

Chapter

**14**

Genetically Engineered Fish

*All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.*

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## Previous Audits of Responses to Environmental Petitions Genetically Engineered Fish

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### Main Points

#### What we examined

We sought to determine whether Fisheries and Oceans Canada had made satisfactory progress in addressing a recommendation from our 2004 audit, which found that the Department had made little progress on developing regulations and a policy framework covering genetically engineered fish. These were commitments made in response to a petition in 2001. In its response to our audit, Fisheries and Oceans Canada agreed to develop a regulatory approach and a new policy by 2005.

#### Why it's important

Research on genetically engineered (GE) fish and other aquatic organisms began in the early 1980s and has increased rapidly around the world. GE fish are being developed for use in medical applications, to detect pollution, and as aquarium pets. The aquaculture industry is developing GE fish that grow faster than wild fish and that better tolerate cold temperatures. There are concerns about the potential ecological impacts of an accidental release of GE fish into natural ecosystems. For example, faster-growing GE fish may out-compete wild fish for food and territory. Canada's current regulations in this area have weaknesses.

#### What we found

**Progress is unsatisfactory.** Since the establishment of the Federal Biotechnology Regulatory Framework in 1993, Fisheries and Oceans Canada has frequently committed to developing regulations covering transgenic aquatic organisms, including genetically engineered fish. Although it has been working on this matter since 1993, Fisheries and Oceans Canada has not made satisfactory progress toward completing the regulations.

**Fisheries and Oceans Canada has responded.** Fisheries and Oceans Canada has accepted our recommendation. The Department has decided that the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) provides the regulatory framework for GE fish. It is participating in a CEPA, 1999 regulatory review that may address the issues raised in this audit.



## Introduction

**Genetically engineered organism**—An organism with genes that have been altered in a way not occurring in nature.

**14.1** Research on **genetically engineered (GE) organisms**, including GE fish and other aquatic organisms, began in the early 1980s and has increased rapidly around the world. GE fish are being developed for use in medical applications, to detect pollution, and as aquarium pets. The aquaculture industry is developing GE fish that grow faster than wild fish and that better tolerate cold temperatures.

**14.2** Canada does not yet have commercial farming of GE fish, but research is under way that could result in its introduction into Canada. In Prince Edward Island, for example, a United States-based company incorporated a Canadian subsidiary in January 1994, establishing a commercial biotechnology laboratory. This company has been conducting research and working on developments related to the commercialization of GE fish. The company has applied for regulatory approval in the United States, and in late 2006 the US Food and Drug Administration took the first step toward approving GE salmon for human consumption. Canadian government officials note that it is reasonable to expect a similar application for approval of GE fish in Canada.

**14.3** Certain scientists, regulators, and members of the public are concerned about the potential ecological impacts of an accidental release of GE fish into natural ecosystems. Faster-growing GE fish may out-compete wild fish for food and territory. Scientists are only beginning to understand the potential effects of GE fish on the natural environment.

**14.4** The 1993 Federal Biotechnology Regulatory Framework resulted from an agreement among federal regulatory departments and agencies on principles for an efficient and effective approach to regulating biotechnology products, with a high priority on health, safety, and the environment. The Framework established that various departments and agencies would regulate products of biotechnology within their area of expertise.

**14.5** Fisheries and Oceans Canada is the lead federal department responsible for the conservation and sustainable use of Canada's fisheries resources. These responsibilities include developing and implementing related policies and programs; managing fisheries, habitat, and aquaculture; and conserving and protecting aquatic ecosystems. However, without specific fisheries regulations in this area, the regulation of aquatic products of biotechnology, such as GE fish,

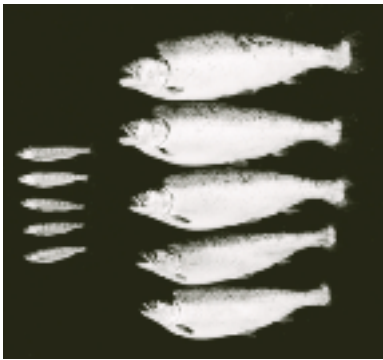
currently resides with Environment Canada and Health Canada under the *Canadian Environmental Protection Act, 1999*.

