PROGRESS REPORT : JUNE 2005

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

Introduction:

Health Canada, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), Environment Canada and Fisheries and Oceans Canada have already published seven progress reports on the *Action Plan in Response to the Royal Society of Canada (RSC) Expert Panel Report* (http://www.hc-sc.gc.ca/english/protection/novel_foods.html).

The eighth 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 2005 was identified. The next progress report will be published in December 2005.

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

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

ACTION	CURRENT STATUS
Substantial Equivalence	
For Health Canada :	
1. HC is committed to update its Guidelines for the Safety Assessment of Novel Foods published in 1994 for them to reflect the latest scientific developments. (This will be done in consultation with national and international experts.)	The revised *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* are in the final stages of the revision process and are being prepared for publication. The revision of the guidelines is based on the experience gained in Health Canada's evaluation of these products and reflects advances in scientific knowledge and technology. The revised guidelines are also consistent with guidance documents adopted at the international level by the Codex Alimentarius Commission with respect to the assessment of genetically modified foods. The Department held stakeholder consultations to solicit expert and public input on proposed revisions to the guidelines. Comments and feedback received from these consultations have assisted Health Canada in the finalization of the revised guidelines. It is expected that the revised guidelines and the summary report of the comments received from stakeholders will be published in 2005. **Next update : December 2005**

For the CFIA :	
2. CFIA is committed to the update of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	The CFIA is committed to regularly updating their policies and scientific knowledge. The CFIA hosted several workshops in the winter of 2005: February 17-18, 2005: Hosted a workshop for the ornamental plant industry in order to raise awareness regarding: 1) what is considered a regulated product (e.g., a plant with novel trait, PNT), and 2) current CFIA import and domestic regulatory requirements for PNTs. In addition, the workshop provided a forum for discussion on assessment criteria that could be used by the ornamental plant industry in determining whether their plant variety is subject to regulatory oversight and to develop an integrated government-industry action agenda for the development of appropriate regulatory guidance for ornamental PNTs. Workshop proceedings will be available on the CFIA's Plant Biosafety Office (PBO) website at the end of August 2005. February 21, 2005: Hosted, under the umbrella of the Ecosystem Effects of Novel Living Organisms (EENLO) initiative, a workshop to discuss the stewardship of herbicide tolerant and insect resistant crops. Participants created comprehensive research projects that would help to fill knowledge gaps identified by CFIA as regulatory needs. Proceedings from this workshop are anticipated to be posted on the CFIA website by the end of July 2005. March 2-3, 2005: Hosted a workshop to solicit feedback on the PBO's preliminary draft guidelines for the environmental release of PNTs intended for plant molecular farming (PMF) and to begin addressing some of the outstanding technical biosafety issues identified in the draft guidelines. Proceedings will be posted on the web site by the end of July 2005. March 16, 2005: The PBO co-hosted, with the CFIA's Feed Section, an internal workshop with inspection staff to assess CFIA's inspection capacity with respect to commercial scale PMF activities. March 30-31, 2005: Hosted a workshop to solicit input from the plant breeding community in regards to the development of a document providing guidance for self-determination of the novelty of plant varieties resulting from plant breeding programs. Proceedings from this workshop are anticipated to be posted on the CFIA website by the end of July 2005. **Next update : December 2005**
3. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of	The CFIA held a follow-up workshop in March 2004 with the plant breeding community regarding the use of novelty as a regulatory trigger. This follow-up workshop's focus was to

