December 18, 2003

PROGRESS REPORT: DECEMBER 2003

Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report

Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada

Introduction:

Health Canada, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), Environment Canada and Fisheries and Oceans Canada have already published four progress reports on the *Action Plan in Response to the Royal Society of Canada Expert Panel Report* (http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm). The fifth progress report provides detailed technical information regarding the key milestones achieved for each of the different actions underway for which the reporting date of December 2003 was identified in earlier progress reports.

Subsequent progress reports will be published in June 2004 and December 2004. Future updates will consider relevant aspects of the report of the Canadian Biotechnology Advisory Committee (CBAC) on the regulation of genetically modified foods (GM foods) in Canada. The government's response to the CBAC report is expected to be published in early 2004.

Comments can be forwarded to us by e-mail at BFPI@hc-sc.gc.ca or by mail at: Bureau of Food Policy Integration, Health Canada, Building #7 (P.L. 0700E1), Tunney's Pasture, Ottawa, Ontario, K1A 0L2.

This document is also available electronically on the Internet at the following address: http://www.novelfoods.gc.ca/.

ACTION	CURRENT STATUS
Substantial Equivalence	
For Health Canada:	
1. Health Canada is committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994 for them to reflect the latest scientific	Health Canada has recently completed a 75-day online public consultation on the proposed revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms*. Comments and feedback received during the public comment period, which was

developments. (This will be done in consultation with national and international experts.)	held from July 15 to September 30, 2003, will be used towards finalizing the guidelines and to further refine relevant policies and regulations. A summary report of the comments will be posted on Health Canada's web site in early 2004 (http://www.novelfoods.gc.ca). The revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* are expected to be finalized in the Spring of 2004. These guidelines reflect the guidance recently adopted by the Codex Alimentarius Commission in this area (see activity update under action 2 for additional details). Besides the guidelines themselves, a consultation document was prepared to assist in soliciting comments. The proposed revised guidelines and the consultation document are available at: http://www.novelfoods.gc.ca. **Next Update: June 2004**
2. We will update Health Canada information material to provide a better insight on the way we apply the concept of substantial equivalence when assessing the safety of novel foods.	In July 2003, the Codex Alimentarius Commission, adopted three documents, developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, which relate to foods derived from biotechnology. These three documents are the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology,* which lays out a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from biotechnology, and two guidelines, which describe the approach to conducting the safety assessments of these foods. The latter two documents are the Codex *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants* and the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms*. Canada made a significant contribution to the development of these documents. These documents now represent the international standard, providing principles and guidelines for the safety assessment of foods derived from recombinant-DNA plants and microorganisms, developed through a consensus

	process. These documents include considerations for a comparative approach that is consistent with the concept of substantial equivalence articulated in the report of the Royal Society of Canada, as well as in the reports from the Expert Consultations on the *Safety Aspects of Genetically Modified Foods of Plant Origin* and the *Safety Assessment of Foods Derived from Genetically Modified Microorganisms* convened jointly by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) in June 2000 and September 2001 respectively. As indicated in the response to action 1, Health Canada's proposed revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* have taken into consideration the guidance provided in the Codex documents mentioned above. **Next Update: Completed**
3. We will make international guidance information accessible through the Health Canada Food Program website by creating links to OECD, CODEX, FAO/WHO.	Links to the recently adopted Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, the Codex *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants* and the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms* will be added under the heading "Novel Foods" of Health Canada's Food Program website (http://www.novelfoods.gc.ca), as soon as the final versions are posted on the Codex Alimentarius Commission's website. A simpler web address has been created to facilitate access to information on novel foods found on Health Canada's website. For information in English users can now use the following web address : http://www.novelfoods.gc.ca. **Next Update: December 2004**
For the CFIA:	
4. CFIA is committed to the update	The CFIA has updated its regulatory directives and

