PROGRESS REPORT: AUGUST 2004

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 five 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/novel_foods.html). The sixth progress report provides detailed technical information regarding the key milestones achieved for each of the different actions underway for which the reporting date of June 2004 was identified in earlier progress reports.

Subsequent progress reports will be published in December 2004 and June 2005. 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 later this year.

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
A. 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 developments. (This will be done in consultation with national and international experts.)	Health Canada is currently completing its revision to the *Guidelines for the Safety Assessment of Novel Foods*. The revised guidelines which are expected to be finalized by the summer of 2004, are consistent with guidance documents recently developed at the international level. A 75-day on-line public consultation was held between July and September 2003 to solicit comments and feedback on the proposed revisions as well as other broader based issues (including animal cloning, regulatory processes, etc.). Comments received during the consultation process are being reviewed and suggestions have been incorporated into the revised guidelines. More information regarding the consultation process, including the proceedings of the Expert Joint HC/CFIA Multistakeholder Consultation session held in May 2002 is now available under the Novel Foods heading of

	Health Canada's Food Program website and on the website of the CFIA. In addition, a summary report of the comments will be posted on Health Canada's website in 2004 (http://www.novelfoods.gc.ca). **Next Update: December 2004**
For the CFIA:	
2. CFIA is committed to the update of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	The CFIA is working toward developing a science-based regulatory framework for commercial plant molecular farming in Canada. In March 2004, the CFIA hosted a technical workshop to examine whether these crops could be adequately segregated from other commodities intended for the food and feed chains. An executive summary is available on CFIA web site (http://www.inspection.gc.ca/english/plaveg/bio/mf/segrege.shtm) and full proceedings will be posted on the CFIA website by the Fall of 2004. **Next Update: December 2004**
3. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of confusing terminology.	The CFIA has been working to improve communications with developers and importers of plants with novel traits (PNTs), to help improve understanding of the regulatory requirements for PNTs. A workshop on the use of novelty as the regulatory trigger was held with plant breeders in March 2004 to discuss options for clarifying the regulatory trigger. Proceedings from this workshop will be posted by the fall of 2004. **Next Update: June 2005**
For Health Canada and the CFIA:	
4. 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	In December 2003, the CFIA and Health Canada attended the 8th Meeting of the Organisation for Economic Cooperation and Development Task Force for the Safety of Novel Foods and Feeds, held in Paris, France. This meeting focussed mainly on finalizing four Consensus Documents (Rice, Barley, Cotton, Alfalfa and other Forages). The CFIA is lead author of the document *Key Nutrients and Antinutrients in Alfalfa and Other Forages*, which is expected to be published by March 2005. These consensus documents contain information for use during the regulatory assessment of a particular food/feed product. Also the CFIA and Health Canada participated in the International Life Sciences Institute "Workshop on Nutritional and Safety Assessment of Foods and Feeds Nutritionally Improved through Biotechnology" (December 2003, Paris, France). The workshop focussed on the discussion of an advanced draft document on the assessment of the "second

	generation" foods and feeds. The final document was published in April 2004. It is available to the public at the following website: http://www.ift.org/pdfs/crfsfs/crfsfsv3n2p0035-0104ms20040106/pdf. **Next Update: December 2004**
B. Use of Precaution	
For All Departments:	
5. Uphold and reinforce regulatory tenets of mandatory pre-market notification and a prudent process of science-based assessments for the potential risks of the introduction of new biotechnology products as food or feed or into the environment.	The CFIA and Health Canada have adopted a policy of harmonized approvals to minimize the potential for unapproved products to enter the Canadian environment, feed and/or food supply. This policy is now included in the CFIA's revised directives *94-08*: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and *95-03: Guidelines for the Assessment of Novel Feed from Plants with Novel Traits*, as well as Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods*. Finalization of the revised guidelines and regulatory directives, which provide more specific direction to applicants in order to facilitate compliance with regulatory requirements, is anticipated by the end of 2004. In addition, the CFIA will be finalizing updates to *Regulatory Directive Dir95-03: Guidelines for the Assessment of Livestock Feed from Plants with Novel Traits* which will be posted on their website in 2004. With respect to specific types of new products (one example being molecular farming), the CFIA has completed the *Interim Amendment to Directive 2000-07 for Confined Research Field Trials of PNTs for Plant Molecular Farming* which explicitly states appropriate terms and conditions for confined research field trials of plants with novel traits for molecular farming. These amendments can be found on the CFIA website at: http://www.inspection.gc.ca/english/plaveg/pbo/dir/doir00077ie.shtml. These regulatory directives are designed to protect the health of humans and livestock, and the environment. The amendments also describe a role for Health Canada in the safety assessment of these trials. In this regard, Health Canada and the CFIA are working together to develop a mechanism through which Health Canada can provide advice to the CFIA as necessary. The various federal departments and agencies involved in overseeing plant molecular farming are committed to working