confusing terminology.	work toward developing a document that would provide guidance for self-determination of the novelty status of plant varieties resulting from plant breeding programs. The proceedings from the CFIA's March 2004 workshop on novelty are available on the Plant Biosafety Office's website at: http://www.inspection.gc.ca/english/plaveg/bio/consult/novnou/novnoue.shtml. Also, the CFIA continues working to improve communications with developers and importers of PNTs to help improve understanding of the regulatory requirements for PNTs. A workshop clarifying the use of novelty as the regulatory trigger as well as what is considered to be a regulated product (e.g., a PNT) was held. See update on action 2 for more details. **Next update : June 2006**
For Health Canada and the CFIA :	
4. We will participate and contribute to national and international expert effort to refine our approaches and further develop analytical tools, such as genomics, proteomics, and metabolic profiling to support the application of the concept of substantial equivalence in the evaluation of more complex novel foods and GM-organisms.	In June 2005, Canada participated in the 10th meeting of the Organisation for Economic Co-operation and Development's (OECD) Task Force for the Safety of Novel Foods and Feeds in Paris, France. An important part of the session focussed on the development of three new consensus documents (sunflower, tomato and mushroom). The purpose of these consensus documents is to provide key nutritional and compositional information for use during safety assessments of novel foods and feeds. Canada is also a lead in the development of a discussion document which will examine guidelines for environmental risk assessments of GM plants. This work is taking place in the OECD Working Group for Regulatory Harmonization of Biotechnology. In addition, the Working Group also continues its work on consensus and guidance documents. Two documents were recently published : *The Consensus Document on the Biology of Helianthus annuus L. (Sunflower)* and *An Introduction to the Biosafety Consensus Documents of the OECD Working Group for Harmonisation in Biotechnology*. Consensus and guidance documents developed by these two groups are available at : http://www.oecd.org/biotrack. Research on global gene expression in transgenic plants, sponsored by the CFIA, has now been published in "The Plant Journal" and is available on-line at the following address: http://www.blackwell-synergy.com/links/doi/10.1111/j.1365-313X.2005.02350.x/full/ The proceedings for CFIA's technical workshop on current

	segregation and grain handling systems and their applicability to commercial PMF is now available on the CFIA website at: http://www.inspection.gc.ca/english/plaveg/bio/mf/worate/reprape.shtml. **Next update : June 2006**
Use of Precaution	
For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-food Canada and Fisheries and Oceans Canada :	
5. The five departments will review their use of precaution to fully clarify its application across the many areas of their responsibility, including the regulation of products of biotechnology.	Health Canada and the CFIA, in collaboration with DFO and EC, are leading the portion of the project *Transforming the Horizontal Regulatory Governance of Biotechnology in Canada*, involving the development of common regulatory governance principles and clear communication on how those are applied. The application of precaution in the context of biotechnology regulation was discussed in an interdepartmental workshop held in March 2005. The concept of novelty was also discussed. The results of this workshop will aid in clarifying the application of precaution across the four departments and the agency. **Next update : June 2006**
6. Uphold and reinforce regulatory tenets of mandatory pre-market notification and a prudent process of science-based assessment for the potential risks of the introduction of new biotechnology products as food or feed or into the environment.	Health Canada participated in the workshop on *Principles for the Risk Assessment of Novel Fruits and Vegetables* organized by the Nordic Steering Group (i.e., Denmark, Norway, Sweden) in May. The purpose of this workshop was to discuss various aspects related to regulation, definition and risk assessment of foods from novel plant sources (that is, plant species that are exotic). Officials from various countries, including Canada were invited to share their respective experiences in regulating and assessing this type of non-GM novel foods. The outcome of these discussions will be considered in a final report that will be posted on the Nordic Council website (www.norden.org/start/start.asp?lang=6). Workshops clarifying the use of novelty as the regulatory trigger as well as what is considered to be a regulated product (e.g., a PNT) for both the ornamental and plant breeding industry in Canada were held in March 2005 by the CFIA. Proceedings from these workshops will be posted on the CFIA web site once they become available. See update on action 2 for more details. The CFIA has also engaged itself further in the development of a regulatory framework for the environmental release fo PNTs intended for PMF by developing preliminary draft guidelines to more clearly identity the technical biosafety issues which remain to be addressed prior to this framework

