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*

A. INTRODUCTION AND BACKGROUND

Health Canada, the Canadian Food Inspection Agency, Environment Canada, Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans are pleased to provide this 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*. The report from the Royal Society (the report) was publicly released on February 5, 2001 (www.rsc.ca).

We recognize the need to continually enhance our regulatory processes and protocols. The recommendations in the report form the basis for this action plan, which we intend to re-visit on a regular basis. We will report on key milestones as they are achieved, communicate the results of work upon completion, and add new activities as they are initiated. We will also re-visit the action plan after we receive further advice from the Canadian Biotechnology Advisory Committee (CBAC). Their final report on genetically-modified foods (GM-foods) is expected to be released in early 2002.

This document is composed of three parts: this introduction which provides background information on the Royal Society of Canada's Expert Panel Report; an action plan summary; and, the detailed action plan we have developed to address the report of the Expert Panel.

The Future of Food Biotechnology

Federal departments and agencies undertake a comprehensive review of products of food biotechnology. However, current products on the market consist mostly of plants with simple genetic modifications, typically addition of one or two traits. We recognize the dramatic potential for increased complexity of these products in the future.

As a result, in December 1999 the Ministers of Health, Agriculture and Agri-Food, and Environment requested that the Royal Society of Canada convene an Expert Scientific Panel to provide advice on scientific issues related to the safety of new food products being developed through the use of genetic engineering technologies.

The Expert Scientific Panel was asked:

To forecast:

- the types of food products being developed through biotechnology that could be submitted for regulatory safety reviews by Health Canada and/or the Canadian Food Inspection Agency over the next 10 years;
- the science likely to be used to develop these products; and
- any potential short- or long-term risks to human health, animal health and the environment due to the development, production or use of foods derived from biotechnology.

To assess:

- approaches and methodologies developed in Canada and internationally to evaluate the safety of foods being developed through biotechnology.

To identify:

- the scientific capacity that will be needed to ensure the safety of new foods derived from biotechnology, including human resources for research, laboratory testing, safety evaluation, and monitoring and enforcement; and
- any new policies, guidelines and regulations related to science that may be required for protecting human health, animal health and environmental health.

The report provided us with a number of recommendations which have been examined over the past few months. This report, like other reports on food biotechnology, (i.e., National Academy of Science in the United States, the American Medical Association Scientific Council, and the British Royal Society), does not raise concerns about the safety of GM-foods currently in the marketplace. (Note: The Expert Panel was not specifically asked to comment on the safety of foods currently on the market.)

The Government's Plan of Action

The action plan summary and the detailed action plan identify our perspective on the recommendations made in the report that clearly fall within our mandates. They outline the various activities that are already underway or are being planned by the involved departments/agencies. While each recommendation noted was studied and addressed within the context of the action plan, the plan does not aim to comment on each recommendation individually, but rather, addresses them under common headings noted below.

While the Expert Panel concentrated on the science of human, animal and environmental impacts, they also noted some broader issues, such as economic benefit and cost and ethical questions. The government recognizes the importance of these issues and will consider them in the near future when other work, including that of CBAC, the National Standards Committee on Voluntary Labelling under the Canadian General Standards Board and the study of the issues related to labelling of GM-foods by the House of Commons Standing Committee on Health, is completed.

The action plan organizes the recommendations in the report and the government's response according to the following headings:

- Substantial Equivalence
- Use of Precaution
- Transparency and Increasing Public Confidence
- Potential Human Health Impacts
- Environmental Safety and GM-Plants (Plants with Novel Traits)
- GM-Animals (including Fish) and GM-Feeds (Novel Feeds)
- Other Recommendations

Health Canada, the Canadian Food Inspection Agency, Environment Canada, Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans are committed to implementing this action plan and to reporting on our progress on a regular basis.

We would like to receive any comments you may have on this action plan and are committed to consider all input received as we proceed with our action plan. If you are interested in providing comments, please send them to us by e-mail at BFPI@hc-gc.gc.ca or by mail at: Bureau of Food Policy Integration, Health Protection Building (P.L. 0700E1), Tunney's Pasture, Ottawa, Ontario, K1A 0L2.

B. ACTION PLAN SUMMARY

Health Canada (HC) , the Canadian Food Inspection Agency (CFIA), Environment Canada (EC), Agriculture and Agri-Food Canada (AAFC) and the Department of Fisheries and Oceans (DFO) have prepared this action plan and summary. The recommendations contained in the Royal Society of Canada Expert Scientific Panel Report (the report) will contribute to our future regulatory policy and developments regarding GM-foods. It re-affirms for us that the regulatory system, including the one for GM-foods, continues to benefit from an ongoing exercise whereby regulators take stock of the products forecast for the future and the steps needed to enhance our system.

This summary identifies the various activities underway or planned throughout the federal government as they relate to the safety assessment of food biotechnology and agri-food products or research in support of regulatory decision-making. Each section of the Action Plan Summary provides the federal outlook on the report recommendations and then specifies the types of actions which we intend to carry out now and/or over the next 1-5 years.

We will re-visit this action plan on a regular basis. It reflects a commitment to transparency through: reporting on key milestones when achieved; communicating the results of work upon completion; and adding new activities as they are initiated.

Our perspectives and plans:

Substantial Equivalence

We agree with the Expert Panel that GM-foods and organisms from which they are derived (e.g. plants with novel traits) should be subject to rigorous scientific assessment.

We agree that substantial equivalence should be used as a comparative approach - as a safety standard as referred to by the Expert Panel - in the assessment of biotechnology products and not as a decision threshold.

Actions:

- Revise relevant documents and create new information materials explaining the regulatory system (*Report on progress by January 2002*)
- Contribute to the elaboration of effective and appropriate application of substantial equivalence (i.e., as a safety standard) at the international level (*Report on progress by January 2002*)
- Further develop tools, e.g., genomics, proteomics, etc., that support the evaluation of more complex novel foods (*Initiated, report on progress by May 2002*)

Use of Precaution

We fully support a precautionary approach when reviewing products for safety to human and animal health and the protection of the environment.

The language of Principle 15 of the 1992 *Rio Declaration on Environment and Development,* and the approach that it represents are consistent with today's regulatory practices in the field of environmental protection in Canada.

Actions:

- Review use of precaution by the five departments to clarify its application in our many areas of responsibility (*Initiated, Report on Progress by May 2002*)
- Update protocols as product complexity increases and as science improves with contributions from internal and external experts, at the national and international levels to increase the level of certainty (*Report on progress by January 2002*)

Transparency and Increasing Public Confidence

We agree with the need for and the benefits of the recommendations related to transparency and increasing public confidence.

We will also exercise great care to maintain our objective and neutral stance about the risks and benefits of biotechnology in public statements and interpretations of the regulatory process.

Actions:

- Examine the approach taken by other countries which provide for more public and expert consultations in order to determine the best model for the Canadian regulatory process. (*Report on progress by January 2002*)
- Investigate what other countries do to increase transparency including the disclosure of information about individual submissions (*Begin immediately, report on progress by May 2002)*
- Propose to have an external expert sit on HC's Food Rulings Committee *(Report on progress by January 2002*)
- Publish decision documents in a timely manner (*Report on progress by January 2002)*
- Ensure all regulatory documentation regarding current requirements are easily accessible and complete (*Report on progress by January 2002*)
- Work with applicants to achieve greater openness regarding the disclosure of specific product information (Begin immediately, report on progress by May
- Work with members of the Expert Panel as well as other external experts on ways of ensuring their continued contribution to the validation of assessments (*Initiated, report on progress by May 2002*)
- Share information and review product assessments with other countries as a mechanism to validate our assessments (*Report on progress by January 2002*)

Potential Human Health Impacts

We agree with the need to further refine our tools and continuously improve our approach for the safety and nutritional assessment of GM-foods and feeds, particularly for future, more complex products. We also agree that we need clear criteria in our guidelines related to toxicological testing, i.e., when and what types of studies are required. We agree that we need to further develop and strengthen our tools for the assessment of the allergenicity potential of novel foods and the nutritional assessment of future GM-foods and feeds with significant composition/ nutritional changes.

