

PROGRESS REPORT : FEBRUARY 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 six 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 seventh progress report provides detailed technical information regarding the key milestones achieved for each of the different actions underway for which the reporting date of December 2004 was identified. Subsequent progress reports will be published in June and 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 :	
<p>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.)</p>	<p>Health Canada is currently completing its revision to the <i>Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms</i>. The revised guidelines which are expected to be finalized early in 2005, are consistent with guidance documents recently developed at the international level by the Codex Alimentarius Commission.</p> <p>A 75-day on-line public consultation was held between July and September 2003 to solicit comments and feedback on the proposed revisions as well as other broader based issues. The consultation mainly sought feedback on the proposed revisions to the guidelines. It also sought feedback on issues related to the general context under which novel foods are regulated in Canada. Those issues include the coordination of regulatory decisions between Health Canada and the CFIA, proposals to increase transparency and create more opportunities for providing input into decisions related to novel foods as well as technical issues such as the use of antibiotic resistance marker genes; and the regulation of foods derived from animals reproduced by cloning.</p>

	<p>Comments received during the consultation process have been reviewed and suggestions have been incorporated into the revised guidelines. More information regarding the consultation process, including the proceedings of the Expert Joint HC/CFIA Multistakeholder Consultation session held in May 2002 is now available under the Novel Foods heading of Health Canada's Food Program website and on the website of the CFIA. In addition, a summary report of the comments has been drafted and will be posted on Health Canada's website early in 2005 (http://www.novelfoods.gc.ca).</p> <p>Next Update: June 2005</p>
<p>2. We will make international guidance information accessible through the HC Food Program website by creating links to OECD, CODEX, FAO/WHO.</p>	<p>Links to the FAO/WHO and Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (which recently adopted the Codex <i>Principles for the Risk Analysis of Foods Derived from Modern Biotechnology</i>, the Codex <i>Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants</i> and the Codex <i>Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms</i>) and the OECD Task Force on the Safety of Novel Foods and Feeds have been added to Health Canada's Novel Foods and Ingredients Webpage (www.novelfoods.gc.ca) under the heading "Related Sites".</p> <p>Next update : Complete</p>
<p>For the CFIA :</p>	
<p>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.</p>	<p>In March 2004, the CFIA hosted a technical workshop on plant molecular farming. An executive summary is available on the CFIA web site (http://www.inspection.gc.ca/english/plaveg/bio/mf/worate/woratee.shtml), and full proceedings were posted in November 2004 (http://www.inspection.gc.ca/english/plaveg/bio/mf/worate/repape.shtml)</p> <p>As reported in the August 2004 progress report, the CFIA updated its directive on plants with novel traits (<i>Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits</i>). Comments received were reviewed and considered in the writing of the final directive. A public response to the comments was posted on the CFIA Web site in September 2004 on the Plant Biosafety Office (PBO) website at: http://www.inspection.gc.ca/english/anima/feebet/bio/revisione.shtml. The final version of this directive was posted in October 2004 (http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml)</p>

	<p>CFIA officials are committed to regularly updating their policies and scientific knowledge. As mentioned in the December 2003 progress report, the PBO held a workshop on the management of herbicide tolerant crop cultivation. The final report titled "Technical Workshop on the Management of Herbicide Tolerant Crops Report" was posted in August 2004 and can be found on the PBO website at: http://www.inspection.gc.ca/english/plaveg/bio/consult/herbtolrepe.shtml.</p> <p>Next update : June 2005</p>
<p>For Health Canada and the CFIA :</p>	
<p>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.</p>	<p>Health Canada and the CFIA participated in the 9th Session of the OECD Task Force on Novel Foods and Feeds in October, 2004. The document, <i>Consensus document on compositional considerations for new varieties of alfalfa and other temperate forage legumes: key nutrients, anti-nutrients and secondary plant metabolites</i>, co-authored by Canada and the United Kingdom, was finalised at the meeting, and is expected to be publicly released in 2005. Similar consensus documents on rice, cotton, wheat, corn, potato, sugar beet, soybean and canola are available at: www.oecd.org/biotrack. This series of consensus documents provides key nutritional and compositional information for use during safety assessment of novel feeds and foods.</p> <p>The CFIA is sponsoring research on global gene expression in transgenic plants. Preliminary results have been validated and macroarrays have been designed to obtain quantitative data on expression levels of selected non-target genes in transgenic plants. Macroarray analysis will be carried out in the next phase of the project.</p> <p>The CFIA also organized an expert consultation regarding approaches to testing and segregation for products of biotechnology such as plant molecular farming. An executive summary is available on CFIA web site (http://www.inspection.gc.ca/english/plaveg/bio/mf/worate/segrege.shtml) and full proceedings will be posted on the CFIA website shortly.</p> <p>The CFIA convened an expert consultation to provide input into the update of its directives and guidelines related to plants with novel traits (<i>Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits and Directive 95-03: Guidelines for the Assessment of Livestock Feeds from Plants with Novel Traits</i>). These documents have been updated to reflect advances in knowledge and technology. Final versions of these directives are available on the following pages:</p>

