#### **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* 

Dr. Peter Andrée Environmental and Resource Studies Program Trent University

and

Lucy Sharratt Polaris Institute

**Advisors:** Dr. Rod MacRae (Food Policy Consultant), Elisabeth Abergel (Glendon College, York University), Anne Mitchell (Canadian Institute for Environmental Law and Policy), Dr. Mark Winfield (Pembina Institute), Cindy Wiggins (Canadian Labour Congress), Dr. Richard Beames (Professor Emeritus, University of British Columbia)

**Acknowledgement of assistance:** Dr. Tom Hutchinson, Michelle Swenarchuk, Dr. Stephen Hill, Ellen Desjardins, Dave Bennett

#### Published by:

The Polaris Institute 312 Cooper Street Ottawa Ontario K1S 2N3 (613) 237 1717, fax (613) 237 3359 mailto:polaris@polarisinstitute.org

http://www.polarisinstitute.org/

#### **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<sup>TM</sup>) 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.

#### No demonstrated actions taken:

- 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 socioeconomic 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).