May 31, 2002

PROGRESS REPORT: MAY 2002

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

Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada

Introduction:

In January 2002, Health Canada, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), Environment Canada (EC) and the Department of Fisheries and Oceans (DFO) published the first of several progress reports on the action plan. This second progress report provides detailed technical information regarding the key milestones they have achieved for each of the different actions planned or underway for which the reporting date of May 2002 was identified in either the action plan or the first progress report. (http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm)

Other progress reports will be published in December 2002 and June 2003. 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.

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

ACTION	CURRENT STATUS
Substantial Equivalence	
For Health Canada:	
1. Health Canada is committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994 for them to reflect the latest scientific developments. (This will be done in	Health Canada is currently reviewing and updating the *Guidelines for the Safety Assessment of Novel Foods*. A joint consultation with the CFIA will be held in Ottawa on May 29-31 to solicit expert input and will involve members of academia, industry, public interest groups and consumers associations.

consultation with national and international experts.)	The revised guidelines will be consistent with guidance documents recently developed at the international level (see actions 2 and 5). Information and outcomes of this consultation will be posted on Health Canada (http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_foods_and_ingredient.html) and CFIA (http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_revdirpnte.shtml) websites once available. **Next Update: December 2002**
2. We will update Health Canada information material to provide a better insight on the way we apply the concept when assessing the safety of novel foods.	At the meeting of the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Yokohama, Japan - March 4-8, 2002) the document entitled "*Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*" was completed and forwarded to the Codex Alimentarius Commission for final adoption in 2003. The Guidelines include considerations for a comparative approach which is consistent with the concept of substantial equivalence articulated in the report of the FAO/WHO Expert Consultation held in Geneva in June 2000. Health Canada's *Guidelines for the Safety Assessment of Novel Foods* are being revised taking into consideration the guidance provided in the Codex document mentioned above. **Next Update: December 2002**
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 Feed Section and the Plant Biosafety Office are working on updating the following documents: 1) Regulatory Directive Dir95-03 "*Guidelines for the Assessment of Livestock Feed from Plants with Novel Traits*", 2) Regulatory Directive Dir2000-07 "*Guidelines for the Release of Plants with Novel Traits within Confined Field Trials in Canada*" , and 3) Regulatory Directive Dir94-08 "*Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*".

	Under action 3 of the January 2002 progress report, it was reported that a draft amendment to *Regulatory Directive 2000-07* addressing confined research trials of PNTs for pharmaceutical production would be posted for public comments with anticipated finalization by Spring 2002 (http://www.inspection.gc.ca/english/plaveg/pbo/mf/mfa0007e.shtml). This amendment has not yet been finalized and further refinements of the proposed changes are presently being carried out. As indicated in action 1, the CFIA and Health Canada are planning to hold a joint consultation with stakeholders on May 29-31, 2002. Topics of discussion will also include clarification of the use of terminology such as the definition of "novel" and "familiarity". Information and outcomes of this consultation will be posted on the CFIA and Health Canada websites (http://www.inspection.gc.ca/english/plaveg/pbo/mf/mf_revdirpnte.shtml , http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_foods_and_ingredient.html). **Next Update/Completion: December 2002**
4. The CFIA is reviewing its fact sheets on the assessment process to improve clarity and explanation of the concepts of familiarity and substantial equivalence. The Agency is also preparing new information for posting on the Internet and use in CFIA information kits to explain the use of substantial equivalence and other concepts in its regulation of agricultural products.	The CFIA continues to prepare new information for posting on the Internet available through the CFIA website at: http://www.inspection.gc.ca . Specifically, new fact sheets will be posted starting in late June 2002. Fact sheet topics and terminology are being carefully considered to improve clarity and explanation of the safety assessment of products of biotechnology, including the concepts of substantial equivalence and familiarity .These fact sheets will take into consideration the outcomes of the joint consultation. **Next Update: December 2002**
For Health Canada and the CFIA:	
5. We will participate and contribute to national and international expert effort to refine our approaches and further	A technical discussion with members of the former Expert Panel and other external experts was hosted by Health Canada on April 30, 2002. This discussion focussed on the research that is currently underway in the fields of