	<p>http://www.inspection.gc.ca/english/anima/feebet/bio/dir95-03e.shtml and http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml.</p> <p>Next update : June 2005</p>
<p>Use of Precaution</p>	
<p>For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-food Canada and Fisheries and Oceans Canada :</p>	
<p>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.</p>	<p>Health Canada and the CFIA, in collaboration with the Department of Fisheries and Oceans and Environment Canada, are leading the portion of the project "<i>Transforming the Horizontal Regulatory Governance of Biotechnology in Canada</i>", 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 will be examined as part of this initiative.</p> <p>Next update : June 2005</p>
<p>For the CFIA :</p>	
<p>6. 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.</p>	<p>Following consultations that began in 2002, the Directive 95-03: <i>Guidelines for the Assessment of Livestock Feeds from Plants with Novel Traits</i>, has been updated to reflect current science and ten years of experience in evaluation of novel feeds from plant sources. The revised directive is titled <i>Guidelines for the Assessment of Novel Feeds: Plant sources</i> (Oct 2004) and is available at: http://www.inspection.gc.ca/english/anima/feebet/bio/bfeebet_pe.shtml.</p> <p>The update of protocols by the CFIA is outlined in action 3.</p> <p>The CFIA's has also developed Standard Operating Procedures (SOPs) in order to assist PBO evaluators in conducting and processing applications for both confined and unconfined release. These SOPs are living documents that are continually updated to reflect changes in the Directives and additional scientific information.</p> <p>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. Action 28 outlines some of the research currently being supported by the PBO.</p> <p>Next update : June 2005</p>
<p>For Health Canada :</p>	

<p>7. HC is also committed to update its Guidelines for the Safety Assessment of Novel Foods published in 1994.</p>	<p>Health Canada is currently completing its revision to the <i>Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms</i>. The revised guidelines which are expected to be finalized early in 2005, are consistent with guidance documents recently developed at the international level.</p> <p>See action 1 of this report for more details.</p> <p>Next update : June 2005</p>
<p>Transparency and Increasing Public Confidence</p>	
<p>For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-Food Canada and Fisheries and Oceans Canada :</p>	
<p>8. 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.</p>	<p>The CFIA and Health Canada are continuing their research into various transparency mechanisms and consultation approaches used by other countries. Interdepartmental work was initiated in fall 2004 in order to develop an improved, more coordinated model for transparency in Canada.</p> <p>Next update : June 2005</p>
<p>For Health Canada :</p>	
<p>9. We will seek ways to improve transparency of the regulatory process for novel foods in Canada, including under the Health Protection Legislative Renewal Initiative.</p>	<p>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 <i>Canada Health Protection Act</i> would replace three existing statutes: the <i>Food and Drugs Act</i>, the <i>Hazardous Products Act</i>, and the <i>Radiation Emitting Devices Act</i>, with new measures better adapted to modern technology and society and offering stronger health protection to Canadians.</p> <p>With respect to transparency, the proposed Act would include improved legislative authority regarding the review process for new drugs, genetically modified food and other novel products and also the authority to make the process more transparent.</p> <p>The proposal and other background documents are available on the legislative renewal website (http://renewal.hc-sc.gc.ca). Specific questions regarding the transparency of the review process are listed in the detailed proposal (Section B, Action 8- Review Process).</p> <p>Health Canada is working on policy analysis and, to this end, is completing the report on the comments received during the public consultations on the proposed new act held in 2003 and early 2004 (some 30 workshops and more than</p>