	being completed and adopted. Feedback on draft guidelines was solicited among affected stakeholders and work towards addressing some of the outstanding technical biosafety issues was initiated. **Next update : June 2006**
7. As GM-foods increase in their complexity, the protocols for product review need to be updated through a system for routine review and improvement. As well, as science progresses and more advanced methods become available, protocols will be refined. The government looks forward to the contribution of Panel members and other experts in this work.	As illustrated by the updates on actions 1 to 4, 8 and 9, Health Canada and the CFIA are committed to refining their protocols based on new scientific knowledge. **Next update : Completed**
For the CFIA :	
8. CFIA is committed to the update of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	The CFIA is committed to regularly updating their policies and scientific knowledge. With that objective in mind, the CFIA hosted several workshops in the winter of 2005. See action 2 for a complete list of workshops. Next update : December 2005
For Health Canada :	
9. HC is also committed to update its Guidelines for the Safety Assessment of Novel Foods published in 1994.	Through the revision of the *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms*, Health Canada is ensuring that Canada's criteria for the safety assessment of such foods reflect the latest scientific knowledge. See action 1 for more information. **Next update : December 2005**
Transparency and Increasing Public Confidence	
For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-Food Canada and Fisheries and Oceans Canada :	
10. 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.	Through the project entitled *Transforming the Regulatory Governance of Biotechnology in Canada*, Health Canada, the CFIA, Environment Canada and Fisheries and Oceans are now looking into developing an improved, more coordinated model for transparency and consultation in Canada. Approaches used in other countries are being considered to develop our improved model. **Next update : Completed**

For Health Canada :	
11. We will seek ways to improve transparency of the regulatory process for novel foods in Canada, including under the Health Protection Legislative Renewal Initiative.	On June 9th, 2003, former Minister of Health, Anne McLellan, announced her intention to initiate public consultations on the proposal to renew the federal health protection legislation. The proposed *Health Protection Act* would replace three existing statutes: *the Food and Drugs Act*, the *Hazardous Products Act*, and *the Radiation Emitting Devices Act*, with new measures better adapted to modern technology and society and offering stronger health protection to Canadians. With respect to transparency, the proposed legislation would include improved legislative authority regarding the review process for new drugs, genetically modified food and other novel products and also the authority to make the process more transparent. The proposal as well as discussion papers were released in June 2003 and are posted on Health Canada's website at : http://renewal.hc-sc.gc.ca. (This has been followed by extensive consultations with all interested parties). This exercise has resulted in part with the tabling of the Quarantine Bill (Bill C-12), which received Royal Assent on May 13, 2005. As for other areas such as product safety and health information, Health Canada and the Public Health Agency of Canada are pursuing the policy development in light of the comments received during the last round of consultations. The department is continuing to meet with stakeholders to further refine its policy in some key areas with a view to moving forward with new health protection legislation as soon as possible. More immediate initiatives aimed at increasing transparency and public involvement are currently being undertaken. They include a pilot project which consists of posting "notices of submission" on the Health Canada and the CFIA websites for public comments, and another pilot project where an external expert participates in the Food Rulings Committee's deliberations on novel foods. Please refer to action 12 of the February 2005 report and action 14 of the present report for additional information. **Next update : June 2006**
12. To prepare and post Novel Food Decision Documents on Health Canada's Food Program website in a timely manner.	To date, 71 novel foods, 64 of which are derived from genetic modification, have been approved for sale in Canada. Decision documents for all of these novel foods are posted under the heading "Decisions on Novel Foods" of the Novel Foods and Ingredients web page. As new products are being approved, we will continue posting them in a timely manner. **Next update : Completed**

13. We will share information and discuss specific product assessments with other countries as a mechanism to validate HC's safety assessments.	Health Canada's scientific evaluators take part on an ongoing basis in the exchange of technical information with their colleagues from Food Standards Australia New Zealand and the Food and Drug Administration (USA) on a variety of issues related to the safety assessment of novel foods. **Next update : Completed**
14. HC proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	The Food Directorate continues to move forward with the Pilot Project on External Expert Participation at Food Rulings Committee meetings. The first Food Rulings Committee discussion of the safety assessment of a genetically modified food with the participation of an external expert is expected to occur toward mid-2005. The consultation on the proposed revision to the *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* included questions on this particular project. The comments made by the participants have been taken into consideration in the finalization of the pilot project. A summary of the comments will be available on the novel food website (www.novelfoods.gc.ca) as reported in action 1. **Next update : Completed**
15. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments.	See update on action 14. **Next update : Completed**
For the CFIA :	
16. 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 has published a post-secondary level educators' resource entitled *Regulation of Agricultural Biotechnology: An Educator's Resource*. This resource is currently being distributed to deans of biotechnology/biology/agriculture-related departments in universities and colleges across Canada. This resource is available in hard copy from the CFIA's Office of Biotechnology, and will soon be available on the CFIA website. The CFIA has recently updated its information kit, entitled *Regulating Biotechnology: Safety Comes First*. The updated kit reflects current interests of Canadians about agricultural biotechnology. The CFIA continuously updates and posts fact sheets on its website to provide consumers with up to date information. A new fact sheet titled *APEC Conference:* Agricultural Biotechnology Crops in Centres of Origin, has been added

