Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada

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Report to the Government of Canada
Biotechnology Ministerial Coordinating Committee

Canadian Biotechnology Advisory Committee

August 2002

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Canadian Biotechnology Advisory Committee
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August 26, 2002

The Honourable Allan Rock
Minister of Industry
235 Queen Street, 11th Floor
Ottawa ON K1A 0H5

Dear Minister Rock:

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present to you, in your capacity as Convenor of the Biotechnology Ministerial Coordinating Committee, our report, *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*.

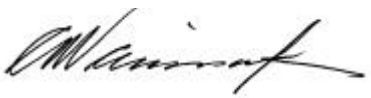
We undertook this project to identify and examine the issues pertinent to the regulation of genetically modified (GM) foods. Our recommendations were guided by research work, consultations with and feedback from key stakeholder groups and the public, as well as the deliberations of the GM Food Steering Committee and other CBAC members.

The issues surrounding GM foods are complex and positions of various stakeholder groups have become polarized. We found no evidence that GM foods, approved under the current regulatory system, pose any greater health or environmental risk than other foods in the marketplace. However, we have identified important opportunities to improve the management and coordination of the system, to improve the communication with the public and to strengthen the regulatory system's capacity to both deal with more complex GM food products now in development and to incorporate scientific and technical advances as they emerge. We are hopeful that our recommendations, taken together, will not only improve the regulation of GM foods, but may also improve the public's confidence in the regulatory process through enhanced transparency and opportunity for public involvement. We would also note that there are a number of non-science based issues, such as social and ethical concerns, that are important to Canadians when considering the acceptability of GM foods. We draw the government's attention to CBAC's support of the development of a tool to incorporate these dimensions into the overall debate and to the need for government to lend its support to further work in this area.

On behalf of CBAC members, I would like to recognize the contribution of the GM Food Steering Committee members, and in particular the committee's co-chairs, Peter Phillips and Suzanne Hendricks. We would also like to acknowledge Roy Atkinson and the staff of CBAC, notably the project managers, Suzanne Fortin and Richard Konchak, for their efforts in producing this report.

I hope you will find this report of interest. We look forward to receiving the government's response to our recommendations.

Yours sincerely,



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Acknowledgments

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I thank all those who have provided their expertise, time and wisdom in the course of the development and completion of this report. They include representatives of a variety of non-governmental organizations, leaders of biotechnology companies and scientific researchers from universities, research institutes and government. We are grateful to those individuals and organizations that took part in the cross-country consultation process and the many Canadians who provided feedback on the Consultation Document or on the draft recommendations in our Interim Report.

Special thanks are due to the members of CBAC who served on the GM Food Steering Committee — so ably led by its co-chairs, Suzanne Hendricks and Peter Phillips — and to the staff of CBAC who served as project managers, Suzanne Fortin initially and Richard Konchak latterly, and as project officer, Kelly Brannen. The overall guidance of Roy Atkinson, Executive Director of the Canadian Biotechnology Secretariat, is greatly appreciated.

Finally, we thank The Honourable Allan Rock, Convenor, and the members of the Biotechnology Ministerial Coordinating Committee (BMCC) for their ongoing support for the work of CBAC.

Arnold Naimark, Chair
Canadian Biotechnology Advisory Committee

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Executive Summary

The issues involved in the production, regulation and marketing of GM foods are complex. Positions are polarized. There are those who believe that modern biotechnology has provided and will provide significant benefits for both farmers and consumers. They are opposed by those who hold that it is only the inventors of genetically modified products who are likely to benefit significantly, while the population as a whole may have to bear unacceptable risks to health and the environment. There are also sharp differences of opinion concerning the implications of agricultural biotechnology for developing countries. Some see it as a means of considerably enhancing food supplies in vulnerable regions of the world, while others fear that it will lead to the exploitation of both growers and consumers in impoverished countries.

The fact that there are divergent views on such a complex issue is not surprising. Nor should it be a reason for failure to take action that is in the public interest — namely, to capture the benefits of biotechnological innovation while providing reasonable protection against potential harms. Our findings and recommendations in this regard fall under four themes: good governance, precaution, information and consumer choice, and social and ethical considerations.

Recommendation 1. Structure, organization and operation of the federal food regulatory system

Good governance is essential for creating and maintaining a regulatory regime that protects the health and safety of citizens and of the environment. As well, it inspires confidence in its efficiency and effectiveness. Good governance entails both legislated accountability and a commitment to transparency, and effective separation of regulatory functions from other potentially conflicting functions of government.

The multiple responsibilities of the federal government relative to foods, as in many other areas, include both regulatory and promotional functions. In fulfilling these responsibilities, steps must be taken to ensure that these functions are not in conflict. Moreover, given that several departments and agencies participate in food regulation, sometimes with overlapping responsibilities, we recommend that their roles and functions be closely coordinated.

While an independent, coordinated and efficient regulatory system is of prime importance, so too is the trust of the public and stakeholders in that system. To this end, we urge the government to enhance the system's accountability and communication to the public, including creation of a single authoritative spokesperson to oversee and coordinate the communication of government policies and practices with regard to GM foods.

Recommendation 2. Transparency and public involvement

The federal government should improve the ways it communicates with, and involves, the public in the regulation of GM foods and the development of associated policies. The government does not provide clear information explaining how GM products are regulated and decisions are made, the roles of the regulatory bodies, or the information considered during safety assessments. Federal regulators need to be more active and transparent in publicly communicating such matters, including the scientific basis for regulatory decisions. While we recognize that regulators are restricted in disclosing "confidential business information," measures should be taken to ensure that the maximum amount of appropriate information is made public.

The public should have greater opportunity for involvement in policy development and decision making concerning GM products and an opportunity to comment on proposed decisions regarding specific products. Moreover, given that the science supporting the safety assessment of GM foods should be able to withstand the scrutiny of independent experts, we urge that mechanisms be created to allow for greater inclusion of the views of outside experts as individuals or as members of scientific advisory panels.

We recognize that implementing these measures will require a fundamental shift in the approach taken by regulators to transparency and decision making. However, we consider these steps essential for building public confidence in the food regulatory system and in the risk assessment and risk management of applications of new technologies. We also believe that they will help to fill the desire on the part of consumers for easy access to reliable information about GM foods.

Recommendation 3. Precautionary elements

All but one of our members, Anne Mitchell, support Canada's current approach in which all plants and foods with novel traits are subjected to rigorous regulatory assessments rather than treating GM plants and foods as a separate category. The committee also supports the use of substantial equivalence as a guide to identifying the differences between conventional and novel crops so that such differences can be rigorously assessed to determine their implications for health and environmental safety. We also endorse the precautionary approach to risk management currently utilized in Canada — an approach that has been shown both nationally and internationally to be an essential component of good regulatory practice. We urge that this approach be used in all stages of a product's life cycle — from initial laboratory research and field trials, through pre-market assessment, to use and disposal.

Research and development of GM organisms has been taking place for nearly 30 years with no evidence as yet of harm to human health or the environment. Nevertheless, we urge an examination of existing standards to ensure that such research is being conducted in a precautionary manner. These activities are currently governed solely by guidelines. We recommend a study to determine whether the guideline approach is effective or whether stronger measures are required, particularly with regard to the propagation of GM plants in greenhouse facilities.

As part of its precautionary approach, government should introduce a long-term program of research into GM and other novel organisms that are part of the food chain. A systematic approach is required to evaluate new research data and to ensure that they are used when warranted to modify approval decisions, revise risk mitigation measures and determine whether and when a plant or food has been in commercial production long enough to no longer be considered "novel." In addition to this ongoing process, regulators should be authorized to initiate a mandatory re-evaluation of product approvals after a pre-determined period following initial product approval (say, every 10 years) — if warranted on the basis of a review of new information provided by the proponent (developer) of the product, the public or external experts.

Recommendation 4. Evaluation and monitoring of long-term health impacts

GM foods currently in the marketplace have arguably undergone greater regulatory scrutiny than their conventional counterparts. Nevertheless, in keeping with a precautionary approach, it is prudent to establish programs to determine whether there are any long-term adverse or beneficial effects attributable to these foods that are not revealed in pre-market assessments. This requires much more information about food consumption patterns than is now available for either conventional or GM foods. This lack makes it difficult to estimate the quantitative significance of GM foods in the Canadian diet.

This challenge is but one of many inherent in designing and implementing an effective post-market surveillance system for GM foods. It is noteworthy that no country currently has such a system in place.

Generalized surveillance in an attempt to link population health outcomes with the consumption of foods categorized by source — whether GM, organic or other food categories — is unlikely to be feasible or cost-effective, given the difficulty of controlling for confounding variables. However, post-market monitoring to detect specific adverse or beneficial effects and their relationship to exposure to a particular GM food may be feasible. In this regard, Health Canada's recent initiative to develop new surveillance methodologies and approaches for monitoring long-term health effects related to the consumption of GM and other foods is noteworthy.

We recommend that the government strengthen its commitment to basic research into long-term health effects related to the consumption of specific foods, including GM products. We also recommend that it initiate a significantly expanded program to obtain comprehensive food consumption data for both conventional and GM foods, and that this new information be incorporated into regulatory decisions and risk management strategies.

Recommendation 5. Environmental stewardship

The current approach to the assessment of environmental risk and ecosystem impacts of GM plants could be improved. There is a need for increased investment in research into both the short- and long-term impacts of GM and other novel crops on the environment.

Currently, environmental impacts are primarily assessed using small-scale confined field trials that may be too small in area to detect impacts that would appear in larger areas or too short in duration to detect effects that would emerge in the longer term. The ability to assess the environmental impacts of large-scale planting of transgenic crops is also hampered by the lack of baseline data on the environmental impacts of agriculture generally. These and other gaps need to be addressed if the monitoring of bio-agricultural practices is to be effective. We also note that studies into the environmental impact of GM crops must examine not only the potential risks but also the potential benefits and how the risks can be minimized and benefits maximized.

Because the experimental field testing phase presents the greatest challenge to risk management, it is essential to ensure the effectiveness of isolation zones to mitigate cross-pollination, and to use detection techniques to ensure traceability should plant material accidentally escape. We urge that auditing programs be implemented at both the field-testing and post-approval stages to ensure compliance. We also urge the creation of an independent panel to review and recommend ecologically meaningful experimental protocols and performance indicators to be monitored for each new class of GM organism introduced into the environment.

The implementation of an ecosystem approach to environmental assessments would benefit from exploiting the potential for making wider use of ecological expertise in the risk assessment process and for international collaboration in ecosystem research. This potential should be systematically investigated and the results of the investigation, together with results of background studies already undertaken by government, published as soon as possible.

Recommendation 6. Improved information to support consumer choice

Government departments and agencies are making progress in improving the quality and quantity of information they make available about GM and other novel foods, but much remains to be done. A centralized consumer food information service is needed to provide information on all aspects of foods

and food production, including relevant laws and regulations, research and development activities, current scientific knowledge, perspectives on ethical and social issues, and ways citizens can help develop policies. We also urge that information be developed that is tailored for use by specific groups, including health care professionals and other intermediaries such as nutritionists, teachers and the media.

Recommendation 7. Labelling

We note that the mandatory labelling of GM foods is already required for health and safety reasons. CBAC recommends that the federal government adopt a voluntary system for labelling GM foods for matters other than health and safety. The majority of CBAC members believe that Canada should begin with a voluntary labelling system for GM foods to allow time for testing the system's adequacy and efficiency and to develop an accepted international standard; to provide consumers who wish to purchase GM-free products with the ability to identify them; to limit costs; and to avoid trade action where a mandatory labelling scheme would contravene trade agreements. The dissenting member, Anne Mitchell, is strongly in favour of proceeding directly to mandatory labelling, and notes that a majority of respondents to our Interim Report urged a mandatory system.

We emphasize that before any labelling system, whether voluntary or mandatory, can be introduced, an effective, agreed-upon standard is essential. The Canadian Council of Grocery Distributors and the Canadian General Standards Board are currently developing such a standard following extensive consultations. We recommend that once a Canadian standard has been developed and agreed upon, it be implemented via a voluntary system and that the system be widely communicated to the public. We recommend that it be evaluated in five years to determine whether it gives consumers sufficient choice concerning the foods they purchase and, if not, that alternatives, including mandatory labelling, be considered. Concurrently, the government should enhance its cooperative efforts with other countries to develop a harmonized approach to labelling, with special emphasis on the development of an internationally accepted standard.

