Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

CFIA's Biotechnology Highlights Report

2001-2002

Canada

CFIA's Biotechnology Highlights Report

2001-2002

PREFACE

This report is a prototype—the first in a proposed series of reports on the Canadian Food Inspection Agency's (CFIA) biotechnology-related activities. We hope that this document will evolve into successive reports that will provide readers with timely information about the CFIA's regulatory work in various areas of biotechnology.

P0300E-03
Catalogue Number: A101-1/2002
ISBN No. 0-662-67476-6

TABLE OF CONTENTS

PRESIDENT'S FOREWORD

As Canada's largest science-based regulator, the Canadian Food Inspection Agency's (CFIA) key role is to protect Canadians' health and safety. The CFIA serves the Canadian public by delivering programs along three key business lines: food safety, plant protection, and animal health. When it comes to biotechnology-derived agricultural products, we work according to our science-based regulatory mandate in order to assure Canadians that these products are safe for the environment and for livestock.

The various government bodies that are involved with biotechnology all have different mandates. The CFIA's performance, like that of all federal departments and agencies, is subject to close scrutiny in Parliament and is monitored publicly through a number of checks and balances. In addition, through various other means—such as posting information on our Web site, writing fact sheets, and creating reports like this one—we share information with Canadians on what we do.

This, the CFIA's first highlights report on biotechnology-related programs, focuses on how the CFIA works to determine that the biotechnology-derived agricultural products available in Canada are safe. We recognize that access to more high-quality information on this topic is important to Canadians, so this report identifies how the CFIA works to meet their information needs. Finally, to make sure that our important international role is clear and transparent, we report on how our international responsibilities are being met.

Biotechnology is an ever-expanding science. As a result, the CFIA has had to meet significant challenges since it was created in 1997, and no doubt such challenges will continue to test us. The accomplishments described in this report reflect the hard work of the CFIA's highly qualified and dedicated employees. I am confident that the professionalism and commitment of CFIA staff will assure Canadians that the CFIA will continue to respond to their safety and information needs and that it will continue to play a strong role in the international arena of agricultural biotechnology.

If you would like to comment on this Highlights Report, we would welcome your suggestions to help us fulfil our mandate.

Richard B. Fadden

EXECUTIVE SUMMARY: CFIA'S BIOTECHNOLOGY HIGHLIGHTS REPORT, 2001–2002

This report discusses the CFIA's work in 2001–02 regarding the regulation of biotechnology-derived products and related matters. It addresses these activities in terms of safety, the commitment to meet Canadians' information needs, and international responsibilities.

Key External Reports: Two major studies took place concerning the regulation of biotechnology-derived food products. The Royal Society of Canada Expert Panel on the Future of Food Biotechnology released a report in February 2001 on how the regulatory system might be strengthened to meet future needs in food biotechnology. CFIA worked with other departments to develop an action plan to address the report's recommendations and, later, a progress report on the plan's implementation.

The Canadian Biotechnology Advisory Committee (CBAC) held extensive consultations with stakeholders and the public regarding the regulation of biotechnology-derived products and released an interim report in August 2001, and a final report in August 2002. CBAC concluded that biotechnology-derived products approved under the current regulatory system pose no greater health or environmental risk than other foods, and identified opportunities to improve the management and coordination of the regulatory system; enhance public communication; and, augment the regulatory system's capacity to deal with the more complex products of biotechnology on the horizon.

On-going Evolution of the Regulatory System: With regard to biotechnology products, The CFIA regulates the environmental safety of plants with novel traits (PNTs), the safety of novel livestock feed, and the safety and potential environmental impacts of transgenic animals. As biotechnology continues to evolve, so too does the CFIA regulatory system—not just to keep pace but to anticipate developments before they appear.

In 2001–02, the CFIA's Plant Biotechnology Office approved 146 submissions of PNTs for release at 289 confined research field trials; approved 3 PNTs for unconfined environmental release; amended Regulatory Directive 2000-07, *Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada*; hosted a workshop on herbicide-tolerant volunteer canola, and co-hosted another one with Simon Fraser University on GM food crops; developed a directive to help regulate trees with novel traits; and sponsored on-going research into the environmental effects of PNTs.

The CFIA's Feed Section developed several new inspection programs; approved one new PNT for feed use (herbicide-tolerant rice); funded research into the potential impacts of novel feeds on livestock; and, surveyed research establishments to determine the work being done on novel feeds.

A new Animal Biotechnology Unit was created in the Animal Health and Production Division. It works with federal departments to develop specific regulations and technical standards for biotechnology-derived livestock to supplement the *Canadian Environmental Protection Act*. In 2001–02, it produced several safety assessment reports on transgenic livestock and birds; continued its on-going review of the current federal regulatory framework for biotechnology-derived animals for internal peer review; and, began preparation of draft *Guidelines for Safety/Environmental Assessment of Biotechnology-Derived Animals*.

Other highlights regarding the regulation of biotechnology-derived products included enhancement of the CFIA's detection and identification capacity for products such as PNTs, novel livestock feeds, and transgenic fish, and the scheduling of four CFIA -administered acts and regulations as being equivalent to the *Canadian Environmental Protection Act.*

Molecular Farming: With the ever-increasing number and complexity of biotechnology products on the horizon, the CFIA must constantly look and plan ahead. One impending area is plant molecular farming—the cultivation of PNTs that produce scientifically, medically, or industrially interesting molecules for the harvesting of those molecules. The CFIA anticipates that companies may soon be seeking approval to commercially approve such plants and, in 2001, initiated public and expert consultations to update the relevant regulatory directives.

StarLink™: The CFIA's inspection functions include border inspections for biotechnology-derived products that have not been approved for safety in Canada. StarLink™ corn is one such product. It was approved in the U.S. for animal feed and industrial purposes, but not for human consumption. It has not been approved in Canada for any purpose and therefore cannot be imported. The CFIA, the Canadian Grain Commission, and Canada Customs and Revenue Agency undertook a major joint initiative to keep StarLink™ corn from entering the country. They worked together to verify that shipments had appropriate documentation proving no StarLink™ content and to sample shipments on a random basis. Between October 15, 2001, and March 31, 2002, more than 20 000 shipments of whole grain corn from the U.S. were reviewed, more than 50 of which were refused.

Informing Canadians / Labelling: Keeping Canadians informed is a CFIA priority. The Agency uses a range of tools that enable Canadians to have the latest information possible and the opportunity to respond and ask questions. An important area of public information concerns the labelling of GM foods.

The CFIA works nationally and internationally to develop labelling standards and guidelines. Domestically, it works with the Canadian Council of Grocery Distributors and Canadian General Standards Board to help develop a national voluntary labelling standard, and responds to parliamentary committees studying the labelling issue.

Internationally, it works on committees and task forces of the Codex Alimentarius Commission and, in 2001–02, helped to formulate Canada's position on labelling guidelines and contributed significantly to the Food Labelling Committee's annual meeting in May 2001 chaired by Canada. The CFIA also worked with Foreign Affairs and International Trade to respond to proposed changes to EU labelling regulations.

International Responsibilities: The CFIA participates in several international organizations and discussions on a range of matters related to its mandate, and frequently helps to develop Canada's position on these matters. One such item is the Cartagena Protocol on Biosafety, designed to help ensure the safe transfer, handling, and use of living modified organisms that could harm biological diversity. Canada signed the Protocol in April 2001 but wants further discussions before it ratifies it. The CFIA and Agriculture and Agri-Food Canada co-hosted several stakeholder consultations, and the information gathered during these meetings contributed to the development of Canada's positions for several international Protocol meetings.

ACRONYMS

APEC	Asia-Pacific Economic Cooperation
ATC	Agriculture Technical Cooperation (Working Group)
Bt.	*Bacillus thuringiensis*
CBAC	Canadian Biotechnology Advisory Committee
CBS	Canadian Biotechnology Strategy
CCAC	Canadian Council for Animal Care
CCGD	Canadian Council of Grocery Distributors
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCRA	Canada Customs and Revenue Agency
CEPA	*Canadian Environmental Protection Act*
CFIA	Canadian Food Inspection Agency
CFS	Canadian Forest Services
CGC	Canadian Grain Commission
CGSB	Canadian General Standards Board
CIDA	Canadian International Development Agency
CRSB	Canadian Regulatory System for Biotechnology
CTFBT	Codex Alimentarius Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology
DFAIT	Department of Foreign Affairs and International Trade
DFO	Department of Fisheries and Oceans
EPA	Environmental Protection Agency
EU	European Union
GEF	Global Environment Fund
GMOs	genetically modified organisms
ICCP	Inter-governmental Committee on the Cartagena Protocol
IPPC	International Plant Protection Convention
ISPM	International Sanitary and Phytosanitary Measures
LMOs	living modified organisms
NAPPO	North American Plant Protection Organization
NIES	Nanjing Institute of Environmental Sciences
OECD	Organisation for Economic Co-operation and Development
PBO	Plant Biosafety Office
PNT	plant with novel trait
POR	public opinion research
RDEAB	Research, Development, and Extension of Agricultural Biotechnology
SEPA	State Environmental Protection Administration
UNEP	United Nations Environmental Programme
USDA	U.S. Department of Agriculture
WTO	World Trade Organization

INTRODUCTION

"Every scientific fulfillment raises new questions; it asks to be surpassed and outdated."

