June 27, 2003

PROGRESS REPORT: JUNE 2003

Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report
Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada

Introduction:

Health Canada, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), Environment Canada and the Department of Fisheries and Oceans have already published three 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 fourth 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 2003 was identified in the progress reports released in January, May or December 2002.

Subsequent progress reports will be published in December 2003 and June 2004. Future updates will consider relevant aspects of the report of the Canadian Biotechnology Advisory Committee (CBAC) on the regulation of genetically modified foods (GM foods) in Canada. The government's response to the CBAC report will be published by the end of 2003.

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.hc-sc.gc.ca/english/protection/novel_foods.html.

ACTION	CURRENT STATUS
Substantial Equivalence	
For Health Canada:	
1. Health Canada is committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994 for them to reflect the latest scientific developments. (This will be done	Health Canada will soon be seeking public comments on the newly revised draft *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms*. There will be a comment period of 60 days.

in consultation with national and international experts.)	Significant revisions in the document are proposed to reflect the experience gained over the past 9 years of conducting safety assessments of novel foods in Canada as well as relevant national and international developments in the area of safety assessment of novel foods. The guidelines for the safety assessment of novel foods derived from plants and microorganisms are expected to be finalized in the Fall 2003. Besides the guidelines themselves, a consultation document has been prepared to assist in soliciting comments. The revised guidelines and the consultation document are available at: http://www.inspection.gc.ca/english/plaveg/pbo/gatconsult/consultinte.shtml. The consultation document provides background information on various sections of the guidelines and highlights the areas where we are most interested in feedback to facilitate the submission of comments on these revised guidelines. This document also covers issues related to the general context under which novel foods are regulated in Canada. Examples of such issues include the coordination of regulatory decisions between Health Canada and the CFIA, transparency and opportunities for public input into decisions related to novel foods, the use of antibiotic resistance marker genes and foods derived from cloned animals. This consultation continues the dialogue initiated during the *Joint Health Canada/CFIA Expert/Multi-Stakeholder Consultation on the Revision of Guidelines and Regulatory Directives on Novel Foods, Plants with Novel Traits (PNTs) and Livestock Feed from Plants with Novel Traits* held in Ottawa in May 2002. Proceedings from the joint consultation and the summary of comments received during the on-line feedback forum ran between August and October 2002 are available under the heading "Novel Foods" on Health Canada's Food Program website (www.hc-sc.gc.ca/food-aliment) and on the CFIA's website (www.inspection.gc.ca/english/plaveg/pbo/gatconsult/consultinte.shtml).

	Next Update: December 2003
2.We will update Health Canada information material to provide a better insight on the way we apply the concept of substantial equivalence when assessing the safety of novel foods.	To provide better insight into the application of substantial equivalence in the assessment of novel foods, Health Canada's *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* have been revised to reflect the risk analysis principles and safety assessment guidelines recently developed by the Codex *Ad Hoc* Intergovernmental Task Force of Foods derived from Biotechnology. At its fourth and final session (Yokohama, Japan, March 11-14, 2003), the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology completed and forwarded the *Draft Guideline for Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*, along with the *Draft Annex on the Assessment of Possible Allergenicity*, to the Codex Alimentarius Commission for adoption. As indicated in the December 2002 progress report, the Codex Task Force already forwarded a number of additional documents to the Commission for adoption at the 26th Session (Rome, Italy, June 30 - July 7, 2003), including: • *Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* • *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* • *Draft Annex on the Assessment of Possible Allergenicity* to the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* Reports from the 3rd and 4th Sessions of the Codex Task Force are available on the Commission's website (http://www.codexalimentarius.net/reports.asp) **Next Update: December 2003**
For the CFIA:	