Recommendation 8. Other social and ethical considerations related to GM foods

The government is called upon to consider the important social and ethical issues that are not explicitly taken into account in the regulatory approval system or in the development of policy on GM foods. These are complex matters involving principles of justice and beneficence (doing or producing good), respect for cultural diversity and traditional knowledge, religious convictions and beyond.

The principles of justice and beneficence require that due consideration be given to the distribution of harms and benefits within and between societies. With regard to the genetic modification of plants for food production, we must therefore be concerned about distributive justice, not only within Canada but also between developed and developing countries. Distributions of economic and technological power, of biological resources and the ability to exploit them, and of proprietary rights to traditional knowledge are issues that must be addressed through international cooperation.

We found that dialogue between those who support GM crops and foods and those against them is hindered by a lack of suitable tools to consider systematically — and evaluate on an ongoing basis — the social and ethical factors that influence public acceptability of a specific food or technology. We recommend that approaches and mechanisms be developed to facilitate dialogue on social and ethical issues, to support initiatives for clarifying the issues and options, and to develop suitable policies.

To this end, we are supporting an initiative involving an Exploratory Committee composed of members from industry and non-governmental organizations in developing a tool called the Acceptability Spectrum to facilitate dialogue on complex issues such as those raised by GM foods.

We conclude that no scientific evidence exists to suggest that GM plants and foods currently in the market pose any greater health or environmental risk than other foods. This does not mean that one should take these products or the underlying technology used to develop them lightly. There is a need not only to develop methods for long-term surveillance of health and environmental impacts, but also to ensure that regulatory processes are able to deal effectively with the more complex products on the horizon. The incorporation of ethical considerations into public policy on biotechnology in general — and on GM and other novel foods in particular — poses a continuing challenge for government and is an important topic in CBAC's ongoing program of activities. We look forward to the government's response to our findings and recommendations.

Recommendations

Theme 1: Good Governance

Recommendation 1. Structure, organization and operation of the federal food regulatory system

We recommend:

1.1 That the federal government enhance the structure, organization and operation of the federal food regulatory system for GM and other novel foods by adopting measures to further systematize and coordinate the operations of its several regulatory bodies and by clarifying mandates so as to remove conflicts and ensure a clear separation of the government's regulatory role from its other roles. In particular, we recommend that:

- the mandates, internal operations of the regulators of GM foods and other novel foods, and their relationships with stakeholders be carefully reviewed and modified where needed to ensure the highest degree of integrity and independence in the conduct of regulatory functions and to avoid the perception of mandate conflict or of conflicts of interest in operations.
- there be effective independence of regulatory functions for GM foods and other novel foods unencumbered by other government functions and responsibilities, including, but not limited to, policy, economic development, negotiation of international policy and trade rules, and trade promotion.
- an assessment be undertaken to determine whether it would be advantageous to apply this recommendation more widely to other facets of the food safety system.

1.2 That standard operating procedures be prepared and published that clearly describe:

- organizational mandates and legislative authority
- the details regarding regulatory authorities, responsibility centres and relevant laws
- the precise steps involved in a product's progression through the regulatory system and the relevant time lines
- the details regarding the stages of risk assessments
- the delegation of decision-making authority
- the procedures to insulate officials from inappropriate influence
- the procedures for effective decision making, including the rationale for engaging non-governmental experts and expert panels in regulatory processes
- the mechanisms to resolve differences of opinion with regard to regulatory decisions

- the policies regarding the preparation of proposed Decision Documents for public review prior to final decision making
- the procedures for providing opportunities for public input at various stages
- the procedures for coordinating with other regulators to avoid potential gaps or duplication of effort
- the details regarding Rulings Committees and other elements of internal reviews.

1.3 That for those regulatory bodies that do not have one, a Rulings Committee be established through which all proposed decisions on GM foods and other novel foods must be vetted.

1.4 That the Auditor General of Canada review and publicly report on regulatory bodies involved in assessments and decision making related to GM foods and other novel foods sold in Canada. The review should assess the independence of regulatory functions as well as the effectiveness and efficiency of the agency's standard operating procedures and their application.

1.5 That all communications be assessed to ensure that they accurately reflect the mandate and operations of the regulatory agency, and convey accurate and reliable information about the systems and procedures that are in place to ensure reliable decisions about the safety of GM foods and the integrity of the operations.

1.6 That in ensuring effective coordination among regulatory bodies to increase efficiency and effectiveness, attention be given to the following matters:

- coordination of product assessments of GM foods and feeds and other novel foods in the areas of livestock feed, human food safety and environmental safety, as well as coordination of communication activities and materials, including proposed and final regulatory decisions
- elimination of any gaps, overlaps and inconsistencies within the regulatory system
- management of the government's scientific and technical expertise to ensure that capacity is maintained and, where necessary, increased; periodic reviews of capacity should be undertaken to ensure the regulatory system is capable of meeting future needs
- periodic examination, not less than once every 10 years, of the government's regulatory capacity to evaluate new and more complex products and to ensure compliance with the conditions of approval, with particular attention given to identifying opportunities for ongoing improvement of risk assessment and risk management activities, including options for optimum use of international regulatory and scientific expertise
- coordination of monitoring and surveillance to detect potential long-term health and environmental effects.

1.7 That a senior authoritative officer responsible for the regulation of novel foods be appointed as the official spokesperson and coordinator of communications pertaining to the government's policies and practices related to GM and other novel foods.

1.8 That the government examine organizational options capable of achieving the responsibilities listed above in 1.6 and 1.7, for example, using one of the following three models:

- an Office for the Coordination of the Regulation of Genetically Modified Foods and Other Novel Foods:
  - it would be the joint creation of the regulators whose activities it coordinates
  - it would be staffed with regulatory officers and managers drawn from departments and agencies involved in the regulation of GM foods
  - an Executive Director would act as the single spokesperson referred to in 1.7 above
- a committee of Assistant Deputy Ministers drawn from federal regulatory bodies:

  - the committee could be assigned responsibility for the coordination of the assessment and approval/registration of GM foods and other novel foods, and related inspection, enforcement, surveillance and monitoring activities
  - the chair of this committee would be the spokesperson referred to in 1.7 above and would be an *ex officio* member of all Rulings Committees
- a new agency that would be responsible for all regulatory activities pertaining to foods:
  - it would take over the food safety aspects of the current regulatory mandates of Health Canada, Canadian Food Inspection Agency, Department of Fisheries and Oceans and Environment Canada
  - the official spokesperson referred to in 1.7 above would be a part of the new agency.

Recommendation 2. Transparency and public involvement

We recommend:

2.1 That in general federal regulators become more effective, transparent and actively engaged in communicating the features of the regulatory system as it relates to GM and other novel foods, including the scientific basis for regulatory decisions related to human and environmental health and safety, and that the regulatory process provide for significantly expanded opportunities for input by the public and external experts.

2.2 That the Canadian public and external experts be involved in the development of laws, regulations, policies and programs related to the Canadian regulatory system for GM foods and other novel foods; opportunities for public involvement should extend not only to the scientific issues of health and environmental safety, but also to other matters of public policy such as social and ethical considerations where relevant.

2.3 That a 45-day comment period be provided for public input on health and environmental safety aspects of proposed decisions and that the public input be considered and reported on as appropriate in the final Decision Document.

2.4 That the detailed scientific and technical data pertinent to the human health and environmental safety assessments of GM foods and other novel foods be made public, except for details that could unduly jeopardize a company's competitive position (e.g. details of how to manufacture the product). In particular:

- the information should be available for products currently sold in Canada and for products being proposed for market approval
- regulatory agencies should implement a policy to the effect that they will not keep confidential any technical or scientific data that are publicly available elsewhere (e.g. data that have been made public by the company itself or data that are already available to the public as a result of product approval in another country)
- regulatory agencies should adopt and promulgate a policy that scientific data relating to the safety of biotechnology products do not automatically fall within the definition of Confidential Business Information (CBI); the policy should clearly identify the types of environmental and human health safety information that might be considered as CBI
- regulatory agencies should require developers to submit "non-CBI" versions of their applications suitable for publication during the pre-approval public comment phase that are sufficiently detailed to allow for independent public and scientific scrutiny of the safety-related data
- if it is determined that the *Access to Information Act* does indeed preclude the release of information as recommended above, the government should consider amending the act.

2.5 That the views of external experts be incorporated in the product evaluation process where the risk assessment is not straightforward or where a precedent might be set by approval of the product.

2.6 That comprehensive information and communications about the federal food regulatory system be provided, including decision trees that clearly illustrate the processes listed in recommendation 1.2 above.

2.7 That a readily accessible public record be maintained of the GM and other novel food products currently under review and the current status of the assessment.

2.8 That information on government inspection programs related to contained field trials be published on an annual basis and be made widely available, including information on compliance with required measures, the frequency of non-compliance and measures applied to rectify non-compliance.

2.9 That information be published annually on the government's research programs and research results related to the health and environmental safety aspects of GM foods, plants and feed, and other novel food products.

2.10 That growers within five kilometres of a field study involving GM crops have access to more detailed information, on request, pertinent to the protection of their own crop production; otherwise, the detailed location of trials conducted on GM crops and other plants with novel traits in the field ("field studies") should not be released.

Theme 2: Precaution

Recommendation 3. Precautionary elements

We recommend:

3.1 That regulatory authorities maintain and strengthen Canada's risk-based approach to the regulation of novel foods and plants with novel traits rather than limiting regulatory oversight to the products of any specific technology, such as recombinant-DNA technology.

3.2 That regulatory authorities take a precautionary approach to all stages of development and commercialization of a GM food (laboratory research, confined field trials, pre-market risk assessment and post-market surveillance) to ensure the application of a conservative safety standard in assessing health and environmental risks related to GM and other novel foods, recognizing that this does not imply "zero risk."

3.3 That regulators use the following guidelines in applying the precautionary approach:

- precautionary decisions should be based on a socially acceptable level of protection
- despite the existence of scientific uncertainty, where there are scientifically credible theoretical or empirical grounds establishing a reasonable case for the possibility of serious harms, the lack of robust experimental data should not be taken as a reason for withholding regulatory restraint
- a highly conservative standard should be applied when there is a plausible risk of catastrophic harm to health or the environment
- precautionary measures adopted should be proportional to the potential severity of the risk being addressed and should take into account the benefits and costs of actions or lack of actions

- precautionary measures should be subject to reconsideration on the basis of the evolution of science, technology and society's views about the acceptable level of protection
- precautionary measures should be non-discriminatory between situations presenting similar risks and should be consistent with measures taken in similar circumstances
- where two or more equally effective options are available to mitigate the risks, the least trade-restrictive option should be given serious consideration
- the administration of the precautionary regime should be transparent, accountable and provide for public involvement.

3.4 That government undertake a study to evaluate the effectiveness of existing guidelines covering experimental work with genetically modified organisms in laboratories and greenhouses, including the extent to which they are currently being applied in public and private research facilities and the degree to which recommended guidelines are applied and enforced, with a view to determining the need for national guidelines or statutory measures.

3.5 That government initiate and fund a broad-based program of long-term research into GM and other organisms that are part of the human food chain, with the objectives of:

- developing new, validated, targeted and non-targeted analytical methods for assessing the health and environmental safety of future GM and other novel foods
- expanding the knowledge base for non-GM foods and crops
- developing strong international connections and access to the world's best research and researchers
- ensuring that the knowledge developed is readily accessible to both regulatory agencies and to private and public sector developers of new GM foods, and other applications involving crops and farm animals.

3.6 That government revise the existing authorization processes for novel foods and plants with novel traits in order to provide for a pre-scheduled (say, 10 years after approval) review of product approval decisions, taking into consideration new information available in the scientific literature, post-market mitigation measures and other scientific evidence:

- the information for this review should be prepared by the product proponent and made available for scientific peer review and public comment
- the relevant regulatory agencies should then assess the evidence and, if conditions warrant, have the authority to require reassessment of all or parts of the product or to suspend product approval pending further assessment
- the criteria for reassessment or suspension of approval should be laid out in the standard operating procedures
- these measures would be in addition to existing "new information requirements."

3.7 That regular reviews be undertaken, not less than once every 10 years, of the emerging implications of modern biotechnology and other transformative technologies for the continuing adequacy of the regulatory regime, and that the reviews take into account:

- current regulatory practices, including the use of substantial equivalence and the precautionary approaches; and health and environmental performance standards
- the science underpinning the regulatory regime
- the adequacy of the regulatory and coordinating structures and their resource levels
- developments in international cooperation and coordination in scientific activities and regulation.