Following the Expert Panel's clarification, we agree with their recommendation on the use of alternative markers in genetically-modified products under development. However, the Expert Panel noted that the current use of antibiotic-resistance markers in genetically-modified foods is not a health or environmental concern and that there was no scientific rationale for changing these products. They do not support removing these markers from currently-approved products.

Furthermore, we support the view of the Expert Panel that partial approvals, for example, where a GM-crop or other plant with novel trait is grown for animal feed, but not for human consumption, should only be granted when certain conditions related to segregation and human safety criteria are met.

Actions:

- Update Health Canada's *Guidelines on the Safety Assessment of Novel Foods* (volume II) and related information materials to make the current range of studies required more explicit (*Report on progress by January 2002*).
- Conduct internal research and contribute to international efforts to refine Canada's approach and develop additional tools for the toxicological and allergenicity assessments of future novel foods (*Report on progress by January 2002*).
- 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 (*Initiated, report on progress by December 2002*).
- Work with product developers as well as national and international experts to determine the "state of the art" regarding alternative markers as a tool in the development of new biotechnology products (*Begin immediately, report on progress by December 2002*)
- Examine formal mechanisms to address issues specific to GM-crops developed for use other than food consumption, e.g., animal feed, production of pharmaceutical products. In the interim, an agreement regarding partial approvals will be developed between Health Canada and the CFIA. (*Begin immediately, report on progress by May 2002*)

Environmental Safety and GM-Plants (Plants with Novel Traits)

We agree with the Expert Panel that environmental safety assessments must be rigorous and thorough.

Parliament has placed a specific duty on the Government of Canada to protect the environment, its biological diversity and human health, including the safe and effective use of biotechnology products through the *Canadian Environmental Protection Act*; the *Seeds Act*, the *Feeds Act*, the *Fertilizers Act*, the *Health of Animals Act*, and the *Pest Control Products Act*. In addition, Health Canada is in the process of developing environmental assessment regulations for GM-foods and other products regulated under the *Food and Drugs Act*.

We recognize the benefits of conducting long-term monitoring studies and research on the impact of GM organisms. We are taking additional measures to improve federal capacities in this area, including ecosystem effects research. We also recognize that expanding the knowledge base for regulatory decision-making may also include the need to access the expertise of the non-government scientific community.

We further agree that it is important for the different regulatory agencies to renew and improve their internal regulatory capacity by increasing the diversity of expertise within organizational evaluation units.

Actions:

- Complete listing of legislation under CEPA 1999, for which proposals have been recently pre-published in Part I of the Canada Gazette *(Completed August 2001)*
- Develop appropriate guidelines and evaluation criteria for new products of biotechnology *(Initiated, report on progress by May 2002)*
- Support relevant research projects such as the project entitled *Ecosystem Effects of Transgenic Plants* or the project entitled *The Ecological Impact of B.t. Corn Pollen on the Monarch Butterfly in Ontario* and make the outcomes of these projects public. *(Initiated, report on progress by December 2002)*
- Increase our scientific and regulatory capacity with scientists trained in molecular biology, entomology, ecology, and other sciences as related to plants, animals and the environment. *(Initiated, report on progress by May 2002)*

GM-Animals (including Fish) and GM-Feeds (Novel Feeds)

We agree with the need for rigorous assessments of GM-animals, as well as transgenic fish and aquatic organisms, and of GM-feeds.

We are working cooperatively to establish clearer authorities and related regulations in these areas.

We are collaborating in areas of human health and environmental impacts regarding GM-foods and GM-feeds

Actions:

- Consider establishing expert advisory panels to advise on the development of regulations, guidelines and risk assessments as related to transgenic animals, fish and aquatic organisms (*Begin immediately, report on progress by May 2002*)
- Revise New Substances documentation to ensure that protocols for generating notification data adhere to animal care and husbandry guidelines (*Begin immediately, report on progress by May 2002*)
- HC, CFIA and DFO to collaborate with EC on the development of environmental assessment regulations for the products they regulate (*Initiated, report on progress by May 2002*)
- Develop and publish Health Canada's guidelines for the safety assessment of novel foods derived from animals, including fish (*Report on progress by January 2002*)
- Continue CFIA participation in international efforts and seek contribution of internal and external experts for the development and validation of testing protocols as well as other tools to address livestock nutritional issues (*Initiated, report on progress by December 2002*)
- With an Interdepartmental Working Group, develop a system to track transgenic animals under the authority of the Animal Pedigree Act for which AAFC is responsible (*Initiated, report on progress by May 2002*)

Other recommendations

There is no disputing the benefits of broad research related to GM-organisms, health and the environment to supplement information provided by applicants and to assist with our safety assessments. We also agree with the benefits of undertaking additional post-approval monitoring.

New developments in regulatory research may be achieved through a variety of means, including studies by:

- government research institutions working in partnership with regulatory departments and agencies;
- external experts as part of on-going research within the academic community or as supported by levels of government, interest groups, agricultural stakeholders such as producers;
- industry research supporting product development as may be published in the public domain i.e. reported in peer reviewed literature.

Action:

- Develop a federal strategy for research on the ecosystem effects of GMOs. *(Initiated, report on progress by December 2002)*
- Support long-term studies to know more about products of biotechnology, either pre-approval or in a post-approval monitoring context *(Initiated, report on progress by December 2002)*

- Initiate an interdepartmental discussion to assess different options regarding the support of regulatory research including work in those areas identified as priorities by the Expert Panel. *(Begin immediately, report on progress by May 2002)*

C - ACTION PLAN

This section of the document provides detailed information regarding the different activities underway or planned by Health Canada (HC), the Canadian Food Inspection Agency (CFIA), Environment Canada (EC), Agriculture and Agri-Food Canada (AAFC) and the Department of Fisheries and Ocean (DFO) in response to the recommendations of the Royal Society of Canada Expert Panel on the Future of Food Biotechnology report released in February 2001. Their report was requested in December 1999 to provide independent advice on scientific issues related to the safety of new food products being developed through biotechnology. The regulatory agencies responsible for the assessment of these products recognize the dramatic potential for increased complexity in these foods in the future.

This action plan describes specific actions and projects which all or some of the departments or agency intend to carry out immediately and/or in the near future in response to the Expert Panel's recommendations. While each recommendation noted was studied and addressed within the context of the action plan, the plan does not aim to comment on each recommendation individually, but rather, addresses them under common headings noted below. We are also committed to reporting back on the status of each initiatives outlined in the summary, including reporting on key milestones when achieved; the result of work upon completion; and also identifying new initiatives as they occur. This will be done through the publication of update summaries on a regular basis.

Lastly, while the Expert Panel report focussed more on the science of human, animal and environmental impacts, they also highlighted broader issues, such as economic benefit and cost, and ethical questions. The government recognizes the importance in addressing these policy issues and will consider them in the near future, once the Canadian Biotechnology Advisory Committee releases its report on the broad issues associated with the regulatory system for GM-foods in Canada. That final report is expected in early 2002.