	<p>1,400 written submissions received). Comments received by respondents will be considered into the development of the policy in support of the proposed legislative framework.</p> <p>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 web sites 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 and 15 of this report for additional information.</p> <p>Next update : June 2005</p>
<p>10. To prepare and post Novel Food Decision Documents on Health Canada’s Food Program website in a timely manner.</p>	<p>To date, 71 novel foods, 64 of which are derived from genetic modification, have been approved for sale in Canada. Decision documents for 64 of these novel foods are posted on the Novel Foods and Ingredients web page (www.novelfoods.gc.ca) under the heading “Decision Documents”. The remaining decision documents are currently being finalized and will be posted on the website when completed.</p> <p>Next Update: June 2005</p>
<p>11. We will share information and discuss specific product assessments with other countries as a mechanism to validate HC’s safety assessments.</p>	<p>Health Canada's scientific evaluators take part on an ongoing basis in the exchange of technical information with their colleagues from Food Standard Australia New Zealand (FSANZ) on a variety of issues related to the safety assessment of novel foods. The next face-to-face meeting will be held in February 2005 in Australia.</p> <p>Additionally, in March 2004, Health Canada scientific evaluators participated in an ice-breaker/learning event in Washington, D.C. with their counterparts from the U.S. Food and Drug Administration's Centre for Food Safety and Nutrition. This event enabled scientific evaluators and regulatory officials from Health Canada and the FDA to meet face-to-face and familiarize themselves with the other country's approach to the regulation and safety assessment of foods derived from biotechnology, as well as to share their experiences in this area. It is anticipated that this ice-breaker event will facilitate future collaboration between the FDA and Health Canada in the area of biotechnology-derived food safety assessment. There are tentative plans for officials from the FDA to visit Health Canada in 2005.</p> <p>Next update : June 2005</p>
<p>12. HC proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.</p>	<p>The Food Directorate is moving forward with the Pilot Project on External Expert Participation at Food Rulings Committee meetings. The roster of external experts was established in late 2004. The first Food Rulings Committee discussion of</p>

	<p>the safety assessment of a genetically modified food with the participation of an external expert will occur early in 2005.</p> <p>The consultation on the proposed revision to the <i>Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms</i> 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) early in 2005.</p> <p>Next update : June 2005</p>
<p>13. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments.</p>	<p>In its report, <i>Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada</i>, the Canadian Biotechnology Advisory Committee (CBAC) expressed overall support for the level of rigour and effectiveness of Canada's current regulatory system for protecting the health of Canadians and the environment when it comes to products of biotechnology. However, to enhance the trust of the public and stakeholders in the regulatory system, the committee recommends that the government enhance the system's accountability and improve communication and transparency surrounding the activities related to the regulation of genetically modified products in Canada.</p> <p>Over the past several months, Health Canada, CFIA, Environment Canada, AAFC, Fisheries and Oceans Canada, International Trade Canada, Industry Canada, the National Research Council of Canada, Natural Resources Canada and the Canadian International Development Agency have examined and considered the advice provided in CBAC's report. A detailed action plan will be published shortly. In the mean time, initiatives are being undertaken in response to the report's recommendations.</p> <p>Next update : June 2005</p>
<p>For the CFIA :</p>	
<p>14. 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.</p>	<p>In August 2004, the CFIA's Novel Feeds website was revised and updated to contain information about the regulation of novel feeds derived from plants, microbes and animals. Information about novel feeds can be found at: http://www.inspection.gc.ca/english/anima/feebet/bio/bfeebet_e.shtml.</p> <p>The CFIA has created 7 information posters on topics related to the regulation of biotechnology which are now included in the information kits on the regulation of biotechnology. These information kit are available upon request (Office of Biotechnology, CFIA, 59 Camelot Drive, Ottawa, Ontario, K1A 0Y9, 613- 225-2342).</p>

