January 31, 2002

PROGRESS REPORT: JANUARY 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 November 2001, the Government of Canada published an action plan in response to the Expert Scientific Panel of the Royal Society of Canada report entitled: Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada (http://www.hc-sc.gc.ca/english/protection/royalsociety/index.htm). The action plan describes specific actions and projects which the departments intend to carry out in response to the Expert Panel's recommendations. As part of the government's dedication to transparency, a commitment was made to implement the action plan and report on the progress on a regular basis.

In this first progress report, Health Canada, the Canadian Food Inspection Agency (CFIA), Environment Canada, Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans have reported on the key milestones they have achieved since the publication of the action plan. This report provides detailed technical information regarding each of the different actions planned or underway for which a reporting date of January 2002 was identified. The progress report organizes the information according to the action items listed under the different headings outlined in the action plan.

Other progress reports will be published in May and December 2002. Future updates will also consider relevant aspects of the report of the Canadian Biotechnology Advisory Committee (CBAC) on the regulatory system for GM-foods in Canada when it is released.

As for the action plan, comments on this first progress report can be forwarded to us by e-mail at BFPI@hc-sc.gc.ca or by mail at: Bureau of Food Policy Integration, Health Protection Building (P.L. 0700E1), Tunney's Pasture, Ottawa, Ontario, K1A 0L2.

ACTION	CURRENT STATUS
Substantial Equivalence	
For Health Canada:	
1. We will update Health Canada information material to provide a better insight of the way we apply the concept when assessing the safety of novel foods.	Information material posted on the Health Canada website is being updated and revised with special attention to substantial equivalence. As articulated by the FAO/WHO Expert Consultation held in Geneva, from May 29th to June 2nd 2000, it is a comparative approach focussing on the determination of similarities and differences between the genetically modified food and its conventional counterpart which aids in the identification of potential safety and nutritional issues. For example, the Q&A's that can be found under the Novel Foods heading of the Food Directorate website have been updated (http://www.hc-sc.gc.ca/food-aliment/). Further development in the application of substantial equivalence might be expected though the work of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology which will be meeting in March 2002. We will update the information material accordingly. **Next Update: May 2002**
2. We will make international guidance information accessible through Health Canada Food Directorate website by creating links to OECD, CODEX, FAO/WHO.	Links to the OECD Biotechnology and Food Safety web page and the FAO's Food and Nutrition Division website related to biotechnology have been added to the Novel Food page of the Food Directorate website for easier access to relevant reports and information posted on the website of these international organizations. The Novel Food web page can be found on the following website : http://www.hc-sc.gc.ca/food-aliment/ under the Novel Foods heading. As further international guidance information is made available, links will be created through the Health Canada Food Directorate website to ensure accessibility. **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.	To begin the development of additional guidelines specifically related to molecular farming, the CFIA held a public forum on molecular farming to gather public views on the topic in the Fall of 2001 (http://www.inspection.gc.ca/english/plaveg/pbo/mf_fore.shtml). This was followed by a consultation with stakeholders

	including governmental representatives, non-governmental organizations, academia, and industry to collect their input. As a result a draft amendment to *Regulatory Directive 2000-07 Addressing Confined Research Trials of PNTs for Pharmaceutical Production* has been proposed and is posted for public comments until February 25, 2002 (http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml). Posting of finalized amendment is anticipated by March 2002. Stakeholder consultations will be convened to address the amendments. A new Regulatory Directive, incorporating these amendments and other general improvements will replace the existing Regulatory Directive 2000-07 by April 1, 2002. **Next Update: May 2002**
4. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of confusing terminology.	As mentioned above, CFIA's Plant Biosafety Office will be revising its Regulatory Directives in 2002, which will include improving the descriptions of the regulatory triggers for when a trait introduced into an existing species in Canada is novel or not. In conjunction with these revisions, the Plant Biosafety Office and the Feed Section of the CFIA and Health Canada are planning a joint consultation on their respective revised Regulatory Directives and Guidelines in the Spring of 2002. **Next Update: December 2002**
5. 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.	A fact sheet has been prepared to provide information regarding substantial equivalence and agency regulation of agricultural products. This fact sheet is part of a series as posted on the CFIA Internet site (http:www.inspection.gc.ca) **Next Update: May 2002**
Use of Precaution	
For all Departments:	
6. As GM-foods increase in their complexity, the protocols for product review need to be updated through a system of routine review and improvement. As well, as science	Government scientists have participated in and provided expert advice in various recent meetings relating to the review and improvement of assessment protocols. In the allergenicity field, they participated in the development of an annex on the assessment of possible allergenicity as well as in expert

