Genetically Modified Organisms and Precaution:

Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?

A report on the
Canadian Government's response to the
Royal Society of Canada's Expert Panel Report
Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada

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Executive Summary:

In 1995 the Canadian Government, through its various regulatory bodies, began approving genetically modified organisms (GMOs) for entry into our environment, food system and society. Since that time regulators have been confronted with increased controversy and uncertainty in the science of biotechnology as well as the prospect of many new and complex GM products. In February 2000, the Royal Society of Canada (RSC) convened an "Expert Panel on the Future of Food Biotechnology" at the request of Environment Canada, Health Canada and the Canadian Food Inspection Agency. The RSC is Canada's senior national body of pre-eminent Canadian scientists and scholars. The Panel was asked to evaluate the Canadian regulatory system and the scientific capacity needed to cope with products in the future. The RSC Panel made 58 recommendations for changes to the regulatory system, many of which would have profound implications. The Government responded with an 'Action Plan;' but are the Royal Society Panel recommendations being implemented? What does the future hold for Canadian consumers, farmers and the environment?

Environmental non-governmental organizations and other civil society groups in Canada collaborated with independent university researchers to produce this report in order to return attention to the recommendations of the RSC Panel. If the Canadian Government is to approve new GMOs then it is essential that all of the RSC Panel recommendations be implemented unless valid arguments are advanced for their rejection.

Full implementation of the Panel recommendations means dealing head-on with the risks of GMOs. This requires a tremendous dedication of human and financial resources. But implementation is not just about money and staffing. It is also about the values that are prioritized in regulatory decisions. The Panel called for a precautionary approach to GMO regulation, and made it clear that this approach should not be compromised by the commercial interests of corporations wanting to get new products to market quickly. A precautionary approach means looking carefully before you leap by weighing all options and the potential risks involved. It means that if uncertainties are too great, if you don't have all the facts, or if the appropriate risk assessment science is not yet developed to give you the facts, you don't leap until you have the information necessary to do so with confidence. This approach seems like common sense, but the RSC Panel found that, in 2001, a truly precautionary approach was not in place for GMO regulation in Canada.

This report tracks what the government has done with regard to implementation of the RSC Panel's recommendations in the three-and-a-half years since the original report was released. It finds that while some progress has been made, there is still a great deal that needs to be done before Canadians have a precautionary regulatory system to protect their families and the environment from the risks of GMOs. Because of the limited progress, this report concludes, based on the rationale presented by the RSC itself in 2001 (p.225), that it is time for the Government to finally legislate mandatory labelling for all GM foods. Given that important holes still exist in the regulation of GMOs and that there has been no public debate, consumers must be given the opportunity to avoid the consumption of GM foods.

When it comes to implementing the RSC Panel recommendations, government departments and agencies appear to have taken some of what the Panel had to say seriously. Since their initial Action Plan, they have published a total of six reports on their progress in trying to meet the Panel's recommendations, and, in a few cases, have risen to the challenge and succeeded in meeting expectations. For this they are to be commended. However, in the case of most of the recommendations, government actions fall far short of what the RSC Panel called for.

Government actions can be divided into four general categories: Actions which fully address the RSC Panel recommendations; Actions for which minimum requirements are not yet met; No demonstrated action taken; and Actions where significant government effort still fails to represent a precautionary approach public safety and environmental protection. The following is a summary of some of the key actions that fall into each of these categories.

Actions which address Royal Society Panel recommendations:

- Both GM food and animal feed crops are now approved concurrently. This action is intended to eliminate the prospect of contamination of the human food supply with animal feed crops not approved for human consumption -- as happened in the United States in 2000 when a variety of corn (StarLink™) that was approved for animal consumption found its way into the human food chain (USFDA 2000).

- A peer-reviewed research program on the interactions between transgenic and wild fish is underway.

Some action taken, but *minimum* requirements not met:

- There have been no meaningful efforts to incorporate independent, arms-length, peer reviews of regulatory decisions, even though the Canadian Food Inspection Agency's website readily admits: "Peer review helps scientists and other readers distinguish between reputable scholarly work and work that is flawed or not of high quality" (CFIA 2004a).

- Nutritional data for GM food decisions and experimental data for GM crop regulatory decisions are still not made publicly available, even though similar data on pesticide approvals are now required to be made available to the public under the 2002 Pest Control Products Act.

- Government departments and agencies have not yet acknowledged the inherent biases in a regulatory approach based on the concept of "substantial equivalence."

- A precautionary approach to food safety and environmental protection is still not institutionalized in regulatory decisions for GMOs.

- An assessment process for GM animals does not yet exist. Instead, experiments continue and accidents have been allowed to happen, inadvertently allowing some transgenic animals into the food chain (CFIA 2004b).

- Comprehensive environmental assessments for GM plants, including assessments of their potential long-term effects, are still not taking place. Instead, the Auditor General has found that some decisions to release GMOs even lack a documentary trail justifying their release on scientific grounds (OAG 2004).

- No moratorium has been established on GM fish approvals and there is still no clear policy to restrict GM fish to land-based facilities.

- Alternatives to antibiotic-resistance marker genes are still not mandated despite the fact that these alternatives do exist and that antibiotic-resistance marker genes have been banned elsewhere on precautionary grounds (e.g. Norway banned them in 1997; Ivars 2002).

- A few research projects have been started to examine the long-term effects of some GMOs on the environment, but there is still no comprehensive, coordinated, national research program on the long-term effects of GMOs in food and the environment as the RSC Panel called for.

<u>No demonstrated actions taken:</u>

- Neither the Canadian Government, nor its advisory body (the Canadian Biotechnology Advisory Committee), have taken action to examine the ongoing domination of the public research agenda by commercial interests.

- Whole food testing is still not part of the safety evaluation of GM foods.

- The government has not taken any action to address potential GM plant/microbe/animal interactions, despite the fact that, according to the RSC Panel, these interactions could result in higher levels of toxins in animal feed (RSC 2001 p.100).

- There have been no government efforts to systematically monitor insect resistance to GM plants designed to be toxic to insect pests, nor has there been any action to ensure compliance with insect resistance monitoring schemes put in place by crop developers at the request of the government.

- There has been no government action to support agricultural genetic diversity conservation despite significant civil society input.

-There has been no new support for research into base-line data for agroecosystems and adjacent biosystems.

Actions where significant government effort still fails to represent a precautionary approach to public safety and environmental protection:

- The allergenicity decision tree demanded by the RSC Panel has been put in place, but it is widely recognized by the scientific community that current tests cannot accurately detect the allergic potential of GM proteins not previously identified as allergens. In order to compensate for these unknowns, government scientists emphasize the need for long-term surveillance strategies. However, such surveillance strategies do not yet exist, and they are almost impossible to implement because researchers cannot distinguish between individuals who consume GMOs and those who do not, due to the lack of GMO labelling.

This report arrives at five key conclusions:

1) **The actions being taken by the government of Canada are not meeting the recommendations of the Royal Society of Canada Expert Panel Report.**

If the government is indeed serious about addressing each of the Panel's recommendations, its Action Plans and Progress Report should establish measurable targets in relation to the original RSC recommendations rather than a list of actions based on its own priorities. We concur with the Canadian Biotechnology Advisory Committee (CBAC) when it stated, in its advisory memorandum of April 2004, that the Federal government should formally and openly commit to implementing, as soon as possible, all of the recommendations of the Royal Society of Canada's Expert Panel in order to strengthen the regulation of genetically modified crops, foods and feeds (CBAC 2004). Regulatory reforms implemented thus far are piecemeal and, in many cases, miss the target set by the RSC entirely. It is important to recognize that many of the RSC recommendations actually conflict with the Government's larger policy direction that supports the biotechnology industry and opposes mandatory labelling. As a result, regulatory changes must be made in concert with new policy directions for the Government of Canada. This will require a larger process of reform and evaluation. To this end, it is crucial that we undertake a full national debate on GMOs and that Parliament finally address the issue of mandatory labelling.

2) **Significant federal government investment in scientific capacity is still required in order to meet the recommendations of the RSC Panel.**

To date, federal investment has been dismal in relation to the high standards set by the RSC Panel. For example, only $350,000 was spent by Environment Canada over two years to coordinate a research strategy aimed at revealing "ecosystem effects of GMOs", as called for by the Panel (CBS 2004a). This funding pales in comparison to government investment in Genome Canada, which amounts to $375 million since its inception in 2000 (Genome Canada 2003). We agree with the RSC Panel that investment in scientific capacity to understand the potential effects of GMOs "should be regarded as a necessary long-term investment" (RSC 2001 p.190). Given current weaknesses in the regulatory

system, new funding should prioritize risk assessment capacity and risk management in the fields of ecology, evolutionary biology and epidemiology.

3) **The government must commit to a truly precautionary approach to the assessment of GMOs in order to meet the high expectations of the RSC panel's recommendations.**

A "conservative" response in the face of scientific uncertainty, as currently recognized in the federal government's Framework on the Application of the Precautionary Principle (PCO 2003), is only one dimension of this precautionary approach. Applying the precautionary principle to GMO assessment requires a comprehensive regulatory process that evaluates specific new crops and foods, as well as new technologies in general, in relation to clear goals for the food system. This assessment must begin with a thorough examination of both the benefits and risks, real and theoretical, of GMOs in relation to alternative means of achieving the same goal. Alternatives would include non-GM technologies as well as management strategies (like integrated pest management and organic farming). A Precautionary assessment must be open and transparent, and must include a clear characterization of potential harms and benefits, as well as the degree of uncertainty associated with these characterizations (Barrett and Raffensperger 2002). This assessment should not only be based only on independently verified experimental data related to health and environmental risks, but also on an examination of socio-economic issues and ethical concerns (i.e. the broader set of issues recognized by the RSC Panel as being critical to the food biotechnology debate; RSC 2001 p.2-9). Precaution would clearly prioritize public safety and environmental protection above industrial development and economic growth. Given the breadth of this type of technology assessment, participation of both the general public and non-government experts in a precautionary assessment of GMOs is critical.

4) **The Government of Canada must take real action to achieve full transparency of regulatory data, and undertake arms-length peer reviews of all regulatory decisions.**

The RSC Panel repeatedly highlighted the importance of peer review and full transparency of the information upon which decisions are made to good scientific practice, yet these recommendations have received almost no concrete action. When it comes to transparency, whistle blower protection, and the development of a public review mechanism for GMOs like that found in the 2002 Pest Control Products Act, are two important steps to be taken. With regards to peer review, we believe that government departments and agencies should work with the Royal Society of Canada as an independent body to establish appropriate peer review protocols for all safety assessments of genetically modified organisms, food and feed. Peer reviews of regulatory decisions are particularly critical at the present historical juncture: GMOs still represent a relatively new innovation; advances in the technology are rapid and complex; and the Auditor General has recently reported that the CFIA cannot even provide the documentary evidence for some of its previous regulatory decisions on GMOs (OAG 2004). We also believe that peer reviews involving members of the RSC and other

independent scientists are appropriate for all stages of regulatory policy formulation that involve scientific determinations of safety.

5) Mandatory labelling of all genetically modified foods is now a necessity.