3.8 That steps be taken to make the regulatory process as efficient and timely as possible without compromising regulatory effectiveness, and that systems be designed to assist small and medium-sized enterprises in coping with the burdens involved in securing regulatory approval, provided these measures can be implemented without limiting regulatory effectiveness.

3.9 That substantial equivalence continue to be used as a guide to identifying the differences between conventional and novel crops so that such differences can be rigorously assessed to determine their implications for health and environmental safety; as knowledge advances, specific scientific performance standards should be developed and applied in the regulatory assessment process to minimize risks to human health and the environment.

3.10 That the definition of "novel trait" within the *Seeds Act* be revised to remove the reference to substantial equivalence; and that the regulations be amplified to provide additional guidance to developers as to when a trait is in fact a "novel trait," or to elaborate an unambiguous process for making this determination.

Recommendation 4. Evaluation and monitoring of long-term health impacts

We recommend:

4.1 That government establish a major long-term program of research designed to test specific hypotheses about the long-term health effects related to the consumption of specific foods and food groups, including GM and other novel foods or food ingredients.

4.2 That government initiate a program to substantially improve the quality and timeliness of food consumption data for conventional foods, GM foods and other novel foods, and to make these data accessible to academic researchers, food producers, epidemiologists and private and public sector technology producers to help develop surveillance methodology and determine potential exposures during pre-market risk assessments.

4.3 That mechanisms be established to facilitate timely incorporation of new information related to food consumption patterns and for reviewing approvals of existing products based on valid post-marketing data.

Recommendation 5. Environmental stewardship

We recommend:

5.1 That government establish a continuing program of research to improve knowledge about the long-term effects of GM and other novel plants and crops on agricultural and unmanaged ecosystems, and that this research effort involve a strong international collaboration component. We further recommend that the research focus include identification of specific biological indicator species for use in:

- pre-market environmental risk assessment
- long-term surveillance of potential impacts on agricultural and unmanaged ecosystems.

5.2 That the following actions be undertaken to ensure the effectiveness of the pre- and post-approval management of health and environmental risks:

- the sizes of isolation zones currently applied to confined field trials should be reassessed in light of the latest scientific information regarding pollen drift for various agricultural crops, based on an achievable standard for reproductive isolation
- detection techniques, or other methods for ensuring traceability, should be a requirement to be met prior to the authorization of confined field trials of GM plants, or other plants with novel traits
- audit programs to establish the effectiveness of, and level of compliance with, post-approval risk mitigation measures should be implemented.

5.3 That government strengthen the ecosystem perspective of the environmental assessment of GM organisms used as foods, or in food production, by:

- undertaking a feasibility study, to be published within one year, exploring national and international research collaboration needs and the potential for making wider use of ecological expertise within the risk assessment process
- establishing an independent panel to review and recommend ecologically meaningful experimental protocols, performance standards and monitoring indicators for each new class of GM organism to be introduced.

Theme 3: Information and Consumer Choice

Recommendation 6. Improved information to support consumer choice

We recommend:

6.1 That the government put in place enhanced mechanisms and allocate additional resources to help Canadians make informed choices about the foods they consume, and allocate additional resources to provide Canadians with accurate and comprehensive information on GM and other novel foods, the food regulatory system, and food standards and regulations.

6.2 That the mechanisms include a centralized food information service as the primary venue through which the government provides information about foods, including GM and other novel foods, to Canadians; that the service reflect effective cooperation among all parts of government with roles related to food regulation, food research, food safety, food policy and consumer protection; and that it be organized and operated within a comprehensive funding strategy that integrates related government communication and information activities.

6.3 That reliable information be developed and made available in a form that is appropriate for use by health care professionals and other intermediaries (such as doctors, nurses, nutritionists, dieticians, teachers, community workers, consumer associations, civil society groups and the media).

Recommendation 7. Labelling

We recommend:

7.1 That Canada establish a voluntary labelling system for foods with GM content based on a set of clear labelling criteria, derived from a broadly accepted standard. It is essential that any label statements regarding genetic modification are verifiable, and that programs, processes and methodologies are in place to ensure their validity.

7.2 That this voluntary system be assessed on the basis of its adequacy and effectiveness; that early consideration be given to the criteria and methodology to be used to evaluate whether the voluntary labelling regime has provided adequate choice to consumers; that a review be undertaken five years after implementation to determine if the system has provided Canadians with sufficient choice regarding the foods they consume; and that, if it has not, other approaches, including mandatory labelling, be considered.

7.3 That the voluntary system be widely promulgated and promoted.

7.4 That Canada enhance its continuing effort, in concert with other countries, to develop a harmonized approach to labelling in regard to GM foods with special emphasis on the development of an internationally accepted labelling standard.

Theme 4: Social and Ethical Considerations

Recommendation 8. Other social and ethical considerations related to GM foods

We recommend:

8.1 That the government facilitate further study and analysis to identify effective ways to address the social and ethical issues related to biotechnology by supporting such study and analysis within government and its advisory bodies and by non-governmental stakeholder groups. In this regard, the government may wish to pay particular attention to the outcome of CBAC's pilot project on the development of a consultation tool — the Acceptability Spectrum — and methods for its use as a suitable approach to addressing these issues.

8.2 That the government work with domestic and international agencies to develop the capacity of developing countries to protect and exploit their traditional knowledge and resources; such efforts should build upon the progress already made through the International Treaty on Plant Genetic Resources for Food and Agriculture as well as through the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization.

8.3 That the government achieve the objective of recommendation 8.2 above in part by establishing a program, through the Canadian International Development Agency, to assist developing countries in:

- using modern biotechnology where appropriate to achieve their objectives with respect to agricultural productivity, improvements in the nutritional qualities of domestic crops and protection of their environment as well as to prevent or treat diseases prevalent in the developing world
- establishing or strengthening regulatory processes to protect against potential risks of modern biotechnology.

The program would work with other national development agencies and international agencies, such as the United Nations Development Programme, the Food and Agriculture Organization, the World Health Organization, the United Nations Environment Programme and the Consultative Group on International Agricultural Research (CGIAR), as well as with local non-governmental, academic and business groups.

Introduction

Who We Are

CBAC is an independent expert advisory body created by the Government of Canada to assist it in the formulation of public policy on a range of biotechnology subjects. We provide our advice to the Biotechnology Ministerial Coordinating Committee, which consists of the federal ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade. For information on the mandate, origin and activities of CBAC, visit our Web site (www.cbac-cccb.ca) or call our toll-free telephone number (1 866 748-2222; TTY/ATS: 1 866 835-5380). A list of our members is presented at the very beginning of this document.

History of the GM Foods Project

At our inaugural meeting in October 1999, we identified the regulation of genetically modified foods (GM foods) as a priority subject for study. We identified three main areas of interest: the science base supporting regulatory processes; the organization and governance of regulatory systems; and social and ethical considerations in regulating GM foods. In early 2000, the ministers of Health, Agriculture and Agri-Food, and Environment asked the Royal Society of Canada to convene an Expert Panel to provide the federal government with advice on the scientific capacity required by Canada's regulatory system to ensure the safety of new food products being developed through biotechnology. In view of the Expert Panel's mandate, we decided to focus our attention on strengthening regulatory structures and processes, and on approaches to assessing the social acceptability of GM foods.

The project proceeded in three phases. In Phase 1, we commissioned background research by experts to identify issues and options in specific areas. A bibliography of research reports and other relevant documents reviewed in the course of our deliberations is presented in Annex 4. In Phase 2, national stakeholder and public consultations were conducted, based on a Consultation Document outlining 10 topics for discussion. These discussion topics are listed in Annex 2.

Phase 3 began in August 2001 with the publication of an Interim Report *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*. In it, we presented several draft recommendations and introduced the Acceptability Spectrum, a consultation tool intended to foster a meaningful dialogue on the acceptability or non-acceptability of certain GM foods and feeds (see Annex 6). Canadians were invited to comment on the report, and 160 submissions were received, mostly from consumers and interested citizens (see Annex 2 for a summary of the responses).

Structure of This Report

The report begins with a brief reference to the ethical principles guiding CBAC's work. This is followed by a discussion of the science, governance and regulation of GM foods in Canada, a look at some of the recent policy developments in Canada and around the world, and an outline of some of the economic, environmental and socio-ethical elements of the GM foods debate.

The major portion of the document discusses our eight recommendations, organized under four themes:

- **Good Governance**
- **Precaution**
- **Information and Consumer Choice**
- **Social and Ethical Considerations.**

In preparing this report we took into account recent events in Canada and abroad. These include technological, legislative or regulatory developments as well as reports issued by various advisory bodies. We took special note of the Report of the Expert Panel of the Royal Society of Canada and the government's response to it. Discussion of the Expert Panel's recommendations in areas that are germane to our own deliberations is included in the relevant sections of this report.

Seven annexes are provided at the end of this report. Annex 1 lists the research and companion documents that CBAC commissioned or prepared to help inform its deliberations on GM foods. Annex 2 is a summary of the written input that CBAC received on the Interim Report. Annex 3 presents an introduction to possible second and third generation GM foods and the questions they raise. This annex originally appeared in the Interim Report and has been updated for this report. Annex 4 is a bibliography of related reports. Annex 5 is a Policy Analysis Matrix that summarizes — for three scenarios — the relative impact of labelling GM foods on a number of public policy issues. Annex 6 outlines a framework to consider the acceptability of GM foods and work to date on this framework. Annex 7 is a letter to CBAC from the Exploratory Committee that was established to develop the framework.

Ethical Context of CBAC's Work

Public policy recommendations are, or ought to be, formulated in an ethical context. Ethical judgments are not stand-alone judgments; rather, they are all-things-considered judgments that take into account a multitude of values important to Canadians. These include, among others, the health of Canadian citizens, quality of life, the environment, the prosperity of Canadians and a sustainable, peaceful global community.

With this in mind, we have identified a set of ethical principles and values to guide our consultations and discussions with stakeholders and Canadians at large and to inform our analysis of issues.

Statement of Principles and Values Guiding CBAC

Justice A commitment to ensure a fair distribution of benefits and burdens. A commitment to ensure that policies and practices do not contribute to the oppression of vulnerable groups.
Accountability A commitment to be transparent and answerable.
Autonomy A commitment to promote the conditions necessary to allow Canadians to pursue their fundamental values and interests. A commitment to promote informed choice.
Beneficence A commitment to pursue benefits for Canadians and others throughout the world.
Respect for diversity A commitment to ensure respect for diverse ways and forms of life.
Knowledge A commitment to value both scientific and traditional knowledge.
Caution A commitment to adopt a precautionary approach when knowledge is incomplete.

This set of principles and values represents the lens through which we have viewed the central issues involved in the regulation of GM foods in Canada and that we believe should be an explicit part of the context within which public policy is developed. Our experience in applying these principles to the study

of GM foods, and the feedback we received about them in the course of our consultations, will be used in our continuing work on the elaboration of an ethical framework for public policy development related to biotechnology in general.

GM Foods: Science, Governance and Regulation

As it is commonly used, the term "genetically modified" (GM) foods refers to foods that have been produced using recent advances in gene technology that are collectively referred to as modern biotechnology.[1] These advances have generated a set of tools for "genetically engineering" organisms such as plants, animals and bacteria to possess novel traits.[2]

As discussed more fully later, Canada's regulatory system differs from those in other countries. Canada's system is not designed to focus solely on GM crops or GM foods, but rather on any crop or food displaying novel, or unfamiliar, characteristics. As a result Canadian regulators use the terms "plants with novel traits" (PNTs) and "novel foods." However, for the purposes of this report, which is primarily intended to explore and make recommendations on the governance and regulation of food products of modern biotechnology, we have chosen to use the narrower terms "GM crops" and "GM foods." Notwithstanding this focus, many of our observations and recommendations are applicable to the broader category of novel foods and PNTs, and even more generally within the agri-food regulatory system.

The Science Behind GM Foods

Throughout most of recorded history, agriculture has relied on trial and error to select plants and animals with desired characteristics. Even in the absence of any formalized knowledge of genetics, plant breeders were able to utilize practical experience to develop improved crops. A good example of this is the Russet Burbank potato, introduced in 1876 by Luther Burbank, which remains one of the most popular potato cultivars today.

