

**RESPONSE OF THE FEDERAL DEPARTMENTS AND  
AGENCIES TO THE PETITION FILED  
SEPTEMBER 25, 2003 BY GREENPEACE CANADA  
UNDER THE *AUDITOR GENERAL ACT*:**

***CONCERNING THE FEDERAL GOVERNMENT'S POSITION AND POLICY  
REGARDING THE RELEASE OF GENETICALLY ENGINEERED FISH:  
AN UPDATE***

**January 22, 2004**

**Minister of Fisheries and Oceans  
Minister of the Environment**

**Minister of Health  
Minister of Foreign Affairs**

## **Foreword**

In responding to the petition about genetically engineered (GE) fish, submitted by Greenpeace Canada under the *Auditor General Act*, federal departments and agencies have worked together, contributing their collective knowledge and expertise to this response. This effort has been made in order to provide a considered, integrated response that would be relevant to all Canadians who are interested in biotechnology-derived products, specifically as this topic relates to GE fish and sustainable development.

This response builds on previous responses to petitions submitted under the *Auditor General Act*, which provided an in-depth look at the existing regulatory system for biotechnology – aspects covering health, the environment, trade and socio-economic questions, as they pertain to regulation and sustainable development in this country. Those responses provided an overview of the comprehensive manner in which Canada regulates developers' products. They also describe the "checks and balances" in the system as well as such forward-looking developments as the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. The specific questions related to genetically engineered fish presented in the petition are addressed in this response. The reader is invited to review previous petition responses, which are publicly available on the website of the Office of the Auditor General of Canada, for information on the overall regulatory framework (<http://www.oag-bvg.gc.ca/domino/petitions.nsf/english>).

Canada has one of the safest and most effective regulatory systems for biotechnology products in the world. In its renewal of the Canadian Biotechnology Strategy, which followed extensive public consultations, the Government of Canada expressed its goal of being a world leader in the responsible development of biotechnology. This means that the Government must apply rigorous standards to the manner in which it regulates and monitors biotechnology-derived products, particularly as they relate to human and animal health and the environment. The Government will continue to assure Canadians that the products and processes of biotechnology are subject to the highest standards of scientific testing for health, safety and environmental impact.

Internationally, Canada has a long and prestigious record for its science-based regulatory system – a system that is in line with principles laid out by organizations such as the World Health Organization (WHO), the Organisation for Economic Co-operation and Development (OECD), the United Nations Environment Programme, the Food and Agriculture Organization (FAO), the International Plant Protection Convention, the Codex Alimentarius Commission, and the Office Internationale des Épizooties. Canada is a world leader in helping to shape international policy directions in areas such as the labelling of biotechnology-derived foods.

One of the fundamental principles of the *1993 Federal Regulatory Framework for Biotechnology* is that the development of Canadian biotechnology regulations be open and include consultation with Canadian citizens. Canadian values must be at the heart of the public discussion on biotechnology. It is in this light that the Government of Canada welcomes and values a transparent dialogue with Canadians.

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## **Acronyms**

AAFC	Agriculture and Agri-food Canada
CBAC	Canadian Biotechnology Advisory Committee
CEPA	Canadian Environmental Protection Act
CCFAM	Canadian Council of Fisheries and Aquaculture Ministers
CCRA	Canada Customs and Revenue Agency
CFIA	Canadian Food Inspection Agency
DFAIT	Department of Foreign Affairs and International Trade
DFO	Fisheries and Oceans Canada
EC	Environment Canada
FAO	Food and Agriculture Organization
IBSFC	International Baltic Sea Fishery Commission
GE	Genetically Engineered
HC	Health Canada
IC	Industry Canada
INAC	Indian Northern Affairs Canada
NASCO	North Atlantic Salmon Conservation Organization
NPAFC	North Pacific Anadromous Fish Commission
NSNR	New Substance Notification Regulations
OECD	Organisation for Economic Cooperation and Development
OIE	Office International Des Epizooties
UNCBD	United Nations Convention on Biological Diversity
UNEP	United Nations Environment Program
USFDA	U.S. Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

## **Background**

On September 8, 2003, Greenpeace Canada (hereafter referred to as the Petitioner) filed a petition pursuant to Section 22 of the *Auditor General Act* with the Commissioner of the Environment and Sustainable Development. This petition, hereafter referred to as the Petition, deals with the federal government's position and policy regarding the release of genetically engineered (GE) fish and provides an update to a previous petition (Petition #38) for which a response was released in April 2002.

The petition process is a means by which Canadians can express their views and seek more information on matters of federal policy in the context of the environment and sustainable development. The four responding Departments wish to assure the Petitioner and their fellow Canadians that responsible stewardship is a central priority to the federal decision-making framework for biotechnology.