Max Weber

Science is always changing—it's the nature of the discipline. With this in mind, the Canadian Food Inspection Agency (CFIA) knows that its regulatory system for products of biotechnology needs to continue to keep pace with scientific knowledge. As the largest science-based regulatory agency in the Government of Canada, the CFIA is committed to this on-going evolution.

As a vital step in its evolutionary process, the CFIA has sought input from expert panels, committees, the scientific community, and available scientific literature. Contributing significantly in this regard have been the Royal Society of Canada Expert Panel on the Future of Food Biotechnology and the Canadian Biotechnology Advisory Committee.

The Royal Society panel made recommendations about government transparency and the need to increase Canadians' confidence about the regulation of biotechnology-derived foods. With this in mind, and believing that the CFIA should raise public awareness about its activities, the CFIA presents this report on its biotechnology-related activities for 2001–02. The report reflects three themes: meeting safety needs, meeting information needs, and meeting our international responsibilities. Within these themes you will recognize the CFIA's three business lines—food safety, plant protection, and animal health.

ROYAL SOCIETY OF CANADA REPORT

Meeting safety needs

The Royal Society of Canada Expert Panel on the Future of Food Biotechnology was brought together in 1999 at the request of the Ministers of Agriculture and Agri-Food, Environment, and Health. Ministers asked that the committee provide recommendations in respect of a strengthened regulatory system that can respond to future needs in food biotechnology. On February 5, 2001, the committee released its report, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*.[1] The report's 53 recommendations fall into the following themes:

- substantial equivalence
- use of precaution
- transparency and increasing public confidence
- potential human health impacts
- environmental safety and biotechnology-derived plants (plants with novel traits)
- biotechnology-derived animals (including fish) and feeds (novel feeds)
- other recommendations

In November 2001, the CFIA, along with Agriculture and Agri-Food Canada, Fisheries and Oceans Canada, Environment Canada, and Health Canada, released an action plan in response to the report's recommendations, many of which fall under CFIA responsibility. Of the 48 items in the action plan, 14 were directed toward the CFIA alone and 10 others were shared by the CFIA and other departments.

The Royal Society of Canada report provided an opportunity for various departments and agencies to more cohesively communicate their roles through the need to co-operatively draft and update the Internet-posted Government of Canada action plan. This inter-disciplinary, inter-departmental approach to communicating about the Government's regulation of biotechnology-derived agricultural products reminds us that even though promotional and regulatory functions are separate, departments and agencies can work together to more effectively to inform Canadians about the regulatory system.

Meeting information needs

The above-noted action plan and progress reports are posted on the CFIA Web site at: **http://www.inspection.gc.ca/english/ppc/biotech/tech/reprape.shtml#royal**

The CFIA has developed several factsheets response to the Royal Society's recommendation that the government increase transparency and public confidence. These are posted on the CFIA Web site at: **http://www.inspection.gc.ca/english/ppc/biotech/tech/reprape.shtml**

The factsheets cover the following topics:

- An Overview of the Royal Society Report on the Future of Food Biotechnology
- The CFIA Assessment Process and What is Expected from Industry
- Data Required for Safety Assessments of Biotechnology-Derived Plants and Feeds
- Finding Out About the Regulatory Decisions Made for Products Derived Through Biotechnology
- Inspection and Monitoring
- Involving Canadians in the Regulatory System
- Long-Term Testing/Substantial Equivalence
- Promotion and Regulation: Different and Distinct Government Roles

In January 2002, a progress report was published showing the key milestones achieved for each of the elements in the action plan. Departments and agencies will continue to update this report throughout 2003. By way of these activities and others, Canada's regulatory system and capabilities will keep pace with future applications of biotechnology.

[1] The full report can be found on the Royal Society of Canada's Web site at www.rsc.ca

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE (CBAC)

In 1999, the Government of Canada established the Canadian Biotechnology Advisory Committee (CBAC) to study social, economic, scientific, regulatory, and health aspects of biotechnology and to advise federal Ministers accordingly. The 21-member committee was drawn from the scientific, business, general public, ethics, and environmental communities. CBAC is mandated to raising public awareness and engaging Canadians in a dialogue on biotechnology-related issues.

In the spring of 2001, CBAC held five consultations across Canada with industry stakeholders, academia, and civil society to discuss the regulation of biotechnology-derived foods. CFIA officials participated in each workshop to provide technical and regulatory information as required. CBAC released an interim report in August 2001, and CFIA officials met with CBAC members to comment on the report. Canadians were given until January 2002 to give their comments.

CBAC's full report was released in August 2002.

ON-GOING EVOLUTION OF THE REGULATORY SYSTEM

Meeting safety needs

Plants

The CFIA's Plant Biosafety Office (PBO) is responsible for regulating the environmental safety of plants with novel traits (PNTs) in Canada. PNTs can be produced by conventional breeding, mutagenesis, or through techniques of biotechnology such as recombinant DNA technology. Safety assessments are required for all PNTs to be imported into Canada or to be released into the environment. The CFIA's Feed Section is responsible for assessing novel livestock feeds, while the Seed Section is responsible for the testing, inspection, quality, and sale of seed. Health Canada is responsible for safety assessments of novel foods.

In fiscal year 2001–02, the PBO approved 146 submissions of plants with novel traits for release at 289 confined research field trials.

In fiscal year 2001–02, the PBO granted *unconfined* environmental release for three PNTs.

On-going evolution of the regulatory system

As scientific knowledge expands—and it does so constantly—regulations and safety assessment criteria have to keep pace. The PBO regularly examines the regulations it is responsible for and seeks input when updating them.

In February 2002, the PBO amended its regulatory document *Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada* (Regulatory Directive 2000-07). Some of the amendments include:

- changes in restrictions on the size and number of confined research field trial locations
- changes for records and reporting of confined research field trials
- changes to isolation distances
- use of GPS (global positioning satellite) coordinates
- increases in monitoring frequency after the novel plants have been harvested, while the site is still subject to land-use restrictions

Crop kind*		Breeding objective**	Provinces where the field trials took place***
alfalfa: 63	monoccum: 2	fungal resistance: 26	Alberta: 44
barley: 2	perennial ryegrass: 1	genetic research: 12	Manitoba: 35
brown mustard: 25	poplar: 1	insect resistance: 21	Ontario: 103
canola/*napus*: 44	potato: 10	male sterility/restoration: 9	Quebec: 11
canola/*rapa*: 1	safflower: 2	modified oil composition: 17	Saskatchewan: 96
corn: 22	soybean: 10	novel herbicide tolerance: 122	
creeping bentgrass: 1	spruce: 3	nutritional change: 1	
flax: 10	sugarbeet: 2	plant molecular farming: 3	
grape vine: 6	tobacco: 5	stress tolerance: 82	
lentils: 16	wheat: 59	other: 23	
	white clover: 4		

More details found at: http://www.inspection.gc.ca/english/plaveg/pbo/st/st_01e.shtml

* Data are based on the number of field trials that were approved and that took place.

** Data are based on the number of field trials that were approved and that took place. Some field trials have more than one breeding objective, therefore the number of field trials listed under breeding objective may exceed the total number of trials authorized.

*** Data are based on the number of field trials that were approved and that took place.

- further guidance on removing volunteer plants and related species before they flower
- the posting of summaries of authorized confined research field trials on the CFIA Web site

As is the case with monitoring frequencies of trial sites during the trial period, post-harvest monitoring frequencies vary according to the plant species that was tested at the site. Information about monitoring frequencies can be seen at: **http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir0007amende.shtml**

Workshop on Herbicide-Tolerant Volunteer Canola

In response to questions raised by faculty in the University of Manitoba's Plant Science Department, on February 18, 2002, the PBO hosted a workshop on herbicide-tolerant volunteer canola derived from approved novel canola. Workshop participants included researchers from the University of Manitoba and Agriculture and Agri-Food Canada, representatives of the developers of the canola varieties being discussed, as well as representatives from the Canadian Seed Growers Association, the Canadian Seed Trade Association, and the Canola Council of Canada. Two Manitoba farmers who have had first-hand experience with herbicide-tolerant canola also participated.

The goals of the workshop were to:

- identify the actual scale of agronomic challenges with currently approved herbicide-tolerant canola with respect to volunteers and to stacking of multiple herbicide tolerances
- discuss the potential agricultural challenges for future herbicide-tolerant canola lines
- explore recommendations for regulating additional herbicide-tolerant canola lines and other crops in relation to crop rotation and management of volunteers

The PBO will consider the recommendations arising from this workshop when it is developing future policies and regulatory directives on the environmental release of herbicide-tolerant canola and other plants with novel traits.

Trees

The PBO has been working closely with the Canadian Forest Service (CFS) to develop regulatory directives for forest trees with novel traits. In November 2001, PBO personnel visited confined research trials in Quebec and met with CFS scientists and management. In February 2002, PBO officers participated in the Federal-Provincial-Territorial Academic Expert Meeting on Regulations Relating to Forest Trees with Novel Traits in Canada. The PBO presented an update on current Canadian regulations for PNTs (including trees) and participated in discussions about the regulations. As a result of those discussions, revised tree-specific regulatory guidelines will be drafted for further consultations.

