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Chapter 4

Canadian Food Inspection Agency—
Regulation of Plants with Novel Traits

Office of the Auditor General of Canada

The March 2004 Report of the Auditor General of Canada comprises seven chapters, a Message from the Auditor General, and Main Points. The main table of contents is found at the end of this publication.

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Chapter

4

Canadian Food Inspection Agency

Regulation of Plants with Novel Traits

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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Main Points

4.1 The Canadian Food Inspection Agency regulates the environmental release of plants developed through biotechnology, which are included in a broad category called plants with novel traits. Our audit identified weaknesses in the Agency's practices related to the management of risks associated with the environmental release of these plants. Our findings raise concerns that the Agency may not be regulating the unconfined release of these plants in a consistent manner.

4.2 Our audit focussed on the processes that the Canadian Food Inspection Agency had in place to ensure that it was meeting its responsibilities with respect to the regulation of plants with novel traits. As such, our audit procedures were not designed to determine whether undeclared and undetected plants with novel traits were entering Canada, whether any unauthorized ornamental plants with novel traits were present in Canada, or whether the Agency had approved any plants with novel traits that should not have been. No information came to our attention that any of these situations had occurred.

4.3 Our findings provide an early warning signal that some important aspects of the Agency's regulatory processes for plants with novel traits need strengthening. Given that the next generation of plants with novel traits could pose new and more complex environmental risks, it is important that the Agency act on our recommendations if it is to be prepared to meet these future challenges.

4.4 We found that there is a risk that undeclared and undetected plants with novel traits could be imported into Canada, and may therefore escape Canada's regulatory system. There is also a risk that unapproved ornamental plants with novel traits could be present in Canada.

4.5 The Agency has required insect resistance management as a condition whenever it authorizes insect-resistant plants with novel traits. However, the Agency's audits of conditions for unconfined release of insect-resistant corn have not yet enabled it to fully verify compliance with the conditions imposed.

4.6 To maintain quality and consistency in the delivery of the regulatory program for plants with novel traits, we would expect the Agency to have documented and implemented a quality management system to guide its evaluations. To support its decisions regarding unconfined release, we found deficiencies in standard operating procedures, a lack of complete documentation in the files, and incomplete definition of data quality

standards to guide the evaluations. For example we found that the Agency did not have complete documentary evidence and, therefore, was not transparent about how it was evaluating the long-term effects on the environment before authorizing unconfined release of plants with novel traits.

Background and other observations

4.7 The Government of Canada has identified biotechnology as a key industry for economic growth and international competitiveness. Consequently it has invested heavily in research, promotion, economic development, and the regulation of biotechnology.

4.8 Three federal organizations currently share responsibility for regulating products developed through biotechnology for their potential effects on health and the environment. This audit focussed on the Agency's regulatory activities to manage the environmental risks of plants with novel traits, a broad category that includes plants developed through biotechnology. The Agency states that Canada is the only country to use this regulatory approach.

4.9 Having and implementing a strong regulatory framework is essential if Canada is to capitalize on the potential benefits of plants with novel traits while appropriately managing the potential risks. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

The Agency has responded. The Agency agrees with our recommendations. Plans and actions it has underway are indicated in the responses in the chapter.

Introduction

4.10 The Government of Canada has identified biotechnology as a key industry for economic growth and international competitiveness. Consequently it has invested heavily in research, promotion, economic development, and the regulation of biotechnology (Exhibit 4.1 provides some recent examples). Biotechnology has been broadly defined as the use of biological processes, especially genetic manipulation, for industrial and other purposes. It can refer to traditional as well as modern processes. Most often, the term biotechnology is used interchangeably with modern biotechnology. In this chapter we use biotechnology to mean modern biotechnology (for more details see Biotechnology on page 8).

Federal role in biotechnology

4.11 The federal government fulfils many roles related to biotechnology, including

- regulating products,
- conducting in-house government research and supporting private sector research,
- promoting the economic development of the industry, and
- providing information to the public.

Exhibit 4.1 Examples of federal investment in biotechnology

Organization or program	Amount
Technology Partnerships Canada A technology investment fund in Industry Canada that supports research, development, and innovation through repayable contributions	Technology Partnerships Canada has approved provision of $263 million in repayable contributions to biotechnology projects since its launch in 1996
Expenditures on biotechnology research and development (in-house and external)	Ongoing For example: $492 million for 2001–02
Genome Canada Involved in developing and implementing a national strategy to help develop the biotechnology industry	$375 million to date
Canadian Biotechnology Strategy	$28.56 million from 2002–03 to 2004–05
Funding to strengthen the federal regulatory system for biotechnology	$90 million between 2000–01 and 2002–03 $34.6 million per year starting in 2003–04

Note: Figures not audited by the Office of the Auditor General

Source: Government of Canada publications

4.12 **Research and development.** Several federal organizations are involved in research, or the development of biotechnology. Examples include Agriculture and Agri-Food Canada, Industry Canada, the National Research Council, and Natural Resources Canada.

4.13 **Regulating products.** Three federal organizations currently share responsibility for regulating products developed through biotechnology: Health Canada, the Canadian Food Inspection Agency, and Environment Canada. These organizations evaluate the potential effects on health and the environment of products developed through biotechnology. They are also involved in research activities to support their regulatory roles. Fisheries and Oceans is developing regulations under the *Fisheries Act* to regulate aquatic organisms with novel traits, including fish developed through biotechnology.

4.14 **Regulating food.** Federal responsibility for regulating food, including food developed through biotechnology, is shared by Health Canada and the Canadian Food Inspection Agency (the Agency). Health Canada is responsible for establishing standards and policies governing the safety and the nutritional quality of food and developing labelling policies related to health and nutrition. The Agency is responsible for policy development for non-health and safety-related labelling (misrepresentation and fraud), and enforcement of this policy, including inspection. It also enforces Health Canada's health and safety-related food labelling policies. In addition, Health Canada is responsible for regulating pest control products and the human safety of drugs, medical devices, and cosmetics developed through biotechnology. The Agency is responsible for regulating plants, animal feeds, fertilizers, and veterinary biologics (for example, vaccines for animals) developed through biotechnology.

4.15 **Regulating products not regulated under other acts.** Products developed through biotechnology not regulated under other acts are regulated by Environment Canada under the *Canadian Environmental Protection Act, 1999*. The assessment responsibility is shared: Environment Canada evaluates the effects on the environment, and Health Canada evaluates the effects on human health.