The RSC Panel considered the question of labelling GMOs in relation to health and environmental risk and concluded that there was not "at this time sufficient scientific justification for a general mandatory labelling requirement." The majority of Canadians have repeatedly called for mandatory labelling but the desire of Canadians for the right to information and choice fell outside of the RSC Panel's focus on examining scientific arguments for labelling (Greenpeace 2002). As a result, the RSC Panel recommended voluntary labelling "premised on the assumption that the other recommendations… concerning the conditions for the effective assessment and management of the risks and GM organisms are fully implemented by the regulatory agencies" (RSC p225). Our report shows in detail that the Panel's recommendations have not been fully implemented, leaving consumers and the environment to bear the risks of inadequately tested GMOs. Given the lack of full implementation, mandatory labeling is now appropriate so that consumers who want to avoid unnecessary risks are able to do so. Some consumers, for example, may be concerned that government scientists admit that risk assessors still lack animal models for assessing GM food allergenicity and that this situation poses "serious problems" for industry and governments expected to assess novel protein allergenicity prior to the marketing of GM foods (Tryphonas et al. 2003 p.221). A further argument for labelling rests on the fact that the RSC recommendations on surveillance and monitoring for long-term health impacts of GM food consumption can only be achieved if consumers are able to distinguish between GM and non-GM foods. In concert with the establishment of mandatory labelling, the government of Canada should also formally address issues of GM segregation from non-GM crops and food and establish traceability mechanisms for all GM products (such as those under development in Europe).

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Introduction:

In February 2000, the Royal Society of Canada (RSC) convened an "Expert Panel on the Future of Food Biotechnology" at the request of Environment Canada, Health Canada and the Canadian Food Inspection Agency. The RSC is Canada's senior national body of pre-eminent Canadian scientists and scholars. The Expert Panel consisted of 15 RSC fellows with a wide range of relevant scientific and policy-related expertise. The Panel was mandated to provide advice on the Canadian regulatory system, and scientific capacity requirements, for products developed through the use of biotechnology. Among its terms of reference, the Panel was asked to specifically consider any 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, and to assess approaches and methodologies developed in Canada and internationally to evaluate the safety of foods being developed through biotechnology.

The RSC Expert Panel released its report "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada" in February 2001 (RSC 2001). The report contained substantive critiques of Canadian regulatory processes and scientific capacity. It concluded with 58 recommendations to address issues in four areas: 1) fundamental policies and principles governing the regulation of biotechnology; 2) specific regulations and guidelines; 3) the regulatory process itself; and 4) scientific capacity for the regulation of food biotechnology.

For the purpose of "enhancing regulatory rigor", the government of Canada, led by Health Canada, responded to the Royal Society of Canada Panel in November 2001, with a detailed Action Plan "to address each of the recommendations" (CBS 2004b). The government has since published six progress reports (January 2002, May 2002, December 2002, June 2003, December 2003, August 2004) as well as a report from an April 2002 "Technical Discussion on the Health and Safety Aspects of the Government of Canada Action Plan." Two more progress reports are expected (December 2004, June 2005). In each of these reports, government departments and agencies have summarized the steps that they are taking to implement the RSC Panel recommendations.

To date, the Royal Society of Canada Expert Panel report remains the most comprehensive and respected overview of Canadian regulation of Genetically Modified Organisms (GMOs). Until now, however, there has been no comprehensive review of the government's actions in response to the Panel's recommendations. The purpose of this report is to assess the actions and progress of Canadian government departments and agencies in relation to the RSC Panel's original recommendations. The dialogue established between the RSC Panel report and the government through its Action Plan and progress reports provides a rare opportunity to examine the way that federal departments and agencies understand and engage with a series of critical issues related to the regulation of GMOs. The aim of this report is to contribute constructively to this dialogue.

Methods:

This report is the result of a comprehensive review of the Royal Society of Canada Expert Panel report, the government Action Plan and progress reports, documents made available from government websites and through Access to Information, as well as reports from the Canadian Biotechnology Advisory Committee, Genome Canada, Office of the Auditor General, and relevant civil society organizations. The main body of this report consists of a table with three columns. The first column lists the RSC Panel recommendations. The second column summarizes the most relevant government actions proposed and/or taken to address the recommendation, along with relevant outcomes. (Where there was repetition between the government progress reports, outcomes presented in the most recent reports are referred to). The third column states whether or not the recommendations have been met and outlines any outstanding issues of concern.

The Government of Canada Action Plan consolidated and reorganized the RSC Panel recommendations into several broad action categories. This reorganization meant that some of the original recommendations were never actually addressed in the Action Plan. Subsequent progress reports then repeated these omissions, because they only referred back to the first Action Plan rather than to the original RSC Panel recommendations. In other cases, recommendations were addressed in the Action Plan and initial progress reports, but then mysteriously disappeared from subsequent documents.

The body of this report divides the RSC recommendations according to the original four categories presented in the Executive Summary of the Expert Panel's recommendations and presents them in the same order (with the exception of some re-grouping of recommendations for logical consistency). Unlike the Government's Action Plan, this report tracks each RSC Panel recommendation, so subdivisions within each of the four categories are sometimes different from those chosen by the government. For example, this report divides the Action Plan category of "Transparency and Increasing Public Confidence" into three separate sections dealing with "Peer Review", "Transparency and Public Scrutiny," and "Objectivity". This specific division is important because the subject of transparency is consistently incorrectly correlated with "public confidence" in the government Action Plan and subsequent progress reports, rather than being recognized as an issue of democratic accountability.

Acronyms used in the table:

AAFC Agriculture and Agri-Food Canada
AP Government 2001 Action Plan
CFIA Canadian Food Inspection Agency
DFO Department of Fisheries and Oceans
GM Genetically Modified
HC Health Canada
PR Government Action Plan Progress Report
RSC Royal Society of Canada Expert Panel on the Future of Food Biotechnology

Panel Recommendations	Government Stated Actions and Outcomes	Outstanding Concerns
A) Recommendations Concerning Underlying Policies and Principles Guiding the Regulation of Agricultural Biotechnology		
Use of Substantial Equivalence:		
7.1 The Panel recommends that 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. 8.1 The Panel recommends the precautionary regulatory assumption that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe. The Panel rejects the use of "substantial equivalence" as a	The government agrees that GM foods and the organisms from which they are derived should be subject to rigorous scientific assessment, and that Substantial Equivalence should be used as a safety standard and not as a decision threshold (AP 2001 p.4). <u>Actions:</u> Update information to avoid confusion around how Substantial Equivalence is used by Health Canada and the CFIA (AP 2001 p.12). Update Health Canada and CFIA guidelines and protocols to reflect the latest scientific developments - make international guidance on Substantial Equivalence accessible through government websites (AP 2001 p.12). Participate in international efforts to refine	Health Canada and the CFIA have made an effort to provide clear information about the way that they consider scientific data in order to assess the safety of transgenic organisms. However, one central issue of concern to the RSC Panel has never been addressed by either Health Canada or the CFIA. According to the Panel, there are cases when a determination of substantial equivalence appears to have been made on the basis of assumptions that "no changes have been introduced into the organism other than those directly attributable to the novel gene" (RSC p.182). This practice can allow unanticipated effects of the genetic engineering process to be missed in the safety assessment. In the Panel's view, a "safety standard" determination of substantial equivalence would require rigorous scientific investigation to establish that "the new food does not differ from its existing counterpart in any way other than the presence of the single new gene and its predicted phenotypic change. In every other way, phenotypically and in terms of its impacts on health and environment, it will have been demonstrated to be identical to the existing food" (p.182). Substantial equivalence (in the context of food safety) must be based on a detailed examination of the novel organism and its conventional comparator at four levels: DNA structure (including a search for unanticipated insertions); gene expression; a proteomic

decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities because such a regulatory procedure is not a precautionary assignment of the burden of proof.	approach and further develop analytical tools for evaluation of complex novel foods (AP 2001 p.12). <u>Outcomes:</u> Health Canada's revised guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms are almost finalized, and reflect guidance recently adopted by the Codex Alimentarius for risk analysis on the safety and nutritional aspects of food derived from biotechnology (PR 2003b p.2). Health Canada made a significant contribution to the development of these Codex documents, which "include considerations for a comparative approach that is consistent with the concept of substantial equivalence articulated in the report of the Royal Society of Canada" Health Canada's website has been updated (PR 2003b, p.2-3). CFIA Regulatory directives for plants with novel traits and novel feed have been updated (PR 2003 b p.4). CFIA documentation has been revised to clarify how "novelty" is used as a regulatory trigger and clarifies actions required in specific cases such as	analysis; and secondary metabolite profiling (rather than a standard proximate analysis)(p.187-189). Rather than accept the RSC Panel's concern that determinations of substantial equivalence may have been made too quickly in the past, and work to correct this practice by ushering in an institutional value change coupled with more rigorous data requirements and peer reviews of that data, Health Canada has denied the existence of a problem. In a 2001 letter to the President of the RSC, retrieved through an Access to Information request, the Deputy Minister of Health Canada argued that the RSC Panel may have had a "fundamental misunderstanding" of Health Canada's application of substantial equivalence since his department does review scientific data in determining substantial equivalence (including molecular biological data, composition, possibility of toxins, allergens, etc.; Green 2001). In their response, the Chairs of the RSC Panel write that Health Canada never provided the Panel with "sufficient information to allow us to assess the extent or rigour of the protocols used" (Brunk and Ellis 2001). Furthermore, "it did...appear that examination of molecular biological data during the Health Canada assessments did not routinely extend to possible pleiotropic [secondary] impacts of the transgene" (ibid.). Health Canada and the CFIA have yet to acknowledge the seriousness of the RSC Panel's challenge to their use of substantial equivalence. There is no evidence that departments and agencies make determinations of substantial equivalence based on the level of detail and scientific rigour called for by the RSC Panel. (For more detail see CIELAP 2004 or Andrée 2002)

	intraspecies/interspecies crosses, re-transformation and re-mutation of approved plants with novel traits and intentional gene stacking (PR 2003b, p.5). CFIA has been working to improve communication with developers and importers of Plants with Novel Traits in order to improve understanding of the use of "novelty" as the regulatory trigger (PR 2004 p.2). CFIA and Health Canada staff participated in several international meetings focused on the assessment of new GM foods and feeds including a meeting of the International Life Sciences Institute designed to develop assessment criteria for the "second generation" of biotech foods and feeds (PR 2004 p.2).	With regards to developing new regulatory approaches, it is important that government scientists participate in international efforts. However, it is disturbing to see that some of the efforts Canadian government scientists participate in are actually organized by the private sector itself. For example, the International Life Sciences Institute, which hosted a workshop designed to develop assessment criteria for "second generation" biotech foods that Canadian government scientists participated in, is primarily funded by the worlds largest food and biotechnology companies (ILSI 2004).
Precaution:		
8.2 The Panel recommends that the primary burden of proof be upon those who would deploy food biotechnology products to carry out the full range of tests necessary to demonstrate reliably that they do not pose unacceptable risks. 8.3 The Panel recommends	<u>Actions:</u> All Departments and Agencies need to 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 (AP 2001 p.14).	The government's effort to clarify uses of the precautionary approach in the new *The Framework for the Application of Precaution in Science-based Decision Making about Risk* is a small step towards realizing precautionary decision-making in risk analysis of GM organisms, food and feed. However, the government needs to take several more steps before the RSC Panel's recommendations are fully addressed. First, there is nothing in the federal Framework that requires a precautionary approach be taken in the assessment of transgenic organisms (or in any other area, for that matter).