	to the CFIA site and can be found at: http://www.inspection.gc.ca/english/sci/biotech/capac/agrbioe.shtml. **Next update : Completed**
17. We will work with applicants to achieve greater openness regarding specific product information.	CFIA continues to post notices of submission on its website at the following address : http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml. Six notices have been posted so far. Health Canada's and CFIA's evaluators are working with petitioners to encourage them to make their notices of submission public. The CFIA's Plant Biosafety Office is in the process of updating its web-based table summarizing which products have been approved for environmental release, for use as a novel feed and/or for use as a novel food. Users will be able to search for approved products by plant species, novel trait, original applicant, designated name, or a combination of any of these options. He updated table will be posted on the CFIA web site shortly. In addition, Canada's decisions regarding both the authorization for environmental release of PNTs and their use as livestock feed ingredient (including any products derived therefrom) are accessible from the Canadian Node of the Biosafety Clearing-House at the following web site: http://www.bch.gc.ca **Next update : June 2006**
18. We will continue to make spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and the public.	The CFIA distributed information about the regulation of agricultural biotechnology to secondary school teachers at several teachers' conferences. The CFIA continues to make available spokespersons to respond to enquiries, and gives presentations to stakeholders on various topics. For more information, please contact the CFIA's Media Relations office at (613) 225-2342. **Next update : Completed**
19. We will ensure all regulatory documentation regarding current requirements are easily accessible and complete.	The CFIA now lists its plant-species specific terms and conditions for confined field trials on its website separate from its Directive 2000-07, entitled *Conducting Confined Research Field Trials of Plants with Novel Traits in Canada*, in an effort to increase information accessibility.

	Next update : Completed
For Environment Canada :	
20. Improve access to all its existing guidelines, advisory notes, conditions on website; formats for risk assessment reports are currently being revised to facilitate public release.	A first Risk Assessment Summary has been posted on the Canadian Node of the Biosafety Clearing House website (www.bch.gc.ca), and more will be posted shortly. The *Guidance Document for Testing the Pathogenicity and Toxicity of New Microbial Substances to Aquatic and Terrestrial Organisms* (EPS 1/RM/44) has been translated and is available to the public (http://www.etc-cte.ec.gc.ca/organization/spd/pubs/pubs_en/1RM44%20English.pdf). **Next update : December 2005**
Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada :	
21. Update and publish Guidelines for Safety Assessment of Novel Foods (vol. I & II - microorganisms and plants). The documents will reflect current international developments.	The revised *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* reflect recent international development, including the range of toxicological testing required as part of these assessments. See action 1 for more information. **Next update : Completed**
22. Work at the national level and in collaboration with international organizations, such as OECD and the FAO/WHO to further developing and refining tools for toxicological assessments.	Health Canada is currently seeking additional targetted funding to continue its projects aimed to assess potential long-term toxicological and health effects of soy derived food products (non-GM) and transgenic fish in animal models over the 2005/2008 period. In addition, a technical workshop to discuss recent developments in methodologies and animal models for whole food testing is also planned to be organized later this year. **Next update : June 2006**
Allergenicity	
For Health Canada	
23. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly.	Through the Allergen Method Committee, Health Canada, the CFIA and the University of Nebraska, U.S, hosted the Third Workshop on Food Allergen Methodologies in Vancouver, B.C., from March 7-9, 2005. The following topics were discussed: method development, evaluation and validation; proficiency testing; risk assessment and risk