4.16 **National Biotechnology Strategy.** In 1983 the government developed the first National Biotechnology Strategy, which focussed on research and development, the availability of skilled workers, communication and collaboration between researchers, and creating a favourable climate for private sector investment.

4.17 In 1993, the government outlined its principles for regulating biotechnology:

- maintaining Canada's high standards for protecting the health of Canadians and the environment;
- using existing laws and regulatory departments to avoid duplication;
- developing clear guidelines that are in harmony with national priorities and international standards for evaluating biotechnology products;

- providing a sound, scientific knowledge base on which to assess risk and evaluate products;
- ensuring that the development and enforcement of Canadian biotechnology regulations are open and include consultation; and
- contributing to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation, and the adoption of sustainable Canadian biotechnology products and processes.

4.18 **Canadian Biotechnology Strategy.** In 1998 the National Biotechnology Strategy was updated as the Canadian Biotechnology Strategy. The current approach to biotechnology builds on the earlier strategy, which had been more narrowly focussed on the economic aspects of biotechnology. The Canadian Biotechnology Strategy was designed to specifically address the regulatory and ethical dimensions of biotechnology. The vision of the new strategy is:

> to enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology.

The Canadian Food Inspection Agency regulates plants with novel traits

4.19 The Canadian Food Inspection Agency regulates the environmental release of plants developed through biotechnology, which are included in a broad category called plants with novel traits (PNTs).

Plants with novel traits—"A plant variety possessing a characteristic that is intentionally selected or created through a specific genetic change and is either not previously associated with a distinct and stable population of the plant species in Canada or expressed outside the normal range of a similar existing characteristic in the plant species."—Canadian Food Inspection Agency

4.20 The Agency, through the Plant Biosafety Office, regulates all plants with novel traits primarily under the Seeds Regulations Part V. PNTs could be agricultural, horticultural, or ornamental plants; or forest trees. The Agency also regulates imported PNTs under the *Plant Protection Act*; its purpose is to control pests to plants. Under this Act, the Agency grants permits for importing PNTs.

Did you know?

Plants with novel traits have been regulated in Canada since 1988.

A Statistics Canada report *VISTA on the Agri-Food Industry and the Farm Community, December 2002* shows that almost a third of the corn and soybeans grown in both Ontario and Quebec in 2002 were varieties with novel traits.

The Canola Council of Canada estimates that in 2001 approximately 80 percent of the canola acreage harvested in Canada was from plants with novel traits.

(Figures not audited by the Office of the Auditor General.)

4.21 The 1993 Federal Regulatory Framework for Biotechnology established that it is the final plant product that determines the potential risk to the environment, not whether the plant was developed through traditional or more modern processes. Therefore, plants with novel traits are regulated in the same way, no matter how they were developed. The Agency states that Canada is the only country to use this regulatory approach. Other countries regulate new plants based on the process used to create them.

4.22 PNTs cannot be legally released into the environment in Canada unless authorized by the Agency. Proponents (that is, companies or individuals) apply to the Agency for authorization for either confined or unconfined release into the environment. Authorization for confined release allows proponents to conduct field-research on PNTs under controlled conditions. Authorization for unconfined release is one of the regulatory approvals needed before plants with novel traits can be sold for widespread planting in Canada.

Toxic—According to the Seeds Regulations Part V, a PNT "is toxic if it is entering or may enter the environment in a quantity or concentration, or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health."

Did you know?

According to the Canadian Food Inspection Agency's Plant Biosafety Office, it or its predecessor in Agriculture and Agri-Food Canada:

- authorized 5,862 confined field trials of plants with novel traits for research purposes (includes only trials that took place) from 1988 to 2003
- issued 41 letters authorizing the unconfined release of plants with novel traits under the Seeds Regulations Part V from 1995 to 2003
- percentage of the unconfined releases that were for plants with novel traits produced through recombinant DNA biotechnology: **about 85 percent**
- percentage of the total number of unconfined releases that were for plants with novel traits tolerant to herbicides or resistant to insect pests: **about 85 percent**

4.23 The Seeds Regulations Part V require the Agency to evaluate the risks to the environment before approving PNTs for either confined or unconfined release. This includes the requirement to assess whether PNTs are toxic. The Agency bases its evaluations primarily on data submitted by proponents, the Agency's information on the unchanged plant species, scientific information in the public domain, research contracted by the Agency, and where necessary, consultations with external experts. The Agency's Regulatory Directives outline the evaluation criteria and the information required from proponents to support their PNT applications.

4.24 Exhibit 4.2 lists the environmental safety assessment criteria used by the Agency prior to authorizing the release of PNTs. It also explains some of the potential effects of PNTs on the environment. The Agency expects to soon receive applications for new PNTs that will likely have different risks, and therefore may pose new regulatory challenges.

4.25 The Agency has the authority to place conditions to manage the risks to the environment when it approves the environmental release of PNTs. Conditions for confined release include restricting the size and number of the field trials, using measures to prevent the spread of pollen and seeds, requiring proponents to monitor the trial sites, and restricting how the land may be used afterwards. Agency inspectors visit the trial sites to verify whether proponents are complying with the conditions. The Agency has also placed conditions on certain authorizations of PNTs for unconfined release, and has in some cases monitored compliance with these conditions.

4.26 Having and implementing a strong regulatory framework is essential if Canada is to capitalize on the potential benefits of plants with novel traits while appropriately managing the potential risks. Approval of a plant with a novel trait that harms the environment or human health could undermine public confidence in the regulatory system.

Focus of the audit

4.27 We focussed our first major audit of biotechnology on the federal government's regulatory activities to manage the environmental risks of plants with novel traits, a broad category that includes plants developed through biotechnology. The Canadian Food Inspection Agency has assessed many of the products currently on the market that required environmental assessments. Therefore our Office decided to audit the regulatory activities of the Agency's Plant Biosafety Office. It, or its predecessor in Agriculture and Agri-Food Canada, has been regulating the environmental release of plants with novel traits since 1988. Further details about our scope and approach can be found in **About the Audit** at the end of this chapter.