On-going Research Regarding Environmental Effects of Plants with Novel Traits

Part of recognizing that science evolves is the realization that on-going research is required. One of the areas that the PBO is looking at is the long-term unexpected environmental effect of PNTs. While PNTs are thoroughly assessed for their environmental impact, the PBO is sponsoring research into the ramifications of future possibilities, such as the combining of traits that are not currently in PNTs, and molecular plant farming. The PBO is also looking at PNTs over the long term to monitor any changes in biological diversity or insect resistance, so that regulations can be adjusted, if necessary, to meet those challenges.

The PBO commissioned several independent research studies in 2001–02. They include topics such as:

- herbicide tolerance management
- plant molecular farming
- gene stacking and biodiversity
- agriculture and its impact on biodiversity in general
- a refugia project to review rootworm mating behaviour resulting from potential Bt.-resistance evolution

Feed Section

The CFIA administers a national feed program to verify that livestock feeds manufactured and sold in Canada or imported into Canada are safe, effective, and appropriately labelled. The program is delivered by way of pre-sale product evaluation and registration by Feed Section staff and post-market inspection and monitoring by CFIA field staff across Canada.

In the 2001–02 fiscal year, the Feed Section developed several new inspection programs. These programs are designed to enable proponents of novel feeds to strictly comply with federal inspection and monitoring requirements:

- Program 2A: Inspection of Plants With Novel Traits Confined Research Trials
- Program 2B, C, D: Inspection of Research Trials with Novel Feeds
- Program 2E: Inspection to Confirm Segregation of Specialty Products
- Program 2F/2G: Inspection and Enforcement of Unapproved Novel Feeds/Enforcement of Registration Requirements for Novel Feeds
- Program 2H: Fermentation Plant Inspections
- Program 3A: Fermentation Byproduct Manufacturer Survey

One new plant with novel traits (herbicide-tolerant rice produced through mutagenesis) was approved for feed use.

To contribute to the on-going evolution of knowledge about potential impacts of novel feeds on livestock, the Feed Section funded research projects with government researchers. These include:

- "The Effect of Transgenic Canola Meal on Rumen Microflora and the Growth and Meat Quality of Ruminants and Monogastrics"—this project examined the effects of transgenic canola on the growth characteristics of two livestock species (lambs and pigs), the stability of transgenic DNA, and the likelihood of horizontal gene transfer.
- " The Fate of Forage Transgenes in Silage and Artificial Rumen"—this project examined the fate of transgene DNA and protein derived from Bt. corn, in silage and in an artificial rumen model.

The Feed Section also conducted a survey of research establishments to determine what work was being done on novel feeds. The resulting information contributes to a broader awareness of the research being done by giving Feed Section officials another way to stay up-to-date on feed-related scientific knowledge and by informing researchers as to their regulatory responsibilities.

Animals

In November 2000, the CFIA established a new Animal Biotechnology Unit within the Animal Health and Production Division. For the time being, pending development of specific legislation, staff in the Unit provide animal health advice to Environment Canada officials in their assessment of notification applications for biotechnology-derived animals that are submitted to Environment Canada under the *Canadian Environmental Protection Act–New Substances Notification Regulations* (CEPA–NSNR). The Animal Biotechnology Unit works with Environment Canada and other departments to develop specific regulations and technical standards for biotechnology-derived livestock to supplement current CEPA notification requirements.

In 2001–02, the Animal Biotechnology Unit researched, wrote, and distributed for internal peer review several reports on transgenic livestock and bird safety assessments. Some of the objectives of the reports were to:

- identify and characterize potential biological hazards that may be associated with transgenic animals
- identify and describe screening methods that can be used to identify transgenic animals
- identify and characterize the potential hazards associated with transgenic animals through the first five generations
- gather information that can be used to develop qualitative and quantitative risk assessment models

In terms of legislation, the Animal Biotechnology Unit continues to review the current federal regulatory framework for biotechnology-derived animals in order to identify areas of responsibility, gaps, and potential solutions through amendments to the *Health of Animals Act* and *Regulations*; and to work with other departments and agencies. The unit is also preparing draft *Guidelines for Safety/Environmental Assessment of Biotechnology-Derived Animals*.

In early 2001, the unit prepared a draft "road map" identifying areas of responsibility for regulating transgenic animals and their products in Canada. Based on this, a parallel document showing the U.S., Australian, and New Zealand regulatory systems was prepared and was presented at a trilateral meeting of officials from Canada, Mexico, and the U.S. at the North American Animal Health Committee in Montréal in February 2002. It was also presented at a quadrilateral meeting attended by representatives from Australia, Canada, New Zealand, and the U.S.

The unit also provides scientific advice and regulatory input to an inter-departmental working group that examines animal biotechnology topics, such as xenotransplantation, biotechnology-derived livestock and fish, and biopharmaceuticals. As well, it consults on these topics with non-government agencies, universities, and industry. One example is a meeting with the Canadian Council for Animal Care (CCAC) to discuss ways of regulating biotechnology-derived animals. Also discussed was CCAC's work on developing guidelines for research, teaching, and transgenic animal testing. These guidelines will aid animal care committees in Canada's research and development community.

Fish

To date, the Government of Canada has not evaluated any applications for approval for food or feed use or environmental release of biotechnology-derived fish.

Should Health Canada approve fish and fish products of modern biotechnology for use as food, those products would have to meet the requirements of the CFIA's Fish Inspection Program. This program is directed primarily at federally registered establishments and is mandatory for fish that is imported, exported, or shipped interprovincially. Under the program, CFIA officials:

- monitor activities for compliance with specific standards for safety, quality, and identity and for fraudulent representation
- require all registered fish processing plants to develop and implement an in-plant quality management program
- enforce licensing, processing, and product standards requirements for an import inspection program

The *Fish Inspection Act* and *Regulations* gives the CFIA its authority in this regard. The *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*, as they relate to food, are also enforced by the CFIA.

Detection and Identification Capacity

Work was also begun to enhance the CFIA's detection and identification capacity for various biotechnology-derived products, including PNTs, novel livestock feeds, and transgenic fish. CFIA policy states that approval for environmental release and livestock feed use depends, in part, on product developers making available the appropriate detection and identification methodologies and providing relevant reference samples. The CFIA's Laboratories Directorate also receives copies of the molecular characterization data that the developers submit for environmental and feed safety assessment, to assist in the potential development of CFIA detection and identification tests.

In order to improve their detection and identification capacity, CFIA laboratories acquired necessary equipment and supplies, as well as available reference samples. Multiple PCR primers were also acquired, so that the CFIA has a set of PCR primers targeting a variety of transgenic elements and traits, thus generally enhancing the capability of the researchers and the Molecular Analysis and Testing Units (MATUs) to detect and identify these elements in foods, plants, feeds, and seeds. Details of much of the work have been annotated in a database that is accessible to all MATUs.

Researchers participated in several detection and identification projects in 2001–02. Topics included developing alternative or refined techniques for detection of biotechnology-derived products, including plants, fish, and processed foods.

President's Graduate Assistantship Program

The CFIA's President's Graduate Assistantship Program is designed to encourage education and career development for graduate students registered in biotechnology-related programs at the University of Guelph. The program engages successful candidates in research and collaboration in the areas of CFIA's mandate. Recipients are required to spend 20% of their time providing research assistant services to the CFIA. This research can contribute to the on-going evolution of the CFIA's regulatory system. The program was established in 2000 by the President of the CFIA as a three-year pilot project, initiated as part of a Memorandum of Understanding (MOU) with the University of Guelph. It is co-ordinated by the CFIA's Office of Biotechnology, the Faculty of Graduate Studies at the University of Guelph, and the Canadian Institute for Food Inspection Research.

Up to three people can receive funding per year. In 2001–02, two new candidates received funding. Their research topics are:

- expressing therapeutic fusion peptides under the control of a harvest-inducible promoter in alfalfa
- using DNA microchip technology to rapidly and accurately detect many microbial contaminants in a single test

Two of the previous year's recipients also had their funding renewed. They are working at:

- identifying strategies to improve pathogen detection protocols
- producing fast, inexpensive, dependable tools to identify the food-borne pathogens *Listeria monocytogenes* and *E. coli* O157:H7

CEPA "Scheduling"

In order to protect the Canadian environment, the Government of Canada requires any person or company wanting to import, to manufacture, or to sell a new substance in Canada to notify the appropriate regulatory authority so that the new substance is evaluated for potential effects on human health and the environment. Under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), Environment Canada has the authority to do these assessments.

Other Acts also provide for environmental assessments, and sub-sections 81 (6) and 106 (6) of CEPA, 1999 recognize this fact. These sections indicate that if other legislation meets the following criteria, that legislation may be "scheduled" as being CEPA-equivalent:

- the person or company must provide notification to the appropriate authority about the new substance before it can be released (this includes a variety of ways to notify, such as registration and applying for a permit)
- an assessment of "toxic"

Thus, if an Act is CEPA-equivalent, an environmental assessment of a new substance could be done under one Act, instead of under two. By reducing this kind of duplication, such scheduling makes the regulatory system more efficient, less costly for taxpayers, and less onerous for industry.