3. 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 has updated its regulatory directives and guidelines on plants with novel traits (Regulatory Directive 94-08: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*) and livestock feeds derived from plants with novel traits (Regulatory Directive 95-03: *Guideline for the Assessment of Novel Feed from Plants with Novel Traits*). These updates reflect policy changes made because of advances in science and the CFIA's increased experience in regulating products of biotechnology. Consultation has been and continues to be a key part of this process. New drafts of the regulatory directives mentioned above are now available on the Plant Biosafety Office (PBO) website (http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir9408de.shtml) and the Feed Section's website (http://www.inspection.gc.ca/english/anima/feebet/bio/safasse.shtml). They were posted in May 2003 with a 60-day public comment period. Additionally, the Feed Section has commissioned two literature reviews dealing with occupational exposure in order to aid the safety evaluation of novel feeds. The first investigates common features in what triggers allergenic reactions from microbial, plant, or fertilizer sources. The second is a review of the mode of action of toxic proteins. The papers were received and are currently being reviewed by scientists in the Feed Section. **Next Update: December 2003**
4. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of confusing terminology.	As indicated above, the CFIA has revised Regulatory Directive 94-08: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and Regulatory Directive 95-03: *Guidelines for the Assessment of Novel Feed from Plants with Novel Traits*. The revised draft directives provide a detailed description of how the CFIA uses novelty as a regulatory trigger. The documents also include a

	definition of novelty, and clarify actions required in specific cases such as intraspecies/interspecies crosses, re-transformation and re-mutation of approved PNTs, and intentional gene stacking of PNTs. The documents also contain an expanded glossary. Regulatory Directive 95-03 clarifies the use of substantial equivalence in livestock feed safety assessments. **Next Update: December 2003**
For Health Canada and the CFIA:	
5.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	Both Health Canada and the CFIA participated in a Joint Session of the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds (Paris, France - February 12-14, 2003). At this meeting a project to identify the key parameters in the molecular characterization of the regulatory safety reviews was discussed. This project is scheduled in the programme of work for 2003-2005 for the Task Force and the Working Group. Both groups will continue to work jointly on this project under the lead of Health Canada. More information regarding the work of the OECD Working Group and Task Force, including proceedings of recent workshops and consensus documents can be found at: http://www.oecd.org/biotrack/. **Next Update: June 2004**
Use of Precaution	
For All Departments:	
6. 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.	In the revised regulatory directives referred to in actions 1, 3 and 4, Health Canada and the CFIA have provided more specific direction to applicants which will help compliance with regulatory requirements. Also, 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

	and 95-03, as well as Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms*. Finalization of the revised guidelines and regulatory directives is anticipated by the end of 2003. 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, a Memorandum of Understanding between CFIA and Health Canada is being developed. The Department of Fisheries and Oceans continues to enhance the science base for the assessment of potential risks of the introduction of new aquatic biotechnology products into the environment. The Department is also reviewing its legislative mandate and developing the regulations with a view to assuming regulatory responsibility for this sector in the future. In the interim, the Department is concluding a Memorandum of Understanding with Environment Canada and Health Canada to conduct scientific risk assessments of new aquatic biotechnology products under the *Canadian Environmental Protection Act* 1999 (CEPA, 1999). **Next Update: June 2004**
7. 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	As indicated in actions 1 and 3, Health Canada and the CFIA are completing the update of their respective regulatory directives and guidelines. A technical discussion on the health and safety aspects of the Action Plan was hosted by Health Canada on

methods become available, protocols will be refined. The government looks forward to the contribution of Panel members and other experts in this work.	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 objectives of this discussion were to identify and prioritize research needs in the various areas related to the assessment of novel foods and to identify possible partnership opportunities between Health Canada and the scientific community. The report of this session is now available on the Department's website at: http://hc-sc.gc.ca/english/protection/royalsociety/technical_report_april.html. **Next Update: June 2004**
8. Health Canada is also committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994.	See action 1 for relevant activity update. **Next Update: December 2003**
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.	After examining the approach taken by Food Standards Australia New Zealand (FSANZ) which provides an opportunity for public input during the review of individual novel foods, the Food Directorate is pursuing a pilot project in which the scientific evaluators of the Directorate and FSANZ would work together on the review of a submission. The objective of this project is to assist the Directorate in determining how to refine the process currently in place for novel foods in Canada. Further information regarding this initiative is provided in the consultation document (see action 1). The CFIA and Health Canada are also working on a pilot project to post Notices of Submission for public viewing on the Internet when plants with novel traits (PNTs) and novel feeds and novel foods derived from PNTs are submitted for approval. Members of the industry association CropLife Canada have volunteered to write and include Notices of Submission as part of