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.	molecular characterization, analytical methods, allergenicity, toxicology, nutrition and long-term surveillance of GM-foods. New research needs, including some in the field of genomics, proteomics and metabolomics, were identified and plans for future collaboration were strongly supported by the group. The meeting report will be posted on the Health Canada website shortly. In March 2002, the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology adopted the *Draft Principles for the Risk Analysis of Foods derived from Modern Biotechnology*. It will be presented for final consideration at the 25th Session of the Codex Alimentarius Commission in 2003. The Principles provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. They also recognize the need for consistency with the Codex Working Principles for Risk Analysis and therefore address risk assessment, risk management, risk communication, consistency, capacity building, information exchange and the need for review processes to address new scientific knowledge. The Task Force also completed and forwarded for final adoption the annex entitled "*Assessment of Possible Allergenicity (Proteins)*" developed by the Codex *Ad Hoc* Open-Ended Working Group on Allergenicity which was chaired by Canada, and the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants*. The report of this meeting can be found on the Codex Alimentarius Commission website at http://www.codexalimentarius.net. In addition to chairing the Working Group on Allergenicity, consistent with the commitment, Canada made a significant contribution to the development of the Principles and Safety Assessment Guidelines text. Also, Canada, on behalf of the OECD Task Force for the Safety of Novel Foods and Feeds and the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology, is taking a lead role in developing a consensus document on the molecular characterization data

	requirements and related quality standards for the safety assessment of novel foods, feeds and plants. As a first step, a discussion document has been prepared which compares the criteria arising from similar international harmonization efforts, as well as those from selected countries with established biotechnology regulatory systems. The document will be reviewed by the two groups mentioned above at their next meeting in June 2002. The purpose of this discussion document is to compare relevant approaches, requirements, and standards, with the aim of identifying points of consensus and "best-practices". **Next Update: December 2002**
Use of Precaution	
For all Departments:	
6. 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.	The Federal Government published a discussion paper entitled "*A Canadian Perspective on the Precautionary Approach/Principle*" in November 2001. This discussion paper outlines proposed "guiding principles" to support overall consistency in how the precautionary approach is used in science-based risk decision-making in government. These principles would constitute the key elements of a framework for the precautionary approach. The public was invited to submit comments until the end of March 2002. Comments received are being reviewed and analysed. The feedback obtained will serve to inform the government's thinking on whether the guiding principles are appropriate, would improve consistency, provide an appropriate balance of flexibility and predictability, and be adaptable to various functional areas. **Next Update: December 2002**
Transparency and Increasing Public Confidence	
For all Departments:	
7. 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	Representatives from Environment Canada and Health Canada met with Australian officials responsible for new substances assessment from February 15 to March 1, 2002. They also met with the newly established "Office of the Gene Technology Regulator" and exchanged information on transparency under the "Gene Technology Act" (see

public and expert consultations. This will help us determine which model would best be suited for the Canadian regulatory process.	http://www.health.gov.au/ogtr/index.htm). Representatives from Health Canada and the Canadian Food Inspection Agency also met with the Australia New Zealand Food Authority (ANZFA) representatives from May 16 to May 22. These discussions have facilitated the sharing of information and experience in the regulation of genetically modified foods by the participating regulatory agencies. The following items were discussed: • approaches to maximize transparency, including the posting of public notifications and the establishement of a public consultation period during the product approval process, • consultation among external experts and peer review during the product assessments, • confidential business information, • implemention of the approaches noted above in terms of implications for the range of stakeholders involved, and • relevance of these approaches to other product areas requiring pre-market review. Food Directorate officials have also reviewed the proposed new *Pest Control Products Act (Bill C-53)*, which includes provisions to enhance transparency and public involvement in decision making, to identify which elements could be appropriate for the regulatory process of novel foods. Also, the Canadian Biotechnology Strategy (CBS) Working Group on Regulations is preparing to explore mechanisms to increase transparency and disclosure as may impact across regulatory departments and agencies, this includes the study of the approach taken by other countries. To this end, the CFIA has also held internal discussions of its current practices and upcoming initiatives to address this situation. **Next Update: December 2002**
For Health Canada:	
8. Health Canada proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	The working group on external participation established to examine this proposal is conducting a review of related initiatives addressing issues of transparency and public trust underway within the Department. These issues include the appropriate selection process, the period of service, the