The development of the science of genetics in the 20th century created a revolution in agriculture. The application of the rules of heredity, originally posited by Gregor Mendel based on his studies with the garden pea,[3] gave rise to a systematic approach to selective plant breeding, which has produced new varieties of crops with higher yields, increased resistance to disease and pests, and other desirable qualities. Beginning in the 1930s, crossbreeding was supplemented with the techniques of induced mutagenesis as a means of accelerating genetic changes in plants. Mutagenesis involves applying chemicals or ionizing radiation to seeds or other embryonic plant tissue to induce random mutations in

[1] "Modern biotechnology" as defined in the Cartagena Protocol on Biosafety Article 3(i) means the application of (a) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[2] "Genetically modify" means to change the heritable traits of a plant, animal or micro-organism by means of intentional manipulation. Food and Drug Regulations: Division 28 Novel foods (B.28.001). "Novel food" means (a) a substance, including a micro-organism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or micro-organism that has been genetically modified such that (i) the plant, animal or micro-organism exhibits characteristics that were not previously observed in that plant, animal or micro-organism, (ii) the plant, animal or micro-organism no longer exhibits characteristics that were previously observed in that plant, animal or micro-organism, or (iii) one or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for that plant, animal or micro-organism. SOR/99-392, s. 1.

[3] Much of Mendel's success was based on his selection of a plant species, the garden pea, which is normally self-pollinating — allowing him to use genetically pure varieties as parental lines — but which is also easily cross-pollinated. Mendel found that certain traits of the parent plants, such as dwarfism, blossom colour and seed shape, were distributed among the offspring in predictable ratios that are due to the segregation of paired units of heredity. These "factors" of heredity were given the name "genes" by Wilhelm Johannsen in 1905.

the plant's genetic structure. Some of these mutations can result in the expression of desirable traits that can be further selected and transferred into commercial varieties. These methods of crop improvement and selection led to the "Green Revolution" in cereal production of the 1960s and 1970s.

In addition to crossbreeding between plants of the same or different species, new methods are constantly being developed that allow crosses between non-sexually compatible plants, thus enabling the introduction of even greater genetic variability in the progeny. For example, embryo rescue[4] has been used to create oat–corn hybrids in which the oat genome is supplemented by the addition of one or more corn chromosomes.[5] Such techniques clearly introduce the potential to transfer allergens, anti-nutrients, or toxicants from one species to another (for example, transferring a corn allergen to oats).

Using modern biotechnology, specifically recombinant-DNA technology,[6] plant breeders are able to introduce specific genetic material derived from any species of plant, animal or micro-organism, or created synthetically within the laboratory, into many different species of plants and animals. Specific gene sequences encoding particular traits, such as resistance to insect pests or disease-causing plant viruses, or tolerance to specific broad-spectrum herbicides, can be introduced into plant cells using *Agrobacterium*-mediated transformation,[7] micro-particle bombardment with DNA-coated metal beads,[8] or direct uptake of DNA by plant protoplasts.[9]

Based on current research, one can anticipate the future development of crops with increased tolerance to salinity and drought, improved disease and pest resistance, enhanced yield potential, modified nutritional qualities, and crops that can act as delivery vehicles for vaccines and therapeutic proteins. Foods with new functional and nutraceutical or pharmaceutical attributes are expected to exhibit more complex traits that, in many cases, will blur the boundary between foods and pharmaceuticals. Some examples of such foods include potatoes that express a vaccine against Norwalk virus (responsible for viral gastroenteritis, which makes up about 25 percent of the cases of "traveller's diarrhea"), tomatoes with elevated levels of lycopene (a pigment whose intake has been associated with reduced risk of cancer), and the highly publicized "golden rice," which contains increased levels of the vitamin A precursor, ß-carotene. Non-food crops such as tobacco are also being engineered to act as "plant factories" for the production of therapeutic agents to treat the herpes virus, or the production of biodegradable polymers as substitutes for plastic. These developments are described in more detail in Annex 3.

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[4] Rescue of embryos from a cross between two plants that normally, in nature, would not result in offspring, thus enabling certain "wide crosses." The plant is pollinated naturally but the seedpod is then removed and grown in a laboratory tissue culture, eventually producing new plants.

[5] R. G. Kynast et al (2001), A complete set of maize individual chromosome additions to the oat genome, *Plant Physiology* 125: 1216–27.

[6] There are other techniques used in biotechnology, such as recombinant-RNA and cell fusion. The first recombinant deoxyribonucleic acid (DNA) molecule was created in 1972 by researchers at Stanford University. The group, led by Paul Berg, who received a Nobel Prize for the work, used enzymes found in bacteria — called restriction endonucleases — to cut DNA from two different sources (a bacterium and a virus) and used a different enzymatic reaction to splice these two foreign pieces of DNA together into a functional, hybrid DNA molecule. In 1973, Stanley Cohen, also from Stanford, and Herbert Boyer, from the University of California at San Francisco, took this work to the next step by transferring a recombinant-DNA molecule into a bacterium, where it functioned alongside the bacterium's own genes. In doing so, they created the first "genetically engineered" organism.

[7] *Agrobacterium tumefaciens*, which is the cause of crown gall disease, is a soil-borne bacterium that uses genetic engineering processes to subvert the host plant cell's metabolic machinery. It does so to divert some of the host's organic carbon and nitrogen supplies to produce nutrients (opines), which can be specifically metabolized by the invading bacteria. Parasitized cells are also induced to proliferate, and the resulting crown gall tumour disease is a direct result of the incorporation of a tumour-inducing region of DNA carried by *A. tumefaciens*, into the host plant genome. The bacterium can be manipulated to replace the tumour-inducing genes with genes encoding for specific desired traits, and the altered bacterium can be used as a means of introducing these new gene sequences into plants.

[8] Microprojectile bombardment (also known as microparticle bombardment and biolistic transformation) is a technique used to directly deliver DNA to the host genome and has proven to be useful for the transformation of plant tissues recalcitrant to *Agrobacterium* infection. In short, plasmid or linearized DNA with the gene(s) of interest is fixed to tungsten or gold particles (microcarriers), which are delivered to host cells at high speed to penetrate the nucleus of the plant cells. In the nucleus, the DNA may separate from the microcarrier and become integrated into the host genome.

[9] A protoplast is a plant or bacterial cell whose cell wall has been removed.

Global Impact of GM Foods

Worldwide, the first small-scale environmental releases of GM crops in confined field trials occurred in 1987 in the United States and 1988 in Canada. The first attempt at commercially marketing a bio-engineered food product was the Flavr Savr™ tomato, which was developed by Calgene Corporation to delay softening. This tomato, which was approved for environmental release in the United States in 1992 and for human consumption in 1994 and in Canada by Health Canada in 1995, did not succeed commercially, largely due to production issues unrelated to the transgenic nature of the product.

To date, Health Canada has authorized 51 novel (42 transgenic) foods for marketing in Canada, and the Canadian Food Inspection Agency (CFIA) has authorized 39 plants with novel traits (31 transgenic) for unconfined environmental release. Forty GM crops (31 transgenic) have been approved for use in livestock feeds, including some not grown in Canada, such as cotton.

A similar number of products have been commercialized in the United States, with a smaller subset of products authorized for commercial use in other countries, including Argentina, Australia, China, Japan, Russia, South Africa, and the European Union. These first-generation products are generally based on crop plants that have been genetically modified to resist insect pests, such as varieties of corn, potato and cotton containing a toxin-encoding gene from strains of the soil bacterium, *Bacillus thuringiensis* (*Bt*); plants with tolerance to broad-spectrum herbicides; and plants such as papaya,[10] potato and squash with resistance to disease caused by specific plant viruses. There are also a very limited number of products with modified quality traits such as high-oleic acid canola and soybean, and delayed-softening melons and tomatoes.

The International Service for the Acquisition of Agri-biotech Applications estimates that the global area of transgenic crops in 2001 was about 53 million hectares, a more than 30-fold increase since 1996, grown by 5.5 million farmers in 13 countries.[11] Four countries, the United States (68 percent), Argentina (22 percent), Canada (6 percent) and China (3 percent), account for nearly all of this area, with nine other countries making up the remaining 1 percent. It is noteworthy that the four principal countries growing transgenic crops are represented by two nations from the "North" and two nations from the developing world. Indeed, between 2000 and 2001, developing nations adopted these crops at a higher rate than did industrialized countries (26 percent versus 17 percent). For example, between 2000 and 2001, China increased its cultivation of insect-resistant *Bt* cotton threefold, from 0.5 million hectares to 1.5 million hectares.

Globally, the principal transgenic crops are herbicide-tolerant soybean (63 percent of total acreage in 2001), insect and/or herbicide-tolerant corn (19 percent), insect and/or herbicide-tolerant cotton (13 percent), and herbicide-tolerant canola (5 percent). Of the global aggregate area of these four crops (271 million hectares), about 19 percent was planted to transgenic varieties in 2001. Specifically, this represents 36 percent of total soybean area, 20 percent of total cotton area, 11 percent of total canola area and 7 percent of total corn area.

Canada's Approach to Regulating Novel Foods

Canada is the only country where regulatory oversight is triggered by "novelty" rather than "process." This means that the novelty of traits expressed by plants, or the novel attributes of foods or food ingredients, irrespective of the means by which the novel traits were introduced, are subject to

[10] Genetically modified papaya is commercialized in the United States, but not in Canada.
[11] C. James (2000), Global status of commercialized transgenic crops, *ISAAA Briefs* 23.

regulation. Numerous scientific bodies and expert consultants have validated this approach.[12] U.S. National Research Council (2000): "No strict distinction exists between the health and environmental risks posed by plants genetically engineered through modern molecular techniques and those modified by conventional breeding practices." (See also Annex 4 for bibliographies.) By contrast, some form of "process-triggered" regulation is the rule in all other countries that have developed regulatory systems for GM foods. The Cartagena Protocol on Biosafety also focusses specifically on living modified organisms, defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."

The difference between "novelty" and "process" triggers for regulatory oversight can be illustrated using the example of herbicide-tolerant canola. Genetic engineering has been used to create canola varieties that are glyphosate-tolerant.[13] More established methods such as accelerated mutagenesis have been used to create varieties that are imidazolinone[14]-tolerant.[15,16] Both technologies have the potential to introduce genetic changes resulting in unintended or unanticipated consequences, and both could have environmental impacts if outcrossing creating herbicide-tolerant progeny were to occur. Also, both technologies can be used to create either glyphosate-tolerant or imidazolinone-tolerant varieties. However, only in Canada would both varieties be subject to environmental or food safety risk assessment and regulatory oversight. In other countries, only the varieties produced through genetic engineering would be regulated.

Since the scope of Canada's regulatory approach is broader than just GM foods, Canadian regulators have adopted unique terminology and definitions. Rather than referring to GM plants or GM foods, the guidelines and regulations refer to plants with novel traits and novel foods, respectively. The regulations define a novel food as any food that does not have a history of safe use as a food, or has been manufactured or packaged in a way not previously applied to that food and that causes a significant change in the food's properties. A third category of novel foods is GM foods, including foods derived from mutagenesis.

Similarly, the *Seeds Act* defines a plant with a novel trait as "a plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated species of plant in Canada and that has been intentionally selected, created or introduced into a population of that species through a specific genetic change."[17] This can include plants produced through genetic engineering as well as plants produced through accelerated mutagenesis, cell fusion, wide outcrossing, and even conventional crossbreeding. This is a more demanding approach than that taken by regulators in other countries. In Canada, regulators are required to determine when a plant is in fact a "plant with a novel trait" as defined in Canadian

[12] OECD (2000): "There is no scientifically valid reason to treat possible gene transfer events involving GM organisms differently from those involving naturally occurring organisms. . . . It is the gene and the trait that it confers, and whether or not it brings a reproduction or selection advantage to the recipient organism, that are critical concerns when possible impacts of potential gene transfer are being considered." FAO/WHO (2000): "The potential occurrence of unintended effects is not unique to the application of recombinant DNA techniques but is also a general phenomenon in conventional breeding."

[13] Glyphosate is an amino acid analogue that specifically binds to, and inactivates, the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). The EPSPS enzyme, which is present in all plants and micro-organisms but not in humans or animals, is involved in the biosynthesis of essential aromatic amino acids. Because these amino acids are needed for protein synthesis, which is required for plant growth and maintenance, the application of glyphosate quickly results in plant death.