	their regulatory submissions to the CFIA and Health Canada for PNTs, and novel feeds and novel foods derived from PNTs. These notices will have a description of the product and information about its safety assessment. This will complement the current practise where the CFIA and Health Canada post decision documents after a product has been assessed for safety. The pilot project will be launched by summer 2003. **Next Update: June 2004**
For Health Canada:	
10. We will share information and discuss specific product assessments with other countries as a mechanisms to validate Health Canada's safety assessments.	Health Canada's scientific evaluators continue to regularly exchange technical information with their colleagues from FSANZ on GM-food submissions. Additionally, the Food Directorate and FSANZ held a second bilateral meeting on March 21, 2003. The reasons for the meeting were to share information and identify actions regarding food policy issues of common interest, including the signature on the revised Memorandum of Understanding, which was updated to broaden its scope and add more specific targets and outcomes. Signature of the document is anticipated in the next couple of months upon agreement by both parties. **Next Update: December 2003**
11. Health Canada proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	On March 4, 2003, a proposal from the Working Group on External Participation was discussed by the Food Rulings Committee. It was decided that the Working Group would develop Terms of Reference and criteria for the selection of external experts in order to conduct a pilot project focussing on their participation in the Committee's deliberations regarding novel foods. In the long term, we hope to extend this practice to all products regulated by the Food Directorate so that our decisions benefit from the scientific perspective of additional experts from academia and other non-governmental organizations. In addition, this issue is addressed in the consultation

	document developed in support of Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* (see action 1 for more information). **Next Update: June 2004**
For Environment Canada:	
12. 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.	As a result of a comprehensive multi-stakeholder consultation process on the chemicals and polymers portion of the CEPA *New Substances Notification Regulations*, eight recommendations were made concerning options for increasing public access and transparency of the regulatory process, policy, and risk assessment decisions. Although these recommendations were made to target the chemical and polymer portions of the regulations, the recommendations on transparency have broad applications to the regulation of products derived from biotechnology. They will be reviewed for applicability and implementation by the Biotechnology Division. The final report of the Multi-stakeholder Consultation Recommendations for Chemicals and Polymers was published in May 2002 and can be viewed at http://www.ec.gc.ca/substances/ Environment Canada is also taking steps to increase public access to and transparency of the regulatory process and decisions on biotechnology products by revising our website to improve navigation and facilitate access. A framework for posting summaries of risk assessment reports will be an integral part of the revised website. The revised website is targeted to be operational in 2004. **Status: Complete**
13. 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 regulatory and emerging biotechnology issues. **Next Update: June 2004**

Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada:	
14. 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, the revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* will be posted for public comment in the near future. Changes have been made to the sections on toxicological considerations for them to reflect the range of toxicological testing required as part of the safety assessment of novel foods derived from microorganisms and plants. These revisions also take into consideration the recent work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (see action 2 for further information on these activities). The revised guidelines for novel foods derived from plants and microorganisms will be finalized and posted on Health Canada's website towards the end of 2003. **Next Update: December 2003**
15. 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.	Food Directorate scientists are continuing their projects to assess long-term toxicological and health effects of soy products (non-GM) and transgenic fish in animal models in partnership with the University of Manitoba, the Department of Fisheries and Oceans, and the CFIA. So far, a multi-generation study carried through to three generation, and one study on induction of mammary gland and colon cancer using soy products as experimental models for future GM-foods have been completed. Tissues are currently being analysed to assess effects on metabolism, reproduction, general and neural development, and the potential for tumour development. In addition, a rat toxicity study is underway to assess any potential adverse health effects due to the genetic modification of fish. The ultimate goal of the above research is to develop molecular biomarkers using genomics and proteomics