Exhibit 4.2 **How the Agency assesses the environmental safety of plants with novel traits**

Environmental safety assessment criteria	Reasons for criteria
"potential of the PNT to become a weed of agriculture or be invasive of natural habitats"	Weeds are usually defined as plants growing where they are not wanted. Weediness may be increased by changing the "fitness" characteristics of a plant. These characteristics could help the plant outcompete other plants. Some examples include • the ability of the plant to resist diseases or pests, • the ability of the plant to resist cold or survive the winter, and • the amount of seed a plant produces, or its ability to produce seed earlier than other plants.
"potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive"	Plants spread their genes by pollen and seed dispersal. The extent of gene flow depends on the plant's biology, whether there are related plants growing in Canada, and the way the plant is managed when cultivated as a crop.
"potential for the PNT to become a plant pest"	Plants can act as hosts for diseases that can spread to other plants. For example, could genetic recombination in a novel virus-tolerant plant result in a plant virus with an enhanced ability to infect plants?
"potential impact of the PNT or its gene products on non-target species, including humans"	Plants that are grown in the environment will come into contact with a wide range of organisms, from soil microbes to humans. PNTs could have unintended, negative effects on some organisms.
"potential impact on biodiversity"	Biodiversity can be defined as the number and variety of organisms (species) within a geographic region. Organisms are linked in an ecosystem in complex ways, for example, through food chains. Therefore, changes in biodiversity could affect many other organisms.

Source: Canadian Food Inspection Agency

Biotechnology

What is it?

Biotechnology has been broadly defined as the use of biological processes, especially genetic manipulation, for industrial and other purposes. Biotechnology can refer to traditional as well as modern processes. However, the term modern biotechnology is often used to denote one category of biotechnology called recombinant DNA technology. This technology enables scientists to directly transfer specific genetic traits from one organism to another, including between species that would not naturally interbreed. Most often, the term biotechnology is used interchangeably with modern biotechnology. In this chapter we use the term biotechnology to mean this category of modern biotechnology.

Did you know?

People use many different terms to refer to plants, foods, or other products that have been developed through modern biotechnology:

- genetically modified (GM)
- GM plants, GM foods, or genetically modified organisms (GMOs)
- genetically engineered (GE)
- recombinant DNA (rDNA)
- transgenic

Why should Canadians care?

People hold differing opinions about biotechnology. In preparing for this audit, we found that some stakeholders were more interested in the potential benefits, and some were more concerned about the potential risks.

Overall the Canadian biotechnology sector is growing rapidly. Statistics Canada's *Biotechnology Use and Development Survey—2001* shows that between 1997 and 2001

- the number of "innovative biotechnology firms" increased from 282 to 375, and
- the number of "biotechnology products and processes" on the market from these firms increased from 1,752 to 9,661.

However, this survey notes that the agriculture biotechnology sector declined from 90 firms in 1999 to 65 in 2001. It attributes this decline to several factors: consolidation of firms, firms shifting from the agriculture sector to the food processing sector, and, to a lesser degree, fewer firms because some ceased operations.

The same survey indicates the contribution of innovative biotechnology firms to the economy in 2001

- 49 percent of the sector's 11,897 people employed in biotechnology-related positions were in highly skilled jobs in the scientific research/direction, and technician categories; and
- the agriculture biotechnology sector had 3,498 products and processes in the research and development phase, compared to 2,017 human health products and processes in the same phase.

Benefits. The federal government's *1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process* notes that biotechnology has the potential to generate important new economic, environmental, and health benefits. Such potential benefits could include

- new products to remedy environmental contamination,
- more effective treatments for life-threatening diseases,
- improved crop yields,
- improved food quality, and
- increased use of agricultural practices that are more environmentally friendly.

The Strategy also notes that some of these benefits have already been realized. In addition, biotechnology is expected to play a key role in ensuring that Canada's agri-food sector remains competitive internationally.

Risks. However, concerns have been expressed about the potential social, ethical, and economic risks of biotechnology. For example, there is a risk that agricultural products developed through biotechnology that have been approved in Canada will not be approved in other countries. Therefore Canada may need to be able to segregate biotechnology from non-biotechnology crop products to protect its export markets. Another potential economic risk is the presence of pollen or seeds from biotechnology-derived crops in organic or non-biotechnology crops.

There are also concerns about the potential impacts on the environment, and the potential health effects of products developed through biotechnology. Furthermore, plants may be modified to produce medical products, for example, drugs and vaccines, or industrial products such as biodegradable plastics and lubricant oils. These plants could pose different environmental or health risks.

Observations and Recommendations

4.28 A regulatory system must capture all products that are required to be submitted for approval. The Canadian Food Inspection Agency regulates both imported and domestically produced plants with novel traits (PNTs) that are released into the environment. We therefore examined the Agency's procedures relating to imported PNTs. Since the regulations apply to all plant species, we also examined the Agency's oversight of ornamental plants with novel traits.

4.29 The Agency's evaluation process should adhere to key principles for maintaining quality and consistency. We examined whether quality management principles are built into the overall evaluation process for unconfined release, including how the Agency protects the confidential business information submitted by proponents. We also examined the Agency's documentary evidence for the aspects of its evaluations related to the long-term environmental effects of PNTs.

4.30 The Agency may impose conditions on proponents to manage the environmental risks, and should know whether these conditions are being complied with. Thus we examined the Agency's approach for monitoring compliance with conditions after PNTs are authorized for unconfined release. Finally, we assessed the clarity of the regulatory framework.

Imports and ornamentals

Risk that some imported plants with novel traits may be escaping regulation

4.31 Under the *Plant Protection Act* and its Regulations, the Canadian Food Inspection Agency requires importers to obtain a permit before importing plants with novel traits (PNTs) into Canada. The Seeds Regulations Part V apply to all PNTs that are imported and released into the environment. The Agency's Plant Biosafety Office and its predecessor have overseen the import of PNTs since 1988.

Did you know?

According to the Canadian Food Inspection Agency:

- the number of new plant import permits that the Agency issues each year: **about 6,000**
- in 2002–03, the value of plants and plant products imported into Canada: **about $10 billion**

4.32 The Agency uses the permit process to identify whether legally imported plants are PNTs and hence subject to the Seeds Regulations Part V. The Agency said that it obtains information on unapproved PNTs that could be imported into Canada, from regulatory authorities in other countries, industry intelligence, and international organizations.

4.33 We expected that the Agency's activities and decisions would support the achievement of the environmental safety objectives and goals of the regulatory program for PNTs. We therefore examined whether the Agency's approach to regulating imports enables it to effectively identify whether imported plants are PNTs.

4.34 At the time of our audit, we found that, instead of using the term "plant with a novel trait," the import permit application form asked importers to declare whether the plant is a "product of biotechnology." When the information provided indicates that the plant could be a PNT, Agency officials send the applications to the Plant Biosafety Office for review. The Agency told us that it relies on the import permit system to correctly identify

whether an imported plant is a PNT. Thus, in our opinion, importers' awareness of their legal responsibilities, and the questions asked on the import permit application form, including the guide attached to it, are critical to helping importers accurately complete the form.