[14] Imidazolinone herbicides are active against the enzyme acetohydroxyacid synthase (AHAS), also known as acetolactate synthase (ALS). This enzyme catalyses the first step in the biosynthesis of the essential branched chain amino acids isoleucine, leucine and valine.

[15] Using the former approach, the gene encoding a herbicide-tolerant form of a bacterial enzyme (analogous to the same enzyme present in plants) is introduced into the plant genome using recombinant-DNA technology, while with the latter method, mutations in the plant genome are induced by the application of mutagenic chemicals or ionizing radiation. In each case, plants displaying the trait of herbicide tolerance are selected (usually in tissue culture) and the new trait is subsequently transferred into commercially important varieties via traditional crossbreeding.

[16] By 2000, the Food and Agriculture Organization of the United Nations estimated that more than 2200 cultivars worldwide had been produced either directly or indirectly from this technique. See M. Maluszynkski et al, Officially released mutant varieties: The FAO/IAEA database, *Mutation Breeding Review* 12 (Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and FAO/IAEA Agriculture and Biotechnology Laboratory, 2000).

[17] Regulatory Directive 94-08 *Seeds Act*.

regulations[18] rather than simply apply the test of whether or not it was produced using recombinant-DNA (or cell fusion) technology. (Note: The use of the term "substantial equivalence" within the definition of a novel trait in Canadian regulations is discussed later in this report.)

Regulatory Structures and Processes

In Canada, the regulation of GM plants and foods involves Health Canada, the Canadian Food Inspection Agency (CFIA) and Environment Canada.[19] It may in future involve the Department of Fisheries and Oceans. These agencies have used existing acts to incorporate new regulations or amend existing ones in order to deal with GM foods. Although each body has its own area of responsibility, there are overlaps. For example, Health Canada and CFIA share responsibility for Canada's food labelling policies. Health Canada is responsible for labelling related to health and safety issues, such as foods that could contain allergenic substances. CFIA handles general food labelling policies and regulations not related to health and safety, such as preventing misrepresentation and fraud.

There is also potential overlap in the conduct of environmental assessments. Under the *Canadian Environmental Protection Act* (CEPA), Environment Canada has overall responsibility for performing environmental risk assessments of new substances manufactured or imported into Canada, including organisms produced through biotechnology. The requirement, under CEPA, for an environmental assessment by Environment Canada does not apply if the product is regulated pursuant to another act requiring equivalent environmental assessment, as determined by the Governor-in-Council. Thus, CFIA conducts all environmental assessments for plants with novel traits because the applicable statutory instruments have been deemed to be equivalent.[20] The same is not true for other applicable acts such as the *Food and Drugs Act*, the *Plant Protection Act* and the *Fisheries Act*. Accordingly, the Department of Fisheries and Oceans is currently developing draft regulations on transgenic aquatic organisms, and Health Canada has published a Notice of Intent to develop Environmental Assessment Regulations under the *Food and Drugs Act*. These would cover all foods, including novel foods.

Research and development involving genetically modified organisms (GMOs) and occurring within a contained setting such as a laboratory or greenhouse is not currently subject to regulatory oversight and authorization in Canada. The Canadian Institutes of Health Research have guidelines designed to prevent the environmental release of GMOs. Most research institutions — both public and private — have their own codes of conduct and oversight committees.

Canadian Food Inspection Agency

CFIA is responsible for regulating the importation (*Plant Protection Act*), environmental release (*Seeds Act*), variety registration (*Seeds Act*) and use in livestock feeds (*Feeds Act*) of plants with novel traits (PNTs). For PNTs produced or evaluated in Canada, the first point of contact with the regulatory system is the evaluation of these plants in research trials. These small-scale field trials are conducted subject to CFIA-mandated conditions of reproductive isolation designed to severely restrict the interaction of the plants with the larger environment. This means that these plants are grown under conditions that mitigate the transfer of pollen to other plants. The experimenter and CFIA field inspection staff monitor

[18] Agriculture and Agri-Food Canada (1996), JUS-96-004-01 (SOR/DORS): Amendments to the Seeds Regulations — Release of Seed (http://www.inspection.gc.ca/english/plaveg/pbo/96004e.shtml).

[19] Further information can be obtained from Health Canada (www.hc_sc.gc.ca/english/food.htm#novel); Canadian Food Inspection Agency (www.inspection.gc.ca/english/toc/bioteche.shtml); and Environment Canada (www.ec.gc.ca).

[20] *Pest Control Products Act* and Pest Control Products Regulations; *Feeds Act* and Feeds Regulation; *Seeds Act* and Seeds Regulation; and *Health of Animals Act* and Health of Animals Regulations (veterinary biologics).

them, and the trial site is subject to post-harvest land use restrictions and further monitoring.[21] PNTs are typically evaluated in confined field trials over a number of years to collect agronomic and environmental impact data. Those that appear to the developer to have commercial promise are then subject to the appropriate assessments (e.g. environmental, livestock feed, and human food safety assessments) before being authorized for unconfined environmental release or allowed to enter the marketplace.

CFIA science evaluators also conduct a critical review of a scientific information package submitted by the proponent. Each application for approval is evaluated on a case-by-case basis that incorporates an examination of the biological processes involved as well as the environmental impact, primarily on agricultural and natural ecosystems. Following molecular characterization of new genetic material, PNTs are compared with their conventional counterparts. The objective is to see if the new trait(s) has changed the plant's characteristics and consequently its environmental influence through, for example, gene flow from a novel plant to other species or through the novel plant's impact on non-target organisms and on biodiversity.[22] An authorization for an unconfined release is granted only when CFIA has determined that any environmental risks associated with the release of any novel plant are acceptable and/or manageable.

CFIA also regulates PNTs and their by-products used in experimental animal feeding trials as well as in domestic and imported manufactured feeds. As with the environmental safety assessment, CFIA evaluators conduct feed safety assessments and each product is evaluated on a case-by-case basis. The characteristics of a novel feed are compared with those of its conventional counterpart in terms of its molecular, compositional, toxicological and nutritional makeup. The information requirements include data on the stability of the novel feed, its environmental fate and a determination of whether or not the gene products and by-products will reach the human food chain. Novel feeds cannot be used unless duly assessed and authorized by CFIA.

Canada has a system of variety registration for certain newly developed crop varieties that is designed to ensure that only those varieties with proven merit are sold. In the case of GM plants, varieties must receive the necessary environmental, livestock feed and food safety authorizations prior to moving forward through the variety registration system and possible commercialization. Once authorized, GM varieties, like all others, are assessed in regional field trials. Those selected and supported by national advisory committees move forward for registration.

Health Canada

Health Canada is solely responsible for assessing the safety of foods for human consumption, including GM foods and other novel foods, and for allowing them to be sold in Canada. It is responsible for implementing the provisions of the *Food and Drugs Act* that relate to public health, safety and nutrition; for establishing policies and standards for the safety and nutritional quality of foods sold in Canada; and for assessing the effectiveness of CFIA activities related to food safety (for example, sampling and inspection for food contaminants).

At the heart of Health Canada's safety assessment process is the principle that novel foods can be compared with traditional foods that have an established history of safe use, and that this comparison can be based on an examination of the same risk factors that have been established for the counterpart food. This approach, which reflects the internationally applied concept of substantial equivalence

[21] The information requirements for an application to conduct a confined trial as well as the restrictions placed on confined trials are published in Regulatory Directive 2000-7: Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada (http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir0007e.shtml).

[22] The assessment criteria are described in Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits (http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir9408e.shtml).

(discussed in more detail under *Theme 2: Precaution*), seeks to establish the relative safety of the new food product to ensure, with reasonable certainty, that no harm will result from intended uses under anticipated conditions of processing and consumption. Under this approach, the safety assessment focusses on the differences between the new food and conventional foods and requires a critical assessment of molecular, compositional, toxicological and nutritional data. The potential allergenicity of the novel food, as well as dietary exposure by the average consumer and population subgroups, must also be addressed. The information requirements are set out in Guidelines for the Safety Assessment of Novel Foods. Evaluations are summarized in a report that is subject to review by a Rulings Committee.

Approvals of GM crops and foods are eventually published in summary form by CFIA and Health Canada and can be accessed on their respective web sites. For GM plants approved for environmental release, Canadian regulations require that developers — or anyone who becomes aware of additional or new safety-related information — convey that information to the regulatory authorities. In addition, all novel plants, feeds and foods remain subject to Canada's basic regulatory regime for conventional plants, feeds and foods.

Environment Canada

Under the *Canadian Environmental Protection Act* (CEPA), Environment Canada is responsible for administering the New Substances Notification (NSN) Regulations for products not covered under other acts and regulations, and for performing environmental risk assessments of substances to determine if they are toxic, as defined under CEPA. The regulations cover organisms that may have been produced through biotechnology. The NSN Regulations under CEPA 1999 require that all "new" substances, including products of biotechnology, are reported and assessed for their potential to adversely affect human health and the environment before being manufactured in Canada or imported across its borders. The program is jointly administered by Environment Canada and Health Canada. The new substances assessment considers all phases in the life cycle of the new substance from the time it is first manufactured for research and development through to its commercial use and disposal.

Until the regulations on transgenic aquatic organisms currently being drafted by the Department of Fisheries and Oceans are in force, any application for the environmental release of transgenic fish is assessed under CEPA. (No such applications have appeared to date.)

International Aspects of Regulation

Nine international bodies are currently involved in the coordination and regulation of biotechnology products. They cover a spectrum of functions from institutions that primarily set science-based standards[23] to ones with broader objectives such as food security, trade facilitation, environmental protection, and other social and political goals.[24] The science-oriented organizations seek mainly to contribute to the development of standards and procedures for identifying and assessing the risks of GM foods, while the organizations with broader objectives concentrate on developing international consensus on procedures for coordinating assessments, adjudicating disputes and building mechanisms associated with their mandate. Canada is a significant actor in all of these entities, at times leading the efforts to develop international consensus on matters of science, governance and/or policy.

[23] International Plant Protection Convention, International Office of Epizootics, CODEX Alimentarius.

[24] Food and Agriculture Organization, Organisation for Economic Co-operation and Development, various bilateral and regional initiatives, World Trade Organization, Cartagena Protocol on Biosafety and World Health Organization.

Implications of Future Foods for the Regulatory System

It is expected that over the coming years a new generation of GM foods will be proposed for market introduction. These foods are described in detail in Annex 3, and some of their implications are reviewed here.

The plant biotechnology products now under development will present a wider range of novel traits and will be more complex than the current products. The GM foods commercialized to date involve primarily single-gene insertions, whereas the products being developed involve the introduction of multi-gene traits that either produce entirely new metabolic pathways or significantly alter existing ones. This will make the prediction and assessment of side effects more difficult.

In evaluating the possible unintended consequences of genetic modifications, existing safety assessment protocols have employed a targeted approach to identify differences in the levels of specific nutrients, toxicants and anti-nutrients. For example, when evaluating possible side effects arising from the genetic modification of potatoes, it is common practice to measure the levels of naturally occurring glycoalkaloid toxins in the modified potato. All potatoes normally produce two glycoalkaloids (solanine and chaconine) that can give rise to toxic effects if ingested in sufficient quantities.[25] Regardless of whether the new variety was produced via genetic engineering or traditional plant breeding, it is important to verify that the production of these compounds has not been significantly altered as a result of the genetic modification.

A key limitation to this targeted approach to assessing unintended consequences is that it relies on prior knowledge of what to measure. Alternative methodologies are being developed to allow for a more generalized non-targeted assessment of changes in plant physiology. It is hoped that these techniques, which include methods to look for changes in the concentrations of proteins, secondary metabolites and altered gene activity, will provide a metabolic profile of the modified plant that could be compared with a similar profile from a conventional counterpart.[26] While promising, none of these metabolic profiling methods is sufficiently advanced and validated to be routinely included in a food safety assessment at the present time.

The 42 GM foods (representing a subset of the 51 novel foods) approved for use in Canada are derived from plants into which a narrow range of new traits (characterized by the expression of a small number of new or modified proteins) has been introduced. For the most part, these novel proteins are either one of a few bacterial enzymes that are tolerant to or facilitate the breakdown of herbicides, insecticidal proteins from *Bacillus thuringiensis*, or proteins from plant viruses. All of these proteins were derived from commonly occurring bacteria, plant viruses or other plants. It can be argued that we have had at least some prior exposure to them that, in the case of plant virus proteins, would be considerable, since all major food crops are commonly infected with these agents.