	<p>In addition, factsheets on the CFIA's role in regulating biotechnology-derived products continue to be created and added to the CFIA Web site. New titles include : "Do Bt Crops Affect Monarch Butterflies?" and "Peer review : What is it and how does it work?". The factsheets are available at : http://www.inspection.gc.ca/english/sci/biotech/gen/facrene.shtml.</p> <p>Next update : June 2005</p>
<p>15. We will work with applicants to achieve greater openness regarding specific product information.</p>	<p>The CFIA and Health Canada are exploring ways to encourage other developers to participate in the Notice of Submission pilot project. This pilot project consists of posting notices of submission on the web, allowing public comments before a decision is made. When meeting with non-CropLife-member companies for pre-submission consultations, the CFIA and Health Canada will invite these companies to participate in the project.</p> <p>The CFIA ensures that each plant with novel trait authorization is now accompanied by a corresponding decision document. These decision documents, on the determination of environmental and livestock feed safety, are posted on the CFIA website at: http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml.</p> <p>Next update : June 2005</p>
<p>For Environment Canada :</p>	
<p>16. 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.</p>	<p>No update at this time. See progress report of August 2004 for the latest information.</p> <p>Next update : June 2005</p>
<p>Potential Human Health Impacts</p>	
<p>For Health Canada :</p>	
<p>17. Update and publish Guidelines for Safety Assessment of Novel Foods (vol. I & II - microorganisms and plants). The documents will reflect current international developments.</p>	<p>Health Canada is currently completing its revision to the <i>Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms</i>. The revised guidelines are expected to be finalized early in 2005.</p> <p>See action 1 in this report for further information.</p> <p>Next update : June 2005</p>
<p>18. 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</p>	<p>Health Canada attended the Third Food Allergy Research and Resource Program Scientific Roundtable on Thresholds, sponsored by ILSI-North America and ILSI-Europe, from October 3-5, 2004. This international initiative is directed toward establishing thresholds of response to common food allergens. Quantifying such thresholds for common food</p>

<p>contribution of all experts.</p>	<p>allergens would assist in development of the safety assessment of the potential allergenicity of novel proteins (i.e. proteins not commonly found in the human diet that are expressed in foods derived from organisms developed using recombinant DNA technology).</p> <p>Through the Allergen Method Committee, Health Canada, the CFIA and the University of Nebraska, U.S, will host the Third Workshop on Food Allergen Methodologies in Vancouver, B.C., from March 7-9, 2005. The following topics will be 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 and the report of the 2nd workshop is available at: http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e_ amd_program.html.</p> <p>Next update : June 2005</p>
<p>Environmental Safety and Genetically Modified (GM)-Plants (Plants with novel traits)</p>	
<p>For Environment Canada :</p>	
<p>19. Continue CEPA Listing Process in cooperation with other government departments, including HC and CFIA.</p>	<p>No update at this time. See August 2004 progress report for the latest information.</p> <p>Next update : June 2005</p>
<p>20. 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.</p>	<p>No update at this time. See August 2004 progress report for the latest information.</p> <p>Next update : June 2005</p>
<p>Genetically Modified (GM)-Animals (including fish) and Genetically Modified (GM)-Feeds</p>	
<p>For the CFIA :</p>	
<p>21. 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.</p>	<p>The Animal biotechnology Unit (ABU) convened a Consultation on Animal Biotechnology in February 2004 as a follow-up to the Animal Biotechnology Focus Group meeting held in March 2003, during which developments and future regulations of animal biotechnology were discussed. A summary of this meeting was provided to all participants on a compact disc and has been posted at : http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech2004/tablee.shtml.</p>