The Petition deals with genetically engineered (GE) fish and was specifically directed to the following Ministers on behalf of their departments (hereafter referred to as the Ministers) for response:

- Minister of Fisheries and Oceans
- Minister of the Environment
- Minister of Health
- Minister of Foreign Affairs

The main focus of the Petition concerns the federal government's position and policy regarding the release of GE fish and in particular GE salmon, including information on the authorization, regulation and monitoring of GE fish. The Petitioner requests information regarding the existing regulatory system for biotechnology (policies and programs related to regulations, enforcement, compliance and institutional arrangements), and the federal response to the potential approval of genetically engineered fish in Canada.

The Petition was received by the Auditor General's office on September 8, 2003. It was sent to the Ministers on September 25, 2003. For this reason, the 120 days allowed for the government to respond to the Petition began on September 25, 2003.

## **The Response of the Federal Departments and Agencies to the Petition**

### ***Introduction***

The Ministers of Fisheries and Oceans, Environment, Health, and Foreign Affairs have provided this document as a joint response to Greenpeace Canada, the Petitioner.

Providing a joint response is consistent with the federal government's commitment to improve its management and coordination of matters related to biotechnology and the environment as reflected in several previous petition responses, as well as other joint work referenced in those responses.

Overall, the Ministers believe that Canada's existing regulatory system provides for the risk assessment and management of biotechnology-derived products from a sustainable development perspective. In previous responses to petitions, the Government of Canada has already provided information regarding:

- the 1993 federal regulatory framework for biotechnology, and
- the federal development of Sustainable Development Strategies.

Readers may refer to previous petitions for extensive background information on regulating biotechnology in Canada at [www.oag-bvg.gc.ca/domino/petitions.nsf/english](http://www.oag-bvg.gc.ca/domino/petitions.nsf/english).

## **Response to Questions of the Petition**

**Question 1:** *Could the Ministers provide a general up-date on the situation regarding GE fish and in particular GE salmon since their response (dated April 4, 2002) to Greenpeace's petition (#38) on the same topic submitted in November 2001, using original 1 to 9 as a guideline for an up-dated response?*

### ***Response to Question 1:***

1. The four departments (Fisheries and Oceans Canada, Environment Canada, Health Canada, and the Department of Foreign Affairs and International Trade) are pleased to provide you with a general up-date on the activities of our respective departments with respect to genetically engineered (GE) fish, and in particular GE salmon, by responding to questions 2 to 8, inclusive, of your current petition #38B. Our earlier response to the previous petition (Petition #38) provided you with information concerning the policy of the government of Canada to the issues of the release of genetically engineered fish, and this response limits itself, as requested, to an outline of any changes in policy since April 4, 2002.

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**Question 2:** *In particular, could the Ministers confirm if the Government of Canada has received (or not) a formal request to authorize the release and the commercialization of any GE fish and/or aquatic species in Canada since April 4, 2002? If yes, could the Ministers give details about this request and about the expected government timeframe for dealing with the request?*

### ***Response to Question 2:***

2. The four departments have not received any formal request to authorize the release and commercialization of any genetically engineered (GE) fish and/or aquatic species in Canada. No such products have been authorized for release and commercialization by the Government of Canada since April 4, 2002.

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**Question 3:** *In particular, could the Ministers give details about any correspondence and/or contact since April 2002 (numbers of correspondence/contact, dates, topics, agreements/understanding, etc.) with any companies related to A/F Protein, for example, AquaBounty Farms, Seabright and/or Genesis, that made public its intention to request permission to release and commercialise GE salmon in Canada?*

### ***Response to Question 3:***

3. Fisheries and Oceans Canada, the Canadian Food Inspection Agency, and Environment Canada have had discussions with companies involved in GE fish research. Exchanges concerned

publicly available scientific articles related to research findings, to further understand the genetic engineering technologies currently in development.

4. Other information requested by the Petitioner in this question may include personal information, confidential third party information, advice or recommendations to the Minister, or information subject to solicitor-client privilege, and therefore may be protected under the *Access to Information Act*. For this reason, the four departments believe that it would be more appropriate for the Petitioner to submit these requests under the *Access to Information Act*, in order to ensure that the Act's exemptions are properly applied.

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**Question 4:** *Could the Ministers confirm that the current policy of the Government of Canada is still the same as stated on April 4, 2002, and in particular that the Government of Canada 'supports the NASCO policy statement that the use of transgenic salmon is to be confined to secure, self-contained, land-based facilities' (government's response #29, page 12)?*

**Response to Question 4:**

5. Fisheries and Oceans Canada continues to support the North Atlantic Salmon Conservation Organization (NASCO) policy statement.