	management and its impact on methodology development; development of reference material; confirmatory techniques; and standardization of techniques and evaluation criteria. As a follow-up to the 2003 workshop, this initiative aims at expanding the consultation, information exchange and harmonisation of allergen methodologies. More information on Health Canada Food Allergen Program is available at : http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e_amd_program.html. **Next update : December 2005**
24. Through stakeholder consultation, we will update and publish HC's Guidelines for the Safety Assessment of Novel Foods (vol. I & II).	The revised *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* consider latest development at the international level, in particular the approach recommended by the Codex Alimentarius Commission for assessing potential allergenicity of newly expressed proteins. See action 1 for more information. **Next update : Completed**
25. HC recognized 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.	Health Canada participated in the Internaltional Life Sciences Institute's (ILSI) Health and Environmental Sciences Institute's (HESI) Protein Allergenicity Technical Committee Bioinformatics Expert Workshop that took place February 22-24, 2005 in Mallorca, Spain. The purpose of this meeting was to present and discuss new developments in the use of bioinformatics and serum screening as tools to predict the allergenicity of novel proteins introduced into GM crops. Participation in such events is important as it keeps regulators up to date with current thinking in this area of work, which eventually could impact the way allergenicity of novel proteins is assessed, both in Canada and internationally. **Next update : June 2006**
26. HC is working to establish a surveillance strategy which will permit the identification of undesirable health impacts of biotechnology derived products, including GM-foods.	HC has developed a conceptual "toolkit" comprising a probabilistic model and decision tree designed to assist the regulator with pre-approval decision making and forecast the probably nature of post-market oversight requirements. **Next update : Completed**
Alternatives to antibiotic-resistance markers	
For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-Food Canada and Fisheries and Oceans Canada :	
27. We will work with product developers	The Plant Production Division of the CFIA hosted a

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.	workshop on the use of molecular techniques, which will include some discussion on molecular markers. The workshop is entitled "Seminar on Plant Variety Protection and the Use of Molecular Techniques" and was held in Ottawa on June 16-17, 2005. **Next update : June 2006**
Nutritional assessments	
For Health Canada and the CFIA :	
28. 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.	Health Canada is planning a workshop to discuss existing methodologies and animal models used for whole-food testing to assess potential nutritional and toxic effects associated with novel foods, thus addressing the human health and safety issues related to the assessment of safety, nutritional quality and health effects of novel foods. Dates for this workshop have not yet been determined. **Next update : June 2006**
Environmental Safety and Genetically Modified (GM)-Plants (Plants with novel traits)	
For Environment Canada :	
29. Continue CEPA Listing Process in cooperation with other government departments, including HC and CFIA.	No update at this time. See Progress Report of August 2004 for the latest information. **Next update : June 2006**
30. 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 complexity of applications increases, additional capacity will be added.	The New Substances Branch Biotechnology Division increased staffing by two full-time employees in 2004-2005 to meet the increasing demands on the biotechnology portion of the regulatory program. **Next update : Completed**
Genetically Modified (GM)-Animals (including fish) and Genetically Modified (GM)-Feeds	
For Health Canada :	
31. Develop and publish guideline volume III on safety assessment of novel foods derived from animals.	As a preliminary step before the completion of the first draft of these guidelines, Health Canada will draft a paper on safety assessment approaches for foods derived from biotechnology-derived animals. This document will be used to seek input from experts and stakeholders on Health Canada's approach to the safety assessment of these novel foods. The consultation is planned for late 2005, early 2006. **Next update : June 2006**
For Fisheries and Oceans Canada :	