4.35 We found that neither the import permit application form nor the attached one-page guide defined "product of biotechnology." The Agency has 95 active policy directives on imports on its Web site. While one of the policy directives provided further information on importing PNTs and defined what a plant with a novel trait is, neither the form nor the attached guide referred importers to this directive. In our opinion, the importance of the requirements regarding PNT imports warrants making the requirements more accessible to importers, for example, by referring to the directive either on the application form or in the attached guide.

4.36 Agency officials acknowledged that one could interpret "product of biotechnology" as being narrower in scope than the definition of a plant with a novel trait in the Seeds Regulations Part V. However, a recently added explanation to the application form did not sufficiently clarify that importers must declare whether the plants were PNTs. Moreover, this addition was inconsistent with the definition of biotechnology in the policy directive on PNT imports.

Testing for plants with novel traits is difficult

The Agency acknowledged that it is difficult to determine whether imported plants are plants with novel traits (PNTs). This is because there is no practical or cost-effective method to test for them. In general, PNTs are not visibly different from their non-PNT counterparts. While scientific methods to detect some PNTs are available, these methods are unique for each product of biotechnology, because the methods detect only specific genes, proteins, or traits. Testing would require knowledge of all the novel genes, proteins, or traits of all species of all the plants and plant products being imported into Canada.

4.37 If importers declared the plants to be products of biotechnology, they were asked to provide detailed technical information on the novel traits. If importers did not declare the plants to be products of biotechnology, or did not provide details in the supporting information that suggested the product could be a PNT, the Agency told us that it had no basis to investigate further. The exception would be where other sources of information suggest that further investigation is warranted. In our opinion, the information that the Agency obtains from others is only helpful if the information provided by importers indicates that the plants could be unapproved PNTs. Nevertheless, the Agency provided several examples where it had detected and taken action to remove illegally imported products of biotechnology.

4.38 Regulating PNT imports is challenging. This is due to Canada's unique approach based on plants with novel traits, the volume of imports of plants and plant products entering the country, and the fact that importers include medium to large companies, small businesses, individuals, and the public sector. We are concerned that there is a risk that undeclared and undetected PNTs could be imported into Canada and may therefore escape Canada's regulatory system. While no information came to our attention that undeclared and undetected PNTs are entering the country, the Agency concedes that, although unlikely, this is possible.

4.39 **Recommendation.** The Canadian Food Inspection Agency should improve its communications to importers to better enable them to indicate whether the plants they are importing are plants with novel traits.

Agency's response. The Agency agrees to continue to enhance communication with importers. While no information has been presented

that undeclared and undetected PNTs are entering the country, importer awareness continues to be a key component of the Agency's compliance strategy. As such, several communication channels are already available for importers including, for example, the Agency's Web site, the import permit office, and the publication of Regulatory Directives. The Agency will continue to assess what additional information may help importers in better understanding their responsibility.

Risks posed by ornamental plants with novel traits need to be more formally assessed

4.40 According to the Agency, the Seeds Regulations Part V apply to the environmental release of all plant species with novel traits, including ornamental plants with novel traits. The Canadian ornamental industry includes producers (including breeders), retailers, and importers of: nursery bedding plants, ornamental shrubs and trees, potted plants, cut flowers, and seeds.

4.41 We expected that the Agency's activities and decisions on ornamental plants would support the achievement of the environmental safety objectives and goals of the regulatory program for plants with novel traits (PNTs). We therefore examined how the Agency regulates both imported and domestically grown ornamental PNTs.

4.42 To prevent unauthorized release of PNTs in Canada, the Agency told us that it relies on the proponents' obligation to understand and voluntarily abide by the regulatory requirements for PNTs. It also relies on complaints from members of the industry who expect a level regulatory playing field. In our opinion, this approach is only effective if members of the industry are fully aware of the regulatory requirements.

4.43 However, the minutes from one of the Agency's consultations in May 2002, noted that the domestic "ornamental horticultural industry lacks awareness of the [PNT] regulations." The Agency also stated in a funding request for 2003–04, that the ornamental industry has been "undertaking plant breeding for a long time without such [PNT] regulation and are generally not aware of the regulatory implications of novel traits in their products." The Agency has made some effort to inform industry representatives of the Canadian ornamental sector about the regulation of PNTs. While these efforts were worthwhile, we are concerned whether the actions the Agency has taken to date are sufficient to adequately address the issues. We are therefore also concerned that domestic producers of ornamental PNTs, who are unaware of the Seeds Regulations Part V, may not submit applications for confined or unconfined release. As previously discussed, there is also a risk that importers may not always declare whether ornamental plants are PNTs in their applications for import permits.

4.44 The Agency told us that it has never received an application for either confined or unconfined release of an ornamental PNT; nor has it received any complaints about the unauthorized release of ornamental PNTs. While no information came to our attention that unauthorized ornamental PNTs are present in Canada, other countries have approved them, and research is

underway in Canadian laboratories to produce some. We note that a large number of species have been bred to produce an enormous variety of ornamentals. In our opinion, this, along with the indications that the domestic ornamental industry lacks awareness of the regulatory program for PNTs, suggest that there is a risk that unapproved ornamental PNTs could be present in Canada. We therefore expected the Agency to be able to demonstrate that it has assessed the potential risks that different kinds of ornamental PNTs could pose to the environment.

4.45 While we found that the Agency expects the environmental release of some ornamental PNTs to have different impacts than agricultural crops, it has not yet identified the environmental risks that ornamental PNTs could pose. The Agency says this is because it has not yet received an application for an ornamental PNT. However, in our view, more formally and systematically identifying the ornamental species that pose the highest risks to the environment would provide a basis to focus the Agency's regulation of imported ornamental PNTs and its efforts to educate the industry. The Agency has made an effort to be more proactive regarding the regulation of ornamental PNTs, because it requested funds from the Canadian Biotechnology Strategy for 2003–04 to consult with the ornamental industry on the environmental safety issues related to ornamental PNTs. However, the project was not funded.

4.46 **Recommendation.** The Canadian Food Inspection Agency should more formally and more systematically identify the environmental safety issues related to the environmental release of ornamental plants with novel traits.