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**Question 5:** *If the response to the previous question (#4) is positive, could the Ministers indicate if this policy/position also applies to any transgenic aquatic species and how it will be implemented? If not, please justify. If yes, could the Ministers outline the measures at home and initiatives taken abroad by Canada to make sure that this Canadian position and/or policy is implemented and/or shared by the international community (multilaterally – e.g. NASCO and CEC of NAFTA and bilaterally – e.g. US)?*

**Response to Question 5:**

6. Fisheries and Oceans Canada agrees that the potential consequences of genetic and ecological interactions must be considered and that reproductively capable GE fish and aquatic organisms must be kept in secure land-based facilities. The measures and initiatives that have been taken are described briefly below.
7. Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, and Health Canada developed an Action Plan to respond to the Expert Scientific Panel of the Royal Society of Canada report entitled: Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. The Government Action Plan was released on November 23, 2001 and is posted on the Government web site at - <http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm>.



8. The Government Action Plan describes specific actions and projects that the departments intend to carry out in response to the Expert Panel's recommendations. In its commitment to transparency, the government reports on its progress on key initiatives undertaken in response to these recommendations. Five progress reports on the Action Plan in Response to the Royal Society of Canada Expert Panel Report have been published detailing technical information regarding the key milestones achieved for each of the different actions underway for which a reporting date was identified. These documents, including the latest progress report (posted December 2003) may be found on the Health Canada web site (at [www.hc-sc.gc.ca/english/protection/royalsociety/index.htm](http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm)). Subsequent progress reports, including actions underway relating to genetically engineered animals, including fish, will be published in June 2004 and December 2004.
9. Currently, any intention to manufacture or import aquatic organisms with novel traits (including GE fish) requires notification and assessment under the New Substance Notification Regulations (NSNR) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Such notification under CEPA 1999 must properly address all of the information and data items outlined in the NSNR. Fisheries and Oceans Canada provides sector expertise to Environment Canada and Health Canada in processing the notifications and the assessment of the environmental and indirect human health effects.
10. Fisheries and Oceans Canada is developing regulations under the Fisheries Act for aquatic organisms with novel traits, which includes genetically engineered fish. These will meet the CEPA 1999 requirements for the protection of the environment and indirect human health. Regulations will be based on objective scientific data generated from regulatory research programs being conducted at Fisheries and Oceans Canada, which are peer reviewed by international scientific authorities. As part of the Government of Canada's policies and practices, the public will be provided the opportunity to review and comment upon this regulation prior to adoption. The proposed regulations will be accompanied by a full Regulatory Impact Analysis Statement that will address the issues raised in the Petition.
11. In addition to the current regulatory requirements, the Fisheries and Oceans Canada general approach to the prevention of importation of unapproved GE fish and fish products is augmented by ongoing discussions with national and international organizations.
12. Recommendations and discussions with scientific and policy experts at international meetings (North Atlantic Salmon Conservation Organization (NASCO), North Pacific Anadromous Fish Commission (NPAFC), International Baltic Sea Fishery Commission (IBSFC)) will assure the approach used by Fisheries and Oceans Canada is shared and remains up to date with new knowledge and experience.
13. Fisheries and Oceans Canada actively participates in several national and international fora and closely follows issues relating to the developments of GE fish. For example, the NASCO 'Guidelines for Action on Transgenic Salmon' for the protection of wild stocks, identify actions to ensure that GE salmon will not have an impact upon wild salmon stocks, including:

- Advising the NASCO Council of any proposal to permit the rearing of GE salmonids and provide details of the proposed measures to safeguard the wild stocks.
- Taking all possible actions to ensure that the use of GE salmon, in any part of NASCO Convention Area, is confined to secure, self-contained, land based facilities.
- Taking steps, as appropriate, to improve knowledge on the potential impacts of GE fish on wild stocks and their habitat.

Further details of the guidelines can be found on the NASCO web site at:

[http://www.nasco.int/pdf/nasco\\_cnl\\_03\\_57.pdf](http://www.nasco.int/pdf/nasco_cnl_03_57.pdf)

14. Finally, in conjunction with the regulatory departments and agencies, Department of Foreign Affairs and International Trade officials play important roles in facilitating inter-governmental information sharing, helping to increase sector awareness of regulatory obligations between and among countries, assisting in the resolution of bilateral or multilateral market access concerns, and providing effective leadership in trade negotiations.
15. There is ongoing dialogue between Canada and the US on several fronts, at which Canada's views and requirements relating to genetically engineered organisms are made known, including discussion amongst regulatory and trade officials. Under NASCO, these parties will continue to provide comprehensive information to the council in advance of each annual meeting, concerning the measures in force to limit impacts upon wild salmon stocks.