	consistency of this initiative with other initiatives related to developing public trust, and how to achieve transparency. This information will inform the working group on resolving various challenges to implementing external participation. The working group will report back to the Food Rulings Committee by the end of June for discussion. **Next Update: December 2002**
9. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments.	As mentioned under action 5, a technical discussion with members of the former Expert Panel and other external experts was hosted by Health Canada on April 30, 2002. This discussion focussed on the research that is currently underway in the fields of molecular characterization, analytical methods, allergenicity, toxicology, nutrition and long-term surveillance of GM-foods. New research needs, including some in the field of genomics, proteomics and metabolomics, were identified and plans for future collaboration were strongly supported by the group. The meeting report will be posted on the Health Canada website shortly. **Next Update: December 2002**
For the CFIA:	
10. We will publish all decision documents and will do so in a timely manner.	As noted in the January 2002 progress report, there were four outstanding decision documents due for publication by the Feed Section and the Plant Biosafety Office. The last of these decision documents is now being finalized for posting on the CFIA's Internet site (http://www.inspection.gc.ca). Furthermore, CFIA will no longer issue the notification of a decision without the concurrent release of a decision document on its website. **Status : Completed**
11. 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 continues to improve its information for the consumer with the upcoming release of a second set of new fact sheets related to report recommendations. The fact sheets will be posted on the CFIA Internet site (http://www.inspection.gc.ca) starting at the end of June 2002. Following consultations as described in action 3, fact sheet topics or content may be revised. Topics of fact sheets in progress include: • the environmental safety assessment of plants with novel traits related to specific types of products, e.g. herbicide tolerance

	• CFIA and emerging applications of biotechnology • Canada's voluntary labelling approach • detection and testing of biotechnology-derived products • plant-made pharmaceuticals **Next Update: December 2002**
12. We will ensure all regulatory documentation regarding current requirements are easily accessible and complete.	As noted in the January 2002 progress report, documentation about the requirements for the registration of novel microbial supplements (fertilizer) is being posted on the CFIA Internet site and will be completed by May 31, 2002. A feed registration workshop was also held in October 2001. In the future, as new or revised guidelines are completed, they will be posted on the CFIA Internet site. **Status : Completed**
13. We will work with applicants to achieve greater openness regarding specific product information.	The Government of Canada has been approached by industry stakeholder representatives such as BIOTECanada and CropLife Canada. Their members have held discussions within the agricultural biotechnology sector and are ready to have joint discussions with the CFIA and Health Canada about measures they will implement to increase transparency and openness in the Canadian regulatory system. It is anticipated that a meeting will be held before the end of June 2002. **Next Update: December 2002**
For Environment Canada:	
14. We will prepare a report on options for increasing public access and transparency to regulatory decisions, including examining alternatives for periodically engaging experts in reviewing decision making, regulations, guidelines and related scientific methodologies.	Environment Canada is in the process of taking some immediate steps to increase transparency by providing more information on the Environment Canada biotechnology website (http://www.ec.gc.ca/substances/) and will develop a more complete report later in the year. **Next Update: December 2002**
Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada:	
15. Update and Publish *Guidelines for the Safety Assessment of Novel*	As mentioned in action 1, Health Canada is currently reviewing and updating the *Guidelines for the Safety*