that, 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. 8.4 As a precautionary measure, the Panel recommends that the prospect of serious risks to human health, of extensive, irremediable disruptions to the natural ecosystems, 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.	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 (AP 2001 p.14). 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 (AP 2001 p.14). <u>Outcomes:</u> The Government of Canada released *The Framework for the Application of Precaution in Science-based Decision Making about Risk* in July 2003. This framework outlines five principles for the application of precaution: 1. The application of precaution is a legitimate and distinctive decision-making approach within risk management; 2. It is legitimate that decisions be guided by society's chosen level of protection against risk; 3. Sound scientific information and its evaluation must be the basis for applying precaution; the scientific information base	Instead, the Framework outlines how precaution <u>can</u> be implemented consistently. Given the severity of potential consequences (the introduction of potential new food allergens, invasive weeds, etc.), a precautionary approach should be the norm when it comes to the introduction of transgenic organisms into the environment and food system. Regulations and guidelines governing GM products must be revised to clearly state that approvals will not occur until scientific uncertainty is reduced to minimum levels. And, as noted by the RSC Panel, in cases that are potentially catastrophic (such as the escape of transgenic salmon from aquatic netpens) a more conservative "zero-risk" standard is appropriate (RSC 2001 p. 207; CIELAP 2004). Second, whereas the federal Framework focuses on decision-making in the context of scientific uncertainty, the RSC Panel's discussion of precaution was equally concerned with the possibility of decisions made in the context of incomplete scientific evidence (i.e. ignorance). Assurances of the quality and comprehensiveness of scientific evidence upon which regulatory decisions are based is fundamental to a precautionary regulatory system (RSC 2001 p.197-205). Unfortunately, reviews of regulatory decisions made in Canada reveal major deficiencies in the data upon which decisions to approve GM crops have been made. In one case, a variety of GM canola was approved based on data that was the result of methodologically unsound field studies that were of insufficient scope to assess environmental safety (Abergel 2000). In 2004, an Auditor General's study of the CFIA found "deficiencies in standard operating procedures, a lack of complete documentation, and incomplete data quality standards to guide the evaluation" (OAG 2004 p.2). Because of these kinds of deficiencies in regulatory decision-making, the Panel's recommendations on precaution must be understood in the context of all of its recommendations

8.5 The Panel recommends a precautionary use of "conservative" safety standards with respect to certain kinds of risks (e.g. potentially catastrophic). 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 regulation of risks associated with GM foods.	and responsibility for producing it may shift as knowledge evolves; 4. Mechanisms should exist for re-evaluating the basis for decisions and for providing a transparent process for further consideration; 5. A high degree of transparency, clear accountability and meaningful public involvement are appropriate (PCO 2003).	regarding the need for increased scientific capacity to make informed decisions in the federal government <u>and</u> the critical importance of peer reviewed science. *Canadian regulatory decisions cannot be said to be made in the spirit of the precautionary principle until every one of the RSC recommendations is fully implemented.* Third, the RSC Panel's discussion of precaution notes that the precautionary principle invokes the assumption that "it is better to have forgone important benefits of a technology by wrongly predicting risks of harm to health or the environment than to have experienced those serious harms by wrongly failing to predict them". This RSC Panel risk/benefit judgment is exactly the opposite of the risk/benefit judgments still being made by the CFIA and Health Canada. Currently, the benefits of a technology are accepted at face value based on industry claims, and risk analyses are based on limited experimental data. One way to reverse the value judgment implicit in current regulatory practice is for regulators to undertake comparative assessments of a variety of approaches to solving the same problem that a new transgenic organism is designed to solve, including examination of non-GM technologies and new management regimes (such as integrated pest management and organic farming techniques), and then to consider the benefits and risks of the GM organism (and relevant uncertainties) in this context. (For more detail, see Barrett and Raffensperger 2002)
Peer Review:		
7.2 The Panel recommends that the design and execution of all testing regimes of new transgenic organisms should be conducted in open	<u>Actions:</u> All departments are to examine the approach taken by countries such as Australia, New Zealand, the UK and the	The RSC Panel mentions the importance of peer review in seven different recommendations. Nonetheless, three years after the Action Plan, the Auditor General writes of the Agency: "Other than the Reviewers' Checklist, the [CFIA] has not clearly defined what it means by data 'equivalent to

consultation with the expert scientific community. 7.3 The Panel recommends that analysis of the outcomes of all tests on new transgenic organisms 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. 9.3 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. 6.11 The Panel recommends that an independent committee should evaluate both the	US, which provide for more public and expert consultation (AP 2001 p.15). Environment Canada will 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 (AP 2001 p.17). Health Canada proposed to have an external expert sit on its Food Rulings Committee (AP 2001 p.16). <u>Outcomes:</u> Health Canada is pursuing a pilot project involving a joint submission with Food Standards Australia New Zealand (FSANZ) (PR 2003b p.9). Health Canada signed an agreement with the Food Standards Australia New Zealand (FSANZ) involving the exchange of technical information on GM-food submissions. (PR 2003a p.8). HC's Food Directorate has initiated a pilot project which will invite non-government experts to participate in the Food Rulings Committee's deliberations relating to genetically modified (GM) food submissions. Several experts have committed to participating in the project. The Working Group on External	the standards required for inclusion in peer-reviewed research publication…' [and] we found little direct evidence that the standards in the Reviewers' Checklist had been consistently applied" (OAG, 2004 p.14). With regards to steps the government has taken, the exchange of data between regulators in different countries, such as the project involving Food Standards Australia New Zealand (FSANZ), is to be encouraged; However, the FSANZ pilot project is only aimed at increasing transparency and public participation (PR 2003b p.9). The fact that this project is seen by Health Canada and the CFIA as strengthening peer review by departments and agencies shows a fundamental lack of understanding of the nature of peer review. As a United States National Academy of Sciences report points out, peer review should never be confused with peer input, stakeholder consultation, consensus-building or public comment (NAS 2000 p.113). Peer reviews are only credible when reviewers are technically qualified professionals, independent, and free of conflict of interest. Formal processes which ensure that peer reviews are anonymous and that they are recorded and utilized are also critical (ibid. p.113- 16). This is the process that determines the acceptability and validity of scientific research. Significantly, the CFIA recognizes the importance of peer review in science. Its website states that "peer reviews help scientists and other readers distinguish between reputable scholarly work and work that is flawed or not of high quality" (CFIA 2004a). It is therefore surprising that there are still no formal mechanisms in place to ensure CFIA regulatory protocols, and decisions made under such protocols, are independently (and anonymously) reviewed by other scientists.

experimental protocols and the data sets obtained before approvals of new plants with novel traits are granted. 5.1 The Panel recommends that all ecological information on the fate and effects of transgenic biotechnology products on ecosystems required under existing regulations should be generated and made available for peer review. 5.10 The Panel recommends that university laboratories be involved in the validation of the safety and efficacy of GM plants and animals. 6.1 To the extent that existing regulations, such as those under the Canadian Environmental Protection Agency and the Canadian Food Inspection Agency Acts, 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.	Participation continues to address process issues and anticipates that participation of the experts in meeting discussions will begin in the fall of 2004 (PR 2004 p.6) Environment Canada's multi-stakeholder consultation process on the chemicals and polymers portion of the CEPA New Substances Notification Regulations made eight recommendations concerning options for increasing public access and transparency of the regulatory process, policy, and risk assessment decisions. These will be reviewed for applicability and implementation by the Biotechnology Division (PR 2003a p.9). Environment Canada 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. (PR 2003a p.9).	Environment Canada has also made no substantial moves to establish expert advisory panels other than to say it will consider the possibility and is examining the issue of public access and transparency. Such a process could go on indefinitely. Health Canada's proposal for one external person on the Foods Ruling Committee is a far cry from an "arms-length" independent committee to monitor/review all decisions on GM organisms as called for by the RSC Panel. Health Canada should recognize this proposal as inadequate given its positive experience in 2000 with external expert input in the case of the Endocrine Disrupting Substances Working Group (Health Canada 2000). We believe that government departments and agencies should work with the Royal Society of Canada as an independent body to establish appropriate peer review protocols for all safety assessments of genetically modified organisms, food and feed. These peer reviews should have the final say in safety assessments, and should prioritize the inclusion of independent experts in the fields of ecology, evolutionary biology and epidemiology, given the clear weaknesses of federal regulatory departments in these areas. Scientific experts to participate in reviews should be identified through a consultative process and extensive searches through the scientific literature in order to ensure that both mainstream and non-mainstream scientific opinions are included in areas where there is scientific disagreement.

Transparency and Public Scrutiny:		
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. 6.8 The Panel recommends that 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.	<u>Actions:</u> Health Canada will seek ways to improve transparency of the regulatory process including under the Health Protection Legislative Renewal Initiative (AP 2001 p.16). The government will "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" (AP 2001 p.16). CFIA will publish all decision documents and do so in a timely way (AP 2001 p.16). CFIA will work with applicants to achieve greater openness regarding specific product information (AP 2001 p.17). We will continue to create new information products explaining the regulatory system, and how it works in greater detail (AP 2001 p.17). We will continue to make spokespersons available to make presentations and respond to inquiries by stakeholder groups, the media and the public (AP 2001 p.17).	It is critical that the public get better information on how government agencies actually arrive at decisions regarding the use of GMOs, and the public should be able to take for granted that this information is truthful. To this end, we find it extremely disturbing to learn from the Auditor General in March 2004 that when it comes to some public "decision documents" provided by the CFIA, "the Agency's internal files did not provide a comprehensive record of the analyses that supported the summary information or the conclusions in the public-decision documents. Furthermore, in many cases, the files for the evaluations of unconfined release lacked key documents…" (OAG 2004 p.14) The lack of correlation between publicly available documents and the CFIA's own files reinforces the need for decisions to be peer reviewed as well as transparent. With regard to transparency in particular, the "Biotechnology Notices of Submission Project" (also called the "Biotechnology Transparency Project" on the HC website) is only a tentative and partial step forward. There are five main reasons for this: First, the listing only includes a summary of the contents of the product submission package, including a description of studies performed/data received by the CFIA and Health Canada. It does not grant access to the actual research data on environmental impacts as recommended by the RSC. Second, this project relies on the voluntary cooperation of corporations. As a result, it is possible that some corporations will decline to participate and the public will be left uninformed of all products under review – though the public