### Fisheries and Oceans Canada committed to developing regulations

**14.6** In November 2001, petition 38A on GE fish was submitted. The petition asked for information on the regulation of GE fish, as well as confirmation of the federal government’s policy on the rearing of GE fish in Canada. In response to the petition, Fisheries and Oceans Canada committed to developing regulations under the *Fisheries Act* for aquatic organisms with novel traits, including GE fish.

### What we found in 2004

**14.7** In 2004, we reported that Fisheries and Oceans Canada had made little progress on its commitment, even though 12 years earlier it had recognized the need for regulations dealing with aquatic biotechnology. In our recommendation we stated, “Fisheries and Oceans Canada should determine whether or not it will develop regulations on genetically engineered (GE) fish. If it decides to proceed with regulations, it should identify a clear timeline for completing the regulations, establish a work plan, and report publicly on its progress.” Fisheries and Oceans Canada accepted our audit recommendations and agreed to review regulatory options, decide on a regulatory strategy, and develop appropriate timelines for regulatory action, all by the end of 2005. The Department also agreed to revise and finalize its policy on transgenic aquatic organisms by the same date.



Transgenic (right) and non-transgenic (left) coho salmon at one year of age.

Source: Fisheries and Oceans Canada

### Focus of the audit

**14.8** We sought to determine whether Fisheries and Oceans Canada had made satisfactory progress in addressing a recommendation from our 2004 audit on GE fish.

**14.9** More details on the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

## Observations and Recommendation

**14.10** We expected Fisheries and Oceans Canada to have reviewed regulatory options, decided on a regulatory strategy, created appropriate timelines for regulatory action, and finalized a policy on GE fish by the end of 2005. In our view, new regulations could address the weaknesses of Canada’s current regulations in this area. This includes the need to

strengthen oversight of research and develop mandatory reporting requirements for GE fish and for accidental releases of genetically engineered organisms into the environment.

### **Fisheries and Oceans Canada has decided not to develop a policy**

**14.11** In response to our 2004 audit, Fisheries and Oceans Canada indicated it would develop a policy on transgenic aquatic organisms by the end of 2005. However, the Department no longer intends to develop a policy as it now recognizes that the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), including the *New Substances Notification Regulations (Organisms)*, achieves the Department's intended policy objective of protecting fish and fish habitat from the potential risks of products of aquatic biotechnology. Department officials told us that the 2004 commitment to revise and finalize a policy in response to our audit was made without a full understanding of the applicable CEPA, 1999 provisions.

### **Fisheries and Oceans Canada has not yet finalized its regulatory strategy**

**14.12** Our follow-up audit found that Fisheries and Oceans Canada has reviewed its regulatory options but has not yet finalized its regulatory strategy and developed timelines for regulatory action.

**14.13** Currently, Environment Canada and Health Canada regulate GE fish under the *New Substances Notification Regulations (Organisms)* of CEPA, 1999. Department officials told us that the Act functions as a safety net for new substances proposed for import or manufacture, including research and development activities on genetically engineered organisms that are not covered by other legislation. The *New Substances Notification Regulations (Organisms)* under CEPA, 1999, prescribe the information that must be provided to Environment Canada prior to the proposed import to or manufacture in Canada of a new organism that is an animate product of biotechnology. However, under the contained research and development exemption to these regulations, research and development organisms are not required to undergo the same notification and risk assessment process. While researchers and developers are still required to meet the containment provisions of the Regulations, some weaknesses exist, including the following:

- Departmental officials have incomplete knowledge of research and development activities because proponents are not required to disclose that they are conducting research; and

- There is no mandatory reporting of an accidental release of a research and development organism into the environment. Although such a breach is subject to Environment Canada's compliance and enforcement policy, the Department could only act on it once it became aware of the breach.