Agency's response. The Agency concurs that a more formal and systematic approach could be used to determine the extent to which breeders are actually producing ornamental plants with novel traits. The Agency currently adopts a case-by-case approach to the environmental safety analysis of PNTs, which is universally accepted by regulatory agencies throughout the world. Nevertheless, the Agency will continue to formalize its evaluation processes.

4.47 **Recommendation.** Based on the environmental safety issues, the Canadian Food Inspection Agency should develop appropriate approaches for its assessment and regulation of environmental release of ornamental plant species with novel traits.

Agency's response. The Agency agrees that, based on a formal and systematic assessment of the ornamental plant industry, it will determine whether new regulatory approaches are required. As acknowledged in this report, there is currently no evidence that unauthorized ornamental PNTs are present within Canada. The Agency remains committed to working diligently to implement additional measures where warranted.

4.48 **Recommendation.** The Canadian Food Inspection Agency should enhance its efforts to educate the Canadian ornamental industry of its responsibilities under the Seeds Regulations Part V.

Agency's response. The Agency agrees with the recommendation and will continue to provide information to the ornamental industry. To date, there have been considerable efforts in working with ornamental industry associations. The Agency will also endeavor to undertake initiatives that will reach the growers of ornamental plants.

Procedures to evaluate environmental release

4.49 We would expect the Canadian Food Inspection Agency to have documented and implemented a system to maintain the quality and consistency of its evaluations of plants with novel traits (PNTs). The system should incorporate consolidated, complete, and current standard operating procedures, including standards for data quality. Furthermore, activities and decisions of the Agency's program to regulate plants with novel traits should be clearly documented throughout the process. The files should also include evidence of appropriate management challenge, review, and approval.

4.50 Clear and complete documentation of the Agency's analyses and conclusions is important in our opinion because

- the evaluations for unconfined release often represent months of complex scientific effort that require significant use of professional judgement,
- the decisions of the Agency could become the subject of litigation and the Agency may be required to be able to demonstrate to the courts that it had exercised appropriate diligence in carrying out its mandate for regulating PNTs, and
- the efficient analysis of any new information provided after authorization of unconfined release may be dependent on sound documentation of the original evaluation.

4.51 We therefore examined the Agency's procedures for evaluating environmental effects prior to approving confined and unconfined release. We also examined the files for all 19 PNT applications for unconfined release, submitted to, and evaluated by the Agency since its formation in 1997. In addition, we examined 10 of the 43 application files for confined release that the Agency received in 2002. We looked for clear evidence that the Agency has implemented a system to maintain the quality and consistency of its evaluations of PNTs.

Significant improvements needed in controls over evaluation procedures for unconfined release

4.52 We found that the Agency has standard operating procedures for evaluating applications for confined release that are relatively complete and documented. However, at the time of our audit, the Agency did not have complete, up-to-date, standard operating procedures to guide its evaluations of applications for unconfined release.

4.53 We did not assess the quality of the scientific data submitted by proponents or the scientific rigour of the Agency's evaluations for unconfined release. However we did assess the quality of the documentation in the internal files and electronic database for the Agency's analyses and decisions.

We found that the documentation in the files generally comprised correspondence, data supplied by the proponents, and "deficiency letters" sent to proponents by the Agency requesting additional data. The files also showed that the Agency had, on occasion, consulted with external scientists about specific aspects of the evaluations of plants with novel traits (PNTs).

4.54 We also found that the Agency's public-decision documents provided some summary information about its evaluations and conclusions regarding unconfined release. However, the Agency's internal files did not provide a comprehensive record of the analyses that supported the summary information or the conclusions in the public-decision documents. Furthermore, in many cases, the files for the evaluations of unconfined release lacked key documents and were poorly organized. In our opinion, this would make it difficult to conduct a detailed review of the steps and rationales leading to the Agency's decisions. An example of the Agency's lack of documentary evidence is further discussed in the next section. In contrast, the Agency's files for confined release were relatively complete and well-organized.

4.55 The Agency requires that data submitted by proponents to support their applications for unconfined release "be produced using statistically valid experimental designs and protocols (that are equivalent to the standards required for inclusion in peer-reviewed research publications)." However, we noted that standards in published journals may vary. A document called the Reviewers' Checklists outlines quality standards for the evaluation of certain analytical techniques used by proponents. While the Agency states that the document was developed to be used by reviewers in the assessment process, we found only one direct reference to it in the Agency's internal files.

4.56 We also found that, other than the Reviewers' Checklists, the Agency has not clearly defined what it means by data "equivalent to the standards required for inclusion in peer-reviewed research publications." Nonetheless, we found that the Agency routinely issues deficiency letters when it considers data submitted by proponents to be incomplete. These letters require proponents to submit additional or modified data, and some of these letters request information outlined in the Reviewers' Checklists.

4.57 Together, the above practices indicate that the Agency employs some standards for data quality in its evaluations of PNTs. However, we found little direct evidence that the standards in the Reviewers' Checklists had been consistently applied. Further, in our opinion, the Agency needs quality standards for the types of data not included in the Reviewers' Checklists, to provide a basis for ensuring consistency in its evaluations.

4.58 The Agency claimed that in addition to the Reviewers' Checklists, it maintains consistency in the quality of its reviews through the scientific expertise of its evaluators, staff training, and intra- and inter-departmental meetings to discuss data quality and to challenge reviewers' conclusions. The Agency was able to show us that it collaborates with other federal organizations and with other divisions within the Agency on certain aspects of the PNT evaluations and decisions. However, in our review of the

Agency's files, we found no formal records of meetings within the Plant Biosafety Office to discuss the quality of the environmental safety data or to challenge the overall conclusions for unconfined release. While a director signs the final letter to proponents that authorizes the unconfined release of a PNT, we found little other documentary evidence of systematic ongoing management review and challenge of evaluators' analyses and decisions.

4.59 The Agency told us that it takes about one year to train evaluators, during which time it says they are paired with a more experienced staff member. However, a review of statistics since the Agency was created in 1997 indicates that Plant Biosafety Office evaluators leave after working there for an average of 24 months. Thus, given the high rate of turnover, detailed documentation of the results and supervisory review of the evaluations are important.

4.60 In conclusion, for unconfined release, we found deficiencies in standard operating procedures, a lack of complete documentation in the files, and incomplete definition of data quality standards to guide evaluations. Consequently, in our opinion the Agency cannot demonstrate through its internal documentary evidence that it is consistently applying quality management procedures in its evaluations of applications for the unconfined release of PNTs. Furthermore, improvements in quality management will become even more important in the future because the Agency expects applications for PNTs to increase in complexity.