Acting on behalf of the CFIA, the Office of Biotechnology worked with Environment Canada to have certain CFIA-administered acts recognized as CEPA-equivalent with respect to the provisions they contain that address biotechnology-derived products. This work included an assessment of the CFIA's legislation for CEPA equivalency, stakeholder consultations, and, finally, scheduling under CEPA, 1999. Stakeholders unanimously supported the proposed scheduling, which was published in the *Canada Gazette*, Part I, on February 10, 2001. On August 29, 2001, four sets of CFIA-administered acts and regulations were listed in Schedules 2 and 4 of CEPA, 1999, and the amendment was published in the *Canada Gazette*, Part II.

The four CFIA-administered acts and regulations that have been scheduled as CEPA-equivalent are:

- *Feeds Act* and *Feeds Regulations* (Schedules 2 and 4)
- *Fertilizers Act* and *Fertilizers Regulations* (Schedules 2 and 4)
- *Seeds Act* and *Seeds Regulations* (Schedules 2 and 4)
- *Health of Animals Act* and *Health of Animals Regulations* (Schedule 4) (veterinary biologics)

Meeting information needs

Changes that result from the on-going evolution of the regulatory system are posted on the CFIA's Web site. For example, the Plant Biosafety Office (PBO) has given more specific information on the site about the number and type of confined research field trials that have been approved and in which provinces the trials take place. The PBO, as well as other offices such as the Feed Section and the Fertilizer Section, continues to prepare "decision documents" whenever regulatory decisions are made about plants, feeds, or fertilizers with novel traits. Among other things, the decision documents describe how decisions are made to allow the plant or product to be commercially produced. These documents contain detailed explanations about the scientific information that CFIA evaluators reviewed in order to make their decisions and why certain conclusions were reached. Canadians can get these documents in hard copy or on the CFIA Web site.

The CFIA also publishes information about the consultations it does and about its on-going work on the assessment and regulatory amendment processes.

PLANT MOLECULAR FARMING

Being committed to the continuing evolution of the regulatory system also means looking ahead into possible scientific developments. One such area the CFIA has been preparing for is plant molecular farming.

The CFIA's working definition of plant molecular farming is as follows:

> . . . the use of plants in agriculture to produce biomolecules instead of food, feed, and fibre; that is, plants with introduced novel traits that produce scientifically, medically or industrially interesting biomolecules, grown as crops and harvested for the biomolecules.

Some possible applications of plant molecular farming include:

- plants that produce therapeutic proteins for the treatment of diseases
- nutraceuticals (fortified food or dietary supplements that give specific health benefits)
- therapeutic and diagnostic antibodies produced in plants (applications could include prevention of kidney transplant rejection and treatment of breast cancer)
- edible plants that contain vaccines
- bioplastics that produce simple, biodegradable molecules

Meeting safety needs

While there is currently no commercial plant molecular farming in Canada, the CFIA anticipates that developers may seek approval to commercially produce plants with novel traits (PNTs) for molecular farming in three to five years. To prepare for that possibility, the CFIA held consultations to update its regulatory directives regarding PNTs (Regulatory Directives 2000-07 and 94-08), so that it can effectively assess this new technology.

A broad, multi-stakeholder technical consultation on plant molecular farming was held in Ottawa from October 31 to November 2, 2001. Participants included representatives from public interest groups, agriculture and agribusiness, industry, academia, and various departments and agencies from different levels of government. These discussions contributed to the changes that were proposed for Regulatory Directive 2000-07 regarding confined research field trials.

Meeting information needs

The proposed changes to Regulatory Directive 2000-07 were posted on the CFIA Web site, along with a discussion document prepared for the consultation and the report of the proceedings.[2] A set of frequently asked questions[3] was also posted, as was an information article called "Potential Impacts of Plant Molecular Farming on Biodiversity," by David A. Kirk, PhD.[4]

As part of the process of gathering information, the public was invited to a forum held on the evening of October 30, 2001, prior to the technical consultation. This gave the public a chance to hear presentations from experts in the field, to express their opinions and concerns, and to ask questions and participate in discussions. An overview of the forum was posted on the CFIA Web site, as were the four presentations that were given.[5]

An interim report[6] and proposed regulatory changes[7] were posted on the CFIA Internet site and public comments were invited until February 25, 2002. Finalized amendments, in addition to other general improvements, will contribute to a revised Regulatory Directive 2000-07 for 2003.

[2] http://www.inspection.gc.ca/english/plaveg/pbo/mf/reportprocede.shtml
[3] http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_faqe.shtml
[4] http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_kirke.shtml
[5] http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_fore.shtml
[6] http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_communique.shtml
[7] http://www.inspection.gc.ca/english/plaveg/pbo/mf/mfa0007e.shtml

CARTAGENA PROTOCOL ON BIOSAFETY

Meeting safety needs

At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for sustainable development. One of the key agreements adopted at the Rio summit was the Convention on Biological Diversity.[8] A subsidiary agreement to the Convention that was adopted in January 2000, after four years of negotiations, is the Cartagena Protocol on Biosafety (the Protocol).

The aim of the Protocol is to help to provide an adequate level of protection in the safe transfer, handling, and use of living modified organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity. An LMO is a microorganism, plant, or animal that has a novel combination of genetic material obtained through modern biotechnology—that is, using recombinant DNA techniques—and is capable of transferring or replicating its genetic material. The Protocol specifically focuses on the movement of LMOs across international borders ("transboundary movements").

The text of the Protocol was finalized in January 2000, in Montréal and was open for signatures until June 4, 2001, at United Nations Headquarters in New York. Canada signed the Protocol on April 19, 2001, with the condition that, before Canada ratifies it, officials continue to discuss its provisions regarding compliance, documentation, and liability.

Meeting our international responsibilities

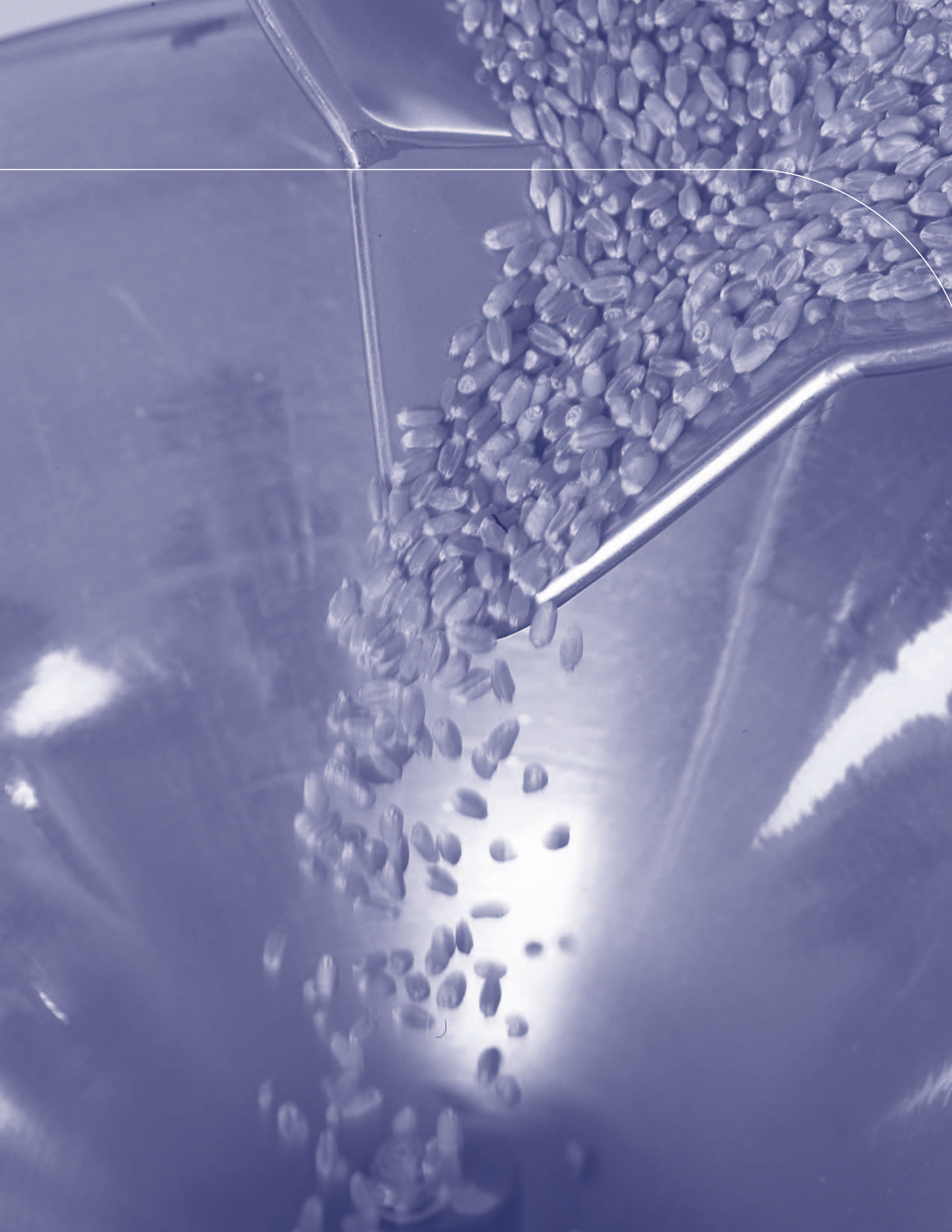
When it enters into force, the Protocol is meant to be a legally binding international environmental agreement on countries that have ratified. It states, "Each party shall take necessary and appropriate legal, and administrative and other measures to implement its obligation under this Protocol." To fulfill Canada's obligations, departments and agencies have been preparing their legislation and regulations for the potential implementation of the Protocol.