The result of these weaknesses is that the extent of research under way in Canada and any accidental release of GE fish may not be fully known.

**14.14** In 2004, Environment Canada and Health Canada began, with Fisheries and Oceans input, to consult with the regulated community about potential changes to the *New Substance Notification Regulations (Organisms)* under CEPA, 1999. This consultation is intended in part to address the weaknesses noted above in dealing with organisms intended for research and development activities, beginning with sections of the Regulations dealing with organisms other than micro-organisms (for example, GE fish). The first phase of these consultations is expected to be concluded in 2008; however, department officials could provide no specific timeline for revisions to the Regulations.

**14.15 Fisheries and Oceans Canada has repeatedly missed deadlines for completing regulations.** Since the Federal Biotechnology Regulatory Framework was established in 1993, Fisheries and Oceans Canada has frequently committed to developing regulations for transgenic aquatic organisms, including genetically engineered fish, and has repeatedly missed deadlines for completing them. We noted that the Department's earlier draft policies and guidelines on GE fish contained guidelines for the physical and genetic containment of transgenic organisms in research facilities. For example, the Department's 2000 draft policy contained explicit guidelines for containment and set out detailed research and development requirements, including mandatory review and approval processes for facilities.

**14.16** Until the *New Substances Notification Regulations (Organisms)* under CEPA, 1999 are amended or new *Fisheries Act* regulations are created, Canada's regulatory approach to addressing genetically engineered aquatic organisms, such as GE fish, will continue to have weaknesses. Fisheries and Oceans Canada officials told us that, in 2006, the Department determined that no new regulations would be developed until new funding was obtained. Officials indicated that the Department will decide on a regulatory approach and allocate resources for developing and implementing regulations provided that it obtains an appropriate new mandate and resources. During our audit, we saw no evidence that regulations are a priority for the Department (Exhibit 14.1).

**Exhibit 14.1 Progress in addressing our recommendation on regulations for genetically engineered fish is unsatisfactory**

Recommendation	Progress
Fisheries and Oceans Canada should determine whether or not it will develop regulations on genetically engineered (GE) fish. If it decides to proceed with regulations, it should identify a clear timeline for completing the regulations, establish a work plan, and report publicly on its progress. (2004 Report of the Commissioner of the Environment and Sustainable Development, Chapter 6, paragraph 6.80)	Unsatisfactory

**Satisfactory**—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation was made.

**Unsatisfactory**—Progress is unsatisfactory, given the significance and complexity of the issue and the time that has elapsed since the recommendation was made.

**14.17 Recommendation.** Given its commitments and the history of this file, Fisheries and Oceans Canada should decide on a regulatory approach for genetically engineered fish and clearly communicate the rationale and timeline for implementation of this approach.

**Fisheries and Oceans Canada's response.** Fisheries and Oceans Canada (DFO) accepts the recommendation. DFO has decided that its regulatory approach for genetically engineered fish is to continue to work under the terms of a Memorandum of Understanding (MOU) with Environment Canada and Health Canada to contribute to the regulation of aquatic organism products of biotechnology, including genetically engineered fish, under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) and the *New Substances Notification Regulations (Organisms)* [NSNR(O)].

The recommendation also suggests that Fisheries and Oceans Canada clearly communicate the rationale and timeline for implementation of this approach. The rationale for implementation of this approach is based on the fact that CEPA, 1999 provides a regulatory framework for animate products of biotechnology that is in place and is effective, and the NSNR(O) are currently already undergoing regulatory review. DFO's responsibilities under the MOU include undertaking risk assessments and assisting Environment Canada and Health Canada with administration of the Regulations. As DFO is already implementing this approach, no further timeline is required.

## Conclusion

**14.18** Although regulations on transgenic aquatic organisms, including genetically engineered fish, have been under development since the early 1990s, Fisheries and Oceans Canada has still not made satisfactory progress in developing them. The Department committed to developing these regulations in response to a petition in 2001 and in response to our audit in 2004.