	<p>On an interim basis, the ABU provides scientific advice to Environment Canada for assessment of transgenic animals filed with Environment Canada under the <i>Canadian Environmental Protection Act, 1999 (CEPA 1999)</i> and <i>New Substances Notification Regulations</i>. For example, the ABU has provided scientific expertise in drafting a guidance document for notifiers, titled "<i>Notification Guidelines for the Environmental Assessment of Biotechnology-Derived Livestock Animals</i>". A draft of these notification guidelines were peer-reviewed within government and is posted on the CFIA website : http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/guidedirecte.shtml.</p> <p>Next update : Complete</p>
<p>For Fisheries and Oceans Canada :</p>	
<p>22. 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.</p>	<p>DFO, EC and HC concluded a Memorandum of Understanding 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 <i>Canadian Environmental Protection Act, 1999 (CEPA 1999)</i> until such time as regulations are developed under the <i>Fisheries Act</i>. DFO is concurrently continuing with the process of policy and regulatory development.</p> <p>Next update : June 2005</p>
<p>23. 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.</p>	<p>DFO continues its 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.</p> <p>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.</p> <p>Next update : June 2005</p>
<p>For Agriculture and Agri-Food Canada :</p>	
<p>24. 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).</p>	<p>The CFIA organized the most recent discussions with animal industry groups and other stakeholders regarding tracking of transgenic animals, held February 26-27, 2004 in Ottawa. Discussion with relevant federal regulatory authorities on a modified registration system to track transgenic animals</p>

	<p>continues.</p> <p>Next update : December 2005</p>
<p>For Health Canada, the CFIA, Fisheries and Oceans Canada and Environment Canada :</p>	
<p>25. 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.</p>	<p>As indicated in action 22, DFO, EC and HC concluded a Memorandum of Understanding 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 <i>Canadian Environmental Protection Act, 1999</i> (CEPA 1999) until such time as regulations are developed under the <i>Fisheries Act</i>. DFO is concurrently continuing with the process of policy and regulatory development.</p> <p>HC has developed a consultation document outlining several possible regulatory options to strengthen environmental assessment related to products covered under the <i>Food and Drug Act</i>. We expect this paper to be distributed, as well as posted on the Environmental Impact Initiative website at http://hc-sc.gc.ca/ear-ree/index_e.html early in 2005. Once posted, 60 days will be allotted for public comments. Additional meetings and/or information sessions may follow completion of this stage.</p> <p>Next update : June 2005</p>
<p>Other Recommendations</p>	
<p>For Health Canada, the CFIA, Environment Canada, Agriculture and Agri-Food Canada and Fisheries and Oceans Canada :</p>	
<p>26. 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 ecosystem research and consideration for those priorities as recommended by the Expert Panel.</p>	<p>The EC-led EENLO (ecosystem effects of novel living organisms) initiative aims at developing a research strategy that enables the coordination of researchers and research results, and facilitates new collaborations. A pilot web-tool is being setup by EC, for use by members of the working group and self-identified interested Canadian researchers. The different Departments continue to be active participants in this initiative. Please refer to action 29 for more details.</p> <p>As indicated in the last progress report, representatives from various federal departments participated in an orientation forum on the assessment of impacts of genetically modified organisms (GMOs) on the environment, human health and society held in Québec City in January 2004. This event, organized by officials from the government of Quebec, was attended by about 60 scientists, interest groups and government representatives and was aimed at identifying potential research areas to be covered in a new research funding program. Follow-up meetings were held in June and October, and others are planned in the upcoming months to further discuss and come to agreement on potential areas of</p>