Substantial Equivalence	Planned Actions	Context/Discussion
7.1 Approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for causing harm to the environment or to human health. Such testing should replace the current regulatory reliance on "substantial equivalence" as a decision threshold.	We agree, substantial equivalence is not to be used as a decision threshold and GM-products should be subject to a rigorous scientific assessment of their potential for causing harm to the environment or to human health. Indeed, in both food and feed safety assessments and the assessment of the impact of genetically-	In assessing GM-foods, we undertake a detailed scientific assessment. We examine how the food was developed, including a full description of the genes involved in the modification, their origin and their integration into the modified product; we consider the

Substantial Equivalence	Planned Actions	Context/Discussion
8.1 In general, those who are responsible for the regulation of new technologies should not presume its safety unless there is reliable scientific basis for considering it safe. This approach is especially appropriate for those who are responsible for the protection of health and the environment on behalf of the Canadian people. Any regulatory mechanism which assumes that the new product is safe on less that fully scientific substantiated basis violates this fundamental tenet of precaution. The Expert Panel rejected the use of substantial equivalence as a decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities(Chapter 7), because such as regulatory procedure is not a precautionary assignment of the burden of proof.	modified plants on the environment, the modified organisms are subject to such an assessment. However, we note that the term "substantial equivalence" is not used uniformly in our current documentation. **Actions:** HC 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.} **Timeline: Report on progress by May 2002. Completion anticipated by September 2002** 2. We will update HC information material to provide a better insight of the way we apply the concept when assessing the safety of novel foods. **Timeline: Report on progress by January 2002**. 3. We will make international guidance information accessible through HC Food Program website by creating links to OECD, CODEX, FAO/WHO. **Timeline: Report on progress by January 2002** CFIA 1. 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 **Timeline: Initiated, report on progress by January 2002.** 2. We will revise documentation related to the safety-based approach to regulation of biotechnology to avoid the use of confusing terminology. **Timeline: Initiated, report on progress by January 2002**.	potential for unexpected or pleiotropic effects; we assess the composition of the product and its nutritional quality; and we assess the potential for the production of toxic or allergenic products. Only when we are completely satisfied do we approve the product. The concept of substantial equivalence is used as a guide in the safety assessment of a GM-food by comparing the novel food to its unmodified counterpart which has a history of safe use. The value of substantial equivalence in food safety assessment has been clearly and effectively demonstrated in its application to the regulation of novel foods in Canada. In addition, at the international level, the recent Joint FAO/WHO Expert Consultation on Foods derived from Biotechnology held in June 2000 concluded that a comparative approach focusing on the determination of similarities and differences between a genetically modified food and its unmodified counterpart aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy for safety and nutritional assessment of genetically modified foods. The comparative approach, as it is often called, should be seen as a key step in the safety assessment process and that its application contributes to a robust safety assessment framework. This approach the panel fully endorses and refers to as the safety standard interpretation (p. 182, 204). In the context of environmental safety and feed safety, the concept of substantial equivalence also represents a safety standard approach. Substantial equivalence is not used, and will not be used, as a decision threshold.

Substantial Equivalence	Planned Actions	Context/Discussion
	3. 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. **Timeline: Initiated, report on progress by January 2002.** The Government agrees with the need to further refine and contribute to the elaboration of effective and appropriate application of substantial equivalence in the evaluation of more complex GM-foods and GM-organisms, including crops, animals and feeds. **Actions:** CFIA and HC: 1. 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. **Timeline: Initiated, report on progress by May 2002.**	As with GM-food, safety assessments of agricultural products require a detailed scientific assessment. Regulators examine submitted data, methodology and analyses in accordance with the evaluation criteria set out in guidelines for Plants with Novel Traits and Novel Feeds derived from Plants with Novel Traits or Microbial Supplements. These and food safety assessment guidelines make reference to terms and concepts including familiarity and substantial equivalence which have not been consistently described to distinguish their meaning and use. To ensure that our approach reflects the latest scientific knowledge, the federal government officials participate actively in international efforts aimed at developing tools for assessing the safety of novel foods, plants with novel traits and novel feeds. These initiatives include the work of the CODEX Inter-governmental Ad Hoc Task Force on Foods Derived from Biotechnology, the OECD Task Force on the Safety of Novel Foods and Feeds, and Expert Consultations organized by the FAO and WHO. The federal government recognizes the importance of genomics research, as demonstrated by funding provided for this activity in recent federal budgets. Regulatory agencies look forward to the information generated by the various genomics, proteomics and metabolic profiling initiatives as this information will further support the application of the concept of substantial equivalence in the safety assessment process. Indeed, we note that university laboratories are presently involved in many such efforts. In conclusion, the government will ensure that the scope and depth of the data requirements will reflect

Substantial Equivalence	Planned Actions	Context/Discussion
		the latest scientific knowledge relevant to safety assessments. Our guidelines will be updated periodically to reflect such advances.

Use of Precaution	Planned Actions	Context/Discussion
8.2 The proponents and developers of food biotechnology products bear a serious responsibility to subject these products to the most rigorous scientific risk assessment. In this sense, the primary burden of proof is upon those who would deploy these food biotechnology products to carry out the full range of tests necessary to demonstrate reliability that they do not pose unacceptable risks. The laws and regulations under which these products are regulated and approved in Canada already place this burden of proof upon producers of these technologies insofar as they require the producers or proponents to carry out the tests and submit data from these tests demonstrating that the products are safe. *8.3 Where there are scientifically reasonable theoretical or empirical grounds establishing a prima facie case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product. In such cases, regulators should impose upon applicants for approval of the technology the obligation to carry out further research which can establish on reasonable weight of evidence that unacceptable levels of risk are not imposed by the technology.* *8.4 Serious risks to human health, such as the potential for allergens in genetically engineered foods, risk of extensive, irremediable disruptions to the natural ecosystems through emergence of highly aggressive or invasive weed species, or of serious diminution of biodiversity, demand that the best scientific methods be employed to reduce the uncertainties with respect to these risks. Approval of products with these potentially serious risks should await the reduction of scientific uncertainty to minimum levels. The Expert Panel supports the view of the British BSE Inquiry, as discussed above, in this regard. Even though the risks appeared remote on the basis of the available evidence, the potential seriousness of the health risks justified extraordinary*	The five departments fully support a precautionary approach when reviewing products for human and environmental safety. The language of Principle 15 of the 1992 *Rio Declaration on Environment and Development*, and the approach that it represents are consistent with today's regulatory practices in the field of environmental protection in Canada. This is expressed in a number of documents including a commitment by the Government of Canada in the preamble of the *Canadian Environmental Protection Act*. **Actions:** 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. **Timeline: Initiated, report on progress by May 2002.** All Regulatory Departments and Agencies: Uphold and reinforce regulatory tenets of mandatory pre-market notification and a prudent process of science-based assessment for the potential risks of the introduction of new biotechnology products as food or feed or into the environment. **Timeline: Initiated** 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 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**. Timeline: Initiated, report on progress by January 2002.** In addition, the following two action items identified in the previous section also apply:	Science always contains uncertainty that must be assessed, communicated and managed. The Government believes that appropriate precautionary measures should be implemented where there is reasonable scientific evidence that a risk to health or the environment exists, even if a cause and effect relationship cannot be fully established. In Canada, developers are required to notify the government prior to import, to conducting field trials and to marketing of products of biotechnology. This allows scientific evaluators to assess the risk associated with the proposed activities. In their reviews of GM-food and GM-organisms, federal regulators do not presume new technologies are safe; on the contrary, they carefully examine the information and data submitted to us by developers. These assessments are scientifically-based. Burden of proof: The burden of proof for demonstrating the safety of a specific GM-product is with, and will remain with, the proponent of the product. Regulatory agencies work with internal and external experts, both nationally and internationally, in order to establish the protocols for product assessments. In-house expertise is in place to ensure that the review of information submitted is detailed and complete. It remains the responsibility of the product proponent to carry-out (or assemble) and document the extensive research and testing that is required to demonstrate the safety of the product. As noted previously, products are not approved until all questions or concerns

Use of Precaution	Planned Actions	Context/Discussion
precaution before a fuller scientific picture was available. *8.5 Regulatory action in accord with the Precautionary Principle means the imposition of more "conservative" safety standards with respect to certain kinds of risks. Where there are health or environmental risks involving catastrophe scenarios (e.g. the potential effects of global warming), the greater the case for more conservative safety standards such as "zero-risk" or low threshold standards, such as that of "substantial equivalence", as articulated above. In the Panel's view, when "substantial equivalence" is invoked as an unambiguous safety standard (and not as a decision threshold for risk assessment) it stipulates a reasonably conservative standard of safety consistent with a precautionary approach to the regulations of risk associated with GM-foods.*	CFIA 1. 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. **Timeline: Initiated, report on progress by January 2002.** HC 2. HC is also committed to update its *Guidelines for the Safety Assessment of Novel Foods* published in 1994. **Timeline: Report on progress by May 2002. Completion anticipated by September 2002**.	regarding the safety of the product are addressed by the proponent. During the course of an assessment, regulators may determine that additional testing is required. This additional work is typically carried out by the product proponents consistent with government's requirements.