of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	guidelines on plants with novel traits (*Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*) and livestock feeds derived from plants with novel traits (*Regulatory Directive 95-03: Guidelines for the Assessment of Novel Feed from Plants with Novel Traits*). These updates reflect policy changes that are the result of advances in science and the CFIA's increased experience in regulating products of biotechnology. Consultation continues to be a key factor in the CFIA's development of regulatory policy. New drafts of the above-mentioned directives were made available for a 60-day public comment period which was held from May 27 to July 25, 2003. Comments received are being reviewed and will be considered in the writing of the final directives. A public response to the comments will be posted on the CFIA Web site in December 2003. The final version of these two regulatory directives will be posted in early 2004. In addition, the Feed Section has commissioned two literature reviews dealing with occupational exposure. The first review investigates common features in microbial, plant, or fertilizer sources that trigger allergic reactions. The second is a review of the mode of action of toxic proteins. Feed Section evaluators will use the information in these reviews in their safety assessments of novel feeds. Plant Biosafety Office (PBO) officials are committed to regularly updating their scientific knowledge and CFIA policies. For example, the PBO held a workshop on the management of herbicide tolerant crop cultivation September 9–10, 2003. Participants included representatives from industry, provincial and federal government bodies, and academia. This workshop was a follow-up to an earlier one held in February 2002. The workshop focused on scientific and technical

	aspects of herbicide tolerant crop cultivation. There were three objectives: 1. gain a better understanding of current management practices as well as problems experienced with the cultivation of herbicide tolerant crops, 2. identify potential solutions to current problems experienced with these crops and to identify future challenges that industry and regulatory bodies alike may face, and 3. Identify any outstanding knowledge gaps regarding the management of herbicide tolerant crop cultivation and identify research priorities. For each objective, presentations were given and participants were organized into breakout groups for discussion. The PBO will be producing a report summarizing the outcome of the workshop. Participants are now reviewing it, and once finalized, it will be made available on the PBO Web page early in 2004 (http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml). **Next Update: June 2004**
5. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of confusing terminology.	As indicated in the response to action 4 and in the June 2003 progress report, the CFIA has revised *Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and *Regulatory Directive 95-03: Guidelines for the Assessment of Livestock Feed from Plants with Novel Traits*. These directives describe how the CFIA uses novelty as a regulatory trigger. The documents also define "novelty" and clarify the actions required in specific cases such as intraspecies/interspecies crosses, re-transformation and re-mutation of approved plants with novel traits (PNTs), and intentional gene stacking of PNTs. The documents also contain an expanded glossary. Regulatory Directive 95-03 clarifies the use of substantial equivalence principles in livestock feed safety assessments (http://www.inspection.gc.ca/english/anima/feebet/bio/b

	feebete.shtml). **Next Update: June 2004**
For Health Canada and the CFIA:	
6. We will participate and contribute to national and international expert effort to refine our approaches and further develop analytical tools, such as genomics, proteomics, and metabolic profiling to support the application of the concept of substantial equivalence in the evaluation of more complex novel foods and GM-organisms.	As mentioned in the response to action 2, the Codex Alimentarius Commission has adopted three documents, developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, that relate to foods derived from biotechnology. Canada contributed to the development of these documents including the section providing guidance on the application of a comparative approach. Canada's current application of substantial equivalence is directly consistent with the approach outlined in these documents. In addition, the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology has been developing a process to recognize methods of detection for biotechnology-derived products, to allow them to be internationally recognized through the Codex Committee on Methods of Analysis and Sampling (CCMAS). A proposal on this issue was prepared by the Task Force and was considered by the CCMAS in November 2002. The CCMAS has established a working group tasked with further developing the Task Force's paper and preparing recommendations for quality control measures in laboratories and evaluation criteria for methods of analysis, for CCMAS' consideration at its next meeting (March 7-14, 2004). Canada will continue to be involved in the development of a process to endorse methods of detection for biotechnology-derived products. Staff from CFIA's Feed Section co-authored a consensus document on "*Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants*" which was published in July 2003 by the Organisation for Economic Co-operation and Development (OECD) and posted on the organisation's website