32. 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.	DFO, EC and HC concluded a MOU in May 2004 which clearly delineates how the departments will work together on the environmental and human health risk assessment of aquatic organisms with novel traits under the *Canadian Environmental Protection Act*, 1999 until such a time as regulations are developed under the Fisheries Act. DFO is continuing with the ongoing process of policy and regulatory development. **Next update : Completed**
33. DFO agrees that research on interactions between wild and non-transgenic fish is important and is already conducting such work together with related work on transgenic and nontransgenic salmon. Such work is used to increase our knowledge about genetically modified fish and to develop a regulatory environment to properly assess and evaluate potential license applications.	DFO continues its ongoing research program on transgenic, domesticated and wild fish populations to gather factual information to enhance the science base for objective evaluation and risk assessment of the potential environmental risks associated with aquatic organisms with novel traits. Research results on physiological and behavioural differences and on the linkage between genotype and phenotype expression are published in peer reviewed journals. In addition, DFO continues to exchange knowledge and research information on the potential environmental effects of aquatic organisms with novel traits through convening and participating in international conferences. **Next update : Completed**
For the CFIA :	
34. 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.	No update at this time. See Progress Report of December 2004 for the latest information. **Next update : June 2006**
For Health Canada, the CFIA, Fisheries and Oceans Canada and Environment Canada :	
35. Health Canada, CFIA and Fisheries and Oceans Canada to collaborate with Environment Canada on the development of environmental assessment regulations for the products they regulate.	The Office of Regulatory and International Affairs of Health Canada has developed an Options Analysis Paper outlining several possible regulatory options to strengthen environmental assessment of substances in products regulated under the *Food and Drugs Act*. The paper has been released June 3rd , 2005 to affected stakeholders in a targeted consultation process. The Option Analysis Paper is also posted on the Environmental Impact Initiative website at : http://hc-sc.gc.ca/ear-ree/index_e.html. A period of 90 days is allotted for stakeholders' comments. After analysis of this input is completed, the Environmental Impact Initiative team plans to hold a stakeholder workshop (likely Fall 2005)

	regarding which legislative authority will be used for the Environmental Assessment Regulations. **Next update : December 2005**
Other Recommendations	
For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-Food Canada and Fisheries and Oceans Canada :	
36. CFIA, HC, EC, AAFC and DFO 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.	In February 2005, the CFIA's PBO hosted a workshop entitled, "Stewardship of Herbicide Tolerant (HT) and Insect Resistant (IR) Crops: Identifying EENLO Research Projects" as part of the "stewardship of approved products" node of EENLO. The objective of this workshop was for participants to develop comprehensive research projects on both herbicide tolerant and insect-resistant crops that would help to fill knowledge gaps identified by CFIA as regulatory needs. The EENLO group, led by Environment Canada, has completed a research paper that provides information about provincial counterparts' interest in their involvement in the EENLO initiative. To better define the research agenda associated with the risk assessment and risk management of micro-organisms under the New Substances Program, EC organized a 2-day Canadian Regulatory System for Biotechnology (CRSB/EC) workshop in May 2004. The executive summary of the workshop proceedings are posted on the New Substances Branch website - http://www.ec.gc.ca/substances/nsb/html/crsb2005_e.html - and the full proceedings of the workshop are available on request from the New Substances Branch. In addition, a research strategy document is currently under development (to be completed Fall 2005) for the biotechnology portion of the New Substances Program. The intent of this document is to ensure that the research priorities identified during the CRSB/EC workshop are given the fullest consideration, and to increase the level of communication and cooperation between the Program and research community within EC and with other federal departments/agencies involved in the regulation of biotechnology. In January 2005, as part of its contribution to the EENLO initiative, HC gathered information on the long term research needs for evaluation purposes. **Next update : June 2006**