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**Question 6:** *If the answer to question #4 above is positive, could the Ministers indicate if they participated (formally or informally and while respecting constitutional divisions of powers) in consultation processes organized by lower levels of government relating to aquaculture or conservation proposal in order to make sure that there is an explicit provision that the use of transgenic salmon is to be confined to secure, self-contained, land-based facilities.*

**Response to Question 6:**

16. The four departments, Fisheries and Oceans Canada, Environment Canada, Health Canada, and the Department of Foreign Affairs and International Trade have not participated in a consultation process with lower levels of government relating to aquaculture or conservation proposals on the potential commercialization or release of GE fish to date. The reason the federal and provincial governments have not consulted on this issue is because there is no commercial production of GE fish at this time, nor is there any request to authorize the release and the commercialization of GE fish. If such situations arise, the Canadian Council of Fisheries and Aquaculture Ministers (CCFAM) could be one of the mechanisms for such federal/ provincial/ territorial discussions. As indicated in earlier responses, the regulation of any commercial production and release falls under existing legislation such as CEPA 1999 and the Fisheries Act.

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**Question 7:** *If the response to question #4 above is positive but if the response to question #6 above is negative, could the Ministers indicate if, how and when, they communicated their position/policy to lower levels of government in Canada (e.g. provinces and territories) to make sure that all levels of government adopt a precautionary approach and refuse the release of GE fish and aquatic species in Canadian waters?*

**Response to Question 7:**

17. Fisheries and Oceans Canada developed the 'Draft Policy on Research with, and Rearing of Transgenic Aquatic Organisms'. The draft policy articulates guidelines for the physical and genetic containment of GE aquatic organisms in research laboratories and the environment and it provides a framework for the assessment of risk to the environment where there is a possibility of access to the natural environment. The intent of the policy is to provide information regarding the roles and responsibilities of the Department in assessing information that proponents and users of GE aquatic organisms will provide. It also outlines the roles and responsibilities of proponents and users.
18. In June 1998, Fisheries and Oceans Canada distributed the draft policy to the provinces and territories, as well as to industry and environmental groups, which was followed by an extensive comment and consultation period with the recipients.
19. Environment Canada has not communicated directly with other levels of government but continues to direct its compliance efforts in this regard to facilities that carry out R&D activities. Environment Canada makes R&D facilities housing transgenic salmon aware that they are responsible for meeting the R&D exemption criteria listed in s.29.16 of the NSN Regulations of CEPA 1999.

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**Question 8:** *Could the Ministers provide a detailed breakdown of government funds made available since April 2002, specifically and only for studies to design test protocols, regulatory requirements and general understanding of the potential impacts of GE fish and/or aquatic species and estimated funds for the forthcoming budget years? Could the Ministers provide a detailed breakdown of government funds made available since April 2002, specifically and only for the development and promotion of GE aquatic species with the view to commercialize GE aquatic species."*

**Response to Question 8:**

20. The government is investing in the Canadian regulatory system for biotechnology. Under this government investment, \$1.495 million per year is devoted to developing the science base and the in-house capabilities at Fisheries and Oceans Canada for the regulation of biotechnology-derived aquatic organisms, including GE fish, for the protection of the aquatic ecosystem and the conservation of marine resources.

21. No government funds were made available for the development and promotion of GE aquatic species with the view to commercialization of these species.
22. As outlined in the progress reports on the Government Action Plan, Health Canada is currently in the process of developing specific guidance for the safety assessment of genetically engineered livestock and fish. Consultation on the first draft of Health Canada's Guidelines for the Safety Assessment of Novel Foods Derived from Livestock and Fish is now planned for 2004. These guidelines are a necessary prerequisite to Health Canada conducting any safety assessment of animals or fish derived through biotechnology.
23. As part of ongoing research to generate knowledge to support the regulatory system and to allow an improved scientific basis for detailed assessments from potential risks of new foods derived through biotechnology, Health Canada had committed \$0.19 million to research on genetically modified fish in 2002-03, and has committed \$0.3 million for 2003-04. It is estimated that another \$0.6 million will be committed to these projects over the 2004-2006 period. Specifically, Health Canada has projects underway to assess long-term toxicological and health effects of GE fish in animal models. A project to develop DNA testing techniques for identification of GE fish through analysis of different parts of the fish is being completed and will be published in a peer-reviewed journal. Additional details on these research projects are available in the progress reports.

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## **Concluding Remarks**

The Ministers named in this Petition remain committed to:

- an effective domestic regulatory system that embodies the concept of sustainable development as it seeks to protect the health of Canadians, and the environment; and
- the broader responsibilities of global stewardship, which Canada shares with other countries, to see that practical and effective measures to protect humans, biodiversity, and the environment are achieved through the design and operation of a science-based, rules-based, and transparent international regulatory framework.