A CFIA working group, chaired by the Office of Biotechnology, was asked to identify the overall approach to implementing the Protocol for the CFIA. The working group analysed the acts and regulations the CFIA administers and enforces, to determine which ones would be affected if the Protocol were to be ratified and to ensure that the gaps between current legislation and the requirements of the Protocol were thoroughly evaluated. Projects included a Regulatory Proposal Assessment (RPA), legislative amendments, and initial work on the Biosafety Clearing-House (an information sharing database that will allow the Protocol to function).

Expert Meeting and Workshop on Capacity Building

In July 2001, an open-ended meeting of experts on capacity building for Protocol implementation was held in Havana, Cuba. This meeting was followed by an international workshop organized by the United Nations Environment Programme (UNEP) and the Global Environment Fund (GEF) to address financing the creation and implementation of national biosafety frameworks.

[8] http://www.biodiv.org/



Technical Expert Group Meetings on Documentation

Technical experts met three times to bring further clarity to Article 18 of the Protocol (on documentation) and to discuss its implementation. Topics of discussion included the type of documentation to be generated and the requirements for information to appear on the documents.

The first meeting dealt with documentation for LMOs exported for contained use or for intentional release into the environment. It was held June 15–16, 2001, in Paris, France, and was co-sponsored by Canada and France. Canada chaired the Sub-Working Group on Article18.2.c Documentation For Living Modified Organisms Meant for Intentional Release into the Environment. This meeting set the stage for the further discussions that took place in Montréal, in March 2002, at a second meeting of technical experts, co-sponsored again by France and Canada.

The third and final meeting on Article 18 of the Protocol focused on documentation to accompany LMOs intended for direct use as food or feed or for processing. This meeting, which Canada chaired, was also held in Montréal in March 2002.

Inter-governmental Committee on the Cartagena Protocol

Following adoption of the Protocol in January 2002, the Inter-governmental Committee on the Cartagena Protocol (ICCP) was struck with the objective of working through outstanding items in the Protocol, to prepare for its implementation. Three ICCP meetings were held: the first in December 2000, the second in October 2001, and the third in April 2002.

At the second ICCP meeting—held from October 1 to 5, 2001, in Nairobi, Kenya—Protocol implementation was discussed, as were:

- information sharing
- monitoring and reporting
- documentation
- the Biosafety Clearing-House

Meeting information needs

Throughout the 2001–02 fiscal year, the CFIA and Agriculture and Agri-Food Canada regularly co-hosted consultations with stakeholders about Canada's positions on Protocol matters. Stakeholders included non-government organizations and the agri-food sector. These meetings encouraged discussion between the government and stakeholders on an wide range of Protocol-related topics, such as provisions on Article 18 in respect of handling, transport, packaging, and identification of LMOs. The information collected contributed to developing the Canadian positions for several international meetings on the Protocol.

STARLINK™

Meeting safety needs

StarLink™ corn is an agricultural product of biotechnology containing the *Bacillus thuringiensis* (Bt.) Cry9C protein, which confers resistance to the European corn borer, an insect pest capable of severely damaging corn crops. This product was developed in the U.S. and approved in 1998 by the U.S. Environmental Protection Agency (EPA) for animal feed and industrial purposes. Although approved for certification, the EPA did not approve StarLink™ corn for human consumption. It remains unapproved in Canada for any use and therefore cannot be imported into Canada for food, feed, or seed. Since the fall of 2000, the CFIA and the Canadian Grain Commission (CGC) have been working together to monitor import shipments of whole grain corn to prevent StarLink™ from being imported into Canada.

The StarLink™ case reflects how CFIA Programs and Operations staff across the country work together. CFIA staff involved in managing the StarLink™ corn case include Operations Branch staff, evaluators and other specialists of the various CFIA Programs Branch commodity groups (including the Plant Biosafety Office and the Feed Section), the technical staff of the Laboratories Directorate, and officers of the Office of Biotechnology.

Through a series of advisories, the CFIA and the CGC reminded importers of their obligation to meet Canadian regulatory requirements. At the same time, the CFIA and the CGC established programs that would allow them to verify importer records for StarLink™ testing and to monitor products by random sampling as needed. From October 2001, the CFIA and the CGC focused their efforts at points of entry on shipments that had to have documentation indicating that the corn had been tested to show that StarLink™ had not been detected.

To carry out this program, the CFIA worked with the Canada Customs and Revenue Agency (CCRA). At the CFIA's request, the CCRA detained all U.S.-origin whole grain corn shipments (feed, seed, food purposes) at the first point of arrival until the CFIA release approval form had been obtained, as required by the CFIA's industry advisory requirements. If importers failed to provide this documentation, shipments were refused entry into Canada.

Between October 15, 2001, and March 31, 2002, CFIA Import Service Centres reviewed documentation for more than 20,000 shipments of whole grain corn. Of these, over 50 shipments were refused entry into Canada because accompanying import documentation was inadequate. A system for sampling whole grain corn and corn products was also put into place and continued throughout the fiscal year, along with the border document review program.

The CGC and CFIA monitoring and surveillance programs, updated in 2001, were on-going throughout 2002 and will continue to be assessed periodically by both organizations as they monitor the status of U.S. management of the potential presence of StarLink™ corn in export shipments.

Meeting information needs

On July 23, 2001, Greenpeace Canada filed a petition under Section 22 of the *Auditor General Act* with the Commissioner of the Environment and Sustainable Development. The petition contained eight questions about StarLink™ corn, specifically on the trans-boundary movement of the corn between Canada and the U.S. and about the Government of Canada's ability to prevent StarLink™ corn from entering the domestic food supply, seed supply, and ecosystems.

On December 10, 2001, the government issued a detailed response to the petition. The joint response was provided by the Canada Customs and Revenue Agency, the CFIA, the Canadian Grain Commission, the Department of Foreign Affairs and International Trade, Environment Canada, and Health Canada. The CFIA's Office of Biotechnology coordinated the interdepartmental response. The on-line version of the document can be found at: **http://www.inspection.gc.ca/english/ppc/biotech/tech/greenstare.shtml**

The response gave an overview of the comprehensive way that Canada regulates biotechnology-derived foods and in what ways the regulatory system continues to evolve to meet challenges such as those posed by the StarLinkTM case. The petitioned departments and agencies continue to work together to develop the necessary policy guidance and enforcement tools to assure the public that the government is appropriately vigilant in verifying regulatory compliance of imports and domestic products of biotechnology.

LABELLING BIOTECHNOLOGY-DERIVED FOODS

Current legislation in Canada requires that all novel foods, including those derived through biotechnology, be labelled if there are any changes in composition, nutrition, and end-use. Canadian policy also allows for consumer choice; for example, food manufacturers may voluntarily label products as being a "product of" or "not a product of" biotechnology, as long as the information is truthful, not misleading, and in compliance with other regulatory requirements.

Health Canada sets the requirements for mandatory food labelling for health and safety matters. The CFIA enforces these requirements. The CFIA also leads the development of general food labelling policies and regulations not related to health and safety. It is responsible for protecting consumers from misrepresentation and fraud with respect to food labelling, packaging, and advertising and for prescribing basic food labelling and advertising requirements.

The CFIA is involved in many domestic and international discussions about labelling for biotechnology-derived foods.

Meeting safety needs

The Codex Alimentarius Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology (CTFBT) met from March 1 to 8, 2002, in Yokohama, Japan. The CFIA contributed to the Canadian position on the guidelines discussed at this meeting. One of these items was a draft guideline document on the safety assessment of foods from rDNA plants. Created in 2000 by the task force working group, the guidelines were later updated based on a workshop on allergens that was hosted by Health Canada in 2001. At the March 2002 CTFBT meeting, the task force reached final agreement on these guidelines. They will be considered for final approval at the Codex Alimentarius Commission meeting in summer 2003.

Agreement in principle was also reached on guidelines for the safety assessment of foods derived from rDNA microbes. The guidelines are to be considered at the next meeting of the CTFBT, scheduled for March 2003. If approved at that time, this guideline could also be presented for final approval at the next Codex meeting in summer 2003.

Another important point that the task force agreed on, and to which the CFIA contributed, was the appropriate use of product tracing as it relates to the safety of biotechnology-derived foods. For more information on product tracing internationally, see below.

Meeting information needs

Continuing work on developing a domestic voluntary labelling standard for biotechnology-derived foods

In 1995, the Canadian Council of Grocery Distributors (CCGD), along with the Canadian General Standards Board (CGSB), began the process of developing a standard for the voluntary labelling of biotechnology-derived foods. The committee tasked with developing the standard consists of approximately 60 voting members and 60 non-voting members and includes a balance of stakeholder representation (from consumer groups; producers' associations; government departments, including the CFIA; universities; environmental groups; and general interest groups).