Foods (vol. I & II - microorganisms and plants). The documents will reflect current international developments.	*Assessment of Novel Foods (vol. I & II)*. Such updates have taken into consideration the recent work of the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology. A joint consultation with the CFIA will be held in Ottawa on May 29-31, 2002 to solicit expert input and will involve members of industry, academia, public interest groups and consumers associations. The guidelines will be revised according to the input received from the consultation and a second draft will be sent to stakeholders by mailout for their comments (July 2002). Following the second revision, a final draft will be present to Food Rulings in September 2002 for final approval. Information and outcomes of this consultation process will be posted on our respective websites once available. **Next Update: December 2002**
16. 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 as well as international organisations (OECD, FAO/WHO) have recognised a need to support research for the design and development of practical and scientifically sound *in vivo* models for toxicity testing of whole foods. To this end, as stated under action 18 of the January 2002 report, Health Canada scientists are continuing their project to develop an animal model to assess potential long-term toxicological and health effects in partnership with Universities of McGill and Manitoba, the Department of Fisheries and Oceans and the Canadian Food Inspection Agency. A multigeneration study and a study on induction of mammary gland and colon cancer using unmodified soy products are underway. In the next steps, the collected tissue samples will be analysed to assess the effects on metabolism, reproduction, general and neural development and the potential for tumour development. These tissues will also be used for the development of molecular biomarkers. Also, wild-type aquaculture and transgenic fish fillets have been sampled and their basic nutrient content analysed. These samples will be used to prepare diets for a rat toxicity study to assess any potential adverse health effects due to the genetic modification.

	Next Update: June 2003
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 under action 5, the Codex Intergovernmental Task Force on Foods Derived from Biotechnology reached agreement on a final version of the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* and decided to include the annex entitled *Assessment of Possible Allergenicity (Proteins)* developed by the Codex *Ad Hoc* Open-Ended Working Group on Allergenicity chaired by Canada. The report of the meeting is available on the Codex Alimentarius website : http://www.codexalimentarius.net Also, the proceedings from the Workshop on Animal Models for the Detection of Allergenicity hosted by Health Canada in November 2001 have been submitted for peer-review and publication in the Environmental Health Perspectives journal. The workshop participants concluded that although there is no single animal model that ideally meets the requirements, each of the models discussed have merits which, when further validated, may contribute to the overall assessment of allergenicity of GM-derived proteins. The CFIA's Feed Section participated in this workshop. **Next update: June 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 for relevant activity update. **Next Update: December 2002**
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 actions 5 and 17, at the third session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology agreed that an integrated, stepwise, case-by-case approach must be used in the assessment of potential allergenicity as reflected in the Annex. This Annex on the "*Assessment of Possible Allergenicity (proteins)*" was forwarded to the Codex Alimentarius Commission for final adoption. It can be found on the Codex Alimentarius website: http://www.codexalimentarius.net

	Also, the proceedings from the Workshop on Animal Models for the Detection of Allergenicity hosted by Health Canada in November 2001 have been submitted and will be published following a peer-review in the Environmental Health Perspectives journal. **Next Update: December 2002**
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.	Health Canada's Centre for Surveillance Coordination is sponsoring an international conference to discuss and expand current and emerging knowledge on the issues, challenges and opportunities emanating from post-market surveillance of GM foods. The conference that will be held in Ottawa (October 16 - 17, 2002) will engage approximately 150 international experts, including researchers and policy analysts from universities, research institutes and inter-governmental organizations such as WHO, FAO and OECD. Among the objectives of this conference is to build and share knowledge on the complexities of post-market surveillance of GM foods and explore opportunities which will help Health Canada in its effort to develop strategies in this area. To further contribute to the development of such strategies, the Centre for Surveillance Coordination has also completed a comprehensive study to identify key international activities and experts in the area of post-market surveillance. A multi-disciplinary discussion paper on the economic impacts is also being developed for presentation at the October conference. **Next Update: December 2002**
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.	Representatives from Health Canada and the CFIA held a two day retreat in April 2002. One of the topics discussed was the concurrence of approvals for GM-food crops. A policy statement indicating that partial approvals will not be permitted will be included in the revised guidelines (see action 1) currently being developed by the two organizations. These guidelines will be discussed at the joint consultation in May. **Next Update: December 2002**