4.61 **Recommendation.** The Canadian Food Inspection Agency should develop, approve, and implement written procedures to guide the evaluation, approval, and documentation of applications for unconfined release of plants with novel traits. The procedures should include some provision for formal, systematic, and documented reviews prior to making final decisions.

Agency's response. The Agency concurs with this recommendation. As noted in the report, the Agency currently has standard operating procedures for confined research field trials. In addition, it has already taken actions to fully document its standard operating procedures for unconfined environmental release assessment. In this regard, the procedures also contain provisions for the documentation of reviews prior to final decisions, while still allowing the assessment of products on a case-by-case basis. This approach continues to enable the Agency to collect the necessary information to address risks that could vary depending on the product being assessed.

Lack of documentation on how long-term environmental effects are evaluated before unconfined release is approved

4.62 The Seeds Regulations Part V require the Canadian Food Inspection Agency to evaluate whether plants with novel traits (PNTs) "have or may have an immediate or long-term harmful effect on the environment or its biological diversity" before authorizing confined or unconfined release. We focussed our examination on the Agency's documentation supporting how it evaluates long-term environmental effects. Our results provide additional evidence of the findings discussed in the previous section.

4.63 We found that the Agency has not formally interpreted the phrase "long-term" from the Seeds Regulations Part V. The Agency states that this is because the duration of environmental effects could vary depending on the species, novel trait, and end use of the PNT. Further, the Agency argues that the evaluation of long-term environmental effects is implicit in each of the five assessment criteria that the Agency uses to structure its evaluations of environmental safety.

4.64 The Agency also states that it takes a case-by-case approach in its evaluation of each individual application. To do this, the Agency told us that it extrapolates the potential long-term environmental effects based on

- data submitted by proponents from laboratory studies and confined research field studies conducted for a number of years in various geographic locations,
- the Agency's biology documents that describe the unchanged parent crop and the Agency's knowledge of the novel trait, and
- information published in scientific journals, as well as a number of scientific reports that the Agency has recently commissioned on the environmental effects of PNTs.

4.65 Therefore, based on the considerations cited above, we expected to find specific evidence in its internal files of the Agency's extrapolations with respect to long-term effects, including its analyses and conclusions. However, its internal files and electronic database for unconfined release applications did not contain a complete record of how it reached conclusions about long-term environmental effects. For example, while the Agency's database includes fields for summarizing the type and duration of effects, these fields were not completely filled out in 8 of the 19 database records that we examined. For another six applications, very little or no scientific data or rationale was provided. The remaining five applications were withdrawn.

4.66 An additional safety measure is the mandatory requirement of the Seeds Regulations Part V for proponents to report unexpected effects after a PNT is authorized for unconfined release. We found that "new information" had been provided three times, and in each case, the new information was about the genetics of the PNT rather than any direct environmental effects. The Agency told us that in each case, the new information did not change the Agency's original conclusions about the environmental safety of the PNTs. However, the Agency is still required under the Seeds Regulations Part V to assess whether PNTs have or may have long-term harmful effects on the environment before approving unconfined environmental release.

4.67 In conclusion, from our review of the documentary evidence in the files for unconfined release, it was not transparent how the Agency evaluates the long-term environmental effects before authorizing unconfined release as legally required.

4.68 **Recommendation.** The Canadian Food Inspection Agency should define more explicitly how its evaluation process considers the long-term effects on the environment.

Agency's response. The evaluation of long-term effects has always been a key component in the assessment and approval of PNTs. Nevertheless, the Agency agrees that better communication is needed to more explicitly define how long-term environmental effects of plants with novel traits are assessed prior to approval. The Agency will also provide more information on the measures it has in place to monitor, following the approval, the unintended long-term impacts of plants with novel traits.

4.69 **Recommendation.** The Canadian Food Inspection Agency should also ensure that it has documentary evidence in its files showing how it is evaluating the environmental effects of plants with novel traits, including the long-term effects.

Agency's response. The Agency agrees with the recommendation and will continue to enhance its procedures. The Agency has already made significant progress in updating its documentation to reflect the recent changes to the Regulatory Directives. The procedures also clarify how the documentary evidence in support of the assessments should be organized.

Post-authorization monitoring

4.70 When it authorizes unconfined release of plants with novel traits (PNTs), the Canadian Food Inspection Agency may impose conditions on proponents to manage the environmental risks. The Agency says that proponents in turn may impose related conditions in their agreements with those who grow the PNTs, that is, the growers. We expected that the Agency's post-authorization activities and decisions would support the achievement of the environmental safety objectives and goals of its regulatory program for PNTs. In our opinion, if the Agency is imposing conditions it should know whether proponents and growers are complying.

4.71 Therefore we examined whether the Agency had an approach that enables it to verify compliance with conditions for unconfined release. Effective monitoring after authorization could become even more important if the Agency imposes conditions when it approves the next generation of plants with novel traits.

More assurance of grower compliance with insect resistance conditions for corn needed

4.72 Since 1995, the Agency's Plant Biosafety Office and its predecessor in Agriculture and Agri-Food Canada, have issued 14 authorizations to 7 companies for the unconfined release of insect-resistant plants with novel traits (PNTs). These plants contain proteins, referred to as "Bt" that are known to be toxic to certain types of insects, and which act as insecticides. The Agency says that insect resistance to these toxins could develop over time. Consequently, the benefits of the toxin could be lost, both when used in insect-resistant crops and when applied as a pesticide spray.

4.73 In an attempt to reduce or delay the development of resistance, the Agency has required insect resistance management as a condition of its authorizations of insect-resistant PNTs. Both proponents and growers play a role in preventing the development of insect resistance. This is because insect

resistance management includes educating seed companies and growers about preventing the development of insect resistance, monitoring for the development of resistance, having procedures to respond to development of unexpected insect resistance, and using specific farming practices. However, in the event of non-compliance with the conditions, the Agency is only able to take action against proponents because it has no legal authority to enforce compliance by growers.

4.74 In examining the Agency's monitoring of compliance with the conditions to prevent the development of insect resistance, we reviewed the Agency's reports on

- two audits of conditions for unconfined release conducted in 2000, one for PNT corn that is insect-resistant, the other for PNT potatoes that are insect-resistant;
- a 2002 follow-up on the 2000 corn audit; and
- the 2002 interviews with 14 growers of PNT corn that is insect-resistant, as well as sampling of field crops.