On August 17, 2001, the draft standard was made available—through the World Trade Organization—for 60 days of public review and comment. After comments were incorporated into the draft in December 2001, the committee distributed a revised draft standard to its voting members. The results were as follows: 27 affirmative, 19 negative, 5 abstained, and 2 members did not vote. After the ballot period closed on January 25, 2002, the CGSB distributed the voting results, including comments, to the whole committee. In March 2002, the committee met to discuss ways to resolve the negative votes.

More information is available on the Canadian General Standards Board Web site at: **http://www.pwgsc.gc.ca/cgsb/text/eng-e.html**

Labelling and Parliament

Bill C-287: An Act to amend the *Food and Drugs Act* (genetically modified food) was a Private Member's Bill to change the *Food and Drugs Act* to require mandatory labelling of biotechnology-derived foods. It was defeated on October 17, 2001, after its second reading in the House of Commons.

The Ministers of Agriculture and Agri-Food, Foreign Affairs and International Trade, Health, and Industry requested that the Standing Committee on Health further consider the labelling question, which it began to do in January 2002. The Standing Committee on Agriculture and Agri-Food also began a similar study, in January 2002 and presented its report, "Labelling of Genetically Modified Food and its Impacts on Farmers" in June 2002.[9] CFIA officials appeared in front of both of these committees, to provide information and answer questions. The Government of Canada response to the report was tabled in Parliament on October 31, 2002.[10]

Meeting our international responsibilities

Codex Alimentarius Committee on Food Labelling

The Codex Alimentarius Commission[11] was created in 1963 by the United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO). Codex develops food standards, guidelines, and other similar texts, with the intention of protecting consumers' health and ensuring fair trade practices in the food trade. Codex also promotes coordination of food standards work done by international government and non-government organizations.

A public consultation meeting was held in Ottawa on April 20, 2001, to discuss the Canadian position for Codex Alimentarius Committee on Food Labelling (CCFL) and to get public comments and feedback.

In May 2001, Canada chaired the annual CCFL meeting in Ottawa. At the meeting, the *Proposed Draft Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering* were considered. Because of time constraints, only minor changes were made to the guidelines. One of the achievements of this meeting was agreement on a clear set of definitions that are consistent with those established under the Cartagena Protocol on Biosafety and the Codex Task Force on Food Biotechnology. Because of this, member countries will be able to use common terminology in further discussions. The CCFL was also successful in agreeing that negative labelling would be further discussed and that a discussion paper drafted by Australia and South Africa would be reviewed.

[9] Found at http://www.parl.gc.ca/InfoComDoc/37/1/AGRI/Studies/Reports/agrirp23-e.htm
[10] A press release on this can be found at http://www.agr.gc.ca/cb/biotech/gm_e.phtml
[11] The Codex Web site is http://www.codexalimentarius.net/

At the 2001 meeting, Canada was asked to chair a working group on labelling of biotechnology-derived foods, to prepare documentation for the May 2002 CCFL meeting. The group was open to all CCFL member countries and to interested international organizations. On Canada's behalf, the CFIA prepared the group's document and circulated it for member countries' comment.

Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology: traceability and detection

Currently there are no internationally agreed-upon methods to detect the use of modern biotechnology techniques in food production. In March 2000, the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology agreed to document the status of methods validation and to collectively submit appropriately validated methods to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for potential endorsement. By March 2001, approximately 25 methods were submitted, and the CCMAS was asked to consider these methods for endorsement at its meeting in November 2002. The CFIA leads the Canadian membership in the working group on methods of analysis and sampling, which is chaired by Germany.

Proposed changes to European Union labelling regulations

In the European Union, the main legislation that authorizes experimental release and marketing of "genetically modified organisms (GMOs)"[12] in EU member countries is Directive 90/220/EC. A new Directive, 2001/18/EC, on the deliberate release of genetically modified organisms was adopted by the European Parliament and the Council of Ministers in March 2001 (it entered into force on October 17, 2002). One change in the directive is an extended labelling regime for biotechnology-derived foods entering EU markets.

The CFIA's International Affairs Division and the Office of Biotechnology, in conjunction with the Department of Foreign Affairs and International Trade (DFAIT), responded to these proposed regulations. The CFIA submitted comments in response to the notification of the proposed regulations under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures. DFAIT responded under the WTO's Agreement on Technical Barriers to Trade.

12 Defined in Directive 2001/18/EC thus:
"For the purposes of this Directive:
(1) "organism" means any biological entity capable of replication or of transferring genetic material;
(2) "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;
Within the terms of this definition:
(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;
(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;"

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=32001L0018&model=guichett

SIMON FRASER UNIVERSITY AND CFIA DIALOGUE ON CONVENTIONAL, ORGANIC, AND BIOTECH CROPS

Meeting information needs

Simon Fraser University (SFU) sponsored a workshop called *Food of the Future? Comparing conventional with genetically modified food crops: Understanding and managing the risks*, held from May 2 to 4, 2001, in Vancouver. The workshop, which included an open public forum, featured presentations by scientists and other experts from industry, government, non-government organizations, and academia. It was designed to discuss topics such as how biotechnology-derived food crops are different from conventional and organic crops. Participants talked about how consumers make decisions about what foods to eat.

The forum was an opportunity for people to talk about understanding and managing the perceived benefits and risks of food biotechnology.

The CFIA co-sponsored the workshop. Dr. Stephen Yarrow of the CFIA's Plant Biosafety Office presented a talk called "Environmental assessments of the biotechnology-derived plants in Canada." Dr. Yarrow's paper, "Environmental Assessment of the Products of Plant Biotechnology," was printed in the report of the workshop proceedings.

Copies of the proceedings, including some of the discussions, are available on the SFU Continuing Studies in Science Web site at: **http://www.sfu.ca/cstudies/science/foodforthefuture/**

Copies of the report, as well as the video produced through CFIA sponsorship, are available from SFU and through on-line request from the CFIA's and SFU's Web sites.

OTHER EXAMPLES OF MEETING INFORMATION NEEDS

The CFIA uses a range of tools to meet other information needs that do not fall into the topic areas discussed above. Some of these activities and projects are discussed in this section.

Canadian Biotechnology Strategy

Reporting and Accountability

In 1993, the Government of Canada established the *Federal Regulatory Framework for Biotechnology*. This framework resulted from an agreement among federal regulatory departments on principles for an efficient, effective approach for regulating products of biotechnology. The framework's six principles were adopted with the view to balancing the practical benefits of biotechnology products and processes with the need to protect human health, animal health, and the environment.

In 1997, the Ministry of Industry was asked to review the policy framework and structures that had been developed for the 1983 National Biotechnology Strategy. As a result, the Canadian Biotechnology Strategy (CBS) Task Force was created to coordinate a renewal process with federal regulatory departments and agencies, provincial partners, and industries and stakeholders.

The new funding was approved with the requirement that a consolidated risk-based audit framework and a results-based accountability framework be developed by the six signatories to the Treasury Board Submission, in consultation with the Treasury Board Secretariat. The CFIA was asked to take the lead role to coordinate and develop the accountability framework for the Canadian Regulatory System for Biotechnology (CRSB).

This work was done through an Interdepartmental Working Committee consisting of members from the CFIA, Environment Canada, Fisheries and Oceans Canada, Health Canada, Industry Canada, Natural Resources Canada, and the Treasury Board Secretariat.

Publications

The Office of Biotechnology prepared a new exhibit, along with communications material for distribution in the exhibit, with input from other CFIA staff. The exhibit includes:

- *a poster outlining key agricultural biotechnology regulation milestones from the last 15 years*
- *a brochure that describes the CFIA's regulation of biotechnology*
- *an information kit with fact sheets on the following:*
  - *the regulatory approval process for products of biotechnology*
  - *the safety of biotechnology-derived crops*
  - *frequently asked questions on biotechnology-derived foods*
  - *labelling of biotechnology-derived foods in Canada*
  - *a sheet of information sources*

Committee members provided key information such as performance indicators, expected results and outcomes, methods of reporting on performance, and evaluation criteria for their funded biotechnology projects. This means that the framework is based on the performance information provided by each department and agency.

The framework includes a provision for an internal audit plan and a program evaluation plan. It sets out clear and comprehensive guidance to departments as to delivery and accountability for the $90 million of project funding that had been approved by Treasury Board in July 2000.

The Biotechnology Assistant Deputy Ministers' Committee approved the accountability framework on April 12, 2001, and the document was approved by the Treasury Board Secretariat on June 28, 2001.

Communications and Outreach

This working group co-ordinates biotechnology communications activities among the departments. The CFIA contributes to this group by:

- providing input to public opinion research (POR) that the Canadian Biotechnology Secretariat is conducting
- providing ideas and advice for public communication of biotechnology-related information to be issued by the Canadian Biotechnology Secretariat, the CFIA, and other departments, such as Industry Canada through its BRAVO Web site
- coordinating with CFIA Public Affairs on comments for information products, strategies, and plans to be used by the CBS, the CFIA, and other departments

The working group coordinated interdepartmental communications to assist Earnscliffe/Pollara in preparing public opinion polls on biotechnology. Some of the CFIA's work included:

- preparing and seeking approval for comments on POR reports prior to publication
- providing briefings on POR results
- providing CFIA input, which included prepared questions for inclusion in upcoming POR studies and focus groups, and providing advice for projects and strategies developed to deliver on the CBS communications strategy
- extracting useful information from POR to help identify new topics for public communication

Regulations

Formed in 1986, the CBS Working Group on Regulations includes members from key federal regulatory departments and agencies. It coordinated the development and the implementation of the 1993 regulatory framework and funding initiatives. It provides leadership for the development of an efficient, effective regulatory system.