	technologies including DNA microarrays and protein arrays. These biomarkers may then be utilized to assess the safety and nutritional quality of future GM-foods. In the January 2002 progress report, it was identified that methods for identification of GM-fish have been developed for different parts of fish using polymerase chain reaction (PCR). This research was published in the Journal of Agriculture and Food Chemistry through the collaboration of CFIA, Health Canada, and the Department of Fisheries and Oceans (Masri et al., 2002, "Detection of genetically modified Coho salmon using polymerase chain reaction amplification", *Journal of Agricultural and Food Chemistry*, 50: 3161-3264). Over the past year, Health Canada scientists have participated in a number of international presentations and discussions on issues related to toxicity testing for GM-foods and current research activities. They include: Jia, X.; Mehta, R.; Curran, I.; McIntosh, C.H.S.; Nian, C.; Fong, C.; Poon, K.H.; Bremsak, I.; Alimkulov, A.; masri, S.; Devlin, R.H. (2002) Detection of transgenic fish in the Canadian food supply and assessment of potential adverse toxic effects. Health Canada Research Forum. Ottawa ON 18-19 November 2002 Abstract 1.18 Mehta, R. (2002). Toxicology and Allergenicity - Issues, Challenges and Current Research in the Food Directorate with Reference to GM-foods. Technical Discussion on the Health and Safety Aspects of the Government of Canada Action Plan, Gatineau, QC, 30 April, http://hc-sc.gc.ca/english/protection/royalsociety/technical_report_april.html Mehta, R.; Hierlihy, A.; Curran, I.H.A. (2002). Identification and characterisation of potential health hazards associated with genetically modified foods: Toxicological considerations. International Conference on Post-Market Surveillance of GM-foods, Issues,

	Challenges and Opportunities, Ottawa, ON, 16-17 October 2002 (http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/gmfcp-agmrc/index.html). Mehta, R.; Barker, M.; Bird, R.P.; Bondy, G.S.; Caldwell, D.; Cooke, G.M.; Curran, I.H.A.; Gill, S.; Jia, X.; Lok, E.; Meuller, R.; Pulido, O.; Rowsell, P.; Schrader, T.J. (2002). Toxicology research in support of the evaluation of safety and long term health effects of genetically modified foods. Health Canada Research Forum Ottawa ON, 18-19 November 2002 Abstract 1.26 **Next Update: June 2004**
Alternatives to antibiotic-resistance markers	
16. 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 is soliciting comments on the use of antibiotic resistance marker genes as part of its current consultation on the proposed revisions to its *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* (see action 1). The comments received will be used to refine Health Canada's policy on this issue. 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 organized by Health Canada (Gatineau - April 30, 2003) and the joint Health Canada/CFIA consultation on proposed revisions to the guidelines and the regulatory directives which was held in May 2002. Both documents are now available at: (http://hc-sc.gc.ca/english/protection/royalsociety/technical_report_april.html) and (http://www.inspection.gc.ca/english/plaveg/pbo/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. A summary will be posted when the review is

	completed. **Next Update: June 2004**
Allergenicity	
17. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly.	As noted in action 2, the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology has completed the *Draft Guideline for Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* along with *the Draft Annex on Assessment of Potential Allergenicity*. These documents have been forwarded to the 26th Session of the Codex Alimentarius Commission for final adoption. Guidance contained in these documents are reflected in Health Canada's Guidelines that will soon be posted for a 60 day public comment. The proceedings from the *Workshop on Animal Models of Allergenicity* hosted by Health Canada in November 2001 have been published in the February 2003 issue of *Environmental Health Perspectives* (see action 19 for full reference). **Next Update: December 2003**
18. Through stakeholder consultation, we will update and publish Health Canada's guidelines for the safety assessment of novel foods (vol. I + II).	See action 1 relevant activity update. **Next Update: December 2003**
19. 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.	As mentioned in action 2, the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology at its fourth and final session (Yokohama, Japan - March 11-14, 2003) completed the *Draft Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*. In addition, the *Draft Annex on the Assessment of Possible Allergenicity*, specific for microorganisms, was appended to these guidelines. Both documents, along with the guidelines and annex for foods derived from recombinant-DNA plants