	(http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)10) Key discussion points include: • assessment of genetically modified feedstuffs • fate of DNA and protein in animal feeding; harvest, storage, manufacture and in the digestive tract; and, • detection of transgenic DNA and protein in animal products. **Next Update: June 2004**
Use of Precaution	
For All Departments:	
7. The five departments will review their use of precaution to fully clarify its application across the many areas of their responsibility, including the regulation of products of biotechnology.	Guidance for the use of the precautionary approach in science-based decision making was released by the Government of Canada on July 25, 2003. The *Framework for the Application of Precaution in Science-based Decision Making about Risk* outlines guiding principles for the application of precaution in areas of federal regulatory activity for the protection of health and safety and the environment and conservation of natural resources. The purpose of the framework is to, among other things, improve the predictability, credibility and consistency of the application of precaution across departments and agencies to ensure adequate, reasonable and cost-effective decisions while minimizing crises and controversies and capitalizing on opportunities. The framework is available on the Privy Council Office's website at: http://www.pco-bcp.gc.ca/ under the "Publications" heading. **Next Update: December 2004**
For the CFIA:	
8. CFIA is committed to the update of protocols as product complexity increases and as science improves	See response to action 4 for update.

with contributions from internal and external experts whether domestic or international.	**Next Update: June 2004**
For Health Canada:	
9. Health Canada is also committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994.	See response to action 1 for update. **Next Update: June 2004**
Transparency and Increasing Public Confidence	
For Health Canada:	
10. We will seek ways to improve transparency of the regulatory process for novel foods in Canada, including under the Health Protection Legislative Renewal Initiative.	On June 9th, 2003, the Minister of Health announced her intention to initiate public consultations on the proposal to renew the federal health protection legislation. The proposed *Canada Health Protection Act* would replace four existing statutes: the *Food and Drugs Act*, the *Quarantine Act*, the *Hazardous Products Act*, and the *Radiation Emitting Devices Act*, with new measures better adapted to modern technology and society and offering stronger health protection to Canadians. This second round of consultations follows consultations held across Canada in 1998. With respect to transparency, the proposed new Act would include improved legislative authority regarding the review process for new drugs, genetically modified food and other novel products, including authority to make the process more transparent. The proposal and other background documents are available on the legislative renewal website a http://renewal.hc-sc.gc.ca. Specific questions regarding the transparency of the review process are listed in the detailed proposal (section B8 - Review Process). More immediate initiatives aimed at increasing transparency currently being undertaken by Health Canada include a pilot project, conducted jointly by Health Canada and the CFIA in co-operation with CropLife Canada, which consists of posting "notices of submission" on the Health Canada and CFIA web sites

	as per receipt of new submissions. These notices describe the products and summarize the scientific information provided for regulatory review. For the first time, the public will have 60 days to provide input on scientific matters relevant to the evaluation of individual product submissions. This initiative was launched in October 2003, and the first notice of submission was posted on December 1, 2003. Further details are provided in the response to action 16. A second pilot project currently being developed is aimed at assisting the Food Directorate in refining the review process in place for novel foods in Canada using the process in place in Australia/New Zealand as a model. To achieve this objective, scientific evaluators from the Food Directorate and from the Food Standards Australia New Zealand (FSANZ) planned on working collaboratively on the review of a submission for a genetically modified food using FSANZ's submission review procedure (where safety data are disclosed and public input is sought at two stages prior to final decision making). The Directorate is currently looking for proponent(s) who would volunteer to participate in this pilot project. **Next Update: June 2004**
11. To prepare and post Novel Food Decision Documents on Health Canada's Food Program website in a timely manner.	To date, 63 novel foods, 60 of which are derived from genetic modification, have been approved for sale in Canada. Decision documents for 58 of these novel foods are posted on the Novel Foods and Ingredients web page (http://www.novelfoods.gc.ca) under the heading of "Decision Documents". The 5 remaining decision documents are currently being finalized and will be posted in early 2004. **Next Update: June 2004**
12. We will share information and discuss specific product assessments with other countries as a mechanisms to validate Health Canada's safety assessments.	Health Canada's scientific evaluators take part on an ongoing basis in the exchange of technical information with their colleagues from FSANZ on a variety of issues related to the safety assessment of novel foods. Additionally, Health Canada's scientific evaluators have