Transparency and Increasing Public Confidence	Planned Actions	Context/Discussion
4.11 The Panel recommends that the Canadian Nutrient File should be updated to include the composition of GE foods and be readily available to the public. *6.1 To the extent that the existing regulations, such as those under the Canadian Environmental Protection Agency and the Canadian Food Inspection Agency Acts (Chapter 3), call for ecological information on the fate and effects of transgenic biotechnology products on ecosystems, the Panel recommends that this information should be generated and should be available for peer review.* *6.8 Research data from experiments conducted by industry on the potential environmental impacts of GM plants used in Canadian Environmental Protection Agency assessments should be made available for public scrutiny.* *6.11 An independent committee should evaluate both the experimental protocols and the data sets obtained before approvals of new plants with novel traits are granted.*	We agree with the need for and the benefits of the recommendations related to transparency and increasing public confidence. We will also exercise great care to maintain our objective and neutral stance about the risks and benefits of biotechnology in public statements and interpretations of the regulatory process. **Actions:** 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. **Timeline: Report on progress by January 2002**	The regulatory agencies responsible for the assessments of GM-foods are committed to increasing transparency - both with respect to the regulatory process, the product review process and decisions on specific products. At present, websites provide general public information on these issues. We will study systems already in place in other countries (eg. Australia, New Zealand, the UK and the US). We will publish information on the regulatory process with increasing detail. We will add detail to the descriptions of our review process, which often reflect the typical data requirements rather than the maximum data requirements which industry must submit to support the safety of their products. As well, we will develop new fact sheets related to such issues as substantial equivalence and use of precaution. We will

Transparency and Increasing Public Confidence	Planned Actions	Context/Discussion
7.2 Design and execution of the testing regimes of new transgenic organisms should be conducted in open consultation with the expert scientific community. *7.3 Analysis of the outcomes of these tests should be monitored by an appropriately configured panel of "arms-length" experts from all sectors, who report their decisions and rationale in a public forum.* *9.2 The Panel recommends that the Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and the scientific rationales upon which their regulatory decisions are based.* *9.3 The Panel recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non-governmental) and independent panel of experts.* *The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review.* *5.5 The Panel recommends that federal and provincial governments ensure adequate public investment in university-based genomic research and education so that Canada has the capacity for independent evaluation and development of transgenic technologies.* *5.10 The Panel recommends that university laboratories be involved in the validation of the safety and efficacy of GM plants and animals.* *9.1 The Panel recommends that Canadian regulatory agencies and officials exercise great care to maintain an objective and neutral stance with respect to the public debate about the risks and benefits of biotechnology in their public statements and interpretations of the regulatory process*	HC: 1. We will seek ways to improve transparency of the regulatory process for novel foods in Canada, including under the Health Protection Legislative Renewal Initiative. **Timeline: Initiated, report on progress by January 2002.** 2. To prepare and post Novel Food Decision Documents on Health Canada's Food Program website in a timely manner. **Timeline: Initiated, report on progress by January 2002.** 3. We will share information and discuss specific product assessments with other countries as a mechanism to validate HC's safety assessments. **Timeline: Initiated, report on progress by January 2002.** 4. HC proposes to have an external expert sit on its Food Rulings Committee which has the final say on all novel food decisions. **Timeline: Report on progress by January 2002** 5. Work with members of the Expert Panel and other external experts on ways of ensuring continued contributions to the validation of safety assessments. **Timeline: Initiated, report on progress by May 2002.** CFIA: 1. We will publish all decision documents, and will do so in a timely manner. **Timeline: Immediately, report on progress by January 2002.** 2. 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. **Timeline: Initiated, report on progress by January 2002.** 3. We will ensure all regulatory documentation regarding current requirements are easily accessible and complete. **Timeline:**	review information provided on specific products to ensure that we are publishing the most information currently permitted under Canadian laws and regulations. Further, we commit to discussions with industry to encourage the publication of further information. We will also consider regulatory and legislative revision to grant us the authority, where not already provided for, to publish further information while respecting legitimate concerns to safeguard the confidentiality of proprietary information. The Government of Canada recognizes the importance of separating its regulatory and promotional functions. The regulatory agencies involved in approvals of GM-foods try to maintain an objective position concerning the products of biotechnology. We note that CBAC is specifically considering this issue in their consultations on GM-foods and look towards their recommendations. We will also discuss with members of the Expert Panel, other external experts and industry how best to ensure validation of assessments, such as a system of peer review. We will take great care to monitor our conflict of interest with respect to the public debate about the risks and benefits of biotechnology in the public statements and interpretations of the regulatory process. All regulatory departments and agencies have experience with using external expert groups to advise on key issues related to the assessment of broad classes of products (e.g., pharmaceutical-producing crops). In addition, the government regularly seeks input from the scientific community in the development of the regulations and guidelines including the design of testing regimes (international panel of experts

Transparency and Increasing Public Confidence	Planned Actions	Context/Discussion
	Initiated, report on progress by January 2002. 4. We will continue to make spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and the public. **Timeline: Initiated** 5. We will work with applicants to achieve greater openness regarding specific product information. **Timeline: Long term with additional consultation, report on progress by May 2002.** <u>EC:</u> 1. 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. **Timeline: Report on progress by May 2002. Completion anticipated by June 2002** 2. Improve access to all existing guidelines, advisory notes, conditions on website; formats for risk assessment reports currently being revised to facilitate public release. **Timeline: Initiated, report on progress by January 2002.**	convened by EC in 1996). Similarly, the Canadian Agri-Food Research Council (CARC), through its network of CARC members, provincial and regional committees, Canada Committees and Expert Committees, represents an external expert group that can provide advice on these issues for the agricultural sector. Health Canada recently signed an agreement with the Australia New Zealand Food Authority involving the exchange of information relating to the safety assessment of GM-foods. This agreement will enhance evaluation activities related to food biotechnology by providing a means to further validate our assessments. The federal government continues to recognize the importance of genomics research, as demonstrated by funding provided for this activity in recent federal budgets. Regulatory agencies look forward to the information generated by the various genomics initiatives.