37. Regulatory departments and agencies will develop strategic, integrated plans for multi-disciplinary projects including consideration of resources. Some groups such as the CFIA have reserved Budget 2000 funding to support relevant initiatives to meet such regulatory needs in the next 2-3 years.	The CFIA specifically set aside funding under the Canadian Regulatory System for Biotechnology funding submission in 2003 to address emerging regulatory issues. For example, a workshop with the ornamental plant industry was held to prepare for future regulation of ornamental plants with novel traits. Also, guidelines and standards for the production of antibody products in livestock and poultry are under development. **Next update : Completed**
38. We will consider sharing recommendations 5.7 and 6.9 with other appropriate federal fora for their consideration such as linking to federal and S&T initiatives.	To maintain and improve its leadership position in biotechnology, the Government (under the lead of Health Canada) is developing a *Stewardship Framework* that provides the foundation for an integrated approach to address biotechnology issues. The framework will set out principles allowing novel and appropriate mechanisms to effectively promote health and sustainability, and contribute to innovation and socio-economic growth. A federal consultation on a draft framework was conducted. Preliminary work was initiated to address implementation issues. **Next update : June 2006**
For the CFIA :	
39. In addition to existing studies, CFIA intends to commission additional research by government scientists or external experts in areas related to: • gene flow and fertility • insect resistance management • detection of transgenes in feed and livestock consuming such feed • herbicide resistance • biodiversity and agricultural ecosystem management • detection processes for biotechnology products • allergenicity for occupational and bystander exposure (feed related studies).	Research projects supported by the CFIA in 2004-2005 included studies on intra and interspecific gene flow, management of herbicide-tolerant canola and wheat volunteers, monitoring of insect resistance to Bt toxins and pleiotropic effects of transgene insertion in plant genomes. The following paper has recently been published: *The stability of the Arabidopsis transcriptome in transgenic plants expressing the marker genes nptII and uidA*. El Ouakfaoui S. and Miki B. (2005) The Plant Journal 41, 791-800. The CFIA held a workshop with the research community to develop comprehensive research projects on both herbicide-tolerant and insect-resistant crops that would help to fill knowledge gaps identified by CFIA as regulatory needs. The CFIA supports independent research. This research contributes to a greater understanding of these complex products and their implications, leading to updates in the protocols. **Next update : Completed**
For Environment Canada :	

40. EC is leading the development of a federal strategy on Generating Knowledge to Understand Ecosystem Effects of GMOs. HC, AAFC, CFIA, and DFO are involved in this effort.	An interdepartmental group led by Environment Canada continues to develop a federal research strategy to generate knowledge in understanding potential long-term and cumulative ecosystem effects of novel living organisms (EENLO) developed using biotechnology. The group is now finalizing the strategy document which has been reviewed interdepartmentally. A pilot network is being initiated to enhance communications between researchers and aid in the generation of new knowledge and approaches. This network is linked together using an on-line community of practice. An EENLO web page has been developed to provide general access to publicly available documents produced by EENLO. Further information can be found on the new EENLO web page at : http://www.ec.gc.ca/scitech/default.asp?lang=En&n=18BE230D-0. **Next update : June 2006**
41. 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 ecological significance of plant diversity in extreme environments.	Environment Canada and its partners have developed PCR-based procedures and generated data on four strains of fungi and six bacterial strains for their ability to persist in the soil environment. Results from the research on fungal strains, which will be used in the screening level risk assessment process undertaken on these strains, have been accepted for publication in the *Canadian Journal of Microbiology*, 50(8): 623-63. A novel genomic-based technique using amplified fragment length polymorphism has also been applied as part of this project. A paper that details this novel technique and the results obtained has been submitted to the *Canadian Journal of Microbiology*, and another one is in preparation. **Next update : June 2006**
For Genome Canada :	
42. 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 has received an initial $160M: recent announcement by the federal government has topped this by $140M bringing the total to $300M.	Additional Funds invested by the federal government: Budget 2003 $75 M, Budget 2004 - $60 M, Budget 2005 - $165 M, for a total investment to date of $600 M. Together with its five Genome Centres (Atlantic, Quebec, Ontario, Prairies and British Columbia) and with other partners, Genome Canada invests and manages large-scale research projects in key selected areas such as agriculture, environment, fisheries, forestry, health and new technology development. In addition, Genome Canada supports research projects aimed at studying and analysing the ethical, environmental, economic, legal and social issues related to genomics research and invests in public outreach and education projects to help inform Canadians

	of the risks and benefits of this research. To date, Genome Canada has invested $386 M across Canada. With funding from other partners, this amounts to an investment of $855 M in 79 innovative genomics and proteomics research projects and science and technology platforms (shared technical facilities). A detailed list of approved projects and platforms is available on the Genome Canada website at: http://www.genomecanada.ca/projects. Genome Canada's education website can be found at: http://www.genomeeducation.ca. **Next Update: Completed**