The responsibility for chairing this working group rotates among the CFIA, Environment Canada, and Health Canada. The group serves the interests of the biotech community by addressing issues of shared importance, such as renewal of regulatory funding; by responding to expert advice; and by consulting on and co-ordinating regulatory initiatives.

In fiscal year 2001–02, the working group focused on developing a results-based management and accountability framework. It also responded to the report of the Expert Panel of the Royal Society of Canada, E*lements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*. This included work in the following areas:

- transparency initiative
- long-term research
- human resources
- regulations and policy

Stewardship

As part of an ongoing readjustment of priorities under the Canadian Biotechnology Strategy, the CFIA co-chaired a working group with Health Canada under the stewardship pillar. The group developed a work plan that identified overall themes and strategic priorities for CBS 2002–03, while striking a balance between new policy planning research and currently funded CBS projects. The themes the working group identified as priorities are:

- transparency and public involvement
- science in support of knowledge building and decision making
- regulatory evolution
- international work (to effect a greater Canadian leadership role in international harmonization and standards)

Governance mechanisms for biotechnology at the CFIA

The CFIA's Office of Biotechnology facilitated the agency's Biotechnology Task Force in 2001. Because the biotechnology file is so complex and involves work across branches, the task force evolved, resulting in the creation of an additional body, the CFIA Executive Advisory Committee on Biotechnology.

This committee provides policy guidance to help manage CFIA priorities in the regulation of biotechnology. It reports to the Executive Vice-President (the Agency's champion for biotechnology) and is chaired by the Vice-President, Programs. Its four priority areas are:

- the CFIA as a policy driver: biotechnology regulation and environmental stewardship, and delivering on today's policy challenges (unapproved events, traceability, etc.)
- regulatory coherence (conveying Canada's regulatory framework internationally)
- transparency to meet public needs and engage stakeholders
- challenges on the horizon (e.g. animals with novel traits, plant molecular farming)

Talking to Canadians

Day to day, the CFIA speaks to Canadians and the media about biotechnology. We do this through a variety of methods. We talk to the media through interviews and press releases. We also use other forms of communication, such as presentations. Some of the groups we give presentations to include:

- *international organizations (for example, OECD, APEC)*
- *governments (domestic and international)*
- *workshops*
- *conferences*
- *schools*

The CFIA discusses the areas of biotechnology that we regulate. Some of these topics of interest to Canadians include biotechnology-derived crops, labelling of biotechnology-derived foods, and bioterrorism.

OTHER EXAMPLES OF MEETING OUR INTERNATIONAL RESPONSIBILITIES

As discussed in many of the topic areas, the CFIA plays many international roles. This section talks about some of our other international biotechnology-related activities that are not covered in the topics above.

Asia-Pacific Economic Cooperation (APEC)

The Asia-Pacific Economic Cooperation (APEC) forum was formed in 1989 to create a sense of community among its members, in a number of diverse areas. Originally formed with 12 members, APEC now has 21 members.

APEC has three major committees and 11 working groups. Member economies decide on work programs and funding for these groups at each annual Ministerial Meeting. One of these groups is the Agriculture Technical Cooperation Working Group (ATC Working Group). There are seven priority areas under the ATC Working Group, including the sub-group "Research, Development, and Extension of Agricultural Biotechnology" (RDEAB). This sub-group was formally established in October 1996 to be a place for member economies to have constructive dialogue on topics related to agricultural biotechnology. Some goals include:

- discussing transparent, science-based frameworks for risk assessment and management of products of biotechnology
- expanding the capacity building in member economies
- furthering technical cooperation and information exchange
- encouraging effective communications approaches to enhance public awareness and understanding of agricultural biotechnology

In 2000, Canada became the Shepherd of the RDEAB Sub-Group. The CFIA's Office of Biotechnology is responsible for this role. This gives Canada an opportunity to communicate its commitment to a science-based approach to biotechnology, while contributing to sound international policy.

The CFIA's APEC accomplishments in fiscal year 2001–02 include:

- overall management of the Sub-Group Research, Development, and Extension of Agricultural Biotechnology (RDEAB)
- distributing the best practices guide entitled *Communicating About Agricultural Biotechnology in APEC Economies*
- presenting briefing notes and progress reports at meetings for the ATC Working Group, senior officials, and trade ministers
- participating in a U.S.-organized senior-level policy dialogue on agricultural biotechnology

Presentations and workshops that the CFIA organized or participated in include:

- *5th RDEAB Workshop on Capacity Building, Risk Assessment and Communications in Agricultural Biotechnology* (Bangkok, Thailand, September 10–12, 2001):
  - led the development of an updated implementation plan
  - hosted a training workshop on environmental and feed safety assessment (delivered by the CFIA) and food safety assessment (delivered by Health Canada).
  - *APEC High Level Policy Dialogue on Biotechnology* (Mexico City, Mexico, February 24, 2002):
  - presented the overall work of the RDEAB

Organisation for Economic Co-operation and Development (OECD)

OECD Task Force for the Safety of Novel Foods and Feeds

The Government of Canada hosted the Organisation for Economic Co-operation and Development (OECD) Workshop on the Nutritional Assessment of Novel Foods and Feeds in Ottawa, February 5–7, 2001, and the CFIA participated in this workshop. It was held as part of a program of work of OECD's Task Force for the Safety of Novel Foods and Feeds and was built on conclusions from the Joint FAO/WHO expert consultation on Foods Derived from Biotechnology held in June 2000. The Workshop included 79 participants from 19 countries, the European Commission, the Food and Agriculture Organization of the United Nations, OECD's Business and Industry Advisory Committee (BIAC) and the International Association of Consumer Food Organizations (IACFO).

The objective of the workshop was to discuss aspects of nutritional assessments of novel foods and novel feeds. The participants reviewed and made recommendations in the following key areas:

- nutritional assessment as a tool to substantiate nutritional and efficacy claims and establishing safety
- challenges in assessing the nutritional value of future products for which compensatory changes are expected to occur in the plant
- the need consider total diet, in contrast to the current approach that is focused at the single food/feed product level
- identification of specific novel livestock feed nutritional assessment issues as compared with those of novel foods

After the workshop, a report was circulated to participants, and a number of comments were received and incorporated into the text. The report, which includes 17 conclusions and recommendations, is available on the OECD Web site, at:
http://www.olis.oecd.org/olis/2002doc.nsf/43bb6130e5e86e5fc12569fa005d004c/4aab32b252612217c1256b3c005c02f3/$FILE/JT00119206.DOC

Working Group on Harmonisation of Regulatory Oversight in Biotechnology

The main task of this working group is to achieve harmonization in countries' regulation of biotechnology, focusing on environmental safety. The group's goal is to ensure that the information countries use in risk and safety assessments and the methods they use to assess safety are as similar as possible. An active participant in the working group, the CFIA is represented by officers of the Plant Biosafety Office.

At the 10th meeting of the working group, held in Paris from June 27 to 29, 2001, the group continued progress with regulatory consensus documents, which constitute the key product of its work. As well, the group finalized its work on the concept of unique identifiers for transgenic plants. It also established a formal relationship with the Secretariat for the Convention on Biological Diversity, allowing the secretariat to use the OECD Biotrack database; this will help the secretariat prepare for the Convention's Biosafety Clearing House database for the Cartagena Protocol on Biosafety.

Two new Bureau Members were elected, Canada being one of them (represented by the CFIA's Plant Biosafety Office). The bureau, which includes Austria, Japan, and the United States, assists the working group and the secretariat with its future work plans. This role allows Canada to provide strong regulatory direction for the group, as well as to form stronger ties with other OECD biotechnology-related work.

More information on this working group can be found on the OECD Web site at: **http://www.oecd.org/EN/home/0,,EN-home-529-nodirectorate-no-no-no-27,00.html**

The leaders of the G8 asked this working group, along with the OECD Task Force for the Safety of Novel Foods and Feeds, for advice on risk assessments for genetically modified organisms intended for release into the environment. This resulted in two international meetings being convened. They are as follows:

1. New Biotechnology Food and Crops: Science Safety and Society conference

From July 10 to 12, 2001, the CFIA, along with Agriculture and Agri-Food Canada and Health Canada, attended the conference *New Biotechnology Food and Crops: Science Safety and Society*, in Bangkok. This conference was sponsored by the United Kingdom and the OECD. Representatives from approximately 50 countries attended, as well as from international bodies, non-government organizations, and civil society. The conference followed up on an earlier meeting held in Edinburgh in January 2000 by further examining environmental safety standards that governments use to assess biotechnology-derived products. Topics discussed included transparency of regulatory approaches, the need for further research, and ways to engage civil society in further discussions. The conference closed with six recommendations in respect of these topics. These recommendations complement those of the Royal Society of Canada Expert Panel on the Future of Food Biotechnology.