Potential Human Health Impacts	Planned Actions	Context/Discussion
Criteria regarding toxicological testing and whole food testing *4.1 The Panel recommends that federal regulatory officials in Canada establish clear criteria regarding when and what types of toxicological studies are required to support the safety of novel constituents derived from transgenic plants.* *4.2 The Panel recommends that regulatory authorities establish a scientific rationale that will allow the safety evaluation of whole foods derived from transgenic plants. In view of the*	We agree with the benefits of providing more detailed information about Health Canada's current regulatory requirements. At present, current protocols require complete toxicological testing - we will make this more explicit in our guidelines and public material. In addition, development of validated whole food feeding protocols where there are multiple changes in the novel food has been recognized as a need by HC, as well as internationally. **<u>Actions</u>:**	Current protocols require complete toxicological testing, including teratology tests, if a novel, non-protein, constituent is present. If a protein or other component is present at a level outside of the currently established range, toxicological testing is also necessary. These analyses follow recognized protocols and are often conducted under Good Laboratory Practices (GLP). Examples of such procedures can be found at http://www1.oecd.org/ehs/ehsmono/#GLP as well as in US regulation FDA21 CFR58. We will add

Potential Human Health Impacts	Planned Actions	Context/Discussion
international interest in this area, the Panel further recommends that Canadian regulatory officials collaborate with colleagues internationally to establish such a rationale and/or to sponsor the research necessary to support its development.	HC: 1. Update and publish Guidelines for Safety Assessment of Novel foods (vol. I+II - microorganisms and plants). The documents will reflect current international developments. **Timeline: Report on progress by May 2002. Completion anticipated by September 2002**. 2. 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. **Timeline: Initiated, report on progress by January 2002**	these details to our guidelines and public material. Furthermore, Health Canada scientists have initiated projects to address research needs in support of the evaluation of future GM-foods. We are also working with international organizations, such as OECD and the FAO/WHO to further develop and refine tools for toxicological assessments and will work with members of the External Panel and other interested parties in these efforts. Health Canada's approach to assess the safety of novel foods is in line with HC's Decision Making Framework to Identifying, Assessing and Managing Health Risks (HC, 2000). Principles of the framework are common with those of similar frameworks developed elsewhere, including that of the US National Research Council. In the latest FAO/WHO expert consultation held in Rome in June 2000, it was agreed that the practical difficulties already identified in relation to the application of conventional toxicological studies to whole food preclude their use as a routine safety assessment technique for genetically modified foods. Nevertheless, development of validated whole food feeding protocols has been recognized as a need by HC, as well as internationally (OECD, FAO/WHO), especially with regard to the nutritional assessment of future novel foods with intended nutritional modification or complex modification. We commit to continuing collaboration with national and international experts in this endeavour. CFIA plant, feed, animal health specialists will continue to support and collaborate with HC on initiatives related to food safety assessment matters.

Potential Human Health Impacts	Planned Actions	Context/Discussion
Alternatives to antibiotic-resistance markers *4.3 The Panel recommends that, in view of the availability of suitable alternative markers, antibiotic resistance markers should not be used in transgenic plants intended for human consumption.*	Regulatory agencies agree with this recommendation, with the clarification obtained from the Panel. **Action:** All: 1. We will work with product developers as well as national and international experts to determine the "state of the art" regarding alternative markers as a tool in the development of new biotechnology products. **Timeline: Initiated, report on progress by December 2002.**	The Panel noted that the current use of antibiotic-resistance markers in genetically-modified foods is not a health or environmental concern and that there was no scientific rationale for changing these products. The Panel recommended the use of suitable alternative markers in newly-developed GM-foods, hence a cessation of the use of antibiotic-resistance markers. Our assessments consider the consequence of the transfer and expression of the antibiotic-resistance marker gene in recipient cells and the clinical and veterinary importance of the antibiotic in question, the level of natural resistance and the availability of effective alternative therapies. Similarly, the new alternatives will need to be stringently assessed as to whether they are environmentally benign and as safe as existing first generation markers which are well-studied and understood by regulators and researchers alike. Canada contributes to the work in this area at the international level. An international guideline for the safety assessment of foods derived from genetically modified plants is currently being developed by Codex Task Force on Foods derived from Biotechnology - a section of this document deals specifically with antibiotic-resistance marker genes. The Canadian Biotechnology Strategy Fund is currently supporting a project entitled "Selectable Marker Gene Project" which involves a collaborative effort by three federal departments - Agriculture and Agri-Food Canada, Natural Resources Canada and the National Research Council.
Allergenicity *4.4 The Panel recommends that the Canadian government*	HC agrees with the benefits of refining the assessment of the potential allergenicity of GM-foods. We welcome expert	Health Canada's approach for safety assessment of GM-foods provides for a comprehensive assessment of

Potential Human Health Impacts	Planned Actions	Context/Discussion
support research initiatives to increase the reliability, accuracy and sensitivity of current methodology to assess allergenicity of a food protein, as well as efforts to develop new technologies to assist in these assessments. This would include further research into the identification, purification, characterization and standardization of common food allergens, as well as their respective antibodies (e.g. monoclonal animal antibodies) which can be used in detection systems; development of reliable animal models of human type IgE antibody responses; identification of specific characteristics which can accurately and specifically identify a novel protein as being allergenic; and development of rapid assays (e.g., dipstick-type assays) for use by food processors and consumers to detect allergenic contaminants. *4.5 The Panel recommends the strengthening of infrastructures, and where none exists, development of these infrastructures to facilitate evaluation of the allergenicity of GM proteins. This could include development of a central bank of serum from properly screened individuals allergic to proteins which might be used for genetic engineering, a pool of standardized food allergens and the novel GM food proteins or the GM food extracts, maintenance and updating of allergen sequence databases, and a registry of food-allergic volunteers. These would enhance the ability of government agencies such as the Canadian Food Inspection Agency to broaden the scope of and its technological ability to detect allergenic proteins.* *4.6 The Panel recommends development of mechanisms for after-market surveillance of GM-foods incorporating a novel protein, if there are data to indicate its effectiveness, to detect the emergence of consumers developing allergies to such food either through increase in total diet exposure over the long term, or occurrence of unanticipated and unpredictable allergic reactions.* *This could include a central reporting registry and/or epidemiological studies to assess changes in frequency, patterns and clinical presentations of allergy-related complaints. The infrastructure in recommendation 4.5 could*	guidance in continuously updating our guidelines as improved tools become available. **<u>Actions</u>***:* 1. We will continue to work with experts, nationally and internationally to improve our assessment technologies. We will also update our documentation accordingly. **Timeline:Initiated**, **report on progress by January 2002.** 2. Through stakeholder consultation, we will update and publish HC's guidelines for the safety assessment of novel foods (vol. I+II). **Timeline: Report on progress by January 2002. Completion anticipated by September 2002** 3. HC 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. **Timeline: Initiated, report on progress by January 2002.** 4. HC is working to establish a surveillance strategy which will permit the identification of undesirable health impacts of biotechnology derived products, including GM-foods. **Timelines: Initiated, report on progress by December 2002.**	the potential allergenicity of novel proteins. The assessment of potential allergenicity focuses on the source of the gene, sequence homology of the new protein to known allergens, the immunochemical binding of the new protein with IgE from the blood serum of individuals with known allergies to the source of the transferred gene, and the physicochemical properties of the new protein. The recent FAO/WHO consultation (2000) acknowledged that for GM-foods, the pre-market safety assessment, which includes considerations of potential allergenicity, already gives assurance that the food is as safe as its conventional counterpart. Furthermore, GM-foods that are found to contain an allergen transferred from the organism which provided the DNA will not be considered for marketing approval unless they can be clearly identified in the marketplace and this identity would not be lost during distribution or processing. Such strategy would consider the utility and need for rapid identification assays. Worth noting is the recent participation of HC in the FAO/WHO expert consultation on allergenicity of GM-foods held in Rome in January 2001. As well, HC has internal research directed in this area and will host an international expert workshop to discuss the development of animal models. Lastly, Health Canada is leading a working group tasked with the development of an annex on allergenicity to complement the *Codex draft guidelines on the conduct of safety assessment of foods derived from recombinant-DNA plants*. To that end, HC has hosted an international technical workshop in Vancouver in the summer 2001.

Potential Human Health Impacts	Planned Actions	Context/Discussion
be used to verify scientifically reports of allergic reactions and detect emergence of allergies to GM proteins. *4.7 The Panel recommends that appropriate government regulatory agencies have in place a specific, scientifically based, comprehensive approach for ensuring that adequate allergenicity assessment will be performed on a GM-foods, utilizing currently available techniques combined with currently available knowledge of the characteristics of the GM protein relevant to potential allergenicity, and updating testing requirements in keeping with new technologies. Any decision not to complete a full and comprehensive allergenicity assessment should be made only after careful consideration of the scientific rationale to support that omission. The decision to approve or not approve introduction of a GM food and the need for labelling should therefore be based on a rigorous scientific rationale.*		HC also 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. The issue of post-market surveillance for allergenicity was discussed at the recent FAO/WHO expert consultation on allergenicity of GM-foods in January 2001. HC will consider the recommendation of the panel along with those of the January 2001 FAO/WHO expert consultation once available for determining future actions in this area. This guidance will be incorporated in Health Canada's approach. Lastly, Health Canada has initiated a study of possible post-market surveillance mechanisms to detect potential negative as well as positive health effects related to GM-products, including GM-foods.
Concurrence of approvals for GM-food crops *4.8 The Panel recommends that approvals should not be given for GM products with human food counterparts that carry restrictions on their use for non-food purposes (e.g. crops approved for animal feed but not for human food). Unless there are reliable ways to guarantee the segregation and recall if necessary of these products, they should be approved only if acceptable for human consumption. If a GM food is found to have acquired additional allergenic properties from gene transfer, then that GM food should either not be marketed, or properly labelled if marketed.*	HC and CFIA support this recommendation **Action:** 1. To formalize current understanding between CFIA and HC to restrict partial approvals of GM-food crops or feeds. **Timeline: Initiated, report on progress by May 2002.**	As part of HC food safety assessments, the potential for allergenicity of a novel food is evaluated. Under the *Food and Drugs Act*, mandatory labelling would be required for a GM-food where there was a concern regarding allergenicity. The CFIA would be responsible to enforce this health and safety requirement as established by HC.
Nutritional assessment *4.9 The Panel recommends that all assessments of GM-foods, which compare the test material with an appropriate control, should meet the standards necessary for publication in a*	We agree that the nutritional assessment will become a critical consideration for future novel foods and feeds with modifications at the level of the nutritional and compositional characteristics. **Action:**	In terms of the composition analysis, HC requires that key components, including nutrients and toxicants, of the modified food which are relevant to health be compared to those of the unmodified counterpart. Applicants are required to submit data that meet peer-

Potential Human Health Impacts	Planned Actions	Context/Discussion
peer-reviewed journal, and all information relative to the assessment should be available for public scrutiny. The data should include the full nutrient composition (Health Canada, 1994) and analysis of any anti-nutrient and, where applicable, a protein evaluation such as that approved by FAO. *4.10 The Panel recommends that protocols should be developed for the testing of future GE foods in experimental diets.*	1.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. **HC, CFIA/Timeline: Initiated, report on progress by January 2002..**	reviewed journal quality standards and to follow recognized testing protocols whenever such protocols exist. Actions taken to improve transparency on specific product decisions should also address this recommendation. For novel feed, applicants are required to carry out or compile assessment data generated through toxicological, nutritional or compositional studies which have been conducted using valid statistical designs. The raw and processed data including statistical analyses are evaluated by regulators. The OECD Task Force of Novel Foods and Feeds are currently developing consensus documents that will provide detailed guidance on key components for the different major crop species. In addition, Canada just hosted an OECD Workshop on Nutritional Assessment of Novel Foods and Feeds in Ottawa in February 2001. Both HC and CFIA experts are actively involved in the work of the task force. The recommendations and conclusions of the workshop will be incorporated in our strategy. Testing of whole foods in animals is well recognized as being difficult, nevertheless it is recognized that such testing may be desirable for certain future novel foods, e.g., those exhibiting significant (intended or intended) changes in the nutritional profile. Through its Genomics Initiative, the Food Directorate of HC conducts several projects, including some specific ones to identification of biomarkers that could be used for the testing of future GM-foods. If a protein needs to be tested to determine digestibility, then a feeding study should be done. So

Potential Human Health Impacts	Planned Actions	Context/Discussion
		far none of the novel foods have warranted the need for feeding studies to be conducted to determine protein digestibility. However, in cases where significant differences in amino acid profile are found or where a protein that is new to the food supply is proposed, then feeding studies to determine digestibility would be required.

Environmental Safety and GM-Plants (Plants with Novel Traits)	Planned Actions	Context/Discussion
5.11 The Panel recommends that Environment Canada and the Canadian Food Inspection Agency establish an assessment process and monitoring system to ensure safe introductions of GM organisms into Canada, according to the intent of the Canadian Environmental Protection Act. *6.2 If environmental risks are a concern for a particular biotechnology product, especially with respect to persistence of the organism or a product of the organism, persistent effects on biogeochemical cycles, or harmful effects resulting from horizontal gene transfer and selection, then the Panel recommends that exhaustive and long-term testing for these ecological effects be carried out.* *6.3 The Panel recommends that, in evaluating environmental risks, scientific emphasis should be placed on the potential effects of selection operating on an introduced organism or on genes transferred to natural recipients from that organism.* *6.4 The Panel recommends that a detailed analysis be undertaken of the expertise needed in Canada to evaluate environmental effects of new biotechnology products and, if the appropriate expertise is found to be*	CFIA and EC agree with the recommendations. CFIA is responsible for assessing the environmental impacts of GM-crops, while EC is responsible for the environmental assessment of products not yet covered under other legislation. On August 29, CFIA completed the process of listing their Acts and Regulations under CEPA, indicating compatibility with CEPA requirements. As well, CFIA is responsible for ongoing inspection and monitoring programs. **Actions:** CFIA: 1. 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. **Timeline: Initiated, report on progress by January 2002.**	Our assessments include such aspects as environmental fate and soil degradation. Risk management options can include, when warranted, a requirement for long-term testing. Neither CFIA, EC, DFO nor HC permits the release of any genetically-modified organism that poses a significant environmental risk. The current assessment includes such consideration. "Effects of selection" is a required information element of the New Substances program under CEPA. The Canadian Biotechnology Strategy Fund is currently supporting a project entitled "Ecosystem Effects of Transgenic Plants" which is a collaborative effort involving the federal departments of Environment Canada, Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency. In 2001, CFIA reviewed its assessment processes in response to the proposal to list four of its Acts and regulations on CEPA's Schedule 2 and/or 4. With the acceptance of this proposal, the CFIA's health and environmental assessments for toxicity are equivalent to and replace CEPA assessments.

Environmental Safety and GM-Plants (Plants with Novel Traits)	Planned Actions	Context/Discussion
lacking, resources be allocated to improving this situation. 6.5 *The history of domestication, and particularly the time period and intensity of artificial selection, of GM plants should be taken into account when assessing potential environmental impacts.* *Species with a short history of domestication should receive particularly close scrutiny because they are more likely to pose environmental risks.* 6.6 *Environmental assessments of GM plants and their particular constructs should pay particular attention to reproductive biology, including consideration of mating systems, pollen flow distances, fecundity, seed dispersal and dormancy mechanisms.* *Information on these life history traits should be obtained from specific experiments on the particular GM cultivar to be assessed, not solely from literature reports for the species in general.* 6.7 *Environmental assessments of GM plants should not be restricted to their impacts on agroecosystems but should include an explicit consideration of their potential impacts on natural and disturbed ecosystems in the areas in which they are to be grown.* 6.10 *Companies applying for permission to release a GMO into the environment should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact as outlined in the current guidelines relating to "substantial equivalence" (e.g. CFIA step 2 on page 12 of the document Regulatory Directive 95-01 and in Appendix 3 of Regulatory Directive 2000-07).*	2. CFIA has begun to increase the number of trained inspection staff to further strengthen existing inspection and monitoring programs for agricultural products of biotechnology. **Timeline: Initiated, report on progress by May 2002.** 3. CFIA actions outlined in other sections of this action plan such as under Transparency and Increasing Public Confidence and Other Recommendations (regulatory research) will also strengthen specific aspects of CFIA's risk assessment for microorganisms, plants and insect resistance management. <u>EC:</u> 1. Continue CEPA Listing Process in cooperation with other government departments, including HC and CFIA. **Timeline**: **Initiated, report on progress by January 2002.** 2. Requirement 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. **Timeline: Initiated, report on progress by May 2002.**	As indicated in the mandate given to the Royal Society, the regulatory departments are very interested in determining the future expertise needed in these areas. As well, the 2001 budget allocation of $90 M to regulatory aspects of biotechnology includes support to such initiatives.

Environmental Safety and GM-Plants (Plants with Novel Traits)	Planned Actions	Context/Discussion
6.12 Standard guidelines should be drawn up for the long term monitoring of development of insect resistance when GMOs containing "insecticidal" products are used with particular attention to pest species known to migrate over significant distances.		

GM-Animals (including Fish) and GM-Feeds	Planned Action	Context/Discussion
5.1 The Panel recommends that the Canadian Food Inspection Agency (CFIA) develop detailed guidelines describing the approval process for transgenic animals intended for: *a) .food production or* *b) other non-food uses* *Furthermore, the Panel recommends that CFIA encourage work with the Canadian Council on Animal Care (CCAC) to engage the scientific community in the development of appropriate scientific criteria for assessment of behavioral or physiological changes in animals resulting from genetic modification. (It is anticipated that applications for GM animals will occur within the next 10 years. It would be advisable to develop the decision process and criteria for each step of the process. The process could then be challenged with a test case)* *5.2 The Panel recommends that the approval process for transgenic animals include a rigorous assessment of potential impacts on three main areas:* *a. the impact of the genetic modifications on animal health and welfare;* *b. an environmental assessment that incorporates impacts on genetic diversity and sustain ability;* *c. the human health implications of producing disease-resistant animals or those with altered metabolism (e.g. immune function).* *Any negative effects on animal health and welfare and the environment would require justification on the basis of significant benefit to human health or food safety.* *5.3 The Panel recommends that the tracking of transgenic animals be done in a manner similar to that already in*	We agree with the recommendations related to livestock animals. **Actions:** HC: 1. Develop and publish guideline volume III on safety assessment of novel foods derived from animals. **Timeline: Report on progress by January 2002. Completion anticipated by September 2002** DFO: 1. 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. **Timeline: Initiated, report on progress by May 2002.** DFO agrees that the potential consequences of genetic and ecological interactions must be considered and that reproductively capable transgenic fish and transgenic aquatic organisms must be kept in secure land-based facilities. DFO agrees that research on interactions between wild and nontransgenic fish is important and is already conducting such work together with related work on transgenic and non transgenic 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. **Timeline: Initiated.** EC: 1. Revise New Substances documentation to ensure that protocols for generating notification data adhere to animal care and husbandry guidelines. **Timeline: September 2002, report on progress by May 2002.**	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. Health Canada is responsible for safety guidelines related to transgenic animals for food production. The *Novel Foods Regulations* require mandatory pre-market assessment for all novel foods, including foods derived from transgenic animals or fish. As well, HC is preparing guidelines regarding the slaughter and disposal of transgenic animals. Current regulatory authority for the environmental assessment of transgenic animals including fish resides in CEPA and the New Substances Notification Regulations. However, the latter does not provide the degree of detail recommended by the Panel nor does it reference assessment of behaviour or physiological changes resulting from genetic modification (the regulations focus on the organism as the agent of potential environmental effect and not on the welfare of the organism itself). In the context of decision-making and the appearance of a reliance on literature reviews alone, the Panel commented on the CEPA New Substances Regulations noting the absence of explicit data requirements pertaining to potential effects of non-microbial transgenic organisms on biological diversity. EC considers that other information and data elements that are required by the regulations do provide the necessary information to make a determination of potential effects on biological

GM-Animals (including Fish) and GM-Feeds	Planned Action	Context/Discussion
place for pedigree animals, and that registration be compulsory. 5.4 *The Panel recommends that transgenic animals and products from those animals that have been produced for non-food purposes (e.g. the production of pharmaceuticals) not be allowed to enter the food chain unless it has been demonstrated scientifically that they are safe for human consumption.* 6.13 *The Panel recommends that a moratorium be placed on the rearing of GM fish in aquatic netpens.* 6.14 *The Panel recommends that approval for commercial production of transgenic fish be conditional on the rearing of fish in land-based facilities only.* 6.15 *The Panel recommends the establishment of comprehensive research programs devoted to the study of interactions between wild and cultured fish. Reliable assessment of the potential environmental risks posed by transgenic fish can be undertaken only after extensive research in this area.* 6.16 *The Panel recommends that potential risks to the environment posed by transgenic fish be assessed not just case-by-case, but also on a population-by-population basis.* 5.8 *The Panel recommends that changes in susceptibility of genetically engineered plants to toxin-producing microbes, and the potential transfer of these to the animal and the food supply, be evaluated as part of the approval process.*	AAFC: 1. Work with other Departments and agency on a tracking system for transgenic livestock and fish (via the Interdepartmental WG on Transgenic Livestock and Fish). **Timeline: Initiated, report on progress by May 2002.** CFIA: 1. The CFIA supports and is collaborating with other departments regarding food or non food uses of transgenic livestock and the risk assessment criteria which need to be considered. As co-chair of the interdepartmental working group on transgenic animals including fish, the government will integrate advice from the Expert Panel and others in establishing priorities for policy development and long term research in support of regulation of such new applications of biotechnology **Timelines: Initiated, report on progress by December 2002.**	diversity. However, when the time comes for the next review of the regulations in the next two or three years, public consultation will be a central pillar of the consultation and will include consideration of specific data elements pertaining to potential effects on biological diversity. There was a 1998 federal workshop on regulating livestock animals and fish derived from biotechnology. Health Canada also recently held an international workshop in March 2001 to discuss safety criteria for the safety assessment of foods derived from transgenic animals and fish. In addition, the Expert Panel on Husbandry of Animals Derived from Biotechnology has published its 2nd report, "*A Working Tool for the Assessment of Animal Wellness*," based on a January 2000 conference. The Expert Panel's efforts to date have recently been joined by the Canadian Council on Animal Care, but from a different angle. The mandate of the Canadian Council on Animal Care is the welfare of animals in research, teaching and testing, while the Expert Panel is focused on the welfare of livestock animals derived from biotechnology in the context of the agri-business setting, addressing the issues facing commercial agriculture. AAFC administers the *Animal Pedigree Act* under which animals in Canada are registered. A process is underway to address additional enhancements that might be needed to ensure comprehensive tracking of transgenic animals and to facilitate input to the regulatory process of the respective Departments and Agencies.

GM-Animals (including Fish) and GM-Feeds	Planned Action	Context/Discussion
		The CFIA is committed to undertaking a leadership role in the development of regulations for transgenic livestock and in proceeding with its development of guidelines to assess such animals. There have been no proposals to rear transgenic aquatic organisms outside of contained research facilities in Canada. DFO is actively developing regulations for the evaluation of aquatic organisms that are products of biotechnology, including transgenic fish. Until these regulations are in force, such applications would be subject to a rigorous approval process by Environment Canada under the *Canadian Environmental Protection Act* (CEPA) New Substances Notification Regulations. DFO is currently building its Risk Assessment capacity to i) ensure that in the short-term, appropriate DFO scientific expertise will be provided to EC in conducting environmental assessments of new substance submissions, and ii) support its more long-term approach to pursue its Fisheries Act, and respective Regulations, as candidate for listing under CEPA. DFO and EC are currently developing a Memorandum of Understanding to ouline respective and shared roles and responsibilities to ensure that issues that may arise from the introduction of new substances such as transgenic fish are addressed proactively. DFO guidelines require reproductively capable transgenic aquatic organisms to be maintained in secure land-based facilities. Data on the efficacy of any technique proposed to effect sterility would need to be assessed and peer reviewed before the use of the

GM-Animals (including Fish) and GM-Feeds	Planned Action	Context/Discussion
		proposed technique is officially approved. As part of the continuing program of regulatory research on transgenic salmon, DFO is conducting research on genetic and ecological interactions between transgenic and non transgenic salmon, including pleiotropic effects that might have an impact on reproductive capability and/or spawning behaviour, feeding behaviour, predator avoidance and survival. The AquaNet (NSERC supported) Network has also funded a project on interactions between wild and non-transgenic cultured salmon.

Other Recommendations	Planned Actions	Context/Discussion
5.6 The Panel recommends that the use of biotechnology to select superior animals be balanced with appropriate programs to maintain genetic diversity, which could be threatened as a result of intensive selection pressure. *5.7 The Panel recommends that a national research program be established to monitor the long-term effects of GM organisms on the environment, human health, and animal health and welfare.* *In particular, plant -microbe interactions that could result in increased exposure to toxins in feed or food, and microbial-animal interactions that could increase exposure to human pathogens in food and water need to be studied.* *5.9 The Panel recommends that a data bank listing nutrient profiles of all GM plants that potentially can be used as animal feeds be established and maintained by the federal government.* *6.17 Identification of pleiotropic, or secondary, effects on the*	These recommendations are fundamental to Canada's commitment that its regulatory system is prepared for the next generation of biotechnology products. **Actions:** 1. CFIA, HC, EC, AAFC and DFO are partners in the identification of mechanisms to improve the coordination and initiation of new research supporting environmental decision-making and focussed in critical areas such as eco-system research and consideration for those priorities as recommended by the Expert Panel. **Timeline: Initiated, report on progress by December 2002.** 2. 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. **Timeline: Initiated, report on progress by December 2002.**	Each department has the responsibility to conduct in-house research to support their regulatory capacity and expertise in order for their regulatory decisions to reflect the latest scientific knowledge. At the same time, we recognize that new developments in regulatory research may be achieved through a variety of means including studies by: ‣ government research institutions working in partnership with regulatory departments and agencies; ‣ external experts as part of on-going research within the academic community or as supported by levels of government, interest groups, agricultural stakeholders such as producers; ‣ industry research supporting product development as may be published in the public domain i.e. reported in peer reviewed literature. • programs to support the maintenance of

Other Recommendations	Planned Actions	Context/Discussion
phenotype resulting from the single gene constructs be a research priority. *6.9* *The Panel recommends that a federally funded multidisciplinary research initiative be undertaken on the environmental impacts of GM plants. Funds should be made available to scientists from all sectors (industry, government and university) with grant proposals subject to rigorous peer review.* *6.15* *The Panel recommends the establishment of comprehensive research programs devoted to the study of interactions between wild and cultured fish. Reliable assessment of the potential environmental risks posed by transgenic fish can be undertaken only after extensive research in this area.* *7.4* *Canada should develop and maintain comprehensive public baseline data resources that address the biology of both its major agroecosystems and adjacent biosystems.* *7.5* *Canada should develop state-of-the-art genomics resources for each of its major crops, farm animals and aquacultured fish, and use these to implement effective methodologies for supporting regulatory decision making.* *9.4* *The Panel recommends that the Canadian Biotechnology Advisory Commission (CBAC) undertake a review of the problems related to the increasing domination of the public research agenda by private, commercial interests, and make recommendations for public policies that promote and protect fully independent research on the health and environmental risks of agricultural biotechnology.*	3. In addition to existing studies (see Item 8 below), CFIA intends to commission additional research by government scientists or external experts in areas related to: • gene flow and fertility • insect resistance management • detection of transgenes in feed and livestock consuming such feed • herbicide resistance • biodiversity and agricultural ecosystem management • detection processes for biotechnology products • allergenicity for occupational and bystander exposure (feed related studies) **Timeline: Initiated, report on progress by December 2002.** 4. We will consider sharing those recommendations with other appropriate federal fora for their consideration such as linking to federal S&T initiatives. **Timeline: Initiated, report on progress by December 2002.** 5. AAFC , in consultation with CFIA, is conducting a broadly-based research study planned for at least 12 years to examine the potential long-term environmental impacts of approved and commercially-available GM crops – e.g. corn, potatoes and canola. **Timeline: Initiated a long-term project with ongoing reporting of interim results.** 6. EC is leading development of a federal strategy on Generating Knowledge to Understand Ecosystem Effects of GMOs. HC, AAFC, CFIA, and DFO are involved in this effort. **Timeline: Initiated, report on progress by December 2002.** 7. A number of research projects relevant to issues raised by the Panel are underway: -investigating flow of transgene between into two closely related wild plants via hybridization, -examining ecological hazards of insect resistance to such transgenes under Canadian field conditions -developing a laboratory technique for predicting the survival of a	genetic diversity and the funding of a national research program for the study of potential long term effects of biotechnology products. Post market surveillance of products previously regulated is part of CEPA but not part of the New Substances program (e.g., s. 70) that requires anyone with information that a substance is toxic to notify the Minister. In addition, under s. 71, the Minister has the authority to gather information on and require testing of substances on his/her own initiative. Most current ecosystem science research on GMOs within EC is short-term in nature and funded on a project basis by external sources, such as Canadian Biotechnology Strategy Fund, EC's share of Budget 1999 $55M investment in federal lab genomics capacity, and EC's share of Budget 2000 strengthening of biotechnology regulatory capacity. With respect to Recommendation 5.6, the government recognizes the importance of safeguarding animal genetic resources for food and agriculture. AAFC works in partnership with non-governmental organizations to further this goal. In the 1999 federal Budget, the government announced $55 Million over three years for federal science based departments and agencies in support of the science of genomics. Agriculture and Agri-Food Canada is using $17 million of these funds for the new Canadian Crops Genomics Initiative. The crops selected for study are canola, wheat, soybean and corn. Knowledge derived will be relevant to regulatory decision making. The government also looks forward to the

Other Recommendations	Planned Actions	Context/Discussion
	recombinant microorganism prior to release into a soil environment -exploring the potential for plant-based remediation and restoration techniques and to evaluate the ecological significance of plant biodiversity in extreme environments All of these projects have only one more year of funding left and are scheduled to wind down in March 2002. The preliminary results of this research will contribute to the further development of the research and monitoring programs contemplated by the proposed Strategy. **Timeline: Initiated, report on progress by December 2002.** 8. To develop and maintain public baseline data resources for agricultural and natural ecosystems, considerable re-investment in biosystematics will be required. The Canadian Biodiversity Information Network with others sponsored a 4-day workshop in Ottawa to develop research priorities for Canada. **Timeline: Immediately, report on progress by December 2002.** 9. Considerable work is already in progress in the area of development of state-of-the-art genomics resources, and more is likely to emerge soon, as Genome Canada centres are established with the infrastructure necessary to undertake large-scale genomics projects. Genome Canada has received an initial $160M; recent announcement by the federal government has topped this by $140M bringing the total to $300M.**Timeline: Initiated, report on progress by December 2002.**	recommendations on the issues of increasing involvement of industry in public research programs which will be provided by CBAC. An interim report was released in August 2001. CBAC will consult with Canadians for 6 months prior to the anticipated release of their final report by early 2002.