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.	discussions regarding the development of animal models of allergenicity (see actions 19 and 21 for further details). Health Canada and CFIA's scientists have also participated in the development and refinement of tools for toxicological assessment (see action 20 for further details). In addition, CFIA and Health Canada officials participated in the Codex working group meeting held in Oakland in November 2001. The goal of the working group was to develop a draft guideline for the food safety assessment of recombinant DNA microorganisms. Also worth noting is the CFIA recent decision to require detection and identification tests as part of the petitioners' applications for plants with novel traits and for veterinary biologics. CFIA's Veterinary Biologics Section also uses their own validation testing, in addition to those submitted. A consultation involving stakeholders and experts is scheduled for the Spring of 2002. This new requirement will be incorporated in CFIA's Regulatory Directives. Similarly, Health Canada is currently reviewing its *Guidelines for the Safety Assessment of Novel Foods* (Vol. I and II - Plants and Microorganisms) to reflect the advancement of methods and knowledge regarding product review. These updated guidelines will be subject to a public consultation in a few months and are expected to be published in September 2002. Lastly, a technical discussion on the action plan is being organized by Health Canada to seek the input from experts on how to further develop the projects identified in the action plan as well as identify new activities to be initiated. Due to the technical nature of the dialogue, members of the Royal Society Expert Panel and the Canadian Biotechnology Advisory Committee (CBAC), academics, as well as representatives from other non-governmental organizations and industry will be invited. In order to also take into account the additional advice provided by the CBAC Report on Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada, this meeting will be held after the release of that report. **Next Update: December 2002**
For the CFIA:	
7. CFIA is committed to the update	This specific action was also identified under the heading

of protocols as product complexity increases and as science improves with contributions from internal and external experts whether domestic or international.	"Substantial Equivalence" in the action plan. See activity updates provided under the above-cited section of this progress report. **Next Update: December 2002**
Transparency and Increasing Public Confidence	
For all Departments:	
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.	As a starting point, the departments have studied the paper commissioned by the Canadian Biotechnology Advisory Committee, called *International Comparison of Regulatory Frameworks for Food Products of Biotechnology*, to identify best practices internationally. In addition the departments and agencies have participated in international meetings which have shared objectives to encourage more public engagement and expert consultations in the discussion of biotechnology and its regulation. For example, Health Canada, CFIA and Agriculture and Agri-Food Canada participated at the UK/Organization for Economic Cooperation and Development sponsored conference entitled: *New Biotechnology Food and Crops: Science Safety and Society* held in Bangkok, in July 2001 (http://www1.oecd.org/bangkok). This conference sought to further consult with stakeholders including scientists and civil society regarding the evolution of the international regulatory framework for biotechnology-derived food and crop safety systems, and the transparency/openness of such systems. The system in place for the regulatory review of novel foods in Australia and New Zealand is considered a model of public transparency and expert consultation. Initial contact has been initiated between Health Canada and counterparts at the Australia/New Zealand Food Authority and a meeting is being proposed for the Spring of 2002. **Next Update: May 2002**
For Health Canada:	
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.	As part of the consultation process leading up to the adoption of new legislation, a number of measures could be considered by Health Canada to make the review process more open, while guaranteeing a reasonable degree of protection for confidential personal and commercial information. More specifically, the following questions could be raised in the

	mentioned consultation: • Should the Act provide authority to make public the following information: status of pending submissions for market approval; summary of data presented by the manufacturer to demonstrate the safety of a new product; summary of Health Canada's evaluation of the safety and efficacy of the product; reports of adverse reactions; or other non-proprietary information? • Prior to approving a new product, should Health Canada provide a reasonable opportunity for the public to present written comments? • Should the Act provide the authority to hold public hearings, prior to making a final decision, where considered appropriate by the Minister? • Should Health Canada's assessment of certain novel products be subject to a review by an independent panel of experts? **Next Update: December 2002**
10. To prepare and post Novel Food Decision Documents on Health Canada's Food Directorate website in a timely manner.	The decision documents for 49 of the 50 novel foods are now on the Food Directorate web page under the Novel Foods Heading (http://www.hc-sc.gc.ca/food-aliment/). The 50th decision document is currently being finalized and will be posted shortly. The preparation and publication of future Decision Documents will be expedited. **Next Update: December 2002**
11. We will share information and discuss specific product assessments with other countries as a mechanism to validate Health Canada's safety assessments.	The Australian New Zealand Food Authority (ANZFA) and Health Products and Food Branch (HPFB) of Health Canada have signed a Memorandum of Understanding (MOU) regarding the exchange of information relating to the safety assessment and regulation of genetically modified foods. Since the signature of the MOU in May 2001, there have been exchanges of technical information on submissions for products already approved by Health Canada or ANZFA, or currently being reviewed for approval by both organizations. Particularly, discussion related to genetically modified food submissions, as well as other general issues related to the safety assessment of these products, has enhanced the evaluation activities of both organizations and assisted in the validation of Health Canada's safety assessment decisions. **Next Update: December 2002**