	Outcomes: The CFIA ensures that all PNT authorizations are now accompanied by a corresponding decision document. Decision documents on the determination of environmental and livestock feed safety, are posted on the CFIA website (PR 2004 p.9). In August 2003, the CFIA and Health Canada, in co-operation with CropLife Canada, an industry association representing developers of GMOs, launched a pilot project to post Notices of Submission for public viewing on the Internet. These notices describe the product and summarize the scientific information provided for regulatory review to Health Canada and the CFIA. The public has 60 days to provide input on scientific matters relevant to the evaluation of each of these new submissions (PR 2004 p.5). On June 9, 2003, the Minister of Health announced her intention to initiate consultations on the proposal to renew the federal health protection legislation. With respect to transparency, the proposed Canada Health Protection Act would include improved legislative authority regarding the review process for new drugs, genetically modified food and other novel products and will include the	may be lead to believe that they have a complete list. Third, submissions for approval made before the start of the pilot project were not included. For example, Monsanto's Roundup Ready Wheat was not on the list. Fourth, the project includes an invitation to "readers to give their comments on the content of the notices of submissions". This can barely be described as a public feedback component as there are no clear mechanisms for considering incoming comments. Many independent analysts who have routinely written to the CFIA regarding regulation have little faith in the ability and willingness of the agency to seriously consider their comments and, without clear mechanisms to consider and incorporate such public feedback, are unlikely to accept the invitation to comment. Additionally, in the progress reports, Health Canada clarifies that they are soliciting "input on scientific matters" only rather than on all matters that might be of concern to the public (PR 2003b). This unnecessarily limits the scope of public consultations. Finally, CropLife Canada members were extensively consulted in order to establish this pilot project. There were no consultations with civil society groups or scientific critics that we are aware of. We believe that when government agencies evaluate the pilot project, it is critical that they engage civil society organizations and independent scientists in this evaluation. With regard to the renewed Health Protection legislation, HC's proposals raise the issue of transparency, but give no indication of which direction the government will take (HC 2004c). Past experience suggests that transparency will not increase under a new Health Protection Act. While Health

	authority to make the process more transparent. (PR 2004 p.6-7). The CFIA has published numerous fact sheets including a fact sheet on the data required in assessment. Health Canada's Food Directorate is pursuing a pilot project to work with Food Standards Australia New Zealand (FSANZ) on reviews of submissions using FSANZ's submission review procedure (where safety data are disclosed and public input is sought at two stages prior to final decision making). The Directorate is looking for proponents who would volunteer to participate in the pilot project (PR 2003b p.9; PR 2004 p.5).	Canada does have the authority to collect, use and disclose information in the public interest, it typically chooses to accord an extremely high degree of proprietary confidentiality to test data provided by industry as well as its own scientific data. The Minister of Health's own Science Advisory Board, in a 2000 report on the drug review process, concluded that the current process is "unnecessarily opaque… Health Canada persists in maintaining a level of confidentiality that is inconsistent with public expectation and contributes to a public cynicism about the integrity of the process." (SAB 2000). On the positive side, the Health protection renewal legislation proposals do suggest the possibility of a dispute mechanism regarding transparency and access to information. We believe the FSANZ model of consultations (one public consultation after FSANZ has done a preliminary assessment of the submission received, and a second after the assessment of the safety data submitted is complete and the proposed decision put forward for consideration) offers some hope of enhancing transparency if the invitations for public engagement are accompanied by mechanisms to actually consider and incorporate public comment. We recommend that Health Canada look to its own 2002 Pest Control Products Act (PCPA) for a model that increases transparency. While still withholding some confidential business information (CBI), the PCPA restricts the scope of CBI so that the public can access detailed evaluation reports on registered pesticides as well as view the test data on which these pesticide evaluations are based (HC 2002). This Act is not perfect, but the PCPA is an important step forward for the pest management regulatory system in Canada (Boyd 2002. p.121). A final critical step the government must take to increase

		transparency and public scrutiny is to ensure that existing "whistle blower" legislation is enforced within the agencies and departments involved in the approval of GMOs in Canada (for example section 16(4) of the Canadian Environmental Protection Act; CEPA, 1999) and that new legislation be introduced which strengthens whistle blower protection in Canada. The recent dismissal of three Health Canada scientists who spoke out previously on sloppy science and industry influence in the evaluation of recombinant Bovine Growth Hormone (rBGH) suggests that whistle blowers are not adequately protected in Canada at this time (CBC 2004).
Objectivity:		
5.4 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.	Action: The Government of Canada recognizes the importance of separating its regulatory and promotional functions (AP 2001, p.16). 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 (AP 2001 p.16). Outcome: No specified outcomes.	The CFIA has taken strides to temper their language and use less biased portrayals of biotechnology in its public documents but fundamental issues of conflict of interest remain unresolved and this affects the ability of the Agency to communicate without bias. Most importantly, the dual role of the Minister of Agriculture as both regulator and promoter continues to undermine the objectivity and neutrality of the Government of Canada when it comes to the regulation of GM crops. On the one hand, Agriculture and Agri-Food Canada actively promotes biotechnology. For example, in 2003 it was revealed (through Access to Information rather than public disclosure) that AAFC had been engaged in helping Monsanto develop its Roundup Ready Wheat, and was therefore in a position to receive royalty payments on the product if approved and commercialized. On the other hand, the Minister of Agriculture is also ultimately responsible for product reviews under the auspices of the CFIA. Such conflicts will continue to arise as long as the CFIA reports to the Minister of Agriculture rather than the Minister of the Environment and

		while Agriculture and Agri-food Canada partners with the biotechnology industry at federal research stations across the country. In its factsheet "Promotion and Regulation: Different and Distinct Government Roles", the CFIA states that "no CFIA employee is involved in the economic promotion of agricultural products or foods." Nonetheless, the role of the CFIA in describing the regulatory process in order to instill public and industry confidence often blurs the line between regulation and promotion. For example, at a CFIA workshop at the major industry conference BIO2002, CFIA regulators presented consumer polling results and a document that states: "Canada provides a relatively benign and in some ways quite positive environment for biotechnology development" (BIO2002). The session concluded "with a discussion on the evolution of Canadian consumer perspectives through the last decade, including communications and how they have changed." During the session regulators reassured the industry audience that, "labeling is not a top of mind issue for consumers" (Sharratt 2002). In this example, the CFIA is clearly promoting Canada as a place for the biotech industry while reassuring industry representatives that mandatory labeling would not be an obstacle for them even though the labeling issue is far from resolved in Canada.
Domination of Public Research Agenda by Commercial Interests:		
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	<u>Actions:</u> None taken. The Government lists this recommendation under the category "other recommendations" in the 2001 Action Plan	The lack of any action on this recommendation by either CBAC or government departments is a major concern. As the RSC Panel notes, the "co-opting of biotechnological science by commercial interest contributes to the general erosion of public confidence in the objectivity and independence of the science behind the regulation of food biotechnology… The RSC Panel considers this to be a serious public policy issue

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.	(AP 2001 p.30). No actions are outlined. CBAC has not specifically dealt with this recommendation.	related to the public funding of independent research in the universities…" (RSC 2001 p.217). Federally funded Genome Canada did raise and problematize this issue at its GE^3LS 2004 Symposium February 5- 7 (GE^3LS is the Genome Canada group that examines the ethical, environmental, economic, legal and social issues related to genomics research). However, it is not engaged in a substantive or ongoing discussion of the issue. (Sharratt, 2004). The lack of further discussion on the part of Genome Canada is significant given that this organization commits major funding to biotech research but only provides up to half of the research funds to any particular project, with the rest coming from other public or private partners. (Biotechnology Focus, 2001). Government funding directed to genetics research through the National Research Council, National Sciences and Engineering Research Council, Canadian Foundation for Innovation and other bodies also requires private sector partners for matching funds (Polaris Institute 2003). There is a broadly held concern, shared by the Canadian Federation of Students among others, that independent science in Canada is under threat at our public universities as a result of increased private sector funding (CFS 2004). The Federal Government must address this concern in relation to its commitment to genomics research and the biotech industry through its "Innovation Agenda."
B) Recommendations Concerning Regulations and Guidelines		
Toxicology Testing:		
4.1 The Panel recommends	<u>Action:</u>	Section 4.1.3.6 of Health Canada's (2003a) new draft

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.	Health Canada will work at the national level and in collaboration with international organizations such as OECD and the FAO/WHO to further develop and refine tools for toxicological assessments (AP 2001 p.18) <u>Outcome:</u> Health Canada has updated and published its draft Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms which include changes to the sections on toxicological considerations (Health Canada, 2003a).	Guidelines on Toxicology Considerations begins to deal with the RSC Panel concerns. This section states that, "toxicology studies are not considered necessary where the substance or a closely related substance has been consumed safely in food at equivalent intakes or where the new substance is not present in the food. Otherwise, the use of conventional toxicology studies on the new substance will be necessary." We believe that the Panel would likely concur with this distinction, as long as the compositional analysis of the GM food compared to a traditional food does demonstrate, with sufficient certainty, the equivalence of the genome, proteome, and metabalome (RSC 2001 p.46). Section 4.1.3.6 also considers the question of unintended effects of genetic modification, another issue raised in the RSC Panel report (p.47). The Guidelines note that, "because of the influence of environmental stress on production of endogenous components such as toxins and anti-nutrients, data should be collected from a number of different test sites." Furthermore, "new, more sensitive technologies that allow the determination of alterations to expression of the organisms' genome are presently under development." Health Canada should continue to support the development of these technologies in order to achieve the safety standards required by the Panel's recommendations.
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	"Regulatory agencies agree with this recommendation, with the clarification obtained from the Panel" (AP 2001 p.19). (The clarification obtained is that the Panel did not consider current uses of these markers an immediate health or	No action has been taken to date to require alternatives to antibiotic resistant markers, despite the fact that alternative markers were already available when the RSC Panel produced its report in 2001. As a result, the CFIA and Health Canada continue to approve new GM foods and plants engineered with antibiotic resistant marker genes (e.g. Monsanto

human consumption.	environmental concern, but believed that alternatives would be better in the long-term (AP 2001 p.19). Action: 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 (AP 2001 p.19). Outcomes: Health Canada solicited comments on the use of antibiotic resistance marker genes as part of its consultation on the new Guidelines for the Safety Assessment of Novel Foods. The comments are being reviewed (PR 2004 p.10). Currently, there is no mention of antibiotic resistance marker genes in the Draft Guidelines (Health Canada 2003a). The CFIA commissioned a survey and literature review of current research on alternative selection markers for transgenic plants. This paper was published in the Journal of Biotechnology in February 2004 (PR 2004 p.10).	Canada's Insect Resistant Corn Line Mon 863 approved March 5, 2003; CFIA 2004c).
Concurrence of Approvals for GM-Food/Feed 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.	Health Canada and the CFIA support this recommendation (AP 2001 p.21). Action: To formalize current understanding between CFIA and Health Canada to restrict partial approvals of GM-food crops or feeds. Outcome: Health Canada's revised its Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms and the CFIA's revised draft regulatory directives Dir 94-08 and Dir 95-03 now require that approvals be issued simultaneously (PR 2003b p.14). This is also the case for the CFIA's revised draft regulatory directives *94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and *95-03: Guidelines for the Assessment of Novel Feed from Plants with Novel Traits* (PR 2004 p.12).	This recommendation has been fully implemented by the CFIA and Health Canada.
GM Animal Assessments:		
5.1 The Panel recommends that the Canadian Food Inspection Agency (CFIA) develop detailed guidelines describing the approval process for transgenic animals	The need for detailed guidance in the assessment of transgenic animals has been recognized (AP 2001 p.26). Actions:	Health Canada and CFIA activities demonstrate that the government is aware of the need to develop regulations to assess animal health and welfare, undertake an environmental assessment on genetic diversity and sustainability, and assess human health considerations related to GM animal products, as called for by the RSC Panel. (See the report of the