	previously forwarded by the Codex Task Force will be considered for final adoption by the Codex Alimentarius Commission at its 26th Session (Rome, Italy - June 30- July 7, 2003). The proceedings from the Workshop on Animal Models of Allergenicity hosted by Health Canada in November 2001 have been published in *Environmental Health Perspectives* (Mini Monograph: Allergenicity Models, 111:221-251, February 2003). In addition, Health Canada scientists have participated in international presentations and discussions on issues related to allergenicity testing for GM-foods as follows: Tryphonas, H. (2002). Difficulties in assessing the potential allergenicity of GM products - the need for a post-market surveillance mechanism. International Conference on Post-Market Surveillance of GM-foods, Issues, Challenges and Opportunities. Ottawa, ON. 16-17 October 2002. (http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/gmfcp-agmrc/index.html). Tryphonas, H. (2001). Report on Health Canada's Workshop on Animal Models to Detect Allergenicity to Foods and Genetically Modified Products. Meeting of ILSI, Health and Environmental Sciences Institute-Protein Allergenicity Subcommittee, Washington, D.C. 21 June 2001. Vavasour, E. (2001) Update on Codex activities relating to protein allergenicity. Meeting of ILSI Health and Environmental Sciences Institute - Protein Allergenicity Subcommittee, Washington, D.C. 21 June 2001. **Next Update: June 2004**
20. 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.	As an outcome of the October 2002 International Conference on Post-Market Surveillance of Genetically Modified Foods and previous work completed by the Centre for Surveillance Coordination, the Biotechnology Surveillance Project's work is entering the options analysis phase. The objective of this work

	is to conduct a detailed quantitative assessment of 3-5 scenarios. This will involve modelling information content and costs of the most promising classes of study design as well as multi-generational exposure studies in animal models and consumer complaint networks. Due to the complexity of the models to be developed, the project will engage national and international experts in government, academia, industry and NGOs. Completion of the analysis phase is anticipated for April 2005 (www.healthsurv.gc.ca/biotech). **Next Update: June 2004**
Concurrence of approvals for GM-food crops	
For Health Canada and the CFIA:	
21. To formalize current understanding between CFIA and Health Canada to restrict partial approvals of GM-food crops and feeds.	Health Canada's revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* and the CFIA's revised draft regulatory directives Dir 94-08 and Dir 95-03 now contain a policy requiring that approvals for a new PNT be issued simultaneously under the applicable acts and regulations. This policy is in place to minimize the risk of unapproved products entering the Canadian environment, food and feed supply (See actions 1 and 3 for more information). Final revisions, if any, will be completed in 2003. **Next Update: December 2003**
Nutritional assessments	
22. 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 document. Comments received during the current phase of consultation will be considered in the finalization of these documents (see actions 1 and 3 for more information). Officials from the CFIA and Health Canada participated

	in the recent meeting of the OECD Task Force for the Safety of Novel Foods and Feeds (Paris, France - February 13-14, 2003). A consensus document, *Safety Assessment of Animal Feedstuffs derived from Transgenic Plants*, co-written by Canada and the United Kingdom, was finalized at this meeting. The paper discusses the feasibility of animal feeding trials to address safety and nutritional aspects of the regulatory assessments for foods and feeds. In addition, two consensus documents regarding the compositional consideration for cotton and rice are in the final stages of approval. These documents identify key food and feed nutrients, anti-nutrients and secondary plant metabolites. These documents will be available on the OECD website along with other documents that have been published (http://www.oecd.org/biotrack/). **Next Update: June 2004**
Environmental Safety and GM-Plants (Plants with Novel Traits)	
For the CFIA:	
23. 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.	The CFIA has written a fact sheet about confined research field trials of PNTs. It describes the protective measures required during and following a trial, and the nature of the inspections conducted by the CFIA. The fact sheet is now posted on the CFIA website (http://www.inspection.gc.ca/english/sci/biotech/gen/pntvcne.shtml). The CFIA will post case studies illustrating the type of information used during a safety assessment of a PNT and/or a novel livestock feed. The first of these case studies is expected to be on the CFIA website by summer 2003. **Status: Complete**
24. CFIA has begun to increase the number of trained inspection staff	The CFIA continues to strengthen its inspection and monitoring programs by providing additional training to