	together on a number of actions designed to ensure that their guidelines, regulations, protocols and other tools always stay current with the pace of discovery in this area. The CFIA is also preparing to hold a consultation with potential importers of PNTs regarding their regulatory responsibilities. As well, Fisheries and Oceans Canada (DFO) and Health Canada co-sponsored a meeting for experts on the "Assessment of Environmental and Indirect Human Health Effects of Genetically Modified Aquatic Organisms" from March 30-31, 2004. The information gathered is currently being compiled into a working document on the assessment approach for transgenic fish. The DFO regulatory science program continues to expand the knowledge base on the understanding on the potential environmental impacts of aquatic organisms with novel traits. **Next Update: June 2005**
6. As GM-foods increase in their complexity, the protocols for product review need to be updated through a system for review and improvement. As well, as science progresses and more advanced methods become available, protocols will be refined. The government looks forward to the contribution of Panel members and other experts in this work.	As mentioned in action 2, the CFIA is working toward developing a science-based regulatory framework for commercial plant molecular farming (PMF) in Canada. In March 2004, the CFIA hosted a technical workshop to examine whether PMF crops could be adequately segregated from other commodities intended for the food and feed chains. Proceedings will be posted on the CFIA website by the summer of 2004. In addition, as indicated in action 1, Health Canada and the CFIA are completing the update to their respective regulatory directives and guidelines. **Next Update: June 2005**
For Health Canada:	
7. Health Canada is also committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994.	Please see action 1 for update. **Next Update: December 2004**
For the CFIA:	
8. CFIA is committed to the update of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	To further our knowledge of emerging issues and new products, the CFIA, in 2003, commissioned two literature reviews dealing with occupational exposure. The first review investigated common features in microbial, plant or fertilizer sources that trigger allergic reactions and the second examined the mode of action of toxic proteins. Based on these reviews, an additional study was commissioned on

	predicting dermal and inhalation allergenicity. This study was completed in March 2004. In addition, the CFIA presented a training seminar and participated in an International Centre for Genetic Engineering and Biotechnology (ICGEB) workshop held in May 2004 in Italy. The focus of the workshop was on conducting environmental release risk assessments of genetically modified organisms. **Next Update: December 2004**
C. Transparency and Increasing Public Confidence	
For All Departments:	
9. Our departments will commit to a study over the fall to examine the approach taken by countries, such as Australia, New Zealand, the United Kingdom and the United States, which provides for more public and expert consultations. This will help us determine which model would best be suited for the Canadian regulatory process.	In August 2003, the CFIA and Health Canada, in co-operation with CropLife Canada, an industry association representing developers of biotechnology-derived plants, launched a pilot project to post Notices of Submission for public viewing on the Internet. These "notices" are posted on the Health Canada and CFIA websites when new submissions are received. These notices describe the product and summarize the scientific information provided for regulatory review to Health Canada and the CFIA. For the first time, the public has 60 days to provide input on scientific matters relevant to the evaluation of each of these new product submissions. A first notice, which was for an insect resistant corn line, was posted October 31, 2003. Information, including notices of submission, can be found at: http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml or http://www.novelfoods.gc.ca (Under the heading "Biotechnology Transparency Project"). The CFIA and Health Canada continue to support the "Notice of Submission" pilot project which allows developers to post their submissions for crop, feed, and food approvals on the CFIA web site for public comment. As this is currently a joint project with CropLife members, when CFIA or Health Canada meets with non-member companies of CropLife for pre-submission consultations, these companies will be invited to participate in the project. In addition, the Food Directorate is currently looking for participants from industry to take part in a pilot project that would have scientific evaluators from the Directorate and Food Standards Australia New Zealand (FSANZ) work together on the review of a submission. Utilizing the process in place in Australia/New Zealand, the Food Directorate will review Canada's current approach to determine how

	Canada's process may be refined to provide more opportunities for public input. Comments were also received on this issue during the public consultation recently held in conjunction with the revision to the *Guidelines for the Safety Assessment of Novel Foods*. Please refer to action 1 for additional information. The CFIA's Office of Biotechnology is also continuing its research into various transparency mechanisms and consultations used by other countries. Lastly, Fisheries and Oceans Canada and Health Canada co-sponsored an expert meeting on the "Assessment of Environmental and Indirect Human Health Effects of Genetically Modified Aquatic Organisms", March 30-31, 2004, creating an opportunity for industry, university and government to share views on assessment approaches and regulatory policy direction and social issues for transgenic fish. The exchanges also clarified the understanding of the status of the scientific knowledge in this field. Please see action 5 for additional information. **Next Update: December 2004**
For Health Canada:	
10. Health Canada proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	The Food Directorate has initiated this pilot project which will invite non-government experts to participate in the Food Rulings Committee's deliberations relating to GM food submissions. Several experts have committed to participating in the project. The Working Group on External Participation continues to address process issues and anticipates that participation of the experts in meeting discussions will begin in the fall of 2004. In addition, a summary of comments received in response to questions on this project posed in the consultation document on the revision of Health Canada's *Guidelines for the Safety Assessment of Novel Foods* and Health Canada's responses to these comments will be included in the report on the consultation. Please see action 1 for additional information. **Next Update: December 2004**
11. We will seek ways to improve the 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 three existing statutes: the *Food and Drugs 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.

	With respect to transparency, the proposed Act would include improved legislative authority regarding the review process for new drugs, genetically modified food and other novel products and will include the 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 B 8 - Review Process). The Food Directorate recently completed its review of the proposed Act and will be submitting their comments to the Legislative Renewal Secretariat (Summer 2004). Health Canada is also in the process of compiling and analysing the comments received during a series of public consultations held in 2003 and early 2004 (some 30 workshops and more than 1,400 written submissions received). This analysis will be incorporated into the development of new legislation. 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, external expert participation in the Food Rulings Committee's deliberations on novel foods and working with FSANZ to refine the Food Directorate's review process. Please refer to actions 9 and 10 for additional information. **Next Update: December 2004**
12. To prepare and post Novel Food Decision Documents on Health Canada's Food Program website in a timely manner.	To date, 62 novel foods, 58 of which are derived from genetic modification, have been approved for sale in Canada. Decision documents for 60 of these novel foods are posted on the Novel Foods and Ingredients web page (http://www.novelfoods.gc.ca) under the heading "Decision Documents". The remaining decision documents are currently being finalized and will be posted in the summer of 2004. **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 its report, *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*, 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 and improve communication and transparency surrounding the activities related to the regulation of genetically modified products in Canada. Over the past several months, Health Canada, CFIA, Environment Canada, AAFC, Fisheries and Oceans Canada, the International Trade Canada, 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. A detailed action plan is in the process of receiving ministerial approval. Progress on these commitments will be reported on biannually in a combined Royal Society/CBAC progress report. **Next Update: December 2004**
For Environment Canada:	
14. Improve access to all existing guidelines, advisory notes, conditions on website; formats for risk assessment reports currently being revised to facilitate public release.	Environment Canada's New Substances Program website (http://www.ec.gc.ca/substances/nsb/eng/index_e.htm) is updated on a regular basis to ensure that regulators and the public have access to all existing guidelines, advisory notes and regulatory conditions. An Advisory Note (2002-1) indicating that notifiers are expected to adhere to animal care and husbandry guidelines has been published and is posted on the website at: http://www.ec.gc.ca/substances/nsb/HTML/A0201_e.htm. Environment Canada has completed the development of the guidance document, *Testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms* (EPS 1/RM/44). This document recommends standardized tests that will help notifiers of substances that are "new" to Canada for the purpose 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 notification are in keeping with the Canadian Council of Animal Care (CCAC) guidelines on the care and use of experimental animals. The document can be obtained by contacting the New Substances Branch of Environment Canada or on their website: http://www.ec.gc.ca/substances/nsb/eng/index_e.htm. Environment Canada is leading the development of the Canadian Node of the Biosafety Clearinghouse (CNBCH) with input from Health Canada and the Canadian Food

	Inspection Agency (http://www.bch.gc.ca). The International Biosafety Clearinghouse was established under the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity to exchange information on living modified organisms (LMOs). The CNBCH is a central portal to information on the Canadian regulatory system for LMOs and risk assessments conducted thereunder. **Next Update: December 2004**
For the CFIA:	
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 routinely and actively communicates its roles and responsibilities to a wide range of stakeholders and interested parties. In this on-going work, we will continue to improve and adapt our communications materials, based on audience need. **Next Update: June 2005**
16. We will ensure all regulatory documentation regarding current requirements are easily accessible and complete.	Since May 2002, information for the registration of novel microbial supplements (fertilizers) has been posted on the CFIA Internet site: http://www.inspection.gc.ca/english/plaveg/fereng/fereng-gene.shtml. In March 2004, the CFIA's Feed Section published a brochure *Regulation of Novel Feeds*, which includes information about the regulation of feeds derived from plants, animals and microbes. The brochure can be found at: http://www.inspection.gc.ca/english/anima/feebet/bio/regulatione.shtml. The CFIA ensures that all PNT authorizations are now accompanied by a corresponding decision document These Decision Documents, on the determination of environmental and livestock feed safety, are posted on the CFIA website at: http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml. **Next Update: June 2005**
D. 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	See action 1 for an update.

and plants). The documents will reflect current international developments.	**Next Update: December 2004**
18. Work at the national level and in collaboration with international organizations, such as OECD and the FAO/WHO to further developing and refining tools for toxicological assessments.	Health Canada is planning to organise and host an international workshop to take stock of and discuss existing methodologies and animal models used for whole-food testing to assess potential nutritional and toxicological effects associated with novel foods, thus addressing the human health and safety issues related to the assessment of safety, nutritional quality and health effects of novel foods. **Next Update: June 2005**
Alternatives to antibiotic-resistance markers	
19. We will work with product developers as well as national and international experts to determine the "state of the art" regarding alternative markers as a tool in the development of new biotechnology products.	Health Canada solicited comments on the use of antibiotic resistance marker genes as part of its consultation on the proposed revisions to its *Guidelines for the Safety Assessment of Novel Foods*. The comments received are currently being reviewed and will be used to refine Health Canada's policy on this issue. Please refer to action 1 for additional information. The issue of alternatives to the use of antibiotic resistance markers in novel foods was also covered at the technical discussion on the health and safety aspects of the Action Plan in response to the Royal Society Expert Panel organized by Health Canada (Gatineau - April 30, 2002) and the joint Health Canada/CFIA consultation on proposed revisions to the guidelines and regulatory directives which was held in May 2002. Both documents are now available at: http://www.hc-sc.gc.ca/english/protection/royalsociety/technical_report_april.html and http://www.inspection.gc.ca/english/plaveg/bio/gatconsult/consultinte.shtml. As well, the CFIA commissioned a survey and literature review of current research on alternative selection markers for transgenic plants. The paper was delivered in April 2003 and is currently under review by the CFIA. This paper is now published and a plain language summary of the paper is posted on the CFIA website at: http://www.inspection.gc.ca/english/sci/biotech/trans/marmare.shtml. **Next Update: June 2005**
Allergenicity	

20. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly.	The Food Directorate in collaboration with the CFIA, held a second workshop on food allergen methodologies (Ottawa, October 27-29, 2003). This 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 Summer 2004. In November 2003, a Health Canada delegation was invited by RIKILT, Institute of Food Safety, Netherlands to participate in a Partnering Event for the Canadian and Dutch Biotech Research and Industry Community, held in Amsterdam. The objective of this event was to explore potential partnerships in the area of "omics" in food safety assessment, and GM food surveillance. Several avenues for potential future collaborations were discussed including, the identification and detection of GM events and allergens, as well as the use of "omics" technologies for safety assessment of GM foods. As well, the ILSI Health and Environmental Sciences Institute's (HESI) Protein Allergenicity Technical Committee and the ILSI International Food Biotechnology Committee held a meeting on June 2, 2004 (Washington, DC). This meeting was a follow-up to the meeting on the ILSI activities related to biotechnology that took place October 3, 2002, in Arlington, VA. The goals of the meeting were to create an awareness of ILSI's global activities to advance the science related to conducting safety assessments for biotechnology products, and to learn about the scientific priorities for biotechnology within the regulatory community. As part of the meeting, Health Canada made a presentation on the "Current Scientific Challenges Regarding Biotech Safety Assessment at Health Canada". **Next Update: June 2005**
21. Through stakeholder consultation, we will update and publish Health Canada's guidelines for the safety assessment of novel foods (vol. I + II).	Please see action 1 for update. **Next Update: December 2004**

22. Health Canada recognizes the need for development and strengthening of infrastructures to facilitate the evaluation of the allergenicity of GM proteins. We continue to participate in international efforts in this area and welcome the contribution of all experts.	Please see action 20 for update. **Next Update: December 2004**
23. Health Canada is working to establish a surveillance strategy which will permit the identification of undesirable health impacts of biotechnology derived products, including GM-foods.	The focus of this project has evolved toward the development of a modelling framework which will inform the regulatory decision making process in the pre-market phase as to potential post-market oversight requirements and how best to conduct them. The next stage of work, which is estimated to take about 8 months, is to operationalize the framework (create or adopt software to make it work) and to test it with scenarios from both the food and drugs realm. The framework is designed to apply to any consumer product (not just those derived from genetic modification or bioengineering). Further information can be found at: http://www.hc-sc.gc.ca/pphb-dgspsp/csc-ccs/biotech_e.html In November 2003, representatives of Health Canada and the Centre for Surveillance Coordination met with representatives of the EU to discuss possible areas of collaboration, including GM food surveillance. Potential areas of collaboration are still being considered. For more information, please see action 20. **Next Update: June 2005**
Concurrence of approvals for GM-food crops	
For Health Canada and the CFIA:	
24. 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* and the CFIA's revised draft regulatory directives *94-08*: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and *95-03: Guidelines for the Assessment of Novel Feed from Plants with Novel Traits* now contain a section describing the policy on simultaneous approvals (i.e. no split 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 to the guidelines and regulatory directives, if any, will be completed in the summer of 2004. (Please refer to actions 1 and 5 for additional information) **Status: Complete**
Nutritional assessments	
25. Participate in international efforts and seek contribution of experts for the development and validation of whole food testing protocols and other tools to address nutritional issues.	Input on nutritional assessment of novel foods and feeds received at the joint consultation held by Health Canada and the CFIA and from the subsequent online feedback form has been considered and incorporated into Health Canada's and CFIA's revised guideline documents. Comments received during the current phase of consultation will be considered in the finalization of these documents (please see action 1 for additional information). Officials from the CFIA and Health Canada participated in the recent meeting of the Organisation for Economic Cooperation and Development Task Force for the Safety of Novel Foods and Feeds (Paris, France - December, 2003). Two consensus documents (of four presented) one on rice and one on barley were reviewed at the meeting and the revised texts will be sent for declassification. These documents identify key food and feed nutrients, anti-nutrients and secondary plant metabolites. These documents will be available on the OECD website (http://www.oecd.org/biotrack/) once they have been published along with other previously released documents. Please see action 4 for additional information. In addition, the International Life Sciences Institute (ILSI) recently released the following document, *Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology* on the Comprehensive Reviews in Food Science and Food Safety website at: http://www.ift.org/cms/?pid=1000362. The actual document can be viewed at: http://www.ift.org/pdfs/crfsfs/crfsfsv3n2p0035-0104ms20040106.pdf. **Next Update: June 2005**
E. Environmental Safety and GM-Plants (Plants with Novel Traits)	
For Environment Canada:	
26. Continue CEPA 1999 listing process in cooperation with other government departments, including Health Canada and	Environment Canada and Health Canada finalized a Memorandum of Understanding with Fisheries and Oceans Canada on the regulatory oversight of aquatic organisms with novel traits on May 17, 2004.

CFIA.	Environment Canada and Health Canada are also finalizing a Letter of Understanding with CFIA regarding the regulatory oversight of livestock that are products of biotechnology. The CFIA, Environment Canada, Health Canada and Fisheries and Oceans Canada have collaborated to develop a notification guidance document modelled on Schedule XIX of the New Substances Notification Regulations. This draft document entitled "Notification Guidelines for the Environmental Assessment of Biotechnology - Derived Livestock Animals" has been posted on CFIA's website: http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/guidedirecte.shtml. In the meantime, CFIA will contribute scientific expertise to Environment Canada for policy development and risk assessment of livestock animals that are products of biotechnology notified under the *New Substances Notification Regulations*. **Next Update: December 2004**
27. Requirements for training were recognized in Budget 2000 fund for biotechnology regulation (along with increased resources to meet then existing regulatory workload). As the number and complexity of applications increases, additional capacity will be added.	Environment Canada is maintaining and adding to its human resource capacity in its regulatory program and its compliance promotion projects. Funding has been allocated for training of existing staff and Environment Canada's enforcement staff will be trained in the use of microbial sampling kits to enhance the enforcement of the New Substances Notification Regulations. A workshop organized by Environment Canada under the Canadian Regulatory System for Biotechnology initiative was held on May 18-19, 2004 in Toronto. The primary objectives of the workshop were to provide a forum for the identification of research needs and priorities as they pertain to microorganisms under the New Substances Notification Program and seek input on unsettled issues and approaches for addressing them. Proceedings from this workshop are currently being drafted. The outcomes of this workshop will be used to develop research priorities for the biotechnology portion (as it pertains to microorganisms) of the New Substances Notification Program within Environment Canada. **Next Update: December 2004**
F. GM-Animals (including fish) and GM-Feeds	
For Health Canada:	
28. Develop and publish guideline volume III on safety assessment of novel foods derived from animals.	The third section of Health Canada's *Guidelines for the Safety Assessment of Novel Foods*, which is devoted to the safety assessment of novel foods derived from animals, is currently under development. Please see action 1 for

	additional information regarding the first two sections of Health Canada's *Guidelines for the Safety Assessment of Novel Foods*, which are devoted to the safety assessment of novel foods derived from plants and microorganisms In addition to the results of the FAO/WHO Expert Consultation on Genetically Modified Animals held November 17-21, 2003, the new section of Health Canada's guidelines will reflect the findings of the U.S. National Academy of Sciences report entitled *Animal Biotechnology: Science-based Concerns* published in August 2002 (http://search.nap.edu/books/0309084393/html/) and input from previous national expert consultations organized by Health Canada and other departments in 2001 and 1998. It is anticipated that a consultation on the first draft of these guidelines will take place in 2005. Also, Health Canada sought public comments on the regulation of foods derived from cloned animals as part of its consultation on the proposed revisions to its *Guidelines for the Safety Assessment of Novel Foods*. Comments received as part of this consultation are currently being reviewed and will be used to refine Health Canada's interim policy on foods derived from cloned animals. Please see action 1 for additional information. As an interim policy, Health Canada considers foods produced from livestock developed using the technique of SCNT to be captured under the definition of "novel food" and therefore subject to the *Novel Food* regulations. Developers are, therefore, requested not to release any cloned animals obtained through SCNT, their progeny, or products/by products/by-products (including meat, eggs and milk) into the human food supply. Since at this time, there is insufficient data to guide the safety assessment of these products, developers who wish to use this technology for producing food livestock are being requested to withhold novel food notifications until requirements are determined and further guidance is available. The interim policy can be found at: http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_cloned_animals.html. In addition, in May 2004, the Food Directorate sought additional input on the issue of animal cloning from the Health Products and Food Branch's Public Advisory Committee, including how to move forward with public awareness activities around this issue. This input will be valuable for guiding the Food Directorate's thinking on future approaches to public involvement. Also, as reported in the December 2003 progress report, the Food Directorate, as part of an interdepartmental working

	group on animal biotechnology, is in the process of completing a document which identifies issues related to cloned animals obtained through SCNT. This includes potential human health risks associated with the consumption of cloned animals and products derived from them or their offspring. Once finalized, this document will be posted on the web. It is anticipated that the document will be finalized by the end of Summer 2004. Lastly, to discuss food issues of common interest, Food Directorate officials met with counterparts from FSANZ and the U.S. Food and Drug Administration (FDA) on March 21, 2003, April 3, 2003 and, most recently, on April 18, 2004. The regulatory agencies have agreed to exchange information and to further collaborate in the area of animal biotechnology, including cloned and GM-animals. Such dialogue will facilitate the development of consistent approaches for the regulation and assessment of food products derived from these technologies. **Next Update: June 2005**
For the CFIA:	
29. The regulation of transgenic animals (including fish) and derived products is a shared responsibility in Canada. The need for detailed guidance in the assessment of transgenic animals has been recognized. The government will integrate advice from Expert Panel and others.	The Canadian Council for Animal Care (CCAC) has drafted *Guidelines on the use of Farm Animals in Research, Testing and Teaching*, which includes a subsection on livestock derived from biotechnology. As part of the Farm Animal Welfare Sub-committee of the CCAC, the CFIA's Animal Biotechnology Unit (ABU) attended a meeting on May 18-19, 2004, to discuss the draft guidelines. The ABU also convened a Consultation on Animal Biotechnology in February 2004 as a follow-up to the "Animal Biotechnology Focus Group Meeting" held in March 2003, during which developments and future regulations of animal biotechnology were discussed. A summary of this meeting is posted at: http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/introe.shtml. On an interim basis, the ABU provides scientific advice to Environment Canada for assessments of transgenic animals filed with Environment Canada under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and *New Substances Notification Regulations*. For example, the ABU has provided scientific expertise in drafting a notification guidance document, titled " *Notification Guidelines for the Environmental Assessment of Biotechnology- Derived Livestock Animals*", appropriate for transgenic livestock animals. The draft of these notification guidelines are being

	peer-reviewed within government departments and is posted on the CFIA website for comment at: http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/guidedirecte.shtml. Additionally, the ABU is preparing draft *Guidelines for the Safety/Environmental Assessment of Biotechnology-Derived Animals*, in collaboration with Environment Canada and Health Canada. The draft has been posted on the web for further comments. (http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/guidedirecte.shtml). Lastly, the CFIA has also established contact with its federal regulatory counterparts in Australia, New Zealand, United States and Mexico to discuss regulatory control of transgenic and cloned animals. **Next Update: June 2005**
30. CFIA's Animal Biotechnology Unit, Animal Health Production Division, is working with the Agency's Biohazard Containment and Safety Unit to develop guidelines outlining safety requirements of containment for animal pathogens associated with transgenic animals.	The Animal Biotechnology Unit and the Biohazard Containment and Safety Unit continue their work and discussions on these guidelines. There is no new information to report at this time. **Next Update: June 2005**
For Environment Canada:	
31. Revise New Substances documentation to ensure that protocols for generating notification data adhere to animal care and husbandry guidelines.	An advisory Note (2002-1) indicating that notifiers are expected to adhere to animal care and husbandry guidelines has been published and is posted on the New Substances Program website at http://www.ec.gc.ca/substances/nsb/HTML/A0201_e.htm. **Status: Complete**
For Health Canada, the CFIA, Environment Canada and Fisheries and Oceans Canada:	
32. CFIA, Health Canada and Fisheries and Oceans Canada collaborate with Environment Canada on the development of environmental assessment regulations for the products they regulate.	Regarding Health Canada's Environmental Assessment Regulation Project, the Office of Regulatory and International Affairs completed the issue identification paper and released a final version in the summer of 2003. Prior to completion, consultations were held on a draft issue identification paper in Ottawa on February 18, 2003 and throughout the months that followed. The draft consultation report and the guide to industry (published in May 2002) are available at: http://www.hc-sc.gc.ca/ear-ree.

	The options analysis paper is awaiting approval and should be released to stakeholders late June 2004. Stakeholders will have until the end of September 2004 to submit their comments. Comments will be reviewed and a workshop scheduled in Ottawa for late fall 2004, if required. The legislative option will be chosen and work will commence on building a regulatory framework. As well, Fisheries and Oceans Canada, Environment Canada and Health Canada concluded a Memorandum of Understanding in May 2004, which clearly explains how the departments will work together on the assessment of environmental and indirect human health effects of aquatic organisms with novel traits under the *Canadian Environmental Protection Act* 1999 (CEPA, 1999). Work to implement the MOU will follow. Please see action 26 for additional information. **Next Update: December 2004**
G. Other Recommendations	
For All Departments:	
33. CFIA, Health Canada, Environment Canada, AAFC and Fisheries and Oceans Canada are partners in the identification of mechanisms to improve the coordination and initiation of new research supporting environmental decision-making and focussed in critical areas such as eco-system research and consideration for those priorities as recommended by the Expert Panel.	Health Canada's Office of Biotechnology and Science (OBS) worked on an initiative to look at long term health effects of genetically modified organisms. This project, supported by 2003-2004 Canadian Biotechnology Strategy funds, identified federal capacity and capability to measure long term health effects and it identified external experts that could provide advice to government on these issues. Health Canada also participated in Environment Canada's initiative on Ecosystem Effects of New Living Organisms (formerly EEGMO), including an interdepartmental workshop to identify priority research areas. Results of both initiatives will be used in consideration of integrating policy and regulatory decision making. In addition, representatives from various federal departments participated in an orientation forum on the assessment of impacts of genetically modified organisms (GMOs) on the environment, human health and society which was held in Québec City in January 2004. This event, organized by officials from the government of Quebec, was attended by about 60 scientists, interest groups and government representatives and was aimed at identifying potential research areas to be covered in a new research funding program. A follow-up meeting was recently held (June 2004) in Montreal to further explore potential areas of collaboration with federal departments on this initiative. Exchanges will

	continue over the upcoming months to pursue these potential areas. **Next Update: December 2004**
34. Regulatory departments and agencies will develop strategic, integrated plans for multi-disciplinary projects including consideration of resources. Some groups such as the CFIA have reserved Budget 2000 funding to support relevant initiatives to meet such regulatory needs in the next 2-3 years.	The CFIA has initiated a formal process to determine the use of the Budget 2000 reserved funding for the next couple of years. Priority setting exercises have also been initiated to renew the Canadian Biotechnology Strategy priorities and the Genomics R&D program. For additional information on these two initiatives, please refer to the December 2003 progress report, specifically action 28, which can be found at: http://www.hc-sc.gc.ca/english/protection/royalsociety/progress_report_december2003.html. **Next Update: December 2004**
35. We will consider sharing recommendations 5.7 and 6.9 with other appropriate federal fora for their consideration such as linking to federal and S&T initiatives.	A number of horizontal federal initiatives are currently under way including one on smart regulations that touches upon the subject of biotechnology. Public consultations will begin in the summer of 2004 with a final report expected later in the year. (http://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. A draft framework will undergo an internal review within the next few months. 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. Projects under the 2004-2005 CBS funds have been planned and are currently being approved. **Next Update: June 2005**
For the CFIA:	
36. In addition to existing studies, the CFIA intends to commission additional research by government scientists or external experts in areas related to: • gene flow and fertility	The CFIA recently completed a study "Survey of Plant Breeding in the Ornamental Industry". The study was commissioned in order to determine if the ornamental industry is potentially producing or importing plants with novel traits.