	<p>collaboration with federal departments on this initiative.</p> <p>Next update : June 2005</p>
<p>27. 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.</p>	<p>The CFIA completed its formal process to distribute the reserved Budget 2000 funding for FY2004-05 and FY2005-06. Several emerging issues will be supported for a two year period, including: the development of an import policy for plants with novel traits; the development of regulatory standards and controls for product of antibody products in livestock and poultry; and ornamental plant consultations. With these funds, the CFIA is also supporting additional issues such as transgenic animals, a feed consultation, and the Cartagena Protocol on Biosafety.</p> <p>Health Canada is leading the development of a government-wide biotechnology foresight initiative that would integrate intelligence gathered on emerging technologies and their impacts on the regulatory system, including food biotechnology. Also, the regulatory departments and agencies have developed an integrated implementation plan to determine how the current challenges of horizontal governance of biotechnology could be addressed, such as how decisions are made between departments. These two initiatives are supported by CBS 04/05 funds. Health Canada has also established a departmental working group to develop a common understanding of the impacts that nanotechnology will have on the department, and options on how to address this impact. Health Canada is examining additional issues such as molecular farming.</p> <p>Next update : June 2005</p>
<p>For the CFIA :</p>	
<p>28. In addition to existing studies, CFIA intends to commission additional research by government scientists or external experts in areas related to:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • allergenicity for occupational and bystander exposure (feed related studies). 	<p>CFIA Feed Section has continued to support research into gene transfer in ruminants. Two publications have been published since the last December update, and several more are in preparation. The two recent publications are:</p> <p>Alexander, T. W., Sharma, R., Deng, M. Y., Whetsell, A. J., Jennings, J. C., Wang, Y., Okine, E., Damgaard, D. and McAllister, T. A., 2004. <i>Use of quantitative real-time PCR to assess the stability of the cp4 epsps transgene from Roundup Ready(r) canola in the intestinal, ruminal, and fecal contents of sheep.</i> Journal of Biotechnology 112:255-266. (available at: http://www.sciencedirect.com).</p> <p>Alexander, T. W., Sharma, R., Damgaard, D., Wang, Y., Dixon, W. T., Okine, E., Deng, M. Y., Whetsell, A. J., Jennings, J. C. and McAllister, T. A., 2004. <i>Assessment of the stability of cp4 epsps transgene from Roundup Ready(r) canola in digesta from sheep by quantitative real-time and conventional PCR.</i> Canadian Journal of Animal Science 84:</p>

	<p>(Abstract, In press).</p> <p>In addition, as outlined in the August 2004 progress report, a number of studies which were been granted extension for fiscal 2004-2005, are still ongoing. These studies include:</p> <ul style="list-style-type: none"> • Global Changes in Gene Expression Associated with Highly-Expressed Transgenes in Arabidopsis and Canola. • Gene flow from <i>Brassica juncea</i> to wild mustard. • Management of Resistance to Bt in Adult Corn Rootworm. • Gene-flow in Spring Wheat at the Commercial Scale. • Emergence Periodicity of Volunteer Canola and Wheat in Prairie Cropping Systems. • Baseline Monitoring of Bt-Resistance in the European Corn Borer in Ontario and Quebec. <p>For more information on these projects, please refer to action 24 in the December 2003 progress report (http://www.hc-sc.gc.ca/english/protection/royalsociety/progress_report_december2003.html).</p> <p>As stated in action 4 of the present report, the CFIA continues to support specific research projects and is an active member on the Environment Canada-led interdepartmental working committee with the aim of developing a research on EENLO.</p> <p>Next update : June 2005</p>
<p>For Environment Canada :</p>	
<p>29. 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.</p>	<p>An interdepartmental group led by Environment Canada continues to develop a federal research strategy to generate knowledge in understanding potential long-term and cumulative 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. Please visit the new EENLO web page at:</p> <p>http://www.ec.gc.ca/scitech/default.asp?lang=En&n=18BE230D-0.</p> <p>Next update: June 2005</p>
<p>For Genome Canada :</p>	
<p>30. Considerable work is already in progress in the area of development of state-of-the-art genomics resources, and</p>	<p>Together with its five Genome Centres (Atlantic, Quebec, Ontario, Prairies and British Columbia) and with other partners, Genome Canada invests and manages large-scale</p>

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.

research projects in key selected areas such as agriculture, environment, fisheries, forestry, health and new technology development. Genome Canada also supports research projects aimed at studying and analysing the ethical, environment, economic, legal and social issues related to genomics research (GE³LS).

To date, Genome Canada has invested \$386 million across Canada. With funding from other partners, this amounts to an investment of \$855 million 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>.

The "GEEE! in Genome" is an innovative, multi-dimensional public education project developed by the Canadian Museum of Nature, presented nationally by Genome Canada, in partnership with the Canadian Institutes of Health Research. The project includes a bilingual hands-on travelling exhibition, "suitcase" exhibits for smaller communities, a series of interactive public programmes, curriculum-based school programmes, youth forums, a national forum series and a dynamic Web component. In September 2003 the project's 3-year cross-Canada tour was launched. To date, over 250,000 Canadians have visited the exhibit. For more information visit <http://www.genomeeducation.ca/GEqeee>.

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