to further strengthen existing inspection and monitoring programs for agriculture products of biotechnology.	new staff. It completed several national training program initiatives to enhance specific knowledge in biotechnology staff hired through Budget 2000 funding. The CFIA's Feed Section completed a national training program workshop in November 2002 for inspection staff to provide background and training regarding novel feeds and the Feed Section's newly implemented inspection programs. The inspection programs introduced in that training session are being implemented. Through the CFIA's National Biotechnology Training Fund, 33 staff attended an "Introduction to Biotechnology" workshop in 2002-2003. This two day workshop is designed for those with a minimal science background, or as a refresher for those with a science background. In March 2003, the CFIA completed the last of a series of four training workshops for inspection staff. The content of the workshops included the CFIA's regulatory mandate for PNTs, and issues of insect resistance management for Bt crops; however, their focus was on the regulation and inspection of confined field trials of PNTs. Approximately 100 inspectors attended the workshops held in Guelph, St. Hyacinthe, Kelowna and Saskatoon. Several national training initiatives were funded in part through the Biotechnology Training Fund, to fulfill the biotechnology requirements of CFIA staff in various fields. These included: • Emergency Management • Import Training • Plant Health • Policy Development A "Biotech Primer" is currently being developed by the Professional and Technical Development Section of the CFIA. It is an introduction to biotechnology and the way it impacts on the CFIA's regulation and inspection activities. The Agency plans to have the primer

	available to all staff this fiscal year. **Next Update: Complete**
For Environment Canada:	
25. Continue CEPA 1999 listing process in cooperation with other government departments, including Health Canada and CFIA.	Environment Canada is continuing discussions with the Department of Fisheries and Oceans, Health Canada and the CFIA in the development of Memoranda of Understanding to ensure that appropriate regulatory oversight is maintained and that, in the long term, suitable regulatory authorities exist and are available to these departments and agencies. Once achieved, eligible Acts and Regulations can be listed individually in Schedule 4 of the *Canadian Environmental Protection Act 1999* (CEPA, 1999). The CFIA is assisting Environment Canada in the regulatory oversight of livestock animals that are considered to be products of biotechnology under the *New Substances Notification Regulations* of CEPA 1999. They have done this by providing scientific expertise for drafting a notification guidance document appropriate for such livestock animals. This document will serve to provide further guidance of regulatory requirements to notifiers of livestock animals. The first draft of these notification guidelines are being peer-reviewed within government departments. In addition, a round of comments will be received from outside experts, to help further refine the guidelines, before they go to broader consultations. The CFIA will also contribute scientific expertise for policy development and risk assessment of livestock animals notified under the *New Substances Notification Regulations*. **Next Update: June 2004**
26. Requirements for training was recognized in Budget 2000 fund for biotechnology regulation (along with increased resources to meet then existing regulatory workload). As the number and	Staff have taken supplemental training in molecular biology and bioinformatics. New personnel have been hired. As demands increase, Environment Canada will continue to expand its workforce.