	had informal meetings with their counterparts from the U.S. Food and Drug Administration's Centre for Veterinary Medicine to discuss issues related to animal biotechnology, including cloning. **Next Update: December 2004**
13. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments.	In August 2002, the CBAC released its report entitled "*Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*" (www.cbac-cccb.ca). The report includes 8 general and 44 specific recommendations categorized according to four overarching themes: Good Governance, Precaution, Information and Consumer Choice, and Social and Ethical Considerations. In its report, CBAC expressed overall support for the level of rigour and the effectiveness of Canada's current regulatory system for protecting the health of Canadians and the environment when it comes to products of biotechnology. However, to enhance the trust of the public and stakeholders in the regulatory system, the committee recommends that the government enhance the system's accountability as well as communication and transparency for the activities surrounding the regulation of these products in Canada. Over the past several months, Health Canada, CFIA, Environment Canada, AAFC, Fisheries and Oceans Canada, the Department of Foreign Affairs and International Trade, Industry Canada, the National Research Council of Canada, Natural Resources Canada and the Canadian International Development Agency have examined and considered the advice provided in CBAC's report. Actions taken in response to these recommendations will be detailed in a government response which is anticipated to be released in early 2004. **Next Update: June 2004**
For the CFIA:	
14. We will create new information products explaining	As part of an ongoing commitment to increasing transparency, the CFIA continues to produce and update

the regulatory system, and how it works in greater detail, for posting on the Internet and use in information kits intended for consumers.	information on agricultural biotechnology for the general public and other stakeholders. Fact sheets updated since July 2003 include: • Confined Research Field Trials for PNTs • Biotechnology Products: Plants that Tolerate Herbicides • The Cartagena Protocol on Biosafety • Environmental Safety Assessments for Agricultural Products of Biotechnology • Finding Out about the Regulatory Decisions Made for Products Derived through Biotechnology • Developing a Canadian Standard for the Voluntary Labelling of Foods Derived Through Biotechnology • Codex Alimentarius Commission • The Codex Standards Development Process and the Labelling of Foods Obtained from Biotechnology • International Activity on the Labelling of Foods Derived from Biotechnology These fact sheets are available on the following web page: http://www.inspection.gc.ca/english/sci/biotech/conse.shtml#env **Next Update: December 2004**
15. We will continue to make spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and the public.	The CFIA continues to explain its role in regulating products of biotechnology with stakeholder groups, the media and the public. Since October 2002, CFIA staff gave over 40 presentations and media interviews. Some recent examples include: On April 8, 2003, CFIA officers gave a presentation entitled "*The Regulation of Agricultural Biotechnology: The Canadian Approach*" before students of the Environmental Science Program at the University of Ottawa.

	On December 4, 2003 a CFIA officer gave a presentation before the Association des biologistes du Quebec on the regulation of PNTs in Canada. In addition, on September 25th, 2003 a CFIA representative gave a talk titled: *Regulating Novel Forestry Trees in Canada - Now and in the Future* at the XII World Forestry Congress Panel Discussion and Open Plenary on: Regulatory Challenges in Forest Biotechnology. The panel session was organized by the Canadian Forest Service with help from the CFIA, and considered three thematic questions: • What are the outstanding environmental issues regarding forest biotechnology? • What should our research priorities be given our current knowledge gaps? • What is required of our regulatory framework for the future development of biotechnology in Canada? **Next Update: June 2004**
16. We will work with applicants to achieve greater openness regarding specific product information.	As mentioned in response to action 10, the CFIA and Health Canada have launched a pilot project to post "notices of submission" before a decision has been made regarding a new biotechnology-derived product. These notices describe novel feeds or foods derived from PNTs and summarize the information provided for its safety assessment. CFIA and Health Canada posted the first notice of submission on December 1st, 2003, from Dow AgroSciences Canada for its modified corn Event TC6275 that expresses a *Bacillus thuringiensis* (Bt) Cry1F protein to give the corn the ability to ward off attacking insects. The notice, as well as background information and frequently asked questions (FAQs) regarding the pilot project, can be found at: http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml and http://www.novelfoods.gc.ca. Comments on the notice will be welcome until January 29th. **Next Update: June 2004**

Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada:	
17. Update and Publish *Guidelines for the Safety Assessment of Novel Foods* (vol. I & II - microorganisms and plants). The documents will reflect current international developments.	See response to action 1 for update. **Next Update: June 2004**
Allergenicity	
For Health Canada:	
18. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly.	In June 2003, at it's 26th Session, the Codex Alimentarius Commission adopted the Codex *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants*; the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms*; and the *Annex on Assessment of Possible Allergenicity*. Health Canada's revised Guidelines reflect the guidance provided in these documents. As mentioned in response to action 1, Health Canada's revised guidelines are anticipated to be finalized by Spring 2004. In addition, the Food Directorate's Bureau of Chemical Safety, in collaboration with the CFIA, held a second workshop on food allergen methodologies (Ottawa, October 27-29, 2003). This second workshop was meant to be a follow-up to the 2002 workshop organized by Health Canada, CFIA and scientists from the US Food and Drug Administration. This workshop brought together more than 75 participants: scientists, chemists and analysts from government agencies, university, industry and consumer associations. The workshop aimed mostly at expanding the consultation, information exchange and harmonization of allergen methodologies. Issues related to the detection, identification and characterization of allergens in foods were presented and discussed. The proceedings of this workshop will

	be posted under the heading "Food Allergen Method Development Program" of Health Canada's Food Program website (http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e_amd_program.html) in early 2004. **Next Update: June 2004**
19. Through stakeholder consultation, we will update and publish Health Canada's guidelines for the safety assessment of novel foods (vol. I + II).	See response to action 1 for update. **Next Update: June 2004**
Concurrence of approvals for GM-food crops	
For Health Canada and the CFIA:	
20. To formalize current understanding between CFIA and Health Canada to restrict partial approvals of GM-food crops and feeds.	Health Canada and the CFIA have agreed to a policy that requires coordination of regulatory approvals for novel foods and novel feeds derived from plants with novel traits. Health Canada's proposed revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* and the CFIA's revised draft regulatory directives Dir 94-08 and Dir 95-03 now contain a section describing the policy on simultaneous approvals between the two regulatory bodies. This policy is in place to minimize the risk of unapproved products entering the Canadian environment, food and feed supply. Final revisions, if any, will be completed by the Spring of 2004. (See responses to actions 1 and 3 for more information) Along with consulting on the safety data requirements detailed in the proposed revised guidelines, Health Canada has solicited stakeholder input on a number of issues related to the regulation of GM and other novel foods in Canada, including the coordination of regulatory decisions between Health Canada and the CFIA. **Next Update: June 2004**