12. Health Canada proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions.	This specific action item was discussed by the Food Rulings Committee in early January 2002, it was agreed to further develop the proposal. A number of logistic and operational issues will be addressed, including the (i) implementation of oversight with respect to the integration of science advice into policy decisions and (ii) confidentiality of proprietary data and other information. **Next Update: May 2002**
For the CFIA:	
13. We will publish all decision documents and will do so in a timely manner.	In the future, the release of respective decision documents by the Feed Section and the Plant Biosafety Office will coincide with the announcement of the regulatory decision on a product. Of the current list of approved products, the last four outstanding decision documents are being prepared for posting by Spring of 2002. Decision documents are available on the CFIA's Internet site (http://www.inspection.gc.ca). **Next Update: May 2002**
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.	As a follow-up to a dialogue held in May 2001 on advancing the understanding of the benefits and managing the risks of genetically modified food crops relative to conventional and organic food crops co-sponsored by the Simon Fraser University's Faculties of Art and Science and the CFIA, the CFIA is funding the preparation of a video which will include excerpts from the May 2001 dialogue for distribution to educators, interested groups, cable programmers, etc. The video is anticipated to be completed by February 2002. As part of the May dialogue, the CFIA also released a paper entitled *Environmental Assessment of the Products of Plant Biotechnology*. This paper and other conference resource information are available from the Simon Fraser University web site at (http://www.sfu.ca/cstudies/science/foodforthefuture/) As mentioned in action 5, the Agency has published a series of new fact sheets with information about topics related to report recommendations beginning with the areas described under Substantial Equivalence, Transparency and Increasing Public Confidence and Environmental Safety and Plants with Novel Traits. These fact sheets are posted on the CFIA Internet site (http://www.inspection.gc.ca). **Next Update: May 2002**
15. We will ensure all regulatory documentation regarding current	The CFIA has reviewed its information and found that all regulatory documentation regarding current requirements are

requirements are easily accessible and complete.	complete and accessible on either the CFIA Internet site (http://www.inspection.gc.ca), or on the Department of Justice Internet site (http://www.canada.justice.gc.ca). The exception being requirements for the registration of novel microbial (fertilizer) supplements. In this case, relevant documentation is currently available by mail, and will be made available on the CFIA Internet site in the Spring of 2002. **Next Update: May 2002**
16. We will continue to make spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and public.	Since February 2001, Agency experts have given over 100 media interviews and presentations on various topics about biotechnology and its regulation. The CFIA remains committed to being timely and accessible in responding to requests from stakeholders, media and the public. **Next Update: December 2002**
For Environment Canada:	
17. Improve access to all existing guidelines, advisory notes, conditions on website; formats for risk assessment reports currently being revised to facilitate public release.	The New Substances Website (http://www.ec.gc.ca/substances/) is currently under review to improve the format and layout to facilitate navigation. Completion is anticipated by March , 2002. In addition, revised guidelines for the *Notification and Testing of New Substances: Organisms*, are now available electronically (http://www.ec.gc.ca/substances/nsb/eng/gui_e.htm). A process for revising the risk assessment reports for public release has also been initiated. The first set of reports are anticipated to be available by June, 2002. **Next Update: December 2002**
Potential Human Health Impacts	
Criteria regarding toxicological testing and whole food testing	
For Health Canada:	
18. 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.	In September 2001, Health Canada hosted and actively participated in the Codex Ad Hoc Open-Ended Working Group on Allergenicity in Vancouver. One of the tasks completed was the reorganization of the section on toxicology of the *Codex Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.* The report of the meeting is available on the following website:

	http://www.hc-sc.gc.ca/food-aliment/english/codex/task_force_biotechnology.html. Similarly, Health Canada and CFIA officials participated in another Codex working group meeting held in Oakland in November 2001 to develop a *Draft Guideline for the Food Safety Assessment of Recombinant DNA Microorganisms*. Both meeting reports will be considered by Codex member countries at the third session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology in March 2002. Clear criteria regarding when and what type of toxicological studies are required for foods produced through recombinant DNA technology and other forms of genetic modification will be included in the updated guidelines for the safety assessment of novel foods. A draft version of the section on Toxicological Considerations will be completed by February 2002. This section which will take into consideration guidance such as that under development by the Codex Ad Hoc Intergovernmental Task Force and advice provided by national experts. Health Canada scientists are also working at a national level, in partnership with researchers from the Universities of McGill and Manitoba. They have initiated projects to assess long-term toxicological and health effects of soy products and transgenic fish in animal models. Projects include multi-generation studies to assess effects on metabolism, reproduction, and general and neural development, and cancer studies to assess the carcinogenic potential of these foods. The rationale for these studies is to develop model systems for future testing of whole GM foods or specific ingredients in GM foods. In these studies, it is expected that the further identification of reliable molecular end-points will then provide sensitive biomarkers to assess the safety and nutritional quality of futur GM foods. Methods for identification of genetically-modified fish have been developed for different parts of fish using PCR. A real-time PCR method is under development to quantitate the levels of the growth hormone transgenes. A human cell line expressing growth hormone receptors has been established in the lab to study the capability of fish recombinant growth hormone to induce human insulin-like growth factor I (IGF-1). An Enzyme-Linked Immunosorbent Assay (ELISA) method

	has been developed for the measurement of human IGF-1. The methods for measurement of growth hormone and IGF-1 in fish fillet are under development. A diet preparation and a rat toxicity study will be conducted in the near future. This research initiative is done in partnership with CFIA and the Department of Fisheries and Oceans. **Next Update: May 2002**
Allergenicity	
19. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly.	At the international level, Health Canada officials participated in various expert working groups and committees to improve Health Canada's assessment capabilities for products of biotechnology over the past few months. As noted under action #18, Health Canada hosted and actively participated in the Codex Ad Hoc Open-Ended Working Group on Allergenicity in Vancouver in September 2001. In addition to its consideration of aspects regarding toxicological assessment, the Working Group developed an annex entitled "Assessment of Possible Allergenicity (Proteins)" which focussed specifically on IgE mediated allergenicity . The report of the meeting is available on the following website: http://www.hc-sc.gc.ca/food-aliment/english/codex/task_force_biotechnology.html. This annex will be considered for inclusion in the *Codex Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* at the third session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology in March, 2002. In November 2002, Health Canada also hosted a workshop on Animal Models to Detect Allergenicity to Foods and Genetically Modified Products, bringing in national and international experts to discuss models currently under development. The proceedings of the symposium will be published in the Environmental Health Perspectives journal. Furthermore, Health Canada scientists also attended a meeting of the International Life Sciences Institute (ILSI) in June 2001 and a joint meeting of the US FDA and EPA in December 2001 to prioritize the development of methods for the assessment of the allergenic potential of genetically-modified foods. The proceedings of the joint meeting will also be

	published in the Environmental Health Perspectives journal. **Next Update: May 2002**
20. Through stakeholder consultation, we will update and publish Health Canada's guidelines for the safety assessment of novel foods (vol. I + II).	More detailed guidance regarding nutritional and toxicological studies for foods produced through recombinant DNA technology and other forms of genetic modification is in the process of being included in the updated guidelines for the safety assessment of novel foods. To this end, a revised version of the section on Nutritional Considerations is being developed for inclusion in the guidelines. These guidelines will be the focus of a joint expert consultation to be organized by Health Canada and the CFIA in Spring 2002. Finalized guidelines are expected to be completed by September 2002 **Next Update: May 2002**
21. 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 18 and 19, Health Canada hosted the meeting of the Codex Ad Hoc Open-Ended Working Group on Allergenicity, which convened in Vancouver in September 2001. During this meeting, the Working Group developed an annex entitled "Assessment of Possible Allergenicity (Proteins)" which focussed specifically on IgE mediated allergenicity . The draft meeting report is now available on the Health Canada website : http://www.hc-sc.gc.ca/food-aliment/english/codex/task_force_biotechnology.html. This annex will be considered for inclusion in the *Codex Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* at the third session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology in March, 2002. In November 2002, Health Canada also hosted a workshop on Animal Models to Detect Allergenicity to Foods and Genetically Modified Products, bringing in national and international experts to discuss models currently under development. The proceedings of the symposium will be published in the Environmental Health Perspectives journal. Furthermore, Health Canada scientists also attended a meeting of the International Life Sciences Institute (ILSI) in June 2001 and a joint meeting of the US FDA and EPA in December 2001 to prioritize the development of methods for the assessment of the allergenic potential of genetically-modified foods. The proceedings of the joint meeting will also be published in the Environmental Health Perspectives journal. **Next Update: May 2002**