The potential for inadvertently introducing an allergen is a key consideration during the development and safety assessment of GM foods. The products currently in the marketplace have been assessed for potential allergenicity, accomplished by investigating the breakdown of new proteins under physiologic conditions in the stomach and intestinal tract, and by searching for similarities with known allergenic proteins. A limitation of this approach is that it becomes difficult to predict the allergenic potential of proteins that have some of the properties of both non-allergens (for example, if they have no sequence similarity to known allergens) and allergens (for example, if they are not broken down by digestion). To

[25] The glycoalkaloid content in potatoes varies significantly depending on environmental conditions during growing, mechanical injury, length of storage and potato variety. The glycoalkaloid solanine is also present in apples, bell peppers, cherries, sugar beets and tomatoes.

[26] H. P. J. M. Noteborn et al (2000), Chemical fingerprinting for the evaluation of unintended secondary metabolic changes in transgenic food crops, *Journal of Biotechnology* 77: 103–14.

properly assess future food products that may express a much broader range of novel proteins, improved predictive tools — perhaps including animal models — will have to be developed.

The possibility of using food crops as "plant factories" for the production of industrial or pharmaceutical compounds raises additional issues related to the ability to maintain adequate segregation throughout the production chain to ensure that these products do not enter the human or livestock food chains. This raises questions whether or not such plants should ever be grown outside contained facilities and whether or not segregation systems can effectively ensure adequate separation.

Recent Developments in Public Policy

Since we began our GM foods project, several domestic and international developments have taken place in the public policy arena. These are briefly noted below.

National

The Royal Society of Canada Expert Panel Report titled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* and the federal government's action plan in response to it were published in 2001, and are referred to at relevant points in this report.

The Canadian Council of Grocery Distributors and the Canadian General Standards Board have been engaged, since fall 1999, in a consultative process to establish a standard for the voluntary labelling of foods regarding the role, if any, of genetic modification in their derivation.[27] The most recent draft of this standard, published in December 2001, is currently being revised and will then go to a final ballot.

In October 2001, a Private Member's Bill (Bill C-287) to amend the *Canadian Food and Drugs Act* to require the labelling of GM foods was defeated in the House of Commons. Subsequently, the ministers of Health, Agriculture and Agri-Food, Environment, and Industry asked the House of Commons Standing Committee on Health to hold public hearings on the issue of mandatory labelling and to report to Parliament in June 2002. Health Canada recently initiated a Biotechnology Surveillance Project to establish a national surveillance system to address potential long-term health consequences following the use of biotechnology and/or bio-engineered products.

Other developments at the federal level include release of a publication by Agriculture and Agri-Food Canada titled *Putting Canada First: An Architecture for Agricultural Policy in the 21st Century*, a Privy Council Office initiative titled *A Canadian Perspective on the Precautionary Approach/Principle*, and a joint CFIA-HC consultation on the guidelines for novel feeds, novel foods and environmental assessments. On the provincial level, the Conseil de la science et de la technologie (Québec) published *OGM et alimentation humaine : impacts et enjeux pour le Québec* in January 2002.

[27] Refers to techniques by which the genetic material (deoxyribonucleic acid — DNA — or ribonucleic acid — RNA) of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Examples of the techniques used in gene technology include, but are not limited to:

- recombinant-DNA (rDNA) techniques that use vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism
- cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.

International

Internationally, several governments have been prompted to commission studies, seek the advice of international organizations and expert panels, and undertake public consultations on policies related to GM crops and foods. Canada has been active in many of the international efforts.

Recent reports issued include the CODEX report on the development of internationally accepted principles of risk analysis, and guidelines for the safety assessment of foods derived from modern biotechnology.[28] Reports by the Organisation for Economic Co-operation and Development (OECD), Food and Agriculture Organization (FAO) and the World Health Organization (WHO) addressed food safety and nutritional factors;[29, 30, 31] and allergenicity.[32] Reports have also been published by national scientific bodies, such as the Royal Society of London[33] and the U.S. National Academy of Sciences[34] in the United States, as well as other national and multinational activities,[35] which supplement international consensus-building efforts.

Common Concerns about GM Foods in the International Community

Even a cursory review of recent developments in Canada and abroad reveals many issues of common concern with respect to GM foods. The most prominent are:

- *with respect to food safety*
  - the adequacy and appropriateness of the concept of substantial equivalence as a tool for framing risk assessment
  - limitations in the ability to evaluate the risk of late-onset consequences of genetic modification
  - difficulties in predicting and assessing the potential allergenicity of unique proteins that could be introduced into the human diet
  - the feasibility of effective monitoring of populations to detect long-term effects on health
- *with respect to the environment*
  - impacts of GM crops on non-target organisms
  - the consequences of the spread of transgenes and the traits they encode into related plant species through pollen flow
  - effects on existing agricultural practices
  - effects on biodiversity in managed and unmanaged ecosystems
- *with respect to regulatory systems*
  - reconciling the regulation of GM foods with the regulation of other foods
  - the respective role of scientific and other modes of analysis in public policy
  - research
  - the role of citizen engagement in public policy formulation
  - reconciling the promotional and regulatory functions of government
  - the role of external advisory bodies
  - capacity building and quality assurance in regulatory bodies
  - enhancing public awareness and supporting informed consumer choice.

[28] FAO/WHO, CODEX Alimentarius Commission (2002), Report of the third session of the CODEX *ad hoc* intergovernmental task force on foods derived from biotechnology, ALINORM 03/34, Yokohama, Japan, March 4–8, 2002 (http://www.codexalimentarius.net/Reports.htm#fbt3).

[29] OECD (2000), *Report of the Task Force for the Safety of Novel Foods and Feeds*, pp. 1–72.

[30] FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29–June 2, Geneva, Switzerland, pp. 1–37.

[31] FAO/WHO (2001), *Expert Consultation on Foods Derived from Biotechnology: Genetically Modified Micro-organisms*, September 24–28.

[32] FAO/WHO (2001), *Evaluation of Allergenicity of Genetically Modified Foods*, Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, January 22–25, pp. 1–29.

[33] Royal Society of London (2002), Genetically Modified Plants for Food Use and Human Health: an Update, Policy Document 4/02, February (http://www.royalsoc.ac.uk).

[34] United States, National Academy of Sciences (2002), *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (http://www.nap.edu/books/0309082633/html).

[35] United States, National Academy of Sciences (2002), *European Union/United States Biotechnology Consultative Forum: Final Report*, December 2000 (http://europa.eu.int/comm/external_relations/us/biotech/report.pdf).

The Debate about GM Foods

In both developed and developing countries, the introduction — or potential for introduction — of crops and foods derived through the application of modern biotechnology has sparked a public debate on the associated environmental, human health, economic and social implications. Broadly speaking, the issues include: the adequacy of regulatory oversight for the assessment of potential health and environmental risks; approaches to dealing with uncertainty in both the short and long terms; consumer choice; effects on trading relationships; access to the potential benefits by developing countries while protecting against exploitation and the negative effects of globalization; and the consideration of social and ethical factors in product approval processes.

Economic Issues

The introduction of GM crops has resulted in direct economic benefits to the developers of the GM plants and to the farmers growing them, the latter estimated to be in the order of US$700 million in 1999.[36] However, direct economic benefits to consumers in the developed world have been much less obvious. This may account for a tendency in the public at large to focus on potential harms.

With regard to the economic impact of GM crops in developing countries, concerns have been raised that intellectual property rules and concentration of corporate power will lead to monopolistic behaviour and prevent resource-poor farmers in developing countries from access to biotechnological and other innovations. These are countered by the argument that GM crops have the potential to contribute significantly to sustainable gains in agricultural productivity and to food security. Others contend that excessive preoccupation with hypothetical harms is an expensive luxury that countries struggling to achieve food security cannot afford.

Environmental Impacts

There are sharp differences of opinion about the environmental impacts of GM crops. Proponents believe that crops genetically modified to resist pests and disease and requiring less use of pesticides and herbicides are safer for the environment than conventional crops and are less likely to result in pesticide-related illness or injury or to contaminate groundwater. Others focus on the potential detrimental impacts of GM crops. These include concerns that GM plants producing their own pesticides could accelerate the development of pesticide-resistant insect populations, that outcrossing between herbicide-tolerant crop plants and closely related weeds could lead to "superweeds," that engineered traits could move into adjacent non-GM crops, and that animal and insect species consuming transgenic plants could be harmed. Proponents would counter these arguments by saying that all of these risks exist with conventional agricultural products and their associated agricultural practices.

Ethical and Social Considerations

The current science-based health and environmental regulatory regimes do not address a number of broader social and ethical concerns raised by GM crops and foods. These concerns range from fundamental opposition to the artificial manipulation of plants and animals (playing God with nature) to the belief that global justice and beneficence (that is, doing or producing good) are not being served by

[36] C. James (2000), Global status of commercialized transgenic crops, *ISAAA Briefs* 23.

current applications of biotechnology. There are also consumers' rights issues regarding sufficient information to allow informed choices to be made about food consumption.[37]

Proponents argue that selective breeding and the application of scientific knowledge have resulted in artificial modification of plants and animals throughout history. They note that GM crops hold the promise of substantially increasing both yields and the nutritional value of foods, thus bringing great benefit not only to the farmer but especially to the least developed nations. They conclude that it would be immoral to deny them access to these new crops.

Public Confidence in Regulatory Regimes

In Canada the public has considerable confidence in the food regulatory regime, and substantial majorities believe that foods offered for sale in the food market are safe for human consumption.[38] However, events such as the BSE ("mad cow disease") crisis in the United Kingdom, the tainted-blood scandal in Canada, and dioxin-tainted beef in Belgium can shake public confidence and contribute to a general wariness about the ability of regulatory regimes to protect health and the environment. One can therefore reasonably expect that the intensity of the debate on GM foods will be influenced not only by developments directly related to GM foods but also by the level of public confidence in the regulatory system as a whole.

Observations and Recommendations

Theme 1: Good Governance

Good governance is the key to a regulatory regime that protects the health and safety of citizens as well as of the environment. It also induces public and stakeholder confidence in the efficiency and effectiveness of the regulatory regime.

Recommendation 1. Structure, organization and operation of the federal food regulatory system

Observations

The federal government has many roles and responsibilities relative to food: regulating certain aspects of food production and marketing; ensuring food safety; protecting the environment; promoting economic growth through industrial and trade policy; supporting scientific and technical innovation; and promoting public understanding of nutrition and healthy dietary practices. This multiplicity of roles and responsibilities poses several challenges for the government's regulatory function. These challenges include:

- appropriately segregating the roles of regulatory bodies and other government bodies
- ensuring that regulatory bodies have the necessary authority, expertise and resources to fulfil their mandates and to keep pace with advances in knowledge and product development
- ensuring that the implementation of the mandates of the government's regulatory bodies is efficiently conducted and coordinated
- providing the public with easy access to information about regulatory functions and organizing this information to meet the needs and interests of diverse groups in Canadian society.

[37] One of the most contentious issues in the GM food debate in Canada is whether or not the government should require producers to label foods derived from GM plants. This matter is discussed in the section of this report devoted to the labelling issue.

[38] *Release of the 5th Wave Public Opinion Research into Biotech Issues* is available on the CBS Web site in English (http://biotech.gc.ca/engdoc/opinion.html) and in French (http://biotech.gc.ca/frndoc/opinion.html).

Role Definition and Independence

Whenever an entity has many roles and responsibilities, it faces the possibility of conflicts of interest and commitment. In the case of foods, the issue that has attracted the most attention is the potential conflict between the government's regulatory role and its role in promoting the country's economic interests. The fear is that in seeking to promote the exploitation of technology to capture its economic benefits, the government may downplay the risks of the technology and accentuate its benefits.[39] Since it is generally agreed that the food regulatory system exists primarily to protect health and the environment and that this function should not be compromised by other interests, the point at issue becomes how best to ensure the independence of the regulatory function.