complexity of applications increases, additional capacity will be added.	**Next Update: June 2004**
GM-Animals (including fish) and GM-Feeds	
For Health Canada:	
27. Develop and publish guideline volume III on safety assessment of novel foods derived from animals.	Although originally anticipated for spring 2003, consultation on the first draft of the third section of Health Canada's guidelines, which is devoted to the safety assessment of novel foods derived from animals, is now planned for early 2004. This will take advantage of expert advice from the FAO/WHO Expert Consultation on Genetically Modified Animals scheduled for November 17-21, 2003. In addition to the results of the FAO/WHO Expert Consultation, the new section of the 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/). Input from previous national expert consultations organized by Health Canada and other departments in 2001 and 1998 will also be taken into consideration. Health Canada will also seek public comments on the regulation of foods derived from cloned animals as part of its current consultation on the proposed revisions to its *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* (see action 1). As an interim policy, Health Canada considers foods produced from livestock developed using the technique of somatic cell nuclear transfer (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 (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. As reported in the December update, the Food Directorate, as part of an interdepartmental working group on animal biotechnology, is in the process of identifying 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. This document's completion is anticipated by the end of summer 2003. 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 and April 3, 2003, respectively. 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 2004**
For the CFIA:	
28. 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 now completed an initial survey of the scientists and researchers involved in research pertaining to animal biotechnology, for example cloning and transgenic technologies. A list of scientists has been compiled to use for consultations concerning regulatory approaches to animal biotechnology. These researchers and scientists recently were invited– along with stakeholders from the animal biotechnology industry, animal breeding organizations, animal care and welfare groups and regulators– to a consultative "Animal Biotechnology Focus Group Meeting" held in Ottawa on 27-28 March 2003. The discussions focussed on streamlining the regulatory approach to animal

	biotechnology and the respective roles of industry, academia and regulators in communicating to the Canadian public. A summary of these proceedings will be posted on the CFIA website. See also actions 25 and 26. **Next Update: June 2004**
29. 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 of regulating such new applications of biotechnology.	The CFIA continues to work with the Canadian Council for Animal Care, as a part of the consultation process. Input from the council experts and others, will be used to develop the guidelines or notification documents with respect to livestock animals that are products of biotechnology. An issue identification paper on animal cloning, developed by the interdepartmental working group and referenced in the December 2002 update, is now being finalized (See also action 27). This paper identifies the range of issues associated with this technology. The paper will, along with other tools, assist in decisions regarding regulation of cloned animals, their progeny and the products derived thereof. **Status: Complete**
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 2004**
For AAFC:	
31. Work with other Departments and agency on a tracking system for transgenic livestock and fish (via the interdepartmental working group on transgenic animals, including fish)	A modified registration system is being designed to track transgenic animals taking into account the specific needs of the relevant federal government regulatory bodies and other stakeholders. Discussions with animal industry groups took place in Ottawa from October 18-19, 2002 (organized jointly by AAFC and the Canadian

	Livestock Genetics Association) and March 27-28, 2003 (organized by the CFIA). **Next Update: December 2004**
For the CFIA, Department of Fisheries and Oceans, Health Canada and Environment Canada:	
32. CFIA, Health Canada and Department of Fisheries and Oceans 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 is currently in the process of identifying issues relating to the current regulatory regimes for the various products, including novel foods, regulated under the *Food and Drugs Act*. A consultation on a draft issue identification paper took place in Ottawa on February 18, 2003. The draft consultation report and the guide to industry (published in May 2002) are available at: http://www.hc-sc.gc.ca/ear-ree. Next steps will include the release of a draft options analysis report later this summer followed by a consultation in the fall. As noted in action 25, the CFIA is working with Environment Canada by providing scientific expertise for drafting notification guidelines for the regulation of livestock animals that are products of biotechnology under the *New Substances Notification Regulations*. The CFIA will also provide scientific expertise to help Environment Canada in assessing notifications of livestock animals under the *New Substances Notification Regulations*. The Department of Fisheries and Oceans (DFO), Environment Canada and Health Canada are meeting regularly to conclude a Memorandum of Understanding whereby the Department of Fisheries and Oceans would conduct scientific risk assessments of new aquatic biotechnology products under CEPA 1999, until such time as regulations governing these products are developed by the Department. Health Canada and the Department of Fisheries and Oceans will be consulting with national and international experts on the assessment of environmental and indirect human health risks of