## About the Audit

### Objective

Our objective was to determine whether Fisheries and Oceans Canada had achieved satisfactory progress in addressing commitments made in response to a recommendation in our 2004 audit of genetically engineered fish.

### Scope and approach

Since 2003, the Commissioner of the Environment and Sustainable Development (CESD) has conducted 11 petition response audits on a wide variety of subjects. To identify which of the 11 were suitable for follow-up audit, we examined the information available in our recommendations database, consulted staff involved in the original audits, and conducted research. To rank the audits for potential follow-up audit work, we developed criteria based on internal guidance on performance auditing.

We also considered criteria pertaining to auditability, sensitivity, risk, and availability of resources. On the basis of assessments against these criteria, an advisory committee considered the top-ranked issues and selected four. The results for each of these audits are individually reported in four chapters—11, 12, 13, and 14 (this chapter).

In this follow-up audit, we evaluated the progress that Fisheries and Oceans Canada had made in addressing a recommendation in our 2004 CESD Report, Chapter 6, paragraph 6.80. To do so, we reviewed documentation and interviewed government officials and external experts in the field.

### Criteria

The criteria for the audit were derived from the findings and recommendations of our 2004 audit of genetically engineered fish, and in particular, Fisheries and Oceans Canada's response to the above-noted recommendation of that audit (Chapter 6, paragraph 6.80). We expected that by the end of 2005, Fisheries and Oceans Canada would have

- reviewed regulatory options for genetically engineered fish,
- decided on a regulatory strategy,
- developed appropriate timelines for regulatory action, and
- finalized its policy on transgenic aquatic organisms.

### Audit work completed

Audit work for this chapter was substantially completed on 16 October 2007.

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## Appendix List of recommendations

The following recommendation is found in Chapter 14. The number in front of the recommendation indicates the paragraph number where it appears in the chapter. The numbers in parentheses indicate the paragraph numbers where the topic is discussed.

Recommendation	Response
<b>Fisheries and Oceans Canada has not yet finalized its regulatory strategy</b>	
<p><b>14.17</b> Given its commitments and the history of this file, Fisheries and Oceans Canada should decide on a regulatory approach for genetically engineered fish and clearly communicate the rationale and timeline for implementation of this approach. (14.12–14.16)</p>	<p>Fisheries and Oceans Canada (DFO) accepts the recommendation. DFO has decided that its regulatory approach for genetically engineered fish is to continue to work under the terms of a Memorandum of Understanding (MOU) with Environment Canada and Health Canada to contribute to the regulation of aquatic organism products of biotechnology, including genetically engineered fish, under the <i>Canadian Environmental Protection Act, 1999</i> (CEPA, 1999) and the <i>New Substances Notification Regulations (Organisms)</i> [NSNR(O)].</p> <p>The recommendation also suggests that Fisheries and Oceans Canada clearly communicate the rationale and timeline for implementation of this approach. The rationale for implementation of this approach is based on the fact that CEPA, 1999 provides a regulatory framework for animate products of biotechnology that is in place and is effective, and the NSNR(O) are currently already undergoing regulatory review. DFO’s responsibilities under the MOU include undertaking risk assessments and assisting Environment Canada and Health Canada with administration of the Regulations. As DFO is already implementing this approach, no further timeline is required.</p>



# Status Report of the Commissioner of the Environment and Sustainable Development to the House of Commons—March 2008

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#### Ecosystems

- Chapter 4** Federal Protected Areas for Wildlife
- Chapter 5** Protection of Species at Risk
- Chapter 6** Control of Aquatic Invasive Species
- Chapter 7** Areas of Concern in the Great Lakes Basin

#### Management Tools and Government Commitments

- Chapter 8** International Environmental Agreements
- Chapter 9** Strategic Environmental Assessment
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#### Previous Audits of Responses to Environmental Petitions

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- Chapter 12** Listing of Species at Risk
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- Chapter 14** Genetically Engineered Fish