While Health Canada, Environment Canada and CFIA and, to a lesser degree, the Department of Fisheries and Oceans all have responsibilities in the food regulatory regime, much of the public concern in this regard has centred on CFIA. As described earlier, CFIA is responsible, among other things, for regulation of plants with novel traits, importation of plants and plant material, animal health, feeds, fertilizers and veterinary biologics. It is also responsible for food labelling in areas other than health and safety. It has been alleged that CFIA has an industry bias and promotes biotechnology in its public communications.[40]

The independence and autonomy of Health Canada was also brought into question during the process to approve the release of bovine somatotropin (rBST). rBST is a synthetic hormone used to increase milk production in dairy cows. It has also been noted that Environment Canada has responsibilities for technology development and dissemination as well as regulation, and that these functions report to the same Assistant Deputy Minister.

CFIA also plays a role in international negotiations. However, it is important to distinguish, on the one hand, between the involvement of Canadian regulators in CODEX, OECD, FAO/WHO and other international bodies in the development of scientific and technical standards related to environmental or food safety assessment and, on the other hand, international activities such as trade missions or negotiations that deal with matters bearing on the nature and direction of Canada's regulatory policies. Critics argue that participation in international negotiations of this latter kind is potentially in conflict with the primary role of regulators.

Although CFIA and Agriculture and Agri-Food Canada (AAFC) operate under separate legislative authorities, both report to the Minister of Agriculture whose responsibilities include ensuring that the agricultural sector is efficient, effective and internationally competitive. Although AAFC has no authority over CFIA's regulatory decisions, some believe that the two entities should have separate reporting relationships.

It is not unusual for governments to have their GM food regulatory functions in departments and agencies with multiple and potentially conflicting mandates. In the United States, for example, one branch of the Department of Agriculture is responsible for regulating the environmental release of bio-engineered crops, while another engages in basic agricultural research and technology promotion. The roles are kept separate through the careful articulation of their mandates and through institutional codes of conduct. Confirmation and validation of the effectiveness of these arrangements is accomplished primarily through a transparent product review and approval process.

[39] William Leiss and Christina Chociolko (1994), *Risk and Responsibility* (Montréal and Kingston: McGill-Queen's University Press).

[40] World report, Food agency accused of funding propaganda, CBC Radio, October 11, 2000; Who can you trust?: There's a too cozy relationship between food regulators and producers, *Montréal Gazette*, July 20, 2001; Mark Abley, Magazine insert leaves a bad taste: Ottawa pushes safety of bio-engineered food, *Montréal Gazette*, March 28, 2000, p. A1.

The United Kingdom has taken a different approach by establishing an independent scientific committee to review all applications for the environmental release of GMOs. The Advisory Committee on Releases to the Environment assesses the potential implications of proposed GM products, including potential allergens and toxins and possible environmental impacts, and advises the Minister of the Environment on whether or not approval should be granted. Because the committee is independent of government, it is separate from other potentially conflicting activities. The committee comprises representatives from diverse fields such as agronomy, ecology, entomology, microbiology, molecular biology, plant breeding, rural development, virology and weed ecology. There is no specific representation from the social sciences or from special interest groups.

Resources and Capacities

To function effectively and efficiently, regulatory systems need sufficient scientific and technical expertise to apply the most advanced knowledge and technology to the assessment of products and processes, as well as sufficient numbers of personnel to keep pace with the rate of product development.

In most countries, the expertise within regulatory agencies is supplemented by engaging external experts. Some, such as the United Kingdom, have legislated a system of expert advisory committees while others, such as the United States, rely primarily on scientists and professionals working within government supplemented by expert panels or committees appointed on a discretionary basis. Although these panels and committees do not participate in the evaluation of specific products, the U.S. Environmental Protection Agency Scientific Advisory Panel is an external body that has been used to provide advice on the formulation of government policy and/or regulations, or advice on specific issues such as the allergenic potential of Cry9C protein.[41]

There is a growing appreciation that regulatory systems need to develop enhanced capabilities beyond traditional scientific and technical expertise. These capabilities include, for example, the ability to undertake forecasting studies to identify future regulatory needs, and the ability to re-evaluate their operational efficiency and effectiveness on a regular basis. There also appears to be growing recognition that more investment in research is needed to inform regulatory risk assessment and decision making and that such new knowledge must be integrated into the regulatory process. As several countries are facing these issues, strengthening relationships with the international scientific and regulatory communities may enhance Canada's efforts in these areas.

Efficiency of the Regulatory System and Enhanced Coordination

The developers of new products, whether food crops, pharmaceuticals or pesticides, claim that the Canadian regulatory regime is significantly slower in approving new products than comparable systems in other countries, and that Canadian regulations make it more expensive and time consuming for new products to get to market, thereby reducing the incentive to do business in Canada. They urge increased international cooperation to reduce the duplication of work and the amount of time required to secure approvals for a single product in different countries. However, others are concerned that international harmonization could press Canada into adopting standards that meet a "lowest common denominator" or into ceding its sovereignty and local accountability. To date, Canada's efforts concerning international harmonization have focussed on developing technical standards for risk assessment and guidelines specifying the information required of developers.[42]

[41] FIFRA Scientific Advisory Panel Meeting (2000), Report on Assessment of Scientific Information Concerning StarLink Corn, November 28, Arlington, Virginia.

[42] CFIA (1998), Appendix 1: Molecular genetic characterization data, Plant Biosafety Office (http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml).

As mentioned earlier in this report, Canada's federal food regulatory system relies on several regulatory bodies, some more active in the GM arena than others. The bodies interact but are not highly integrated. Within their specialized spheres, they address similar issues and concerns but generally do not do so in a concerted or sufficiently transparent manner. Regulators in Health Canada and CFIA function closely together, but coordination with the other parts of the system appears weak.

New food products that have either significantly altered nutritional properties or medicinal attributes are likely to blur the existing distinctions between foods and drugs. For these products, effective safety assessment requires carefully managing the coordination of diverse expertise in therapeutics and food safety. In a similar manner, the environmental assessment of plants bio-engineered to produce pharmaceutical or industrial proteins may require an increased emphasis on more cooperative arrangements between evaluators in the Government of Canada.

There are a number of ways government could improve regulatory efficiency. There is considerable scope for different national regulatory bodies (see below) to enhance the sharing of information related to environmental and human health risks associated with new products. Governments should continue to explore ways and means of avoiding unnecessary duplication of effort both by regulators and developers of products.

Communicating with the Public

CFIA and Health Canada share responsibilities for providing information about food safety and nutrition to both professionals and consumers. Four findings relating to communications emerged during our consultations.

- While some respondents allege that materials published by CFIA and Health Canada reveal a bias in favour of biotechnology that calls into question their impartiality as regulators, others regard the information as useful and unbiased.
- Simply making information available is insufficient — educational programs about the production and use of foods are also required.
- Much better information (more user friendly and comprehensive) about the organization, operations, decision-making processes and accountabilities of the regulatory system is needed.
- The public varies considerably in its interest in food-related information, in how it wishes to receive or access information, and in its level of sophistication.

Recommendations

We recommend:

1.1. That the federal government enhance the structure, organization and operation of the federal food regulatory system for GM and other novel foods by adopting measures to further systematize and coordinate the operations of its several regulatory bodies and by clarifying mandates so as to remove conflicts and ensure a clear separation of the government's regulatory role from its other roles. In particular, we recommend that:

- the mandates, internal operations of the regulators of GM foods and other novel foods, and their relationships with stakeholders be carefully reviewed and modified where needed to ensure the highest degree of integrity and independence in the conduct of regulatory functions and to avoid the perception of mandate conflict or of conflicts of interest in operations.
- there be effective independence of regulatory functions for GM foods and other novel foods unencumbered by other government functions and responsibilities, including, but not

limited to, policy, economic development, negotiation of international policy and trade rules, and trade promotion.
- an assessment be undertaken to determine whether it would be advantageous to apply this recommendation more widely to other facets of the food safety system.

1.2 That standard operating procedures be prepared and published that clearly describe:
- organizational mandates and legislative authority
- the details regarding regulatory authorities, responsibility centres and relevant laws
- the precise steps involved in a product's progression through the regulatory system and the relevant time lines
- the details regarding the stages of risk assessments
- the delegation of decision-making authority
- the procedures to insulate officials from inappropriate influence
- the procedures for effective decision making, including the rationale for engaging non-governmental experts and expert panels in regulatory processes
- the mechanisms to resolve differences of opinion with regard to regulatory decisions
- the policies regarding the preparation of proposed Decision Documents for public review prior to final decision making
- the procedures for providing opportunities for public input at various stages
- the procedures for coordinating with other regulators to avoid potential gaps or duplication of effort
- the details regarding Rulings Committees and other elements of internal reviews.

1.3 That for those regulatory bodies that do not have one, a Rulings Committee be established through which all proposed decisions on GM foods and other novel foods must be vetted.

1.4 That the Auditor General of Canada review and publicly report on regulatory bodies involved in assessments and decision making related to GM foods and other novel foods sold in Canada. The review should assess the independence of regulatory functions as well as the effectiveness and efficiency of the agency's standard operating procedures and their application.

1.5 That all communications be assessed to ensure that they accurately reflect the mandate and operations of the regulatory agency, and convey accurate and reliable information about the systems and procedures that are in place to ensure reliable decisions about the safety of GM foods and the integrity of the operations.

1.6 That in ensuring effective coordination among regulatory bodies to increase efficiency and effectiveness, attention be given to the following matters:
- coordination of product assessments of GM foods and feeds and other novel foods in the areas of livestock feed, human food safety and environmental safety, as well as coordination of communication activities and materials, including proposed and final regulatory decisions
- elimination of any gaps, overlaps and inconsistencies within the regulatory system
- management of the government's scientific and technical expertise to ensure that capacity is maintained and, where necessary, increased; periodic reviews of capacity should be undertaken to ensure the regulatory system is capable of meeting future needs
- periodic examination, not less than once every 10 years, of the government's regulatory capacity to evaluate new and more complex products and to ensure compliance with the conditions of approval, with particular attention given to identifying opportunities for ongoing improvement of risk assessment and risk management activities, including options for optimum use of international regulatory and scientific expertise
- coordination of monitoring and surveillance to detect potential long-term health and environmental effects.

1.7 That a senior authoritative officer responsible for the regulation of novel foods be appointed as the official spokesperson and coordinator of communications pertaining to the government's policies and practices related to GM and other novel foods.

1.8 That the government examine organizational options capable of achieving the responsibilities listed above in 1.6 and 1.7, for example, using one of the following three models:

- an Office for the Coordination of the Regulation of Genetically Modified Foods and Other Novel Foods:
  - it would be the joint creation of the regulators whose activities it coordinates
  - it would be staffed with regulatory officers and managers drawn from departments and agencies involved in the regulation of GM foods
  - an Executive Director would act as the single spokesperson referred to in 1.7 above
- a committee of Assistant Deputy Ministers drawn from federal regulatory bodies:
  - the committee could be assigned responsibility for the coordination of the assessment and approval/registration of GM foods and other novel foods, and related inspection, enforcement, surveillance and monitoring activities
  - the chair of this committee would be the spokesperson referred to in 1.7 above and would be an *ex officio* member of all Rulings Committees
- a new agency that would be responsible for all regulatory activities pertaining to foods:
  - it would take over the food safety aspects of the current regulatory mandates of Health Canada, Canadian Food Inspection Agency, Department of Fisheries and Oceans and Environment Canada
  - the official spokesperson referred to in 1.7 above would be a part of the new agency.

Recommendation 2. Transparency and public involvement

Observations

Transparency and public involvement are essential for building trust in regulatory systems. Transparency is about the clarity and openness with which the government conducts its activities. It is also about the government's accountability to Canadians in carrying out these activities while being respectful of personal privacy and the confidentiality of proprietary information. With regard to regulatory systems, transparency refers to the extent to which governments provide information on regulatory processes and outcomes. Lack of transparency can raise questions about the independence and objectivity of the regulatory decision makers. Public involvement refers to the extent to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions.

The call for more openness in government around food safety issues can be attributed in part to high-profile cases such as the BSE ("mad cow disease") crisis in the United Kingdom and the tainted-blood scandal in Canada wherein regulatory processes were inadequate and scientific knowledge was too limited. These shortcomings fuelled the perception by some that consumer interests are sacrificed for the benefit of industry, that science is not as capable of predicting risk as commonly believed, and that governments withhold information that people should know.[43]

[43] For a more complete account of the BSE crisis, see European Environment Agency (2001), *Late Lessons from Early Warnings: the Precautionary Principle 1896–2000* (http://reports.eea.eu.int/environmental_issue_report_2001_22/en).

Constraints

The type of information that regulators can convey to the public may be limited by legal requirements to maintain the confidentiality of a company's "commercially sensitive" proprietary information (referred to as "Confidential Business Information" or CBI). This raises the question of who should determine what constitutes CBI. In its recent report on "Environmental Effects of Transgenic Plants,"[44] the U.S. National Academy of Sciences observed that the extent of environmental risk assessment information treated as CBI has hampered public and independent scientific scrutiny, and that while regulators may have little control over what companies can claim as CBI, they may not be making as much information available to the public as possible.

Canadian regulators also cite legal limitations as "an impediment to more closely linking federal research and monitoring capacity with regulatory functions"[45] and to publicly disclosing product testing data. Canada's *Access to Information Act* prohibits, except under certain specified conditions, disclosure of confidential third-party information[46] or other information the disclosure of which could reasonably be expected to result in harm to the commercial interests of the third party. When changes to statutes and/or regulations are proposed, they must first be published in the *Canada Gazette* to give the public an opportunity to comment on them. However, when the policy decision does not involve a change in a regulation or when a product is undergoing assessment, there is no requirement for public input in advance of the decision nor is there an opportunity for external scientific bodies to review the risk assessment information and proposed regulatory decisions.

One exception is the approach used in the registration of new active ingredients in pesticides under the *Pest Control Products Act* and in assessment of applications for the approval of significant new uses of a previously approved active ingredient. The Pest Management Regulatory Agency (PMRA) publishes Proposed Regulatory Decision Documents, which contain summaries, approved by the proponent, of the product safety data. Canadians have 45 days to comment on the proposed decision, after which PMRA publishes a final decision document that includes its consideration of the comments received.

International Trends

Internationally, biotechnology regulatory systems are evolving toward increased transparency, often with enhanced opportunities for public input. Some countries, such as the United States and Australia, require both public notification and a request for public comments before a final regulatory decision is made. Many regulatory officials believe that allowing for public input provides an additional avenue for considering external sources of safety-related information and fosters confidence in the risk assessment process. In Australia, the pre-notification process applies to confined field trial applications, applications for general environmental release, and food safety approval. In the case of confined trials, Australia requires that the public notification briefly describe the organism being tested, including the nature and effect of the genetic modification, the purpose of the trial, and the general location of the test site. Prior to granting approval for food use, the Australia New Zealand Food Authority publishes draft risk assessments that contain information relating to the molecular characterization of the GM foods, properties of newly expressed proteins, nutritional quality and the potential for toxic or allergenic effects.

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[44] United States, National Academy of Sciences (2002), *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (http://www.nap.edu/books/0309082633/html).

[45] Government response to the report of the House of Commons Standing Committee on the Environment and Sustainable Development, *Pesticides: Making the Right Choice for the Protection of Health and the Environment*, pp. 18.

[46] Section 20 of the act was considered by Justice MacKay in the decision of *Air Atonabee v. Minister of Transport* (1989) 27 F.T.R. 194. He identified three requirements for information to qualify as confidential: (a) the information must not be available from sources otherwise accessible by the public nor obtainable by observation or independent study by a member of the public acting on his own; (b) the information must originate and be communicated in circumstances giving rise to a reasonable expectation of confidence that it will not be disclosed; and (c) the information, whether required by law or supplied gratuitously, must be communicated in the context of a relationship which is either fiduciary or not contrary to the public interest and which will be fostered "for public benefit by confidential communication."

By comparison, public pre-notification is not a requirement in the case of confined field trials in the United States, nor has it been a component of the U.S. Food and Drug Administration's (FDA's) voluntary consultation process with industry. However, the FDA has proposed a rule requiring developers to submit a scientific and regulatory assessment of the bio-engineered foods 120 days before marketing.[47] Under the rule the FDA would publish a pre-market notification, prepared by the developer, at the beginning of the evaluation process rather than at the end. To date, the FDA has engaged in 53 voluntary industry consultations regarding bio-engineered foods and has recently published information on the relevant safety and nutritional characteristics of each of these products.[48]

In February 2001, the European Parliament adopted a directive concerning the deliberate environmental release of GMOs that requires assessment reports be made public and that the public be given an opportunity to comment before the field trials and market approval.[49] While still protecting CBI, the new directive specifically excludes from such protection information pertaining to a general description of the GMO, the name and address of the notifier, purpose and location of the release, monitoring methods and plans, and the environmental risk assessment.

The Royal Society of Canada Expert Panel made a number of recommendations concerning transparency. These include establishing clear criteria for the types of toxicological studies required to evaluate the safety of novel constituents derived from transgenic plants (Rec. 4.1); making all ecological information on the fate and ecological effects of biotechnology products available for peer review (Rec. 6.1); designing and executing testing regimes in consultation with the expert scientific community (Rec. 7.2); and making all information regarding the assessment available to the public (Rec. 4.9).[50]

On the basis of the foregoing observations, we have concluded that there are significant shortfalls in the way the government communicates with and involves the public in the regulatory process for GM foods. The federal government has not provided clear information about how these products are regulated and decisions made, the roles of the various regulatory bodies, and the data that are considered during the safety assessment process. Broader information disclosure and a clear mechanism for including public views in the decision-making process are essential confidence-building measures that should be incorporated within the GM food regulatory system. Increasing transparency and public involvement will require a major commitment on the part of those responsible for the operation of the regulatory system.

Recommendations

We recommend:

2.1 That in general federal regulators become more effective, transparent and actively engaged in communicating the features of the regulatory system as it relates to GM and other novel foods, including the scientific basis for regulatory decisions related to human and environmental health and safety, and that the regulatory process provide for significantly expanded opportunities for input by the public and external experts.

2.2 That the Canadian public and external experts be involved in the development of laws, regulations, policies and programs related to the Canadian regulatory system for GM foods and other novel

[47] U.S. Food and Drug Administration (2001), Pre-market notice concerning bio-engineered foods, *U.S. Federal Register* 66 (12): 4706–38, Docket No. 00N-1396, January 18, 2001.

[48] U.S. Food and Drug Administration, List of Completed Consultations on Bio-engineered Foods (http://vm.cfsan.fda.gov/~lrd/biocon.html).

[49] The directive, 2001/18/EC, repeals the previous Council Directive 90/220/EEC.

[50] The Government of Canada has published an action plan in response to the Royal Society of Canada Expert Panel Report (http://www.hc-sc.gc.ca/english/pdf/RSC_response.pdf) and a progress report on that action plan (http://www.hc-sc.gc.ca/english/pdf/royalsociety/progress_report.pdf).

foods; opportunities for public involvement should extend not only to the scientific issues of health and environmental safety, but also to other matters of public policy such as social and ethical considerations where relevant.

2.3 That a 45-day comment period be provided for public input on health and environmental safety aspects of proposed decisions and that the public input be considered and reported on as appropriate in the final Decision Document.

2.4 That the detailed scientific and technical data pertinent to the human health and environmental safety assessments of GM foods and other novel foods be made public, except for details that could unduly jeopardize a company's competitive position (e.g. details of how to manufacture the product). In particular:

- the information should be available for products currently sold in Canada and for products being proposed for market approval
- regulatory agencies should implement a policy to the effect that they will not keep confidential any technical or scientific data that are publicly available elsewhere (e.g. data that have been made public by the company itself or data that are already available to the public as a result of product approval in another country)
- regulatory agencies should adopt and promulgate a policy that scientific data relating to the safety of biotechnology products do not automatically fall within the definition of Confidential Business Information (CBI); the policy should clearly identify the types of environmental and human health safety information that might be considered as CBI
- regulatory agencies should require developers to submit "non-CBI" versions of their applications suitable for publication during the pre-approval public comment phase that are sufficiently detailed to allow for independent public and scientific scrutiny of the safety-related data
- if it is determined that the *Access to Information Act* does indeed preclude the release of information as recommended above, the government should consider amending the act.

2.5 That the views of external experts be incorporated in the product evaluation process where the risk assessment is not straightforward or where a precedent might be set by approval of the product.

2.6 That comprehensive information and communications about the federal food regulatory system be provided, including decision trees that clearly illustrate the processes listed in recommendation 1.2 above.

2.7 That a readily accessible public record be maintained of the GM and other novel food products currently under review and the current status of the assessment.

2.8 That information on government inspection programs related to contained field trials be published on an annual basis and be made widely available, including information on compliance with required measures, the frequency of non-compliance and measures applied to rectify non-compliance.

2.9 That information be published annually on the government's research programs and research results related to the health and environmental safety aspects of GM foods, plants and feed, and other novel food products.

2.10 That growers within five kilometres of a field study involving GM crops have access to more detailed information, on request, pertinent to the protection of their own crop production; otherwise, the detailed location of trials conducted on GM crops and other plants with novel traits in the field ("field studies") should not be released.

Theme 2: Precaution

Precaution is the cornerstone of safeguarding citizens and the environment, particularly when knowledge is incomplete. The following recommendations concern various aspects of the precautionary approach to the regulation of GM and other novel foods.

Recommendation 3. Precautionary elements

Observations: Precautionary Approach

The term "precautionary approach" is often explained as a better-safe-than-sorry approach in the face of uncertainty about potential harms. Given that there is no way of establishing absolute safety, one is left with having to deal with matters of degree in applying the approach. How safe should a GM crop or food be before it is grown or marketed? How should we decide on such a standard and how should we determine whether a crop meets that standard? These questions are at the centre of national and international debates about GM foods.

The precautionary approach was first formalized as the Precautionary Principle when the United Nations General Assembly adopted the World Charter for Nature in 1982. Since that time, it has been expressed in numerous international publications[51] and agreements on environmental policy. It is listed as Principle 15 of the 1992 Rio Declaration on Environment and Development, which states: "In order to protect the environment, the precautionary approach should be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Because the Precautionary Principle is open to various interpretations, it has been expressed and implemented in forms ranging from "weak" (that is, lack of full certainty is not a justification for preventing an action that might be seriously harmful) to "strong" (take no action unless you are certain it will do no harm). When implemented in the "strong form" (as in cases where no credible theoretical or empirical evidence exists establishing the possibility of harm), it has been criticized as a disguised trade barrier. The Commission of the European Communities attempted to clarify the principle's application in its jurisdiction by issuing a communiqué describing guidelines for using it in a politically transparent manner.[52] Briefly summarized, these guidelines stated:

- "Measures . . . must not be disproportionate to the desired level of protection and must not aim at zero risk . . . " (proportionality)
- "Comparable situations should not be treated differently and . . . different situations should not be treated in the same way, unless there are objective grounds for doing so" (non-discrimination)
- "Measures . . . should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available" (consistency)
- "The measures must be of a provisional nature pending the availability of more reliable scientific data . . . scientific research shall be continued with a view to obtaining more complete data" (current validity).

[51] The Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987) states: "In order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence." The Ministerial Declaration of the Third International Conference on the Protection of the North Sea (1990) further states: "The participants . . . will continue to apply the precautionary principle; that is, to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bio-accumulate even where there is no scientific evidence to prove a causal link between emissions and effects."

[52] EC (2000), Communication from the Commission on the Precautionary Principle, Commission of the European Communities, Brussels, January 26, 2000, COM (2000) 1.

In Canada, the federal government recently completed national consultations (see documentation at http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&Page=precaution) on the principles that should underpin the application of a precautionary approach by regulatory authorities. The consultation document states: the "precautionary approach/precautionary principle is distinctive within science-based risk management. It recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions when faced with the threat of serious or irreversible harm. However, guidance and assurance are required as to the conditions governing the decisions that will be made. Guidance and assurance are particularly needed when a decision must be made regarding a risk of serious or irreversible harm about which there is significant scientific uncertainty. The precautionary approach/precautionary principle primarily affects the development of options and the decision phases, and is ultimately guided by judgment, based on values and priorities." The document identified guidelines that might govern a precautionary approach to managing risks. They are consistent with the guidelines published by the European Commission and embody the following concepts:

- **Legitimacy:** A precautionary approach is a legitimate risk management tool and it is legitimate for decisions to be guided by society's chosen level of protection against risk. Before a precautionary approach can be applied, scientific data relevant to the risk must be evaluated.

- **Burden of proof:** The scientific evidence required should be established relative to the chosen level of protection; the responsibility for providing the scientific information base may be assigned on a case-by-case basis; and the standard of evidence is demonstration that "reasonable testing" was done with no evidence of harm.

- **Consideration of new developments:** Mechanisms should exist for revisiting the basis of decisions triggered by changