December 23, 2002

PROGRESS REPORT: DECEMBER 2002

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 the Department of Fisheries and Oceans have already published two progress reports on the *Action Plan in Response the Royal Society of Canada Expert Panel Report*. This third 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 2002 was identified in either the action plan or the progress reports released in January 2002 or May 2002. (http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm)

Subsequent progress reports will be published in June and December 2003 in combination with updates on the implementation of the recommendations of the Canadian Biotechnology Advisory Committee's (CBAC) report entitled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*. The departments and agencies are drafting a detailed response to CBAC's report and in finalizing this response will be engaging the Chair of CBAC as well as the co-chairs of the GM Food Steering Committee in early 2003 to obtain their feedback. The final response will be published shortly thereafter.

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.

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	Health Canada is currently completing its revisions to the *Guidelines for the Safety Assessment of Novel Foods.* The revised guidelines which are expected to be finalized later in the spring, will be consistent with guidance documents

the latest scientific developments. (This will be done in consultation with national and international experts.)	recently developed at the international level (see action 2). On May 29, 30 and 31, 2002, Health Canada and the CFIA held a joint consultation that brought together a range of experts, stakeholders and government regulators to discuss proposed revisions to the above-cited guidelines and CFIA's regulatory directives for the assessment of plants with novel traits and livestock feeds derived from these plants (see action 4). The consultation was followed by an online feedback forum run from August 16 through October 4. The comments received were reviewed and incorporated into the ongoing revision process. More information regarding the consultation process, including the proceedings of the session held in May and the summary of the on-line feedback received are now available under the Novel Foods heading of Health Canada's Food Program website (http://www.hc-sc.gc.ca/food-aliment/) and on the website of the CFIA. Health Canada's revised guidelines will be made available for further public comment in early 2003. A consultation document which provides background information on selected aspects of these guidelines as well as broader issues related to the regulations of novel foods will also be provided at that time. **Next Update: June 2003**
2.We will update Health Canada information material to provide a better insight on the way we apply the concept when assessing the safety of novel foods.	At the meeting of the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Yokohama, Japan - March 4-8, 2002), the document entitled "*Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*" was completed and forwarded to the Codex *Alimentarius Commission* for final adoption in 2003. The Guidelines include considerations for a comparative approach which is consistent with the concept of substantial equivalence articulated in the report of the FAO/WHO Expert Consultation held in Geneva in June 2000. The Codex Task Force is also developing "*Proposed Draft Guideline for the Conduct of Safety Assessment of*

	Foods derived from Recombinant-DNA Microorganisms". These will be considered at step 6 at the next meeting of the Task Force (Yokohama, Japan - March 11-14, 2003). Health Canada's draft revised *Guidelines for the Safety Assessment of Novel Foods* have taken into consideration the guidance provided in the Codex documents mentioned above. New fact sheets on the regulation of biotechnology have been developed and are available on Health Canada's new "Biotechnology" website: http://www.healthcanada.ca/biotech/. Health Canada is continuing to develop new fact sheets and general information materials that will be made available on this website. Furthermore, technical information material posted under the "Novel Food" heading of Health Canada's Food Program website (http://www.hc-sc.gc.ca/food-aliment/) is periodically revised to reflect the latest developments. Lastly, Health Canada officials have co-authored a chapter on the concept of substantial equivalence (Paul R. Mayers *et al.* (2002), The concept of substantial equivalence, pp.63-73, in Keith T. Atherton (Ed.), *Genetically Modified Crops - Assessing Safety,* Taylor & Francis). This chapter is an analysis of the pros and cons of substantial equivalence conducted through a study of past applications of this concept. **Next Update: June 2003**
3. We will make international guidance information accessible through the Health Canada Food Program website by creating links to OECD, CODEX, FAO/WHO.	To facilitate access to relevant reports and information posted on the websites of international organizations, the links to these organizations, such as the Organisation for Economic Co-operation and Development (OECD), the Codex Alimentarius Commission, the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), through the Health Canada Food Program website (http://www.hc-sc.gc.ca/food-aliment/) have been updated.

	Next Update: December 2003
For the CFIA:	
4. 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 in the process of updating regulatory directives and guidelines on plants with novel traits and livestock feeds derived from plants with novel traits. These updates will reflect policy changes that have been made based on advances in science and on our increased experience in regulating products of biotechnology. Consultation is a key part of this process. In May 2002, the CFIA and Health Canada held a joint stakeholder consultation to discuss revisions to regulatory directives and guidelines on plants with novel traits (CFIA's Dir94-08, *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*), livestock feeds derived from plants with novel traits (CFIA's Dir 95-03, *Guideline for the Assessment of Novel Feed from PNTs*) and novel foods (Health Canada's *Guidelines for the Safety Assessment of Novel Foods).* Attending the consultation were: Government regulators; experts and stakeholders in agricultural and forest biotechnology, human health and food, and livestock health and feed; consumers groups and civil society organizations; and agriculture trade and growers groups. Topics discussed included the definition of novelty and the nature of the information requirements in the nutrition, toxicity and allergenicity sections of the regulatory directives for products of agricultural biotechnology. In addition, public comment regarding the revisions of regulatory directives and guidelines was accepted from August 16 - October 4, 2002. The proceedings of the consultation session and summary of the information gathered on-line are now posted on the CFIA's Plant Biosafety Office (PBO) website (http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml) and under the "Novel Foods" heading of Health Canada's Food Programme website (http://www.hc-sc.gc.ca/food-aliment/). Stakeholder input from all sources will be considered in

	the revisions of the regulatory directives and guidelines. A new draft of the regulatory directive will be made available on the PBO web site (http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml) and the Feed Section's website (http://www.inspection.gc.ca/english/anima/feebet/bfeebete.shtml) in early 2003 for further public comment. **Next Update: June 2003**
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 update on action 4, the CFIA is revising the following two documents: regulatory directive 95-03 *Guideline for the Assessment of Novel Feed from Plants with Novel Traits*, and *Regulatory Directive Dir94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits*. These updated directives will provide greater clarity about what constitutes "novel"and describe the triggers for the regulation of products of agricultural biotechnology. **Next Update: June 2003**
6.The CFIA is reviewing its fact sheets on the assessment process to improve clarity and explanation of the concepts of familiarity and substantial equivalence. The Agency is also preparing new information for posting on the Internet and use in CFIA information kits to explain the use of substantial equivalence and other concepts in its regulation of agricultural products.	In January, 2002 the CFIA updated a fact sheet about the use of substantial equivalence (http://www.inspection.gc.ca/english/ppc/biotech/reg/equive.shtml). The CFIA is continuing to develop new fact sheets and information materials that will be made available in coming months. We will continue to report on the progress of these initiatives under action 19. **Status: Complete**
For Health Canada and the CFIA:	
7.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	Health Canada and CFIA's officials participated in recent meetings of the OECD Task Force on the Safety of Novel Foods and Feeds and the OECD Working Group on Harmonization of Regulatory Oversight (Paris, France - June 2002). As part of its work, the OECD continues to work on consensus documents that outline key parameters for regulatory assessment of particular crop

application of the concept of substantial equivalence in the evaluation of more complex novel foods and GM-organisms.	species as well as food and feed products derived from them. In the area of food and feed safety, consensus documents are being published on the nutrients, anti-nutrients and toxicants naturally present in various crop species and information about the use of these species as food and feed. The most recent document of this series published in August 2002 is on corn and is available under the heading "Consensus documents" of the OECD website (http://www.oecd.org/EN/home/0,,EN-home-530-nodirectorate-no-no-no-27,00.html). In addition, Health Canada and CFIA officials continue to be actively participating in the development of the *Proposed Draft Guideline for the Conduct of Safety Assessment of Foods derived from Recombinant-DNA Microorganisms*. This guideline is at step 6 for consideration at the next meeting of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. Furthermore, as mentioned in the May progress report, a technical discussion on the health and safety aspects of the Action Plan was hosted by Health Canada on April 30th, 2002. Approximately 50 experts attended the technical discussion from academia and industry, the former Royal Society Expert Panel on the future of food biotechnology, the Canadian Biotechnology Advisory Committee (CBAC) as well as other non-governmental organizations. The report of this session will be made available on Health Canada's website in the early 2003. **Next Update: December 2003**
Use of Precaution	
For all Departments:	
8.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	In November 2001, the Government of Canada released the discussion document *A Canadian Perspective on the Precautionary Approach/Principle*. The comment period for stakeholder input on this document concluded in April, 2002.

biotechnology.	Federal departments and agencies are reviewing the comments received and working toward an eventual Government of Canada position on the precautionary approach/principle. The feedback obtained will serve to inform the government's thinking on whether the guiding principles are appropriate, would improve consistency, provide an appropriate balance of flexibility and predictability, and be adaptable to various functional areas. **Next Update: December 2003**
9. 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.	Health Canada and the CFIA are in the process of revising their regulatory guidelines to provide more specific direction to applicants. Also, they have adopted a policy of harmonized approvals to minimize the potential for unapproved products to enter the Canadian marketplace. Harmonized approvals will be included as policy in the CFIA's revised directives 94-08 and 95-03 as well as Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods*. Environment Canada and Health Canada have signed a Memorandum of Understanding (MOU) which provides a framework to ensure the protection of the environment and human health at all stages of the life cycle of new substances in products regulated under the *Food and Drugs Act*. This MOU outlines the roles and responsibilities of the respective departments in ensuring that environmental and health impacts of these products are addressed and that regulatory oversight is maintained. The Department of Fisheries and Oceans is conducting research to study all stages of development of new aquatic biotechnology organisms. The department is continuing to strengthen its science base capacity in order to do so. **Next Update: June 2003**
10. As GM-foods increase in their complexity, the protocols for product review need to be updated through a system for review and	As indicated in action 1 and 4, Health Canada and the CFIA are updating their respective regulatory directives and guidelines.

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.	In addition, as indicated in action 7, Health Canada hosted a technical discussion on the health and safety aspects of the Action Plan. The report of this session will be made available on Health Canada's website in early 2003. The Department of Fisheries and Oceans supports regulatory reviews and is coordinating with national and international regulatory agencies to improve its understanding of biotechnological complexities and challenges. In addition, the Department of Fisheries and Oceans is conducting research to enhance its capabilities and using the new techniques for the conservation and protection of wild and aquacultured fishery. **Next Update: June 2003**
For CFIA:	
11. 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.	See action 4 for relevant activity update.
For Health Canada:	
12. Health Canada is also committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994.	See action 1 and 33 for relevant activity update.
Transparency and Increasing Public Confidence	
For all Departments:	
13. 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	As discussed in the May progress report, representatives from Health Canada and the CFIA, met with Australian and New Zealand officials involved in food and environmental safety assessments of biotechnology-derived foods from May 16 to 22, 2002. Discussions focussed on best practices and challenges regarding the implementation of transparency measures for the regulation of agricultural products of biotechnology.

determine which model would best be suited for the Canadian regulatory process.	Health Canada will be seeking public comments regarding transparency and public involvement issues, including those identified during these discussions, in the consultation document (see action 1) which will released in early 2003. In addition, on June 3, 2002, a representative from Australia's Office of the Gene Technology Regulator (OGTR) visited the CFIA and proposed that the CFIA's Plant Biosafety Office (PBO) and the OGTR begin discussions to develop a bilateral agreement regarding environmental safety assessments of plants derived from biotechnology. The PBO is exploring this agreement, which could include the possibility of exchanging scientific information on risk assessment procedures especially as they apply to the Canadian experience with herbicide-tolerant canola. Furthermore, CropLife Canada, an industry stakeholder group, met with government regulators in July 2002 regarding a proposal to increase transparency for novel food and plant with novel trait submissions. Health Canada and the CFIA are currently considering their proposal. **Next Update: June 2003**
For Health Canada:	
14. We will seek ways to improve transparency of the regulatory process for novel foods in Canada, including under the Health Protection Legislative Renewal Initiative	As noted in the January 2002 progress report, as part of the consultation process leading up to the adoption of new legislation, Health Canada will consider measures to make the review process more open, while guaranteeing a reasonable degree of protection for confidential personal and commercial information. In the recent Speech from the Throne, government has identified the renewal of the health protection legislation as one of its priorities. **Next Update: December 2003**
15. To prepare and post Novel Food Decision Documents on Health Canada's Food Program website in a timely manner.	To date, 53 novel foods have been approved for sale in Canada. Decision documents for 49 of these novel foods are posted on the Food Program web page under the Novel Foods Heading (http://www.hc-sc.gc.ca/food-aliment/). The 4 remaining decision documents are

	currently being finalized and will be posted in early 2003. **Next Update: December 2003**
16. We will share information and discuss specific product assessments with other countries as a mechanisms to validate Health Canada's safety assessments.	Health Canada and the Food Standards Australia New Zealand (FSANZ) signed an MOU in May 2001, for the exchange of information regarding the safety assessment and regulation of genetically modified foods. Since the establishment of this MOU, there have been exchanges of technical information on submissions for products already approved by the Food Directorate and FSANZ, or currently being reviewed for approval by both organizations. These exchanges have enhanced the evaluation activities of both organizations and assisted in the validation of Health Canada's safety assessment decisions. Work is currently underway to update the MOU with the intent of broadening its scope and adding more specific targets and outcomes. **Next update: June 2003**
17. Health Canada proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	Health Canada has committed to having an external expert sit on its Food Rulings Committee in those deliberations and decisions regarding novel foods. The Working Group on External Participation will put forward a proposal to the Food Rulings Committee in January which will indicate the process to include this external participant. In addition, this issue will be addressed in the consultation document which will be made available for public comment in support of Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods* in early 2003. **Next Update: June 2003**
18. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments.	As mentioned in action 7 and 10, in April 2002, a technical discussion with members of the former Expert Panel and other external experts was hosted by Health Canada. Participants identified new research needs, including some in the field of genomics, proteomics and

	metabolomics. In addition key areas for future collaboration were identified by the group. The report from this session will be made available on the Health Canada website in early 2003. **Next Update: December 2003**
For the CFIA:	
19. We will create new information products explaining the regulatory system, and how it works in greater detail, for posting on the Internet and use in information kits intended for consumers.	The CFIA's Office of Biotechnology has prepared new communications material including an information kit about the regulatory approval process for products of biotechnology, a poster that provides an overview of agricultural biotechnology regulation milestones that have occurred over the last 15 years, and a brochure that describes the role of CFIA sections and offices in regulation of biotechnology. Between June and October 2002, over 2500 information kits were distributed in response to requests from interested parties and at conferences and presentations attended by CFIA staff. Additionally, the following six new fact sheets related to biotechnology have been posted under the General Information heading of the CFIA's Office of Biotechnology website (http://www.inspection.gc.ca/english/ppc/biotech/bioteche.shtml): • *Detecting Products Derived Through Biotechnology.* • *Cartagena Protocol on Biosafety* • *Building Partnerships: the Canadian Food Inspection Agency and the Canadian Institute for Food Inspection and Regulation* • *Biotechnology? Modern Biotechnology? GM? GMO? GE? PNTs? What do these terms mean?* • *Livestock and Animal Products Derived Through Modern Biotechnology: Roles and Responsibilities of the Government of Canada* • *Fish Products Derived Through Modern Biotechnology: Roles and Responsibilities of the Government of Canada* **Next Update: December 2003**
20. We will continue to make	The CFIA continues to explain its role in regulating

spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and the public.	products of biotechnology with stakeholder groups, the media and the public. Between May and October 2002, CFIA staff gave over 50 presentations and media interviews. Federal departments and agencies participated in the BIO2002 conference held in Toronto on June 9-12, 2002, and provided information at a conference exhibit. A panel session titled "*Canadian Biotechnology Regulation: Safety Comes First*" was chaired by the CFIA and also included speakers from Health Canada, CFIA and Environment Canada. The session provided a focus on Canada's regulatory framework for products derived through biotechnology, the labelling of biotechnology-derived food, and consumer perspectives. More information is available on the website of Bio2002 (http://www.bio2002.org/sessions/allsessions.asp?tid=8). The CFIA also had representatives at the Agricultural Biotechnology International Conference (ABIC) held in Saskatoon on September 15-18, 2002. CFIA staff gave presentations about the regulation of plants with novel traits and the regulation of animal biotechnology within Canada. The CFIA also provided information kits and answered questions about biotechnology regulation at an exhibit at the conference. **Next Update: December 2003**
21.We will work with applicants to achieve greater openness regarding specific product information.	The CFIA's Plant Biosafety Office and the Feed Section publish decision documents which include information regarding: the nature of the product, newly-expressed proteins and results of studies that address toxicology, allergenicity and environmental fate of the product. In addition, the Plant Biosafety Office encourages developers to provide public notice of confined field trials of plants with novel traits and to notify their immediate neighbours about the conduct of these trials. As mentioned in action 13, in July 2002, CropLife Canada met with government regulators regarding a proposal to increase transparency for novel foods and

	plant with novel trait submissions. The government is currently considering their proposal. **Next Update: December 2003**
For Environment Canada:	
22. We will prepare a report on options for increasing public access and transparency to regulatory decisions, including examining alternatives for periodically engaging experts in reviewing decision making, regulations, guidelines and related scientific methodologies.	Environment Canada is planning to seek public input in 2003 to further refine its policy for the application of specific criteria in the regulatory oversight of biotechnology substances at the research and development stage. Furthermore, in October 2002, Environment Canada convened a workshop of international technical experts from government and private industry to peer review a draft guidance document entitle: *"Testing the Pathogenicity and Toxicity of New Microbial Products to Aquatic and Terrestrial Organisms"*. When finalized, this document will serve as further guidance to notifiers as to the scientific methodologies to be used in generating data for notification under the *New Substances Notification Regulations*. **Next Update: June 2003**
23. 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 continues to facilitate public access to regulatory information through mail-outs, journal publications and publication on the New Substances Website of regulatory advisory notes, guidelines and policies to address emerging biotechnology issues. Environment Canada has recently developed an advisory note in order to further promote public understanding and industry's compliance with the regulatory requirements under the *New Substances Notification Regulations*. Environment Canada is working towards making available to the public risk assessment summaries for biotechnology substances that have been assessed through the *New Substances Notification Regulations*. The *Guidelines for the Notification and Testing of New Substances: Organisms* have been revised to reflect legislative changes and posted on the New Substances website of Environment Canada

	(http://www.ec.gc.ca/substances/nsb/download/Bioge1201.PDF). **Next Update: June 2003**
Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada:	
24. Update and Publish *Guidelines for the Safety Assessment of Novel Foods* (vol. I & II - microorganisms and plants). The documents will reflect current international developments.	As mentioned in action 1, Health Canada is currently updating the *Guidelines for the Safety Assessment of Novel Foods*. Such updates have taken into consideration the recent work of the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology. The revised guidelines provide more detailed guidance in terms of toxicological considerations. **Next Update: June 2003**
Alternatives to antibiotic-resistance markers	
25. 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.	Issues concerning the use of antibiotic-resistance marker genes have been discussed as apart of the joint consultation process initiated in May 2002 by Health Canada and CFIA consultation on proposed revisions to the guidelines and regulatory directives. This topic is also identified in the consultation document prepared by Health Canada in preparation to the next phase of this consultation that will take place in early 2003. In addition, in response to consumer concerns over the safety of biotechnology-derived crops, AAFC in conjunction with Natural Resources Canada and the National Research Council of Canada has received funding through the Canadian Biotechnology Strategy Fund to research the feasibility of developing alternative markers. Since 1999, an AAFC research project has sought morphological marker genes that can detect changes in plant growth rather than resistance to chemical

	compounds such as antibiotics or herbicides. Other objectives are to use genes that originate from crops, that do not change the biochemical makeup of the novel plant, that are no longer active once the novel plant is ready for commercial production and that are more efficient than currently available markers. A publication reporting the first results of this research is: Boutilier, K. et al. 2002. The Plant Cell. 14: 1737 - 1749. Current funding for this project has ended, but additional funding is being sought to continue this research. The CFIA has also commissioned a survey and literature review of current research on alternative selection markers for transgenic plants. The paper is due by April, 2003. **Next Update: June 2003**
Allergenicity	
26. Through stakeholder consultation, we will update and publish Health Canada's guidelines for the safety assessment of novel foods (vol. I + II).	Health Canada will seek further input regarding the proposed revised *Guidelines for the Safety Assessment of Novel Foods* in early 2003. More detailed guidance is now provided in terms of allergenicity considerations. See action 1 for relevant activity update. **Next Update: June 2003**
27. 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.	The proceedings from the Workshop on Animal Models for the Detection of Allergenicity hosted by Health Canada in November 2001 have been peer-reviewed. The proceedings are anticipated to be published shortly in the Environmental Health Perspectives journal. **Next Update: June 2003**
28. Health Canada is working to establish a surveillance strategy which will permit the identification of undesirable health impacts of biotechnology derived products, including GM-	Health Canada's Centre for Surveillance Coordination sponsored an international conference on post-market surveillance of GM-foods (Ottawa, October 16-17, 2002). This workshop brought together 150 participants from a breadth of sectors and countries, as well as national and international organizations (OECD, Codex, WHO, Royal

foods.	Society of Canada). The proceedings are now available at: http://www.hc-sc.gc.ca/pphb-dgspsp/csc-ccs/biotech_e.html. In addition, the Centre for Surveillance Coordination has developed a synthesis document which will be used to help direct internal recommendations on the future plan of action for Health Canada with regards to post-marketing surveillance of GM-foods. **Next Update: June 2003**
Concurrence of approvals for GM-food crops	
For Health Canada and the CFIA:	
29. To formalize current understanding between CFIA and Health Canada to restrict partial approvals of GM-food crops and feeds.	Representatives from Health Canada and the CFIA held a two day meeting in April 2002. One of the topics discussed was the coordination of regulatory decisions for GM-food, plants and feeds in order to minimize the potential for unapproved products entering the Canadian food supply. The policy regarding the coordination of regulatory decisions is now articulated in Health Canada's revised guidelines as well as in the revised regulatory directives of the CFIA (see action 1 and 4). Further public comments will also be sought on this issue in the consultation planned by Health Canada in early 2003. **Next Update: June 2003**
Nutritional assessments	
30. 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 the revised guideline documents described in actions 1 and 4. Furthermore, as discussed in action 7, officials from the Health Canada and CFIA participated in meetings of the OECD Task Force on the Safety of Novel Foods and Feeds (Paris, France - June 2002). A consensus

	document on the compositional consideration for new varieties of maize, including the identification of key food and feed nutrients, anti-nutrients and secondary plant metabolites is now available on the OECD website (http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-document-530-nodirectorate-no-27-24778-27,00.html) along with other consensus documents which have been previously published. Canada and the United Kingdom are also leading the development of an OECD consensus document on the assessment of novel livestock feeds. The paper discusses the feasibility of animal feeding trials to address safety and nutritional aspects of the regulatory assessments for foods and feeds. **Next Update: June 2003**
Environmental Safety and GM-Plants (Plants with Novel Traits)	
For the CFIA:	
31. CFIA will prepare more public information concerning: a) the extent of their environmental assessment; b) the kind of data a field trial generates and protective measures required in the conduct of such studies; and, c) case studies to illustrate step-by-step, the assessment of a plant with novel trait or novel feed. As well, other mechanisms to enhance transparency will be considered.	As described in action 19, new information products were created to further clarify the safety assessment conducted by the CFIA on products of biotechnology, including the roles of CFIA and other departments in the evaluation of biotechnology-derived fish and animals. The CFIA is also currently considering options to make more information available on the regulation of agricultural biotechnology in Canadian academic fora. The CFIA is preparing a fact sheet about confined research field trials of plants with novel traits (PNTs). It will describe the protective measures required during and following a trial, and the nature of the inspections conducted by the CFIA. The fact sheet is expected to be posted on the CFIA website by June 2003. The CFIA has intended to post case studies containing examples of the type of information used during a safety assessment of a PNT or a novel feed. This action has been delayed while we continue to prepare this information and negotiate its release with developers. We will update on the status in June 2003. **Next Update: June 2003**

For Environment Canada:	
32. Continue CEPA 1999 listing process in cooperation with other government departments, including Health Canada and CFIA.	As mentioned in action 9, Environment Canada and Health Canada have signed a Memorandum of Understanding (MOU) which outlines the roles and responsibilities of the respective departments in ensuring that environmental and health impacts of products regulated under the *Food and Drugs Act*, including novel foods, are addressed and that appropriate regulatory oversight is maintained. In conjunction with Health Canada, other agreements are being developed between Environment Canada and the CFIA in respect of products derived from plants with novel traits not intended for uses other than those regulated under the *Seeds Act*, *Feeds Act* and *Food and Drugs Act*. Discussions are also being conducted with CFIA in respect to transgenic livestock animals and with the Department of Fisheries and Oceans in respect of transgenic aquatic organisms. The long term intent is to ensure that suitable regulatory authorities exist and are accessible to these departments and agencies for these groups of new substances. Once achieved, they can be listed individually in Schedule 4 of the *Canadian Environmental Protection Act*, 1999 (CEPA 1999)(see action 34). **Next Update: June 2003**
GM-Animals (including fish) and GM-Feeds	
For Health Canada:	
33. Develop and publish guideline volume III on safety assessment of novel foods derived from animals.	A draft of the third volume of the *Guidelines for the Safety Assessment of Novel Foods* will be available for external consultation in the spring of 2003. In regards to animal cloning, a subgroup of the Interdepartmental Working Group on Transgenic Animals, including Fish, is actively working on a preliminary issue identification paper. This document, which is anticipated to be completed by early 2003, will be used to identify key issues regarding animal clones and derived products. Next steps will include an examination

	of possible options in terms of regulatory oversight of these animals and derived products. Health Canada will also seek public comments on the regulation of foods derived from cloned animals as part of the next consultation phase on the proposed revisions to its *Guidelines for the Safety Assessment of Novel Foods* planned for early 2003 (see action 1) . In addition, as part of its project related to the safety of foods derived from cloned animals and the preparation of the third volume of its guidelines, Food Directorate officials participated in a meeting on animal genetic engineering and animal cloning held September 24-26 in Dallas, USA (http://pewagbiotech.org/events). Food Directorate officials as well as officials of other departments and agencies also exchanged information on this issue with officials from the United States, the United Kingdom and Australia/New Zealand. The third volume of Health Canada's *Guidelines for the Safety Assessment of Novel Foods* will reflect recent scientific and regulatory developments in this field, including the outcome of the issue identification paper and the report of the US National Academy of Science (NAS) entitled *Animal Biotechnology: Science-Based Concerns* published in August 2002. **Next Update: June 2003**
For the Department of Fisheries and Oceans :	
34. Continue developing Regulations under the *Fisheries Act* for aquatic organisms that are products of biotechnology, including transgenic aquatic organisms that will meet CEPA's standards for the protection of the environment and human health.	The Department of Fisheries and Oceans is drafting regulations for biotechnology-derived aquatic organisms with input from Environment Canada and Health Canada to ensure that standards for the notification and assessment of new aquatic substances are consistent with those under CEPA 1999. **Next Update: December 2003**
35. The Department of Fisheries and Oceans agrees that research on interactions between wild and non-transgenic fish is important and is already conducting such	The Department of Fisheries and Oceans is conducting research on transgenic fish to establish science based principles for risk assessment and regulation for modified aquatic organisms.

work together with related work on transgenic and non-transgenic 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.	**Next Update: December 2003**
For the CFIA:	
36.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 CFIA's Animal Biotechnology Unit has surveyed Canadian researchers working in the field of animal biotechnology to collect their input about the development of regulations with respect to animal health. A contact list is being established for future consultations regarding the regulation of new applications of biotechnology to animals. 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. Additionally, the CFIA's Animal Biotechnology Unit is preparing draft Guidelines for the Safety/Environmental Assessment of Biotechnology-Derived Animals, in collaboration with Environment Canada and Health Canada. We will update on the status of these guidelines on our next progress report. **Next Update: June 2003**
37. The CFIA is collaborating with other departments regarding food and non food use of transgenic livestock and the risk assessment criteria which need to be considered. The government, through the interdepartmental working group on transgenic animals, including fish, will integrate advice from the Expert Panel and others in establishing priorities for policy development and long term research in support	The Interdepartmental Working Group on Transgenic Animals, including Fish, has identified the need to examine the issue of cloning as a reproductive technology for animals and the potential impact of this technology on human and animal health and on the environment. The issue of animal cloning is currently being reviewed by regulatory agencies around the world. To this end, as mentioned in action 33, a sub-group has been formed to develop an interdepartmental issue identification paper regarding the regulation of cloned animals in Canada. This will be used as the basis for making recommendations as to whether there is a need

of regulating such new applications of biotechnology.	for products derived from cloned animals and their progeny to be subject to specific regulatory oversight. In addition, the CFIA has contacted the Canadian Council for Animal Care (CCAC) to advise them of their interest and willingness to participate in the working committee on farm animal welfare and biotechnology. The experts (for example, Canadian researchers) identified from a list of contacts will be approached by CCAC for input and advice. **Next Update: June 2003**
For Environment Canada:	
38. Revise New Substances documentation to ensure that protocols for generating notification adhere to animal care and husbandry guidelines.	On September 10, 2002, an advisory note was distributed to stakeholders concerning research and development of higher organisms indicating that "*The handling and care of experimental animals should be in accordance with the recommendations outlined in the Guide to the Care of Experimental Animals, published by the Canadian Council on Animal Care* (http://www.ccac.ca) *and as amended from time to time.*" The full text of the advisory note #2002-01 will be available at http://www.ec.gc.ca/substances/nsb/eng/advisory_e.htm. As mentioned in action 22, Environment Canada is developing a Guidance Document for *Testing the Pathogenicity and Toxicity of New Microbial Products to Aquatic and Terrestrial Organisms*. These Guidelines will also provide guidance for adhering to the requirements of the Canadian Council of Animal Care in the care and use of experimental animals. **Next Update: December 2003**
Other Recommendations	
For all Departments:	
39. CFIA, Health Canada, Environment Canada, AAFC and the Department of Fisheries and Oceans are partners in the identification of mechanisms to	The Government of Canada recognizes the importance of research to study the sustainability and ecosystem and environmental effects of biotechnology. To this end, a research strategy regarding Ecosystem Effects of Genetically Modified Organisms (EEGMO) is being

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.	developed. If implemented, researchers participating in this initiative will conduct long-term research and monitoring of the effects of GMOs on biodiversity/wildlife, biogeochemical cycling and other ecosystem components. The knowledge generated through the results of this research will be integrated into both policy and regulatory decision making processes and publically communicated. The Department of Fisheries and Oceans has been working with other government departments in the consideration of the priorities associated with research in support of environmental decision making. **Next Update: June 2003**
40. 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 federal regulatory departments and agencies have used Budget 2000 funding to commission research projects to help meet regulatory needs in the next 2-3 years. Specific CFIA projects are described in the update on action #41. The federal departments and agencies are currently looking at ongoing needs and priorities and will be re-profiling Budget 2000 funding for the next 3 years. Further discussions to develop multi-disciplinary projects will take place within the Canadian Biotechnology Strategy (CBS). **Next Update: June 2003**
For CFIA:	
41. 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	The CFIA has contracted several short-term research projects to assist in developing regulatory policy and in decision making. A list of projects, funded under Budget 2000 and running in 2002 is provided below. Funding proposals have been submitted to continue some existing projects and initiate others. <u>Environmental Effects of Bt Canola on Non-target Insects.</u> Field studies will be 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.

• biodiversity and agricultural ecosystem management • detection processes for biotechnology products • allergenicity for occupational and bystander exposure (feed related studies).	Gene flow from *Brassica juncea* to wild mustard. Gene flow between herbicide-tolerant *B. juncea* and a related wild mustard plant will be estimated. Both varieties will be planted in an isolated plot. After the growing season, seeds from each wild mustard plant will be harvested and the hybrid status of the progeny determined. Gene Flow in Spring Wheat. This research project will examine pollen flow and determine the potential for novel genes in wheat to introgress into wild relatives. Management of Resistance to Bt in Adult Corn Rootworm. Bt corn resistant to corn rootworm may soon be available to growers. This research project will document the distances rootworms move between the time of emergence through to oviposition. Results will be used to help design resistance-management requirements such as non-Bt refugia. Emergence Periodicity of Volunteer Canola and Wheat in Prairie Cropping Systems. 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. Global Changes in Gene Expression Associated with Highly-Expressed Transgenes in *Arabidopsis* and Canola. Microarray analysis will be used to examine variation in global gene expression in genetically-modified *Arabidopsis* and canola plants expressing the NPTII gene for antibiotic resistance under the control of the Cauliflower Mosaic Virus 35S promoter. Results for some of the most stable and most variable genes will be confirmed by Northern analysis, and compared to the range of gene expression observed when plants are exposed to environmental stress. Physical Modeling of Pollen Dispersal. A computer model is being developed to predict movement of pollen under field conditions. The development of such a model is important given future requirements for crop product

	purity, quality guarantees, environmental impact guarantees, as well as for regulatory assurance. The Effect of Transgenic Canola meal on Rumen Microflora and the Growth and Meat Quality of Ruminants and Monogastrics. 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 two manuscripts have already been submitted and accepted for publication: • K Stanford et al. *Effects of feeding transgenic canola on apparent digestibility, growth performance and carcass characteristics of ruminants.* Canadian Journal of Animal Science (in press) • TW Alexander et al. *Impact of feed processing on the fate of recombinant EPSP synthase and endogenous canola plant DNA in mixed ruminal culture.* FEMS Microbiology Letters (in press). The Fate of Forage Transgenes in Silage and Artificial Rumen. This project addresses the fate of transgene DNA and protein derived from Bt corn, in silage and in an artificial rumen model. Fate of Transgenes in Plant Decay. This research project will examine the fate of transgenes in biotechnology-derived plants and microorganisms when they decompose. Results of this study will assist in determining whether or not composting is an adequate method of disposal for field tested material. Additionally, several government departments collaborated on: Microcosm for GMO Survival Prediction. This tool has been validated for predicting the survival and gene transfer of recombinant microorganisms in the environment. The results of this study were presented at several conferences and also published: JV Gagliardi et al.(2001) *Intact soil-core microcosms compared with multi-site field releases for pre-release testing of microbes in diverse soils and*

	climates. Canadian Journal of Microbiology 47: 237-252. This research paper can be viewed at http://www.nrc.ca/cgi-bin/cisti/journals/rp/rp2_abst_e?cjm_w00-142_47_nf_cjm3-01. **Next Update: December 2003**
42. We will consider sharing those recommendations with other appropriate federal fora for their consideration, such as linking to federal S&T initiatives	Biotechnology is one of the key sectors targeted in the Canadian Innovation Strategy. This strategy is based on five themes: improving the market performance of Canada's research and development; learning; an inclusive and skilled workforce; an efficient regulatory environment; and strengthened communities. A National Summit on Innovation and Learning was held on November 18-19, 2002, in Toronto (http://www.innovationstrategy.gc.ca). The objectives of the summit were to engage partners in the private sector, non-governmental organizations, academia and government in: shaping the priorities for Canada's Innovation Strategy; and seeking commitment from all sectors for a Canadian innovation and learning action plan . **Next Update: December 2003**
For AAFC:	
43. AAFC, in consultation with CFIA, is conducting a broadly-based research study planned for at least 12 years to examine the potential long-term environmental impacts of approved and commercially-available GM crops - e.g. corn, potatoes and canola.	A study was initiated in 2000 at the Agriculture and Agri-Food Canada Research Centre in Lethbridge, Alberta, to determine the environmental and economic impact of the long term production of crops with novel traits. Crops presently 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. Data is collected annually but meaningful results will

	only be available after several years. This study is planned to run for twelve years. **Next Update: December 2003**
For Environment Canada:	
44. Environment Canada is leading the development of a federal strategy on Generating Knowledge to Understand Ecosystem Effects of GMOs. Health Canada, AAFC, CFIA, and the Department of Fisheries and Oceans are involved in this effort.	An interdepartmental group led by Environment Canada is developing a research strategy to generate knowledge to understand potential long-term and cumulative effects of genetically modified organisms (GMOs). If implemented, this strategy will serve as the basis for developing a collaborative and integrated research program on the ecosystem effects of GMOs (EEGMO). The group has identified specific theme areas, analysed needs and gaps, and developed a strategy to address such gaps. Funding was accessed to finance a study to assess activities and the state of EEGMO-related knowledge in Canadian universities, and to fund the development of a conceptual stewardship framework that put the EEGMO research strategy within the overall context of federal stewardship obligations. In addition, an overview of international approaches to EEGMO research is currently being developed. **Next Update: December 2003**
45. A number of research projects relevant to issues raised by the Panel are underway: - investigating flow of transgene between into 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	Two manuscripts containing research results on transgene flow from transgenic Bt canola and the ecological hazards of insect resistance to Bt toxin have been submitted for publication. At least two more manuscripts are in preparation. As a follow up to these projects, further research activities related to the ecological risks posed by the release of GMOs are underway at the National Water Research Institute (NWRI), which is part of the Environmental Conservation Service of Environment Canada. These include projects such as the impact on microbial community in rhizosphere soil, biodiversity in aquatic ecosystems, potential horizontal gene transfer, etc., in collaboration with AAFC and universities. In addition, a molecular laboratory has been set up within NWRI for detecting and monitoring the ecological effects of GMOs posed on the environment.

ecological significance of plant biodiversity in extreme environments. The preliminary results of this research will contribute to the further development of the research and monitoring programs contemplated by the proposed Strategy.	Furthermore, a laboratory technique for predicting survival of a recombinant microorganisms was developed and published in the Canadian Journal of Microbiology, Volume 47, March 2001 (full reference available in response 41). Environment Canada has also undertaken further studies to evaluate the survival and persistence of certain f fungi in soil. This project is due to conclude in March 2003. Two CD-ROMs (PhytoRem and PHYTOPet) containing a global inventory of candidate plant species that could be employed in remediating and restoring metal and total petroleum hydrocarbon contaminated sites. A three year demonstration project has been established with the United States Environmental Protection Agency and seven petroleum companies exploring utility of phytoremediation of petroleum products at thirteen demonstration sites across North America. **Next Update: June 2003**
46. To develop and maintain public baseline data resources for agricultural and natural ecosystems, considerable re-investment in biosystematics will be required. The Canadian Biodiversity Information Network with others sponsored a 4-day workshop in Ottawa to develop research priorities for Canada.	A strategic report from the March 2001 Biodiversity Network Conference is on-line at the Canadian Biodiversity Information Facility (CBIF) web site (http://www.cbif.gc.ca/reports/reports_e.php). The CBIF web site also has on-line biosystematics tools, including the Integrated Taxonomic Information system (authoritative scientific and common names for many North American species), and Species Analyst (access to digital information on certain natural history collections in Canada). A strong recommendation coming from the March 2001 conference was to *establish a focal point in Canada for biodiversity knowledge networking activities*. A small, *ad-hoc* secretariat led by the federal government, but with external participation (provincial governments, biotechnology industry, universities, NGOs), has continued to work towards this goal since the conference. A partnership of federal departments is seeking resources to place this secretariat on a permanent footing, in order to create a more strategic approach to biodiversity science and information management activities, and to enable full

	participation in the Global Biodiversity Information Facility of which Canada is a founding member. A decision on funding should be made by June 2003. **Next Update: June 2003**
For Genome Canada:	
47. 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 Canada centres are established with the infrastructure necessary to undertake large-scale genomics projects.	Genome Canada is dedicated to developing and implementing a national strategy in genomics and proteomics research for the benefit of all Canadians and has received $300 million from the Government of Canada to establish five Genome Centres across the country. These Genome Centres (Atlantic, Québec, Ontario, Prairies and British Columbia) are working closely with other partners such as provincial governments, the private sector, the financial community and national and international foundations to ensure that Canada becomes a world leader in genomics research. Key selected areas of study include agriculture, bioinformatics, environment, fisheries, forestry, health and technology development. Genome Canada also supports research projects aimed at studying and analysing the ethical, environmental, economic, legal and social issues related to genomics research (GE^3LS). A detailed list of approved projects is available on the Genome Canada website (http://www.genomecanada.ca/fsTemp.asp?l=e). Environment Canada and Genome Canada will be exploring the potential for greater collaboration in the areas of applied environmental genomics; environmental impacts of genomics; and genomics, ethics, law and society. **Next Update: December 2003**