GM-Animals (including fish) and GM-Feeds	
For Fisheries and Oceans Canada:	
21. Continue developing regulations under the *Fisheries Act* for aquatic organisms that are products of biotechnology, including transgenic aquatic organisms that will meet the *Canadian Environmental Protection Act*'s standards for the protection of the environment and human health.	Fisheries and Oceans Canada, Environment Canada and Health Canada are putting in place a formal process by which Fisheries and Oceans Canada would provide the expertise in assessing the environmental effects of biotechnology-derived aquatic organisms if such an application is filed prior to regulations being promulgated under the *Fisheries Act*. In addition, Fisheries and Oceans Canada is in the process of compiling the latest international scientific data on transgenic fish to be used for defining the parameters for risk assessment. This information will help form the basis for the regulation of these biotechnology products. **Next Update: December 2004**
22. Fisheries and Oceans Canada agrees that research on interactions between wild and non-transgenic fish is important and is already conducting such work together with related work on transgenic and nontransgenic salmon. Such work is used to increase our knowledge about genetically modified fish and to develop a regulatory environment to properly assess and evaluate potential license applications.	Fisheries and Oceans Canada research program on transgenic fish has gathered factual information on transgenic, domesticated and wild salmon populations, as a basis for objective evaluation and risk assessment of genetically modified salmon. Research results on physiological and behavioural differences, (e.g. disease resistance, ecological effects, effect on predation, and spawning behaviour), and on the linkage between genotype and phenotype expression, are published in the following articles in peer reviewed journals: • Jhingan, E., Devlin, R.H., and Iwama, G.K. 2003. *Disease resistance, stress response and effects of triploidy in Growth Hormone transgenic coho salmon.* J. Fish Biol. (in press) • Sundstrom, L.F., Devlin, R.H., Johnsson, J.I., and Biagi, C.A. 2003. *Vertical position reflects increased feeding motivation in growth-transgenic coho salmon (Oncorhynchus kisutch).* Ethology (in press) • Leggatt, R.A., Devlin, R.H., Farrell, A.P., and Randall, D.J. 2003. *Oxygen uptake of growth*

	hormone transgenic coho salmon (Oncorhynchus kisutch) during starvation, feeding, and swimming. J. Fish Biol. 62:1053-1066. • Lee, C.G., Devlin, R.H., and Farrell, A.P. 2003. *Swimming performance, oxygen uptake and oxygen debt in adult transgenic and ocean-ranched coho salmon (Oncorhynchus kisutch, Walbaum)*. J. Fish Biol. 62:753-766. In addition, research results have been presented at the following international conferences: • Aquaculture and Fisheries Genomics Conference, Jeju, Korea, November 13, 2003. • International Marine Biotechnology Conference, Tokyo, September 26, 2003. • Centre for Dialogue, Simon Fraser University, November 15, 2003. Fisheries and Oceans Canada is seeking feedback on these findings from other regulatory research organisations in Canada and in other countries. This knowledge base is critical to the evaluation of environmental impacts of transgenic fish and the regulations being developed under the *Fisheries Act*. **Next Update: December 2004**
For Environment Canada:	
23. Revise New Substances documentation to ensure that protocols for generating notification data adhere to animal care and husbandry guidelines.	Environment Canada has developed a draft guidance document entitled: *Testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms*. The Department anticipates that a final document will be completed in the second quarter of 2004. This guidance document recommends standardized tests that will help notifiers of substances that are "new" to Canada for the purposes of the

	Canadian Environmental Protection Act, 1999 (i.e. substances that are not on the Domestic Substances List) to generate notification data under *the New Substances Notification Regulations*. The guidelines recommend that tests conducted in support of a notification are in keeping with the Canadian Council on Animal Care (CCAC) guidelines on the care and use of experimental animals. **Next Update: June 2004**
Other Recommendations	
For the CFIA:	
24. In addition to existing studies, CFIA intends to commission additional research by government scientists or external experts in areas related to: • gene flow and fertility • insect resistance management • detection of transgenes in feed and livestock consuming such feed • herbicide resistance • biodiversity and agricultural ecosystem management • detection processes for biotechnology products • allergenicity for occupational and bystander exposure (feed related studies).	In 2002 the CFIA contracted several short-term research projects to assist in developing regulatory policy and in decision making. The projects which were continued in 2003 to further examine promising preliminary results include: <u>Gene flow from *Brassica juncea* to wild mustard.</u> - Gene flow between herbicide-tolerant *B. juncea* and a related wild mustard plant has been estimated. The follow-up study will examine the genetics and reproductive traits of the hybrids as well as the natural mutation rate for herbicide resistance in wild mustard. <u>Management of Resistance to Bt in Adult Corn Rootworm.</u> - A tracking device to monitor adult corn rootworm movements in the laboratory has been developed . The follow-up study will validate behavioral results obtained under laboratory conditions and will examine the feasibility to track the insects in the environment. Results will be used to help design resistance-management requirements such as non-Bt refugia. <u>Global Changes in Gene Expression Associated with Highly-Expressed Transgenes in *Arabidopsis* and Canola.</u> - Microarray analysis have been used to examine variation in global gene expression in genetically-modified *Arabidopsis* plants subject to various environmental stresses. These plants express