Nutritional Assessment	
For Health Canada and the CFIA:	
22. Participate in international efforts and seek contribution of experts for the development and validation of whole food testing protocols as well as other tools to address nutritional issues.	As mentioned in the action plan, Canada hosted the OECD Workshop on Nutritional Assessment of Novel Foods and Feeds in February 2001 in Ottawa. Experts from both Health Canada and the CFIA participated actively in this workshop which focussed on the nutritional assessment of the future generation of novel products which will have altered nutritional characteristics and composition. The need for the development and validation of new methods such as proteosomics and metabolomics was recognized. During the workshop, other areas identified as requiring additional research included better methods to measure food consumption patterns and usual intakes, as well as the identification of biomarkers to aid with the understanding of the mechanisms underlying nutrients bioavailability within conventional and novel foods. The report of the meeting is available on the following website: http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)6 At the national level, Health Canada scientists, in partnership with researchers form the Universities of McGill and Manitoba, have initiated projects to assess the potential long-term toxicological and health effects due to the consumption of soy products and transgenic fish in animal models. The rationale for these studies is to develop model systems for future testing of whole GM foods or specific ingredients in GM foods. In these studies, it is expected that the further identification of reliable molecular end-points will then provide sensitive biomarkers to assess the safety and nutritional quality of GM foods. **Next Update: December 2002**
Environmental Safety and GM-Plants (Plants with Novel Traits)	
For the CFIA:	
23. CFIA will prepare more public information concerning: a) the extent of their environmental assessment, b) the kind of data a field trial generates and protective measures	A fact sheet, titled *Data Required for the Safety Assessment of Biotechnology Derived Plants and Feeds*, has been prepared to help to explain the requirements and content of CFIA's environmental safety assessment process (http://www.inspection.gc.ca/english/ppc/biotech/reg/datae.shtml).

required in the conduct of such studies, and c) case studies to illustrate step-by-step, the assessment of a plant with novel trait or novel feed. As well, other mechanisms to enhance transparency will be considered.	The *Guidelines for the Environmental Release of Plants with Novel Traits within confined field Trials in Canada* is posted on the CFIA Internet site (http://www.inspection.gc.ca). This guideline provides clear and concise instructions to help applicants meet the regulatory requirements of the CFIA for authorization of, or renewal of previously authorized, confined field trials of plants with novel traits for research purposes. CFIA has initiated the development of a step-by step, interactive tool designed to illustrate the safety assessment process for plants with novel traits. It will take the consumer through the environmental safety assessment process from the submission of a product application to the determination of a regulatory decision. **Next Update: May 2002**
For Environment Canada:	
24. Continue CEPA Listing Process in cooperation with other government departments, including Health Canada and CFIA.	The CEPA, 1999 *New Substances Notification Regulations* apply to importation and manufacture of all living organisms and other new substances other than those covered by Acts and Regulations listed in CEPA 1999 Schedules 2 and/or 4. Work is ongoing to develop for addition to the CEPA 1999 Schedules the Food and Drugs Act and Regulations, and the Fisheries Act and Regulations. **Next Update: December 2002**
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.	Health Canada is in the process of drafting *Guidelines for the Safety Assessment of Livestock Animals and Fish Derived from Biotechnology*. These guidelines are based upon information gathered at the Technical Workshop on Food Safety Assessment of Livestock Animals and Fish Derived from Biotechnology held in March 2001, as well as a previous consultation held in 1998 on the Regulation of Livestock Animals and Fish Derived from Biotechnology. Once these draft guidelines are developed they will be the focus of consultations with stakeholders. **Next Update: May 2002**
For CFIA:	
26. The regulation of transgenic animals (including fish) and derived	In November 2001, the CFIA met with the Canadian Council for Animal Care (CCAC) to discuss topics related to the

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 the Expert Panel and others.	regulation of animals derived from biotechnology and the CCAC's ongoing development of guidelines related to the use in research, teaching, testing of transgenic animals that are intended to aid institutional animal care committees within Canada's R&D community. At this meeting, it was agreed that there should be continued discussions regarding protocols, guidelines etc for transgenic animals and that an Agency representative should be added to the CCAC advisory committee on animal welfare and biotechnology. **Next Update: December 2002**