4.75 We found that the methodology used in the 2000 potato audit provided information about the compliance of both the proponents and growers. However, the methodology used in the 2000 corn audit comprised mainly interviews with proponents and reviews of documents, related to their education of growers and company sales staff about practices to prevent the development of insect resistance, and to their monitoring procedures. In 2002, the Agency interviewed 14 growers of insect-resistant corn and sampled field crops. Its report suggested that there was a lower compliance rate with conditions to prevent the development of insect resistance than was found in surveys conducted previously by the industry to monitor its own compliance. As a result, the Agency concluded that it is important to continue its own monitoring of growers.

4.76 The Agency told us that it plans a pilot project to sample the compliance of 100 corn growers, including sampling of field crops. In preparation, the Agency has provided training to its field inspectors on this new inspection activity. Involvement by corn growers will be voluntary because the Agency imposes conditions for insect resistance management on proponents, rather than on growers. However, due to the limited information on grower compliance obtained by the Agency to date, we concluded that its audits of conditions for unconfined release of corn have not yet enabled it to fully verify compliance with conditions imposed to prevent insect resistance from developing. In our opinion, assessing the compliance of growers is important for determining compliance with these conditions.

4.77 **Recommendation.** The Canadian Food Inspection Agency should complete its efforts to develop and implement a systematic approach for verifying compliance with conditions set for the unconfined release of insect-resistant plants with novel traits.

Agency's response. The Agency will continue to ensure that no authorization for an insect-resistant crop is being granted without a

requirement for an insect resistance management plan and will continue to verify compliance by proponents with this condition. The Agency is a global leader in insect resistance management strategies and is internationally recognized for the work it has achieved in this area. The Agency recognizes the need to continue its efforts to evaluate compliance by growers with insect resistance management plans and it has already taken actions to further improve its ongoing compliance program.

4.78 **Recommendation.** The Canadian Food Inspection Agency should seek legal authority to enforce compliance by growers with conditions for unconfined release.

Agency's response. The Agency agrees with the recommendation. As noted in the report, the Agency currently has legislative authority to enforce compliance with the Seeds Regulations Part V by the seed companies. In addition, the Agency will explore options related to the authority necessary to enforce compliance by growers.

Approach for herbicide-tolerant crops under development

4.79 The Agency has taken a different approach regarding herbicide-tolerant PNTs. Use of herbicide-tolerant PNTs enables growers to spray fields with specified herbicides to destroy weeds without killing the crop. The Agency has worked with industry to develop approaches to stewardship of herbicide-tolerant crops. It has also recently decided to require proponents to have "herbicide tolerant crop stewardship plans" for new herbicide-tolerant PNTs. The Agency says that it is working with the industry to develop similar stewardship plans for herbicide-tolerant PNTs that have already been authorized. While proponents will have to submit these plans for Agency review and approval, unlike for insect-resistant PNTs, implementation of the plans will be voluntary. Further, the Agency told us that if the voluntary approach does not result in satisfactory management of herbicide-tolerant PNTs, it will make implementation of the plans mandatory. Therefore, in our opinion the Agency needs to ensure that these plans and any reports on their implementation are sufficiently detailed to enable it to assess whether this approach is resulting in satisfactory management of herbicide-tolerant PNTs.

4.80 **Recommendation.** The Canadian Food Inspection Agency should complete its efforts to develop, implement, and monitor the "herbicide tolerant crop stewardship plans" to ensure the approach is resulting in satisfactory management of herbicide-tolerant plants with novel traits.

Agency's response. The Agency concurs with the recommendation and will continue its efforts to implement herbicide tolerant crop stewardship plans. The Agency is recognized as a world leader in this regard and has already achieved significant co-operation with companies, grower groups, and the scientific community. The Agency will continue to build on its approach in order to ensure satisfactory management of herbicide-tolerant PNTs.

Regulatory framework

Regulatory framework needs to be clarified

4.81 We expected the Canadian Food Inspection Agency to have clear authority in its regulatory framework for its activities and decisions for regulating plants with novel traits (PNTs). While conducting our audit work we found a number of instances that suggest that the Agency should consider clarifying and strengthening the regulatory framework for PNTs.

4.82 Examples of areas where the regulatory framework for PNTs may need clarifying include the following:

- The Seeds Regulations Part V define unconfined release as being unrestricted release. However, they also give the Minister the authority to impose conditions upon unconfined release to manage environmental risks. The Agency may need to clarify that it has the authority to restrict unconfined release to certain geographical regions of Canada as it is currently doing for some PNTs.
- The Regulations provide authority to impose conditions on the proponents to manage environmental risks. Proponents in turn require growers to abide by some of these conditions. However, the Agency does not have the authority to enforce the conditions that proponents impose on growers.
- The Regulations provide very few tools to enforce the conditions imposed on proponents to protect the environment. The Agency can send warning letters, revoke authorizations for PNTs, or refuse to consider future applications: the latter two have very harsh consequences for proponents. The Agency has never refused to consider future applications, and states that it has never had cause to revoke an authorization for unconfined release.
- The government has recently instituted a policy of synchronizing authorizations for PNTs under the *Seeds Act*, the *Food and Drugs Act*, and the *Feeds Act*. This is to prevent contamination of the food or feed supply with unapproved PNTs. Its authority to synchronize decisions under these three acts is unclear.

4.83 **Recommendation.** The Canadian Food Inspection Agency should consider clarifying the regulatory framework for plants with novel traits to strengthen its ability to effectively deliver its regulatory program.

Agency's response. The Agency agrees with this recommendation and will explore avenues for clarifying the regulatory framework related to environmental release of PNTs. The Agency will also continue to update its regulatory directives. In 2002 and most recently in 2004, the Agency has taken steps to strengthen its directives in order to keep pace with emerging science and enhanced knowledge gained from experience with PNTs.

Confidential business information

Confidential business information is not being adequately protected

4.84 Proponents who seek authorization for confined and unconfined release of plants with novel traits provide information to the Canadian Food Inspection Agency that they identify as confidential business information. Proponents consider this information to be proprietary and commercially sensitive. Its unauthorized release or disclosure could affect the company's competitive position or its commercial interests. The Agency views this information as particularly sensitive, which if compromised, could lead to serious injury or economic loss to the company and cause serious embarrassment. This could potentially impair the Agency's ability to regulate plants with novel traits.

4.85 We expected the Plant Biosafety Office within the Agency to protect the confidential business information with appropriate security measures. This means that the Plant Biosafety Office should comply with the February 2002 Government Security Policy, the Agency's 1998 Security Policy, and the Agency's 1999 guidelines for employees and managers. We therefore examined the Plant Biosafety Office's compliance with these policies and guidelines.