	marker genes or genes involved in alteration of physiology and development under the control of a strong constitutive promoter. The follow up study will validate the first results and macroarrays will be designed to obtain quantitative data on expression levels of selected non-target genes in transgenic plants. The results of this study will be used to assess non-intentional compositional changes in transgenic plants. A publication has been submitted on the first phase of the project. Physical Modeling of Pollen Dispersal. - A computer model is being developed to predict movement of pollen under field conditions. The model will be validated on wheat. The field study Emergence Periodicity of Volunteer Canola and Wheat in Prairie Cropping Systems was initiated in 2003. This study will characterize the emergence of volunteer canola and wheat in prairie cropping systems and examine the impact of various agricultural practices on control of both herbicide-tolerant and conventional volunteer plants. The project on Environmental Effects of Bt Canola on Non-target Insects has been completed. Field studies were carried out to assess the impacts of Bt canola on non-target insects that feed on canola and its wild relatives under Canadian field conditions. Research results are awaiting publication. As mentioned in the update to action 4, a literature review on the topic of occupational exposure to biological hazards in the agriculture industries has been completed, related to the Development of Common Predictors for Potentially Allergenic Elements in Feeds and Fertilizers. A project to investigate whether more refined Predictors of Dermal and Inhalation Allergenicity can be developed has been contracted out. Further AAFC research on the stability of transgenic

	DNA in the rumen and the transfer of transgenic DNA to rumen microorganisms has been supported. <u>The Effect of Transgenic Canola meal on Rumen Microflora and the Growth and Meat Quality of Ruminants and Monogastrics.</u> - This research project addresses the effects of transgenic canola on the growth characteristics of two livestock species, the stability of transgenic DNA and the likelihood of horizontal gene transfer. The following manuscripts and reports concerning this project have been published or have already been submitted and accepted for publication: • Alexander, T. W., R. Sharma, E. K. Okine, W. T. Dixon, R. J. Forster, K. Stanford and T. A. McAllister. et al. 2002. *Impact of feed processing and mixed ruminal culture on the fate of recombinant EPSP synthase and endogenous canola plant DNA.* FEMS Microbiol. Lett. 214:263-269. • Lien, K. A. J. L. Aalhus, and M. E. R. Dugan. *Swine performance, carcass composition and pork quality when feeding diets containing Roundup Ready®, parental line or conventional canola meals in Canada*. Final Report • Sharma, R., S. Jacob John, D. M. Damgaard, and T. A. McAllister. 2003. Extraction of PCR-quality plant and microbial DNA from total rumen contents. BioTechniques, 34:92-97. • Sharma, R., T. W. Alexander, S. J. John, R. J. Forster, and T. A. McAllister. *Relative stability and fate of transgenic DNA fragments in mixed ruminal cultures*. (Submitted for publication to the British Journal of Nutrition) • Stanford, K., J. L. Aalhus, M. E. R. Dugan, G. L. Wallins, R. Sharma, and T. A. McAllister. 2003. *Effects of feeding transgenic canola on apparent digestibility, growth performance and carcass characteristics of ruminants.* Canadian Journal