• 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).	Two other studies, *Modelling the Frequency of Imidazolinone-Resistant Wheat Volunteers* and *Physical Modelling of Pollen Dispersal* were completed in June 2004. Other ongoing studies which have been granted extension for fiscal 2004-2005 include: • Global Changes in Gene Expression Associated with Highly-Expressed Transgenes in *Arabidopsis* and Canola. • Gene flow from *Brassica juncea* to wild mustard. • Management of Resistance to Bt in Adult Corn Rootworm. • Gene-flow in Spring Wheat at the Commercial Scale. • Emergence Periodicity of Volunteer Canola and Wheat in Prairie Cropping Systems. • Baseline Monitoring of Bt-Resistance in the European Corn Borer in Ontario and Quebec For more information on these projects, please refer to action 24 in the December 2003 progress report (http://www.hc-sc.gc.ca/english/protection/royalsociety/progress_report_december2003.html). In addition, the CFIA's Fertilizer Section has initiated a study on *Biodegradation at the Molecular Level of Genetically Modified Microorganisms During Thermophilic Composting* to determine the fate of genetic constructs from GM microbes or plants during composting. In March 2004, Agriculture and Agri-Food Canada presented preliminary results of its ongoing research into the insertional effects of transgenes. The scientific paper can now be found at: http://www.inspection.gc.ca/english/sci/biotech/trans/marmare.shtml **Next Update: December 2004**
For Environment Canada:	
37. EC is leading the development of a federal strategy on Generating Knowledge to Understand Ecosystem Effects of GMOs. Health Canada, the CFIA, AAFC and DFO are involved in this effort.	An interdepartmental group led by Environment Canada continues to develop a federal research strategy to generate knowledge in understanding 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. In February 2004, a workshop on ecosystem effects of novel living organisms was held involving experts from within and outside government. The purpose of the workshop was to bring together scientists, science managers and policy specialists to: • review recent scientific advances; • take the first steps toward a research network; • move forward on policy; and • raise the profile of this initiative at the senior levels, both nationally and internationally. Building upon the work of those who participated, a pilot network is being initiated to enhance communications between researchers and aid in the generation of new knowledge and approaches. **Next Update: December 2004**
38. A number of research projects relevant to issues raised by the Expert Panel are underway: • investigating flow of transgenes between two closely related wild plants via hybridization • examining ecological hazards of insect resistance to such transgenes under Canadian field conditions • developing a laboratory technique for predicting the survival of a recombinant microorganism prior to release into a soil environment • exploring the potential for plant-based remediation and restoration techniques and to evaluate the ecological significance of plant diversity in extreme environments.	Environment Canada has generated data on four strains of fungi for their ability to persist in the soil environment. Results from this research will be used in risk assessment and have been submitted for publication in the *Canadian Journal of Microbiology*. Additional information on this research can be found in the June 2003 progress report. Work continues on assessing persistence of approximately twenty bacterial strains using a similar methodology. This work is anticipated to be finished by the end of 2004. **Next Update: June 2005**
39. To develop and maintain public baseline data resources for agricultural and natural ecosystems, considerable re-	The Federal Biodiversity Information Partnership (FBIP) has completed a number of biodiversity data entry projects as part of its start-up phase. More than 1.6 million Canadian specimen and observation records on species in Canada are

investment in biosystematics will be required. The Canadian Biodiversity Information Network with others sponsored a 4-day workshop in Ottawa to develop research priorities in Canada.	available on-line at Canada's national electronic node for the Global Biodiversity Information Facility (http://www.cbif.gc.ca/). Data are housed on four different servers which operate as a true distributed network. Membership in FBIP has expanded to eight federal departments and agencies (Agriculture and Agri-Food, Canadian Food Inspection Agency, Canadian Museum of Nature, Environment, Health, Fisheries, Natural Resources, and Parks). **Status: Complete**