4.86 At the time of our audit, we found that the Plant Biosafety Office was using some security measures to control access to the confidential business information. While the Plant Biosafety Office was taking its responsibilities to protect this information seriously, we found that it was not complying with important aspects of the Government Security Policy or the Agency's own security policy and guidelines. For example, the management of the Plant Biosafety Office had not formally assessed the sensitivity of the information under their control or the related threats and risks. This assessment is required to identify the measures needed to adequately protect this information. Further, the Plant Biosafety Office seldom designated (marked) the confidential business information it received from proponents or its own analyses of these data in accordance with Agency or government requirements. Moreover, we found that managers of the Plant Biosafety Office were unfamiliar with these key aspects of their security responsibilities. This was largely because they had not received any formal up-to-date training on security policies and procedures.

4.87 Our audit procedures were not designed to determine whether the confidential business information had been compromised, and no information came to our attention that it had been. However, the lack of compliance with important aspects of the Government Security Policy and the Agency's own security policy and guidelines led us to conclude that the Plant Biosafety Office was not adequately protecting the confidential business information provided by proponents or its own analyses of these data. However, once the Agency was made aware of our concerns, it began to take action to improve its security program.

4.88 **Recommendation.** The Canadian Food Inspection Agency should, within six months, formally review the Plant Biosafety Office's security practices and provide formal employee security training for all Plant Biosafety Office staff.

Agency's response. The Agency takes seriously its responsibility to protect confidential business information and no information has been presented that business information has been compromised. At the time of the audit, documents containing confidential business information were kept in a secure storage area, with restricted access, or in locked cabinets. Assessment information was recorded in a protected database, and stored on a separate server with restricted access. In addition the Agency has recently taken steps to enhance its security practices by more clearly identifying the classification of documents. Finally, the Agency is committed to conduct a formal review of security practices and take further actions, if warranted, and to provide additional training to the staff of the Plant Biosafety Office.

4.89 **Recommendation.** The Canadian Food Inspection Agency should, within one year, ensure that the Plant Biosafety Office's security practices comply with the Agency's security requirements, as well as those of the Government Security Policy.

Agency's response. The Agency agrees with this recommendation and is confident that, with the existing and enhanced security measures being implemented, it will fully comply with the Government Security Policy.

Conclusion

4.90 We examined whether the Canadian Food Inspection Agency's regulatory framework for plants with novel traits (PNTs) adheres to selected elements of government regulatory policy. We found weaknesses in the Agency's compliance with some key elements of the government's regulatory policy, and we concluded that there could be unassessed risks to the environment. We also had concerns about aspects of the regulatory framework for plants with novel traits. Specifically, we concluded that

- Because there is a risk that some imported PNTs may be escaping the regulatory process, the Agency is not administering the regulatory program for PNTs in such a way that achieves its environmental safety objectives.
- The Agency has not formally or systematically identified the risks that ornamental PNTs could pose to the environment. Our findings also suggest there is a risk that unapproved ornamental PNTs could be present in Canada.
- The Agency's audits of conditions for unconfined release of insect-resistant corn have not yet enabled it to fully verify compliance with conditions it imposes for the unconfined release of insect-resistant PNTs.
- The Agency may need to clarify some of the authorities the Seeds Regulations Part V confer on the Minister.

4.91 We examined whether the Agency's regulatory program for PNTs is managed and delivered in a manner that maintains quality and consistency. We concluded that the Agency has not adequately developed or implemented quality management procedures to ensure quality and consistency in its evaluations of applications for the unconfined release of PNTs.

4.92 Our final objective was to determine whether the Agency's program to regulate PNTs is managed in a transparent, fair, and accountable manner while protecting the confidential business information supplied by proponents. We concluded that

- The Agency was not adequately protecting the information supplied by proponents to the Plant Biosafety Office. Inadvertent disclosure of this information could potentially impair the Agency's ability to regulate PNTs.
- From our review of the documentation in the files, the Agency is not transparent in how it is implementing the Seeds Regulations Part V requirement to evaluate the long-term harmful effects on the environment before authorizing unconfined release of PNTs.

4.93 Our audit focussed on the processes that the Canadian Food Inspection Agency had in place to ensure that it was meeting its responsibilities with respect to the regulation of plants with novel traits. As such, our audit procedures were not designed to determine whether undeclared and undetected plants with novel traits were entering Canada, whether any unauthorized ornamental plants with novel traits were present in Canada, or whether the Agency had approved any plants with novel traits that should not have been; and no information came to our attention that any of these situations had occurred.

4.94 Nonetheless, our findings provide an early warning signal that some important aspects of the Agency's processes for regulating plants with novel traits need strengthening. Given that the next generation of plants with novel traits could pose new and more complex environmental risks, it is important that the Agency act on our recommendations if it is to be prepared to meet these future challenges.

About the Audit

Objectives

We had three audit objectives:

- To determine whether the Canadian Food Inspection Agency's regulatory framework for plants with novel traits (PNTs) adheres to selected elements of the government's regulatory policy.

  Government regulatory policy requires among other things that program activities support the achievement of the goals of the regulatory program and that government regulators reliably identify and manage risks. We also assessed whether the Canadian Food Inspection Agency had authority in its legislation or regulations for its PNT regulatory program activities and decisions.
- To determine whether the Agency's program to regulate PNTs is managed and delivered in a manner that maintains quality and consistency. Government regulatory policy requires that regulatory agencies develop and implement specifications and procedures to guide and control delivery of regulatory programs. It also requires that regulatory agencies document steps taken in decision-making processes.
- To determine whether the Agency's program to regulate PNTs is managed in a transparent, fair, and accountable manner while protecting the confidential business information supplied by proponents.

Scope and approach

Our audit focussed on the regulation of plants with novel traits (PNTs) by the Canadian Food Inspection Agency's Plant Biosafety Office. The Agency's legislation gives it the mandate to evaluate the environmental safety of PNTs before approving their release into the environment. We did not design the audit to enable us to conclude whether the Agency is adequately protecting the environment because we did not evaluate the quality of scientific data on which the Agency bases its evaluations, or the scientific rigour of the evaluations.

We conducted our work by

- interviewing Agency staff, managers, and selected stakeholders; and
- reviewing policies, procedures, and other documents as required; the Agency's electronic database; and selected case files. Note: We did not examine files and activities that occurred after 30 September 2003.

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