intended for (a) food production or (b) other non-food uses, including appropriate scientific criteria for assessment of behavioural or physiological changes in animals resulting from genetic modification. 5.2 The Panel recommends that the approval process for transgenic animals include a rigorous assessment of potential impacts on three main areas: 1) the impact of the genetic modifications on animal health and welfare; 2) an environmental assessment that incorporates impacts on genetic diversity and sustainability; and 3) the human health implications of producing disease-resistant animals or those with altered metabolism (e.g. immune function). 5.4 The Panel recommends that transgenic animals and products from those animals that have been produced for	Health Canada will develop and publish guidelines volume III on safety assessment of novel foods derived from animals (AP 2001 p. 26). The CFIA supports and is collaborating with other departments regarding food or non-food use 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 RSC Panel and others in establishing priorities for policy development and long-term research in support of regulation of such new applications of biotechnology (AP 2001 p.27). Outcomes: The third section of Health Canada's *Guidelines for the Safety Assessment of Novel Foods*, which is devoted to the safety assessment of novel foods derived from animals, is currently under development In addition to the results of the FAO/WHO Expert Consultation on Genetically Modified Animals held November 17-21, 2003, the new section of Health Canada's guidelines will reflect the findings of a U.S. National Academy of Sciences report on Animal Biotechnology published in August 2002 and input from previous national expert consultations	"Animal Biotechnology Focus Group Meeting"; CFIA 2003a). However, there is still no regulatory system for GM animals. This makes it impossible to determine if government departments and agencies are meeting the RSC Panel's recommendations. As noted by a Canadian Biotechnology Advisory Committee advisory memorandum of April 2004, the "lack of a comprehensive regulatory system for agricultural products of biotechnology has the potential ... to undermine public confidence in the regulatory system...." CBAC concludes: "There seems to be a practice of simply extending the target dates to some never quite attainable date in the future." (CBAC 2004 p.2) We think taking time for broad consultation and scientific debate on these complex and controversial applications would be legitimate but instead we see that the consultations that have taken place on GM animals, government departments and agencies appear to be making the same mistakes that they made in the development of GM plant and food safety assessment protocols in the early 1990s. First, there is virtually no participation by civil society organizations representing the public interest in the process of developing regulations. At the above-mentioned focus group meeting, for example, there was no participation from environmental groups or consumers' organizations, and there was only one representative from an animal welfare group (the Canadian Council on Animal Care – an organization focused on university-based research). Focus group participation was largely restricted to regulators, the biotechnology industry, the livestock industry, and a handful of academics.

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.	organized by Health Canada and other departments in 2001 and 1998. It is anticipated that a consultation on the first draft of these guidelines will take place in 2005 (PR 2004 p.14). Health Canada is working on the issue of regulating foods derived from cloned animals and other GM animals (PR 2003a p.19; PR 2004 p.14). As of September 2003, "developers who wish to use SCNT [somatic cell nuclear transfer] technology for producing food livestock are requested to withhold novel food notifications" (Health Canada 2003b). Health Canada Food Directorate officials met with counterparts from FSANZ and the US FDA to exchange information and collaborate in an effort to facilitate consistent approaches for the regulation and assessment of food products derived from biotechnology (PR 2003a p.20). CFIA has had one round of consultations on "streamlining" the regulatory approach to animal biotechnology (27-28 March, 2003) that involved a range of stakeholders including animal welfare groups. CFIA is working with the Canadian Council on Animal Care as part of the consultation process (PR 2003a p.20-21). The Canadian Council for	Second, the above-mentioned meeting has been presented as an effort to "streamline" the regulatory approach to animal biotechnology (PR 2003a p.20-21). Given that no regulatory approach exists yet, an emphasis on streamlining is entirely inappropriate. This demonstrates the willingness of biotechnology regulators in Canada to look for business-friendly approaches before fully addressing public concerns. Third, in the discussions that have taken place to date, there appears to be an emphasis on "science-based concerns" about animal biotechnology (the title of the US National Academy of Science report mentioned in the latest Progress Report). While these issues are important, it is critical that methods of assessing social, economic, and ethical implications of animal biotechnology in relation to alternate (including non-GMO) means of achieving the same ends must be included in a regulatory system developed for GM animals. Finally, while the current "request" to keep GM animals out of the food system is necessary, in the absence of regulations it is clearly insufficient to protect the food system from contamination. In February 2004, three unapproved genetically engineered pigs were accidentally rendered into animal feed in Québec (CFIA 2004b). A similar incident occurred exactly two years earlier in Ontario involving eleven experimental pigs (CFIA 2002).

	Animal Care (CCAC) has drafted *Guidelines on the use of Farm Animals in Research, Testing and Teaching*, which includes a subsection on livestock derived from biotechnology. As part of the Farm Animal Welfare Sub-committee of the CCAC, the CFIA's Animal Biotechnology Unit (ABU) attended a meeting on May 18-19, 2004, to discuss the draft guidelines (PR 2004 p.16).	
Monitoring Insect Resistance:		
6.12 The panel recommends that standard guidelines be drawn up for the long-term monitoring of development of insect-resistance when GM organisms containing "insecticidal" properties are used, with particular attention to pest species known to migrate over significant distances	<u>Action:</u> No specific actions given to deal with this recommendation. <u>Related Actions:</u> The CFIA does intend to commission additional research by government scientists or external experts in areas related to...insect resistance management [included as one in a list of projects] (AP 2001 p.30). Environment Canada has a research project investigating the flow of transgenes between two closely related wild plants via hybridization that is also examining the ecological hazards of insect resistance to such transgenes under Canadian field conditions (PR 2003b p.24-25).	The development of insect resistance to insecticidal plants (such as Bt plants) is considered a major potential problem by the RSC Panel (RSC 2001 p.140). We recognize that the Plant Biosafety Office has worked with the five companies who have received authorization for Bt crops (Monsanto, Novartis, Pioneer, DeKalb and Mycogen) to develop a standard resistance management plan for farmers to follow that requires 20% refuges of non-Bt corn to be planted within 1/4 mile of any Bt field (CFIA 1999). A similar plan exists for Bt potatoes (CFIA, 2001). However, a 2001 study by the Canadian Corn Pest Coalition shows that only 80% of farmers implement this strategy to the letter (CCPC 2001). A 1998 CFIA audit of potato refuges in New Brunswick revealed that Monsanto was not giving farmers enough information and that refuge areas were being sprayed with insecticide, a practice incompatible with the refuge strategy (Laidlaw, 2001). Finally the Auditor General states that the CFIA's own "audits of conditions for unconfined release of corn have not yet enabled it to fully verify compliance with conditions imposed to prevent insect resistance from developing" (OAG 2004 p.18).

		This information suggests that we still do not know how quickly insect resistance is developing even though the RSC Panel believed it "essential that the question of resistance monitoring be addressed immediately to establish meaningful guidelines for the monitoring of resistance" (RSC 2001 p.141). We can only reiterate the Panel and Auditor General's views that the CFIA must develop guidelines for the long-term monitoring of resistance as well as measures to confirm compliance with insect-resistance strategies.
GM Fish Moratorium:		
6.13 The Panel recommends that a moratorium be placed on the rearing of GM fish in aquatic netpens. 5.14 The Panel recommends that approval for commercial production of transgenic fish be conditional on the rearing of fish in land-based facilities only.	"DFO agrees that the potential consequences of genetic and ecological interaction must be considered and that reproductively capable transgenic fish and transgenic aquatic organisms must be kept in secure land-based facilities" (AP 2001 p.26). "There have been no proposals to rear transgenic aquatic animals 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 EC under CEPA" (p.28).	The government has not established the moratorium recommended by the RSC Panel, nor has it instituted a policy to restrict commercial production of transgenic fish to land-based facilities. The Minister of Fisheries did state, in response to a petition by Greenpeace, that the department, "supports the NASCO [North Atlantic Salmon Conservation Organization] policy statement that the use of transgenic salmon is to be confined to secure, self-contained, land-based facilities" (DFO 2002). However, the Minister also acknowledged, in the same statement, that these guidelines do not have legal force. As a result, the department's position remains ambiguous. This ambiguity does not address the clear recommendations of the RSC Panel on transgenic fish. In the 2001 Action Plan, DFO refers to the potential consequences of "reproductively capable" transgenic fish. This is a reference to efforts to ensure reproductive sterility or triploidy in transgenic salmon. However, it should be noted

		that the RSC Panel does not see such efforts as solutions to the problems posed by transgenic fish, "...given that 100 percent sterility cannot be ensured" (RSC 2001 p.166) and that "a fish need not reproduce with another to negatively affect the other's viability and persistence" (p.162). DFO has an opportunity to establish a clear policy on land-based rearing when its regulations for GM fish are developed under the Fisheries Act. However, at this point there are still no regulations in place (PR 2003b p.15). This represents an ongoing obstacle to effective biotechnology regulation in Canada, as noted by CBAC (2004).
GM Fish Research:		
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.	DFO agrees that research on interactions between wild and non-transgenic fish is important and is already conducting such work together with related work on transgenic and 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 (AP 2001 p.26). <u>Outcomes:</u> DFO scientists have gathered factual information on transgenic, domesticated and wild salmon populations, as a basis for objective evaluation and risk assessment of genetically modified salmon. Research results on physiological and behavioural	The research on GM fish currently being undertaken by DFO scientists is a good start towards meeting the recommendations of the RSC Panel. Since this work is published in peer-review literature it also meets the quality of research sought by the Panel. However, it is important to recognize that many of the research questions posed by the RSC Panel have yet to be investigated (RSC 2001 p.157-159).

	differences (e.g. disease resistance, ecological effects, effect on predation, and spawning behaviour) and on the linkage between genotype and phenotype expression, have been published in the Journal of Fish Biology and Ethology. Research results have also been presented at several international conferences (PR 2003b p.15-16).	
C) Recommendations Concerning the Regulatory Process		
Whole Foods Safety Evaluation:		
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 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. 4.10 The Panel recommends that protocols should be developed for the testing of	<u>Actions:</u> "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 changes in the nutritional profile" (AP 2001 p.22). "Development of validated whole food feeding protocols where there are multiple changes in the novel food has been recognized as a need by Health Canada, as well as internationally" (AP 2001 p.17). <u>Outcomes:</u> Health Canada's revised Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms	While Health Canada recognizes the need for whole food testing of GM foods, and is planning an international workshop to consider the issue, there is no mention of whole food testing protocols in the revised Guidelines for the Safety Assessment of Novel Foods. Instead, section 4.1.1.4 (Toxicology Considerations) of the Draft Guidelines states that, "the conduct of studies with whole foods presents some challenges due to the potential for inducing nutritional imbalances when the food is incorporated into the diet at high concentrations. In addition, toxicology studies on novel foods are used to reach a conclusion as to whether the food is safe to consume under expected consumption patterns, rather than to derive a quantitative limit such as an acceptable daily intake in the manner used for simple chemicals like food additives" (Health Canada 2003a). Rather than develop a rationale for the use of whole food testing, as recommended by the RSC Panel, Health Canada appears to have developed a rationale for not using such tests. *While it is important that HC scientists are part of*

future genetically engineered foods in experimental diets.	take into consideration recent work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (PR 2003a p.10). Health Canada Food Directorate scientists are undertaking a variety of projects to assess long-term toxicological and health effects of soy products (non-GM) and transgenic fish in animal models in partnership with the University of Manitoba, DFO and the CFIA. The ultimate goal of this research is to develop molecular biomarkers that can be used to assess the safety and nutritional quality of future GM-foods (PR 2003a p.10-11). Health Canada is planning to organize and host an international workshop to take stock of and discuss existing methodologies and animal models used for whole-food testing to assess potential nutritional and toxicological effects associated with novel foods, thus addressing the human health and safety issues related to the assessment of safety, nutritional quality and health effects of novel foods (PR 2004 p.10).	*international efforts to develop whole-food testing models, the lack of knowledge in this area underscores the fact that diets which include GM foods remain an experiment in themselves; an experiment consumers would choose to opt out of were GM foods clearly labeled (Greenpeace Canada 2002).*
Post-Market Surveillance:		
4.6 The Panel recommends development of mechanisms for after-market surveillance of GM foods incorporating	<u>Action:</u> Health Canada is working to establish a surveillance strategy that will permit the	Health Canada has taken some action on this recommendation. The Biotechnology Surveillance Project initiated through the Centre for Surveillance Coordination has a mandate to "establish a national surveillance system to