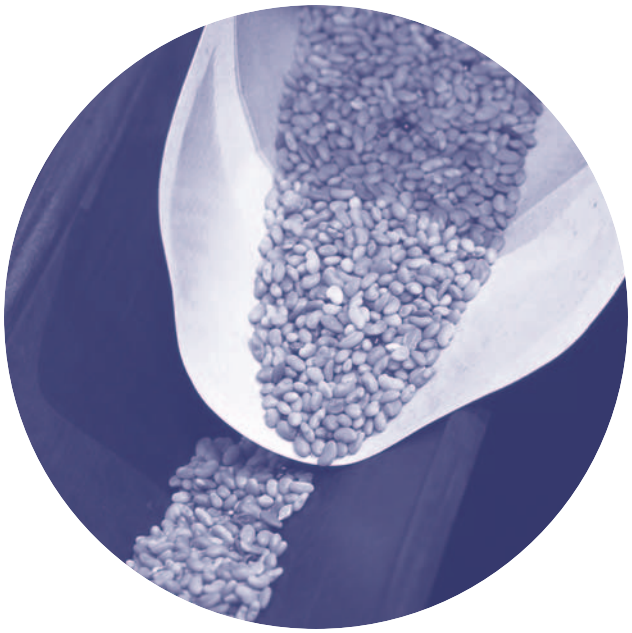
More information can be found on the OECD Web site, at: **http://www1.oecd.org/bangkok/**

2. LMOs and the Environment: An International Conference

From November 27 to 30, 2001, a workshop was held in Raleigh, North Carolina, as a follow-up to *New Biotechnology Food and Crops: Science Safety and Society*. The CFIA participated in this conference, along with Fisheries and Oceans Canada, the Department of Foreign Affairs and International Trade, and Environment Canada. The conference, called *LMOs and the Environment: An International Conference*, was held to discuss the science underlying assessments of living modified organisms (LMOs), with an emphasis on transgenic crops (including trees and fish). Participants from approximately 20 OECD countries and 25 non-OECD countries included people from governments, industry, academia, and civil society. The CFIA sponsored the attendance of a Canadian civil society representative.

The conference provided an opportunity for discussion between developed and developing countries and identified different assessment needs for different countries and regions. Outcomes included agreement that regulations covering LMOs need to be science-based; that a case-by-case, stepwise approach is the best way to assess LMOs; and that risk assessment practices need always to evolve to take into account new developments. Suggestions were made for further research to increase scientific understanding of various aspects of LMOs.

More information on this conference can be found on the OECD Web site at: **http://www1.oecd.org/ehs/raleigh/index.htm**



OECD Seed Schemes

The CFIA is the designated authority responsible for implementing the OECD Seed Schemes in Canada. The OECD Schemes for the Varietal Certification or Control of Seed Moving in International Trade promote the use in agriculture of seed of consistently high quality. Certified seeds are produced and officially controlled according to common procedures that are harmonized in 52 countries.

In June and October 2001, the CFIA participated in the Working Group on Genetically Modified Seed Issues, a subsidiary body of the OECD Seed Schemes. Discussions focussed on the adventitious presence of biotechnology-derived seed in seed of conventional varieties, and work continues to explore options for clearer international provisions in this area.

More information on the Seed Schemes can be found at: **http://www.oecd.org/EN/home/0,,EN-home-173-4-no-no--no,FF.html**

Canada and United States 2001 Bilateral Agreement on Agricultural Biotechnology

Regulatory officials from Canada and the United States have been meeting regularly to discuss various aspects of harmonization between the two countries regarding regulatory assessments of biotechnology-derived agricultural products. Topics discussed in recent years include the molecular genetic characterization components, as well as the environmental components, of the regulatory review process for transgenic plants.

In September 2000, the CFIA met with regulatory officials from the U.S. Department of Agriculture (USDA) Biotechnology Assessment Branch and the U.S. Environmental Protection Agency's (EPA) Office of Pesticides Program, to discuss these components. Amendments to documents were proposed, and a meeting was held May 8–9, 2001, to further discuss these amendments. These discussions were finalized on December 31, 2001.

Such exchanges of information lead to better understanding of different regulatory systems and requirements, and this in turn will help lead to more efficient assessments. Agreements like this one also contribute to the safe commercialization of biotechnology-derived plants.

More information on the bilateral agreement is available on the CFIA Web site at: **http://www.inspection.gc.ca/english/plaveg/pbo/usda/cdausbilate.shtml**

Technical Exchange between CFIA and Nanjing Institute of Environmental Sciences in China

Through funding by the Canadian International Development Agency (CIDA), the CFIA was involved in a capacity-building project with the Nanjing Institute of China. This project is one of the sub-projects for China under the CIDA-funded Public Policy Options Project.

The objectives of the project were to:

- increase the capacity of the Nanjing Institute of Environmental Sciences (NIES)
- provide recommendations to the State Environmental Protection Administration (SEPA) on the development of a regulatory framework for biotechnology
- give technical guidance for risk assessment and risk management

In October and November 2000, a delegation from the Nanjing Institute conducted a study tour in Canada that included attendance at CFIA regulatory sessions in Ottawa. Then in May 2001, representatives from the CFIA's Office of Biotechnology, the Plant Biosafety Office, and the Commercial Affairs Directorate gave presentations and training sessions on biosafety and the Canadian regulatory system to Nanjing University. This completed the CFIA component of the CIDA project with NIES. The Institute prepared a final project report with policy recommendations called *Capacity Building on Biosafety Legislation and Technical Guidelines in China*, which was submitted to the State Environmental Protection Administration in December 2001.

International Plant Protection Convention (IPPC)

In June 2000, the International Plant Protection Convention (IPPC) Working Group on GMOs and Invasive Species recommended developing a standard to address the environmental impacts of quarantine pests, including those that are invasive. This standard is meant to supplement the draft International Sanitary and Phytosanitary Measures (ISPM) on *Pest risk analysis for quarantine pests*. Recently, IPPC member countries have asked for further guidance in evaluating environmental consequences. This standard will assist in that regard. It will also strengthen the ability of IPPC member countries to make informed phytosanitary decisions about quarantine pests. Lastly, it may also help IPPC member countries to address on-going international activities related to species invasion, such as the action plans of the Convention on Biological Diversity and the Global Invasive Species Program.

These recommendations were adopted at the April 2001 meeting of the Interim Commission on Phytosanitary Measures.

North American Plant Protection Organization (NAPPO)

While the International Plant Protection Convention is the official standard-setting body for plant health, regional plant protection agencies such as the North American Plant Protection Organization (NAPPO) are able to develop common ways to address the potential plant pest risks associated with biotechnology-derived plants. NAPPO member countries are currently developing a standard to provide information on common approaches to their regulatory reviews of biotechnology-derived agricultural products, particularly with respect to the pest risk assessment component of the overall environmental assessment. (Although Canada regulates all plants with novel traits, no matter what the method of production used to introduce the trait, NAPPO members have decided that the standard will focus on transgenic plants). This standard, called the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries*, will be an agreement between Canada, the United States, and Mexico.

The CFIA is participating in drafting this standard and has chaired the biotechnology panel. The first two of four modules were completed and posted for public comment in September 2001. Work on the last two modules continues. NAPPO anticipates that the standard will make a significant contribution to similar activities being initiated by the International Plant Protection Convention.

More information on NAPPO standards can be found at: **http://www.nappo.org/Standards/stds-menu-e.htm**

Who's that man pictured on the cover of this report?

If you've seen some of the CFIA's recent biotechnology-related posters, brochures, or reports, you may have noticed the photo of the inspector standing in a field. That photo is of Jake, a member of the CFIA's inspection staff.

Originally, a co-worker of Jake's was asked to pose for the photos, which were intended for use in CFIA annual reports. The co-worker declined but knowing that Jake is a serious amateur photographer, asked him if he was interested in the assignment. While Jake prefers to be the photographer, not the subject, he agreed to help out by choosing the locations and posing for several crop inspection photos.

Jake first heard about his photo being widely used when a CFIA director reported the fact after attending a meeting at CFIA headquarters in Ottawa. While many staff at the CFIA see the photo, Jake claims that he is recognized "only by those who know me." He added that, "It's just a picture of someone outstanding in his field, pun intended." When asked what his family thinks of his new-found fame, Jake replied, "They think it's cool and asked if I got any royalties." (Alas, he does not.)

Jake works as a multi-program inspector, specializing in feeds and pesticides.

CONCLUSION

Food safety, plant protection, and animal health—these are the CFIA's three business lines. This report has illustrated how the business lines are used as the foundation for the CFIA's biotechnology offices to respond to Canadians' safety and information needs, as well as to our international commitments. Working together across the Agency—and with other government departments and agencies—we believe we are achieving success in meeting these needs.

As discussed in the section on the Canadian Biotechnology Advisory Committee (CBAC), the Government of Canada asked CBAC to raise public awareness and engage Canadians in a dialogue on biotechnology-related issues. The information we received from CBAC and other broad consultations will help us to better respond to Canadians' needs, views, and concerns.