Environmental Safety and GM-Plants (Plants with Novel Traits)	
For the CFIA:	
22. 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.	Although initiated, the proposed interactive tool designed to explain the environmental safety assessment process for plants with novel traits is still under development. The objective is to provide information that takes the consumer through a model regulatory process from the submission of a product application to the determination of a regulatory decision. (See action 23 from the first progress report) Case studies using corn and soybean as examples, are being developed to explain safety assessment processes for food, feed and environmental release. **Next Update: December 2002**
23. CFIA has begun to increase the number of trained inspection staff to further strengthen existing inspection and monitoring programs for agriculture products of biotechnology.	The CFIA inspection staff carry out programs such as inspections for compliance to terms and conditions for confined field trials studies (e.g. disposal, storage and post-season monitoring). The Plant Biosafety Office has embarked on a series of training workshops and new equipment (e.g. global positioning systems) has been provided to inspection staff to enhance their capabilities to address the evolving requirements for confined field trial inspections. The CFIA will also undertake National Training program initiatives to enhance specific knowledge in biotechnology of the new operations and program area network staff being hired through Budget 2000 funding. **Next Update: June 2003**
For Environment Canada:	
24. 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.	Environment Canada continues to ensure that its regulatory staff attend and participate in national and international conferences, symposia and other technical fora. An additional two scientific staff are being hired. Staff are also required to attend courses and participate in workshops relevant to the scientific evaluation of products of biotechnology. **Next Update: June 2003**

GM-Animals (including fish) and GM-Feeds	
For Health Canada:	
25. Develop and publish guideline volume III on safety assessment of novel foods derived from animals.	A draft of the third volume of the *Guidelines for the Safety Assessment of Novel Foods* will be available for external consultation in September of 2002. The Interdepartmental Working Group on Transgenic Animals and Fish has met twice since January and its members have identified cloning as an important issue in regards to animal biotechnology. As a result, an issue identification document is being drafted to help in developing policies on unmodified animal clones. As cloning is also often used in the transgenesis of animals, this document will play an important role in the development of volume III of the guidelines. **Next Update: December 2002**
For the DFO:	
26. 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.	An increased coordination between Environment Canada and DFO has been initiated for the development of regulations under the *Fisheries Act* that would meet the requirements for a *CEPA* exemption. Meetings between DFO Science, Legal and Regulatory Affairs have taken place to discuss the scope of the new regulations and timelines for the development (including review, consultation and approval processes) and implementation of the regulations. **Next Update: December 2002**
For the CFIA:	
27. 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 are developing a proposal for guidelines on biocontainment levels for transgenic animals produced by different methods. Discussion of one aspect of this proposal has been initiated with the scientific community through the presentation of a poster entitled *Containment levels for transgenic animals* at the 7th National Symposium on Biosafety: *Managing risk in animal care and use* held in Atlanta (Georgia) in January 2002. **Next Update: June 2003**
For Environment Canada:	

28. Revise New Substances documentation to ensure that protocols for generating notification adhere to animal care and husbandry guidelines.	An advisory note on the regulation of transgenic animals including their care will be prepared and will be incorporated in the next revision to the guidelines. **Next Update: December 2002**
For CFIA, DFO, Health Canada and Environment Canada:	
29. Health Canada, CFIA and DFO to collaborate with Environment Canada on the development of environmental assessment regulations for the products they regulate.	On an interim basis, scientists of the CFIA's Animal Biotechnology Unit continues to provide scientific advice to Environment Canada for assessment of transgenic animals filed with Environment Canada under the *Canadian Environmental Protection Act* (CEPA) and *New Substances Notification Regulations*. This includes Agency collaboration with Environment Canada to develop specific regulations and technical standards for biotechnology-derived livestock to supplement current *CEPA* notification requirements. Also, Environment Canada and DFO are working towards an alternative regulatory regime that can be listed on schedule 4 of CEPA 1999 and so replace the *New Substances Notification Regulations* for products regulated by DFO. **Next Update: June 2003**
For AAFC:	
30. Work with other Departments and agency on a tracking system for transgenic livestock and fish (via the Interdepartmental Working Group on Transgenic Livestock and Fish)	Progress in the Interdepartmental Working Group continues on developing a tracking system. Care is being taken to ensure that a co-ordinated approach is followed which includes all relevant federal government regulatory authorities. **Next Update: June 2003**