	of Animal Science, 83 (2): 299-305. **Next Update: June 2004**
For All Departments:	
25. We will consider sharing recommendations 5.7 and 6.9 with other appropriate federal fora for their consideration, such as linking to federal science and technology initiatives	A number of horizontal federal initiatives are currently under way including one on smart regulations that touches upon the subject of biotechnology. Recommendations of the Royal Society and the Government action under this action plan have been shared with the Smart Regulations Secretariat. (www.smartregulation.gc.ca). To maintain and improve its leadership position in biotechnology, the Government is developing a stewardship framework that provides the foundation for an integrated approach to address biotechnology issues. The framework will set out principles allowing novel and appropriate mechanisms to effectively promote health and sustainability, and contribute to innovation and socio-economic growth. This framework will build on a strong pro-active approach to emerging issues through a foresight initiative, and will address concerns that are foremost to Canadians such as long-term health and environmental impact of products of biotechnology. Lastly, under the Canadian Biotechnology Strategy, a number of initiatives are looking at the capacity and capability to measure long-term ecosystems and health effects of genetically modified organisms. Results of these policy initiatives and analyses could contribute to future research activities in addressing environmental and health impacts of biotechnology products, including the environmental impacts of genetically modified plants. **Next Update: June 2004**
For AAFC:	
26. AAFC, in consultation with CFIA, is conducting a broadly-based research study planned for at least 12 years to examine the	An ongoing study, initiated in 2000 at the AAFC Research Centre in Lethbridge, Alberta, is aimed at determining the environmental and economic impact of long term production of crops with novel traits. Crops

potential long-term environmental impacts of approved and commercially-available GM crops - e.g. corn, potatoes and canola.	currently included in the study are: Roundup Ready® canola, Liberty Link™ canola, Bt corn, Roundup Ready® corn, and Bt potato. Traditional cultivars of each crop also are included for comparison purposes. Data is being collected on the effect of crops with novel traits on: • weed, disease, and insect (pest and beneficial species) populations, • biodiversity of soil microorganisms, • potential gene transfer to other organisms, and • economics of crop production. This study is planned to run for twelve years. Meaningful results are expected to be available only after several years. **Next update: December 2005**
For Environment Canada:	
27. Environment Canada is leading the development of a federal strategy on Generating Knowledge to Understand Ecosystem Effects of GMOs. Health Canada, AAFC, CFIA, and Fisheries and Oceans Canada are involved in this effort.	An interdepartmental group led by Environment Canada continues to develop a federal research strategy to generate knowledge to understand potential long-term and cumulative effects of novel living organisms developed using biotechnology. As indicated in previous progress reports, the group has identified specific theme areas, analyzed research needs and gaps, and developed a strategy to address such gaps. The draft strategy document has been reviewed interdepartmentally and input from other government departments and agencies is being incorporated. International, policy and management aspects of the strategy have been strengthened by commissioning research on international research developments, international policy context, and governance strategies for a future research network. **Next Update: June 2004**
For Genome Canada:	
28. Considerable work is already in progress in the area of development of state-of-the-art genomics resources, and more is likely to emerge soon, as Genome	Together with its five Genome Centres (Atlantic, Quebec, Ontario, Prairies and British Columbia) and with other partners, Genome Canada invests and manages large-scale research projects in key selected areas such as agriculture, environment, fisheries,

Canada centres are established with the infrastructure necessary to undertake large-scale genomics projects.	forestry, health and new technology development. Genome Canada also supports research projects aimed at studying and analyzing the ethical, environment, economic, legal and social issues related to genomics research (GE^3LS). To date, Genome Canada has invested $318 million across Canada. With funding from other partners, this amounts to an investment of $721 million in 60 innovative genomics and proteomics research projects and science and technology platforms. A detailed list of approved projects is available on the Genome Canada website at: http://www.genomecanada.ca/projects. To strengthen networks between researchers, and to encourage research in the area of environmental and comparative genomics Genome Canada co-hosted with Environment Canada, in October 2003, the Environmental and Comparative Genomics Workshop (Toronto, ON). The workshop was attended by some 80 Canadian and international scientists from academia, government and the private sector. The workshop was considered to be an important step toward nurturing opportunities for collaborations among scientists in the diverse fields engaged in environmental research in Canada. Summary proceedings will be posted on the Genome Canada website early in 2004. **Next Update: December 2004**