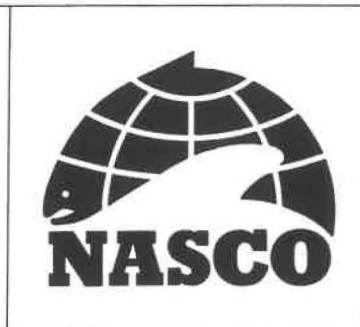
NASCO is an international treaty organization to which the US is a signatory, and as is mentioned in the 30 October letter, NASCO has adopted Guidelines for Action on Transgenic Salmon. I have attached these for your information.

I would like to emphasise that there is considerable interest and concern in NASCO on this matter, and would also like to offer any assistance we can give on the matter relating to the risks to the wild salmon stocks which migrate in the North Atlantic.

Yours sincerely

Malcolm Windsor
Secretary

Ene.



COUNCIL

CNL(97)48

NASCO GUIDELINES FOR ACTION ON TRANSGENIC SALMON

THE PARTIES to NASCO are aware of the development of transgenic salmon (i.e. salmon that contain genes from another organism). While there may be benefits from the introduction of such salmon 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 salmon 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 stocks;
- b) take all possible actions to ensure that the use of transgenic salmon, in any part of the NASCO Convention Area, is confined to secure, self-contained, land-based facilities;
- c) take into account the ongoing work by the Parties to the Convention on Biological Diversity to develop a Protocol on Biosafety;
- d) 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 new Liaison Group established between NASCO and the international salmon farming industry;
- e) take steps, as appropriate, to improve knowledge on the potential impacts of transgenic fish on the wild stocks and their habitat;
- f) examine the trade implications associated with transgenic salmon in accordance with World Trade Organization Agreements and other instruments of international law.

The Council will:

ask the newly established Working Group on the Precautionary Approach to consider specifically the risks and conservation benefits from transgenic salmon as part of its response on introductions and transfers.