	transgenic fish. **Next Update: June 2004**
Other Recommendations	
For all Departments:	
33. CFIA, Health Canada, Environment Canada, AAFC and Department of Fisheries and Oceans 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 will be working on an interdepartmental initiative to look at long term health effects, including environmental effects of genetically modified organisms (GMOs). This initiative which is funded through the 2003-2004 budget for the Canadian Biotechnology Strategy will complement Environment Canada's interdepartmental initiative on Ecosystem Effects of Genetically Modified Organisms (EEGMO) and will be integrated into policy and regulatory decision making processes. **Next Update: June 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 Canadian Biotechnology Strategy (CBS) supports a multi-disciplinary approach toward research projects in biotechnology, including those with a regulatory focus. Projects are funded on a yearly basis, based on criteria for targeted investments following a request for proposal process through approval by the Biotechnology Assistant Deputy Minister Coordinating Committee. Under CBS, Health Canada's Office of Biotechnology and Science will lead an initiative to develop a government wide stewardship and regulatory framework. The initiative will provide a foundation for an integrated and strategic federal approach to address multi-disciplinary biotechnology issues. The Canadian Regulatory System for Biotechnology (CRSB) funding (announced in Budget 2000) has been renewed for 2003-2006 maintaining the same four objectives across the biotechnology departments: ▸ meeting technical capacity and human resource needs, ▸ increased confidence in the regulatory systems

	through improved public awareness and citizen engagement, ▸ increasing efficiency and effectiveness, and ▸ knowledge generation in support of regulations. In following through on commitments made in the CRSB Results Management Accountability Framework (RMAF), the CRSB has undergone a formative evaluation with a report expected by the Fall of 2003. The CBS Interdepartmental Working Group on Regulations has committed to several action items as a result of the formative evaluation of the 2000-2003 Canadian Regulatory System for Biotechnology (presently in draft form), including developing and instituting an annual planning process to identify pressures and emerging needs. By the end of 2004, the RMAF has committed to a summative evaluation which will measure impacts. The Federal Government allocated $55 million in 1999 to initiate the development of core R&D programs on genomics in the seven biotechnology departments. Health Canada's Genomics R&D program is committed to funding overarching thematic proposals/projects that generate knowledge and expertise in genomics relevant to the Department's research, surveillance and regulatory mandate's as well as the Department's need to develop policy in priority areas. One of the four thematic areas is the long term effects on health and safety of GM-foods and other biotechnology products. A brief description of some of the genomics research can be found in action 15. **Next Update: June 2004**
For Environment Canada:	
35. 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,	Research activities within the National Water Research Institute (NWRI) related to the ecological risks posed by the release of GMOs continue. Projects include: the survival and persistence of transgene DNA in the environment, and the natural uptake of extracellular DNA from the environment by microbes in aquatic

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 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.	ecosystems. Laboratory testing using intact soil-core microcosms is ongoing to assess the survival and persistence of four fungal strains listed on the Domestic Substances List in three types of agricultural soils. This work is managed by the Environmental Technology Centre of Environment Canada. One strain was successfully transformed and monitored in the soil cores using a transformation procedure based on the polymerase chain reaction (PCR) method. Results for this strain will be available in the Summer of 2003. A novel procedure based on amplified fragment length polymorphisms (AFLPs) was devised to monitor the remaining three strains in the terrestrial microcosms. Research results on this novel procedure are awaiting publication. **Next Update: June 2004**
36. 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.	To strengthen baseline biodiversity data and capacity to acquire these data through biosystematics research, a Federal Biodiversity Information Partnership (FBIP) has been established as a first step in creating a national coordinating mechanism for biological information, and in enabling Canada's full participation in the Global Biodiversity Information Facility. Funding for a start-up phase of the initiative has now been identified from a variety of federal sources. **Next Update: June 2004**