any novel protein.	identification of undesirable health impacts of biotechnology derived products, including GM foods (AP 2001 p.20). <u>Outcomes:</u> The focus of this project has evolved toward the development of a modeling framework which will inform the regulatory decision making process in the pre-market phase as to potential post-market oversight requirements and how best to conduct them. The next stage of work, which is estimated to take about 8 months, is to operationalize the framework (create or adopt software to make it work) and to test it with scenarios from both the food and drugs realm. The framework is designed to apply to any consumer product (not just those derived from genetic modification or bioengineering) (PR 2004 p.12).	monitor human late health effects." Nonetheless, a national surveillance system is not a foregone conclusion, as no country has yet set up such a system and the obstacles to this work are formidable. In October 2002, Health Canada hosted an "International Conference on Post-Market Surveillance of Genetically Modified Foods" at which it appeared to shy away from building expectations that it would establish a national surveillance system (Health Canada 2002b). Major difficulties confronted by HC include the usefulness of existing surveillance strategies as well as feasibility and cost. With regards to usefulness, most surveillance strategies focus on specific health outcomes defined in relation to specific populations (e.g. people with a particular medical condition). Such surveillance is unlikely to discover or track information on unanticipated health effects of GMOs, may not survey the general population, and is unlikely to bring to light chronic health effects. In terms of feasibility, the pursuit of surveillance raises two difficult issues for HC: First, careful surveillance would require more intensive pre-approval health studies (including human clinical trials and other human health studies) than are currently undertaken. Second, well-designed surveillance studies require the ability to isolate populations of people who are exposed to a product from those that are not. In the case of GM foods, this is achieved most easily where GMOs are labelled. Unfortunately, Health Canada's mandate to pursue surveillance is hindered by federal policy against mandatory labelling, and is contradicted by policies that ensure speedy product approval rather than intensive pre-approval health testing. *Until the federal government commits to mandatory labelling and more comprehensive pre-approval testing, HC*

		cannot move ahead to develop a surveillance system. In setting up its Biotechnology Surveillance Project, HC referred to the need to address public concern and skepticism of GM foods. This statement suggests that even though this project has a clear health protection mandate, the government's preoccupation is with public <u>acceptance</u> of GM foods. This preoccupation has the potential to jeopardize any meaningful progress towards surveillance and only adds to public mistrust of HC's efforts. Finally, in developing post-market surveillance and monitoring strategies, it is important for government agencies to be clear on how this information will feed back into regulatory decisions and regulatory policy development. Surveillance and monitoring must be tied to systematic revisions of regulatory decisions and policies.
Allergenicity Testing:		
3.7 The Panel recommends that the appropriate government regulatory agencies have in place a specific, scientifically sound and comprehensive approach for ensuring that adequate allergenicity assessment will be performed on GM foods. 4.4 The Panel recommends that the Canadian government support research initiatives to increase the reliability, accuracy and sensitivity of	Health Canada agrees with the benefits of refining the assessment of the potential allergenicity of GM foods. Health Canada recognizes the need for development and strengthening of infrastructures to facilitate the evaluation of the allergenicity of GM proteins (AP 2001 p. 19-20). <u>Actions:</u> Health Canada will continue to work with experts, nationally and internationally, to improve our assessment technologies. We will also update our documentation accordingly. We continue to participate in	The revised Guidelines for the Safety Assessment of Novel Foods do reflect the 2003 CODEX guidelines for evaluating GM food allergenicity, and thus do ensure that allergenicity assessment will be performed on a GM food "utilizing currently available techniques..." as called for by the RSC Panel (RSC 2001 p.73). However, Health Canada, in concurrence with the RSC Panel, notes that, "there is still no definitive test that can be relied upon to measure directly the allergenic potential of a newly expressed protein in humans" (2003a section 4.1.3.7; see also RSC 2001 p.60). Elsewhere, Health Canada scientists admit that, "although a large number of in *vivo* and *in vitro* tests exist for the clinical diagnosis of allergy in humans, we lack validated animal models of allergenicity. This deficiency

current methodology to assess allergenicity of a food protein, as well as efforts to develop new technologies to assist in these assessments. 4.5 The Panel recommends the strengthening and development of infrastructure 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.	international efforts in this area and welcome the contribution of all experts (AP 2001 p. 20). <u>Outcomes:</u> CODEX guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants were adopted in June 2003. Health Canada's revised Guidelines reflect the guidance provided in these documents (PR 2003b p.13). Health Canada held a workshop on Animal Models of Allergenicity in November 2001. Proceeds were published in *Environmental Health Perspectives* 111:221-251 (PR 2003a p.14). Another workshop was held in October 2003 on food allergen methodologies (PR 2003b p.13). Health Canada made a presentation on the "Current Scientific Challenges Regarding Biotech Safety Assessment at Health Canada" at a workshop of the International Life Sciences Institute (ILSI) in June 2004 (PR 2004 p.12).	creates serious problems for regulatory agencies and industries that must define the potential allergenicity of foods before marketing" (Tryphonas et al. 2003 p.221). Because of the widely acknowledged limitations of testing protocols for allergenicity, it remains fair to say that we do not yet have "adequate allergenicity assessment" for GM foods in Canada as called for in RSC Panel Recommendation 3.7. Health Canada's response to the limitations of allergenicity testing is to focus on a post-market surveillance strategy designed to identify the "undesirable health impacts of biotechnology derived products, including GM-foods" (PR 2003a p.14); see also Tryphonas, 2002). While such surveillance is important, the results of the 2002 surveillance conference reveal that these strategies are unlikely to catch all unanticipated health effects of GM foods (see the section on post-market surveillance above). Using surveillance to bring to light unexpected allergic reactions is also a far cry from the precautionary approach called for by the RSC Panel. Precaution requires that all risks be fully examined before a product is in widespread use, not afterwards. The lack of definitive allergenicity tests anywhere in the world, combined with the lack of effective surveillance strategies, leave consumers in the position of taking risks that they have no desire to take and no real option of avoiding. *This is one reason why we call for mandatory labels on all GM foods.*
GM Food Assessment:		
4.9 The Panel recommends that all assessments of GM foods, which compare the test	"Applicants are required to submit data that meet peer-reviewed journal quality and to follow recognized testing protocols	The RSC Panel was concerned that biotechnology decision documents restrict information about the nutritional composition of novel foods to basic statements about proteins,

material with an appropriate control, should meet the standards necessary for publication in a 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), an analysis of any anti-nutrient and, where applicable, a protein evaluation such as that approved by the United Nations Food and Agriculture Organization (FAO).	where such protocols exist. Action taken to improve transparency on specific product decisions should also address this recommendation" (AP 2001 p.22). "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" (AP 2001 p.21). <u>Actions:</u> Participate in international efforts and seek contribution of experts for the development and validation of whole food testing protocols as well as address nutritional issues (AP 2001 p.22).	fats, ash content, etc. Recent decision documents made available on the Health Canada website continue this practice (Health Canada 2004a). This approach does not make "all information relative to the assessment...available for public scrutiny" as recommended by the RSC Panel. Furthermore, there is no indication in government actions that Health Canada's final assessment actually meets the standards for publication in peer-reviewed journal. (The Auditor General raises these same concerns with regard to the CFIA; OAG 2004 p.14). Peer review, by definition, requires arms-length and anonymous review by peers before a decision is made (See section on Peer Review above). If Health Canada is serious about the quality of the data submitted by applicants, it should indicate which journal's standards are being met (e.g. Canadian Journal of Plant Science) as each journal has a specific protocol.
Nutrient Profiles:		
4.11 The Panel recommends that the Canadian Nutrient File should be updated to include the composition of genetically engineered foods and be readily available to the public. 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.	"We agree with the need for and benefits of the recommendations related to transparency and increasing public confidence" (AP 2001 p.15). No specific mention of the Canadian Nutrient File.	Because there has been no specific mention of the Nutrient File in progress reports, it remains unclear whether or not the RSC Panel recommendations have been implemented.

Tracking Transgenic Animals:		
5.3 The Panel recommends that the tracking of transgenic animals be done in a manner similar to that already in place for pedigree animals, and that their registration be compulsory.	"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" AP 2001 p.27). <u>Actions:</u> AAFC: Work with other departments and agencies on a tracking system for transgenic livestock and fish. CFIA is assisting EC in regulatory oversight of GM livestock animals, draft of a notification guidance document, the first draft is being peer reviewed inside government. In addition a round of comments will be received from outside experts before they go to broader consultations. <u>Outcomes:</u> A modified registration system is being designed to track transgenic animals taking into account the specific needs of the relevant federal government regulatory bodies and other stakeholders. Discussion	While the development of tracking systems for transgenic animals appears to be underway, contamination events with experimental transgenic animals have continued. In addition to the 2002 accident where experimental GE pigs from the University of Guelph were fed to turkey and chickens in Ontario (CFIA, 2002), in 2004 the Quebec company TGN biotech sent biopharmaceutical pigs for rendering rather than incineration (CFIA 2004b). These contamination events point to an urgent need to monitor experiments taking place with transgenic animals in order to ensure public and environmental health.

	with animal industry groups took place in Ottawa from Oct 18-19, 2002 and March 27 and 28.	
Genetic Diversity Conservation:		
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.	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 (AP 2001 p.30).	Beyond a suggestion that AAFC is working with non-government organizations to further this goal, there are no specific commitments made, despite significant guidance given to government departments by academics (e.g. Milligan 2002) and non-government organizations. For example, in its January 2003 policy document, the Canadian Farm Animal Genetic Resource Foundation (CFAGRF) outlined, in detail, steps to be taken by the Canadian Government to redress the lack of capacity for farm animal genetic resource conservation in Canada. These steps include the establishment of a Canadian Centre for Germplasm Conservation along the lines of the United States National Animal Germplasm Program (CFAGRF, 2003). To date, there has been no response from government to this and other CFAGRF recommendations.
GM Plant/Microbe/Animal Interactions:		
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	<u>Actions:</u> None specified.	There is a lack of demonstrated government response to these two recommendations concerning toxins in animal feed resulting from GM plant/microbe interactions. This is of concern, according to the RSC Panel, because "genetic transformation of plants may have an impact on patterns of gene expression. The resulting changes in the plant's composition, physiology or morphology will influence the populations and species of micro flora associated with the plant and may thereby lead to the introduction of new, or previously less common, toxins into the animal diet" (RSC

feed or food and microbial-animal interactions that could increase exposure to human pathogens in food and water need to be studied. 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.		2001 p.100).
Comprehensive Environmental Assessment:		
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	"CFIA and Environment Canada agree with the recommendations" (AP 2001 p.23). In 2001, The 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 and replace CEPA assessments. "Our assessments include such aspects as environmental fate and soil degradation. Risk management options can include, when warranted, a requirement for long-	Though the CFIA and Environment Canada "agree with the recommendations", their response to the recommendations is to note that RSC Panel concerns are already incorporated in current risk assessment protocols. As a result, proposed government actions focus on ways to increase the transparency of environmental assessments. This approach does not reflect the substance of the Panel's recommendations regarding environmental risk assessment, which are aptly summarized on page 131 of their report: "We recommend that before GM crops are released they should be subjected to a more thorough ecological risk assessment than has been conducted to date" (RSC 2001). There are several reasons for remaining concerned about the environmental assessments undertaken by the CFIA: First, the CFIA requires crop developers to produce data using statistically valid experimental designs and protocols,

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, 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. 6.5 The Panel recommends that 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.	term testing" (AP 2001 p.23). "Effects of selection" is a required information element of the New Substances program under CEPA (AP 2001 p.23). <u>Actions:</u> CFIA will prepare more public information on environmental assessments, field trials, etc. (AP 2001 p.23). CFIA actions outlined in other sections of its action plan will strengthen specific aspects of CFIA's risk assessment for microorganisms and plants.	equivalent to what is required for peer-reviewed publications. However, because there are no peer reviews of regulatory decisions, and because this data is not publicly available, it is impossible to know whether the experimental data provided by companies is generated using ecologically meaningful experimental protocols. Second, the only independent analysis of a CFIA decision document published to date, one which reviews the data Monsanto supplied for its Roundup Ready Canola (GT73), suggests major problems that would preclude the data from being published in a scientific journal. These problems include: poorly performed tests with a lack of duplicate measurements; small sample sizes; uneven comparative scales; inappropriate data pooling; comparison of the parent with varieties other than that subject to the application; a lack of statistical consistency; indiscriminate use of data from trials to support the applicant's claim of substantial equivalence; and conclusions that are not supported by the actual data (Abergel 2000; see also CIELAP 2002 p.35-38). Third, a review of the CFIA's novel food decisions undertaken by the Auditor General suggests that decisions to allow unconfined releases of GMOs are poorly made and improperly documented: "At the time of our audit, the Agency did not have complete, up-to-date, standard operating procedures to guide its evaluation of applications for unconfined release, [and] the Agency's internal files did not provide a comprehensive record of the analyses that supported…conclusions in…public-decision documents" (OAG 2004 p.13-14). Fourth, the Auditor General notes that while the CFIA is required to assess the long-term environmental effects prior to making regulatory decisions on GM plants and other novel

6.6 The Panel recommends that environmental assessments of GM plants 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 The Panel recommends that 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 The Panel recommends that companies applying for permission to release a GM organism into the environment		organisms, "it was not transparent how the Agency evaluates the long-term environmental effects before authorizing unconfined release as legally required" (OAG 2004 p.16). Fifth, Chapter 6 of the RSC Panel report emphasizes the need for environmental risk assessments to rely on experimental data on ecological impacts in a variety of environments (and not just agroecosystems) rather than literature reviews. Because the data submitted to the CFIA to date has normally been collected in confined field trials that were also designed to determine agronomic/silvicultural characteristics, it is fair to assume that this data does not illustrate how the plants grow in natural ecosystems (CFIA 2003b). Finally, the Auditor General's report found that some imported novel plants (particularly ornamental plants) may be escaping regulatory scrutiny entirely. While the OAG could not document specific problems, the report concludes: "There could be unassessed risks to the environment" (OAG 2004 p.22).

should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact.		
D) Recommendations Concerning Scientific Capacity for the Regulation of Food Biotechnology		
Research into Long-Term Effects:		
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. 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.	<u>Actions:</u> Departments will improve coordination and initiation of new research supporting environmental decision-making and focused in critical areas such as eco-system research and consideration for those priorities as recommended by Expert Panel (PR 2003a p.23). A number of research projects relevant to issues raised by the Panel are underway: - investigating flow of transgene between into two closely related wild plants via hybridization - examining ecological hazards of insect resistance to such transgenes under Canadian field conditions - developing a laboratory technique for predicting the survival of a recombinant microorganism prior to release into a soil environment - exploring the potential for plant-based	There has been considerable activity in the area of long-term effects and this work is to be commended. However, no national research program has been established to monitor the long-term effects of GM organisms on the environment, human health, and animal health and welfare as called for by the Panel, and the research which has taken place to date remains limited in scope. A number of Environment Canada, CFIA and AAFC-supported studies have been undertaken looking at environmental impacts of GM plants, the fate of antibiotic resistance marker genes in the environment, etc. Still, the only long-term study on environmental effects currently underway is the Lethbridge study led by Dr. Bob Blackshaw of AAFC. While this study is useful, it only focuses on four crop varieties (2 Canola, 1 corn and 1 potato) in one ecosystem. Furthermore, this study, which was initiated before the RSC Panel report was commissioned, does not deal with human health issues (Swihart, 2000). For its part, Health Canada's research program into the long-term effects of GM food appears to be limited to the development of molecular biomarkers to identify genetically modified components in food (PR 2003a, p.10-11; Health Canada 2004b). While this is

	remediation and restoration techniques and to evaluate the ecological significance of plant biodiversity in extreme environments. CFIA will also commission further research (AP 2001 p. 30-31). Environment Canada is developing a research strategy regarding Ecosystem Effects of Genetically Modified Organisms (EEGMO). If implemented, researchers participating in this initiative will conduct long-term research and monitoring of the effects of GMOs on biodiversity/wildlife, biogeochemical cycling and other ecosystem components. The knowledge generated through the results of this research will be integrated into both policy and regulatory decision making processes and publicly communicated (PR 2002c p.21-22). Research activities within the National Water Research Institute related to the ecological risks posed by the release of GMOs continue. Projects include: the survival and persistence of transgene DNA in the environment and the natural uptake of extracellular DNA from the environment by microbes in aquatic ecosystems (PR 2003a p.24-25). "We will consider sharing recommendations 5.7 and 6.9 with other appropriate federal fora for their consideration, such as linking to federal	also important research, it should only be one component of a comprehensive long-term research project focused on the health effects of GM-foods. Health Canada hosted a workshop in 2003 to develop a common understanding of biotechnology stewardship and the government's role. (Stewardship is understood to be a framework to aid decision making for both biotechnology policy and regulatory activity where all aspects of an issue need to be considered: social, cultural, political, economic, environmental, ethical, technological, health, scientific; Health Canada 2004b). The proceedings of this workshop suggest that this framework is still at a very preliminary stage. Stakeholders other than government departments and agencies as well as a few representatives of the Canadian Biotechnology Advisory Committee have yet to be included in the development of this framework (Health Canada 2003c). There is no indication in these proceedings that an integrated stewardship framework will lead to increased government efforts to undertake long-term research and monitoring. There is no information available on Environment Canada's program intended to understand Ecosystem Effects of GMOs, nor is it clear that civil society organizations were invited to participate. It is clear that this project only received $350,000 over two fiscal years (2002-2004). This shows the low priority the Canadian government has given the issue of long-term research and monitoring of GMOs (CBS 2004a). By comparison, Genome Canada received $375 million from the federal government for undertaking genetics-related research since its inception in 2000.

	science and technology initiatives" (PR 2003b p.20). <u>Outcomes:</u> "Under the Canadian Biotechnology Strategy, a number of initiatives are looking at the capacity and capability to measure long-term ecosystems and health effects of genetically modified organisms" (PR 2003b p.20). In 2003, CFIA funded studies on Gene flow from *Brassica Juncea* to wild mustard, Management of Resistance to Bt in Adult Corn Rootworm, Global Changes in Gene Expression associated with Highly-Expressed Transgenes in *Arabidopsis* and Canola, Physical Modeling of Pollen Dispersal, Emergence Periodicity of Volunteer Canola and Wheat in Prairie Cropping Systems, Environmental Effects of Bt Canola on Non-Target Insects. Also undertaken: a literature review of Development of Common Predictors for Potentially Allergenic elements in Feeds and Fertilizers. Research on Predictors of Dermal and Inhalation Allergenicity has been contracted out. Research on the stability of DNA in rumen and the transfer of transgenic DNA to rumen microorganisms has been supported and several papers have been published on this (PR 2003b p.17-19).

	AAFC, in consultation with CFIA, is conducting a broadly based research study planned for at least 12 years in Lethbridge Alberta to examine the potential long-term environmental impacts of approved and commercially available GM crops... Data is being collected on the effect of crops with novel traits on weed, disease, and insect populations, biodiversity and soil microorganisms, potential gene transfer to other organisms, and economics of crop production" (PR 2003b p.20-21). Environment Canada's Ecosystem Effects of Genetically Modified Organisms (EEGMO) study has identified specific theme areas, analyzed research needs and gaps, and developed a strategy to address such gaps. The draft strategy document has been reviewed interdepartmentally and input from other government departments and agencies have been incorporated (PR 2003b p.21). Health Canada's Office of Biotechnology and Science (OBS) worked on an initiative to look at long term health effects of genetically modified organisms. This project, supported by 2003-2004 Canadian Biotechnology Strategy funds, identified federal capacity and capability to measure long term health effects and it identified external experts that could provide advice to government on these issues (PR 2004 p.18).

	The Federal Government allocated $55 million in 1999 to initiate the development of core R&D programs in genomics in the seven biotechnology departments. Health Canada's Genomics R&D program is committed to funding projects in four areas. One of these areas is the long-term effects on health and safety of GM-foods and other biotechnology products. Research includes a project assessing long-term toxicological and health effects of soy products (non-GM) and transgenic fish in animal models (PR 2003a p.24, 12). Representatives from various federal departments participated in an orientation forum on the assessment of impacts of genetically modified organisms (GMOs) on the environment, human health and society which was held in Québec City in January 2004 as well as a follow-up meeting in June 2004 (PR 2004 p.18). A number of horizontal federal initiatives are currently under way including one on Smart Regulation that touches upon the subject of biotechnology (PR 2004 p.19). The Government is developing a stewardship framework that provides the foundation for an integrated approach to address biotechnology issues. A draft framework will undergo an internal review within the next few months (PR 2004 p.19).

	Under the Canadian Biotechnology Strategy (CBS), a number of initiatives are looking at the capacity and capability to measure long-term ecosystems and health effects of genetically modified organisms. Projects under the 2004-2005 CBS funds have been planned and are currently being approved (PR 2004 p.19).	
Expertise Analysis:		
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 lacking, resources be allocated to improving this situation.	"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" (AP 2001 p.24). <u>Actions and Outcomes:</u> Environment Canada's budget 2000 includes training. As demands increase, Environment Canada will continue to expand its workforce. CFIA have undertaken a number of initiatives to increase the number of trained inspection staff and to further strengthen existing inspection and monitoring programs for agricultural products of biotechnology (AP 2001 p.24). As the number and complexity of applications increases, additional capacity will be added. The 2001 budget allocation of $90 million to regulatory aspects of	Recommendation 6.4 calls for a detailed analysis of the expertise needed to evaluate environmental effects of new biotechnology products. The actions specified by the government give no indication that this analysis has taken place. And, if it has taken place, the recent critique of CFIA practices by the Auditor General suggest that there is still considerable room for improvement. Specifically, both Abergel's 2000 study and the OAG's 2004 report point to a lack of expertise in ecological assessment of GMOs. Like the RSC Panel, we believe that the CFIA should conduct a thorough and public review of its own capacities in the area of environmental assessment.

	biotechnology. In March 2003 CFIA finished a series of four training workshops for inspection staff – included issues of insect resistance management – focus on the regulation and inspection of confined field trials of PNTs. A "Biotech Primer" is being developed for CFIA staff.	
Research into Secondary Effects:		
6.17 The Panel recommends that identification of pleiotropic, or secondary, effects on the phenotype resulting from the insertion of single gene constructs into GM organisms be a research priority.	<u>Actions:</u> None specified.	There is no evidence in the Action Plan or subsequent progress reports that the study of secondary effects of genetic modification is a research priority. The only examples found of government-supported research that specifically look at secondary effects is a study undertaken to look at Global Changes in Gene Expression associated with Highly-Expressed Transgenes in *Arabidopsis* and Canola (PR 2003b p.18) and the research undertaken by DFO scientists on the secondary effects of genetic modification on transgenic Salmon (PR 2003b p.15-16).
Research into Baseline Data:		
7.4 The Panel recommends that Canada develop and maintain comprehensive public baseline data resources that address the biology of both its major agroecosystems and adjacent biosystems.	<u>Action:</u> 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	Efforts taken to date focus on sharing existing information about biodiversity among federal and provincial government departments, universities, museums, NGOs, etc. (CBIF 2003). This is a very different project from that envisaged by the RSC Panel when writing recommendation 7.4. Specifically, the Panel states, "…baseline ecological studies across our major crop production areas and adjoining unmanaged ecosystems...need to be undertaken...[T]hese development costs should be regarded as a necessary long-term

	priorities in Canada (AP 2001, p.31). Outcome: A Federal Biodiversity Information Partnership (FBIP) has been established as a first step in creating a national coordinating mechanism for biological information. The Federal Biodiversity Information Partnership (FBIP) has completed a number of biodiversity data entry projects as part of its start-up phase. More than 1.6 million Canadian specimen and observation records on species in Canada are available on-line at Canada's national electronic node for the Global Biodiversity Information Facility (PR 2004 p.21).	investment..." (RSC 2001 p.190). There is no evidence that government departments are undertaking such studies, even though the federally-sponsored Biodiversity Knowledge and Innovation Network recognizes that "to date we are only able to name and classify less than half of the species in Canada and we understand the distribution and ecology of less than 5% of these species (BKIN 2001 p.16).
Genomics Research:		
7.5 The Panel recommends that Canada 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.	Action: Further develop tools, e.g. genomics, proteomics, etc., that support the evaluation of more complex novel foods (AP 2001 p.4). Outcome: 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	The goal of this RSC Panel recommendation is to enable detailed knowledge of the genome and proteome of each of our major food crops to be freely available as a routine research tool. With these tools in hand, it should be possible to accurately define the structural and functional differences between any two genotypes within a crop species at four levels: DNA Structure, Gene Expression, Protein Profiling, and Metabolic Profiling (RSC 2001 p.187-9). The $17 million used by AAFC for the Canadian Crops Genomics Initiative was dedicated to canola, wheat, soybean and corn because these crops have "the best short-term potential for rapid gene discovery" and "the best long-term

	centres are established with the infrastructure necessary to undertake large-scale genomics projects (AP 2001 p. 31). By December 2003, Genome Canada had invested $318 which, with funding from other partners, totaled $721 million for 60 genomics and proteomics research projects and scientific platforms (PR 2003b). 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 (AP 2001 p.31).	potential for generating economic benefit from enhanced performance." While the government states that this research will be relevant to regulatory decision-making, this is not actually a stated goal of the research project (AAFC 2003a). Instead, this research is framed in terms of economic questions and is focused on issues relating to cold tolerance, disease, seed quality and insect resistance. AAFC has filed for six patents based on this research, which could take the results out of the public domain (AAFC 2003b) though AAFC states that the data and intellectual property from the initiative are made available to researchers in Canada. This suggests that regulators from other countries may not have free and open access to the data. The progress report refers to Genome Canada's investment of over $300 million (Genome Canada has now received over $375 million from the government) in 60 projects related to this recommendation, but this is misleading. An analysis of the projects funded to date shows that over three-quarters of them are in the field of medicine (Genome Canada 2003). Of the six agricultural and two fisheries projects, a central goal of the genomics research is to enhance the commercial value of these crops and fish being studied (e.g. "Enhancing Canola Through Genomics"). While this approach does not preclude the possibility that these projects may contribute to the public database for regulatory purposes as envisaged by the RSC Panel, there is no evidence that this is an explicit goal of Genome Canada-funded projects.
University-Based Genomics Research and Education:		
5.5 The Panel recommends that federal and provincial governments ensure adequate public investment in	No actions specified (AP 2001 p.16).	Some of the federal money previously cut from transfer payments to post-secondary education is being put back into the university system though various grants and programs, most directed to the sciences. However, much of this new

university-based genomic research and education so that Canada has the capacity for independent evaluation and development of transgenic technologies.		funding requires private sector partnership and/or matching funds which means that the public investment called for by the RSC Panel is actually being tied to private investment. This approach is completely at odds with the intent of Recommendation 5.5. Without having undertaken an investigation of the increasing domination of the public research agenda by commercial interests as recommended by the RSC Panel, increased federal investments in genomics research at universities may actually be adding to the problem of involvement of private interests, potentially compromising independent evaluation and development (See section on Domination of Public Research Agenda by Commercial Interests above).

Conclusions:

Despite committing to address the RSC Panel recommendations, the Government of Canada has not adopted the precautionary approach advocated by the Panel. Rather than take concerted action to build scientific capacity and adapt policy and regulations, the government response appears to focus on increasing public information about the regulatory process. This repeats a pattern of responding to criticism of GMO regulation with public relations material rather than substantive dialogue and procedural change. Many of the scientific questions raised by the Panel have not been addressed and there has been insufficient allocation of resources to address them properly. Even if more resources were devoted, there would remain important holes reflecting the government's lack of seriousness in response to the Panel's recommendations. The analysis of this report supports the following conclusions:

1) **The actions being taken by the government of Canada are not meeting the recommendations of the Royal Society of Canada Expert Panel Report.**

If the government is indeed serious about addressing each of the Panel's recommendations, its Action Plans and Progress Report should establish measurable targets in relation to the original RSC recommendations rather than a list of actions based on its own priorities. We concur with the Canadian Biotechnology Advisory Committee (CBAC) when it stated, in its advisory memorandum of April 2004, that the Federal government should formally and openly commit to implementing, as soon as possible, all of the recommendations of the Royal Society of Canada's Expert Panel in order to strengthen the regulation of genetically modified crops, foods and feeds (CBAC 2004). Regulatory reforms implemented thus far are piecemeal and, in many cases, miss the target set by the RSC entirely. It is important to recognize that many of the RSC recommendations actually conflict with the Government's larger policy direction that supports the biotechnology industry and opposes mandatory labelling. As a result, regulatory changes must be made in concert with new policy directions for the Government of Canada. This will require a larger process of reform and evaluation. To this end, it is crucial that we undertake a full national debate on GMOs and that Parliament finally address the issue of mandatory labelling.

2) **Significant federal government investment in scientific capacity is still required in order to meet the recommendations of the RSC Panel.**

To date, federal investment has been dismal in relation to the high standards set by the RSC

Panel. For example, only $350,000 was spent by Environment Canada over two years to coordinate a research strategy aimed at revealing "ecosystem effects of GMOs", as called for by the Panel (CBS 2004a). This funding pales in comparison to government investment in Genome Canada, which amounts to $375 million since its inception in 2000 (Genome Canada 2003). We agree with the RSC Panel that investment in scientific capacity to understand the potential effects of GMOs "should be regarded as a necessary long-term investment" (RSC 2001 p.190). Given current weaknesses in the regulatory system, new funding should prioritize risk

assessment capacity and risk management in the fields of ecology, evolutionary biology and epidemiology.

3) The government must commit to a truly precautionary approach to the assessment of GMOs in order to meet the high expectations of the RSC panel's recommendations.

A "conservative" response in the face of scientific uncertainty, as currently recognized in the federal government's Framework on the Application of the Precautionary Principle (PCO 2003), is only one dimension of this precautionary approach. Applying the precautionary principle to GMO assessment requires a comprehensive regulatory process that evaluates specific new crops and foods, as well as new technologies in general, in relation to clear goals for the food system. This assessment must begin with a thorough examination of both the benefits and risks, real and theoretical, of GMOs in relation to alternative means of achieving the same goal. Alternatives would include non-GM technologies as well as management strategies (like integrated pest management and organic farming). A Precautionary assessment must be open and transparent, and must include a clear characterization of potential harms and benefits, as well as the degree of uncertainty associated with these characterizations (Barrett and Raffensperger 2002). This assessment should not only be based only on independently verified experimental data related to health and environmental risks, but also on an examination of socio-economic issues and ethical concerns (i.e. the broader set of issues recognized by the RSC Panel as being critical to the food biotechnology debate; RSC 2001 p.2-9). Precaution would clearly prioritize public safety and environmental protection above industrial development and economic growth. Given the breadth of this type of technology assessment, participation of both the general public and non-government experts in a precautionary assessment of GMOs is critical.

4) The Government of Canada must take real action to achieve full transparency of regulatory data, and undertake arms-length peer reviews of all regulatory decisions.

The RSC Panel repeatedly highlighted the importance of peer review and full transparency of the information upon which decisions are made to good scientific practice, yet these recommendations have received almost no concrete action. When it comes to transparency, whistle blower protection, and the development of a public review mechanism for GMOs like that found in the 2002 Pest Control Products Act, are two important steps to be taken. With regards to peer review, we believe that government departments and agencies should work with the Royal Society of Canada as an independent body to establish appropriate peer review protocols for all safety assessments of genetically modified organisms, food and feed. Peer reviews of regulatory decisions are particularly critical at the present historical juncture: GMOs

still represent a relatively new innovation; advances in the technology are rapid and complex; and the Auditor General has recently reported that the CFIA cannot even provide the documentary evidence for some of its previous regulatory decisions on GMOs (OAG 2004). We also believe that peer reviews involving members of the RSC and other independent scientists are appropriate for all stages of regulatory policy formulation that involve scientific determinations of safety.

5) Mandatory labelling of all genetically modified foods is now a necessity.

The RSC Panel considered the question of labelling GMOs in relation to health and environmental risk and concluded that there was not "at this time sufficient scientific justification for a general mandatory labelling requirement." The majority of Canadians have repeatedly called for mandatory labelling but the desire of Canadians for the right to information and choice fell outside of the RSC Panel's focus on examining scientific arguments for labelling (Greenpeace 2002). As a result, the RSC Panel recommended voluntary labelling "premised on the assumption that the other recommendations… concerning the conditions for the effective assessment and management of the risks and GM organisms are fully implemented by the regulatory agencies" (RSC p225). Our report shows in detail that the Panel's recommendations have not been fully implemented, leaving consumers and the environment to bear the risks of inadequately tested GMOs. Given the lack of full implementation, mandatory labeling is now appropriate so that consumers who want to avoid unnecessary risks are able to do so. Some consumers, for example, may be concerned that government scientists admit that risk assessors still lack animal models for assessing GM food allergenicity and that this situation poses "serious problems" for industry and governments expected to assess novel protein allergenicity prior to the marketing of GM foods (Tryphonas et al. 2003 p.221). A further argument for labelling rests on the fact that the RSC recommendations on surveillance and monitoring for long-term health impacts of GM food consumption can only be achieved if consumers are able to distinguish between GM and non-GM foods. In concert with the establishment of mandatory labelling, the government of Canada should also formally address issues of GM segregation from non-GM crops and food and establish traceability mechanisms for all GM products (such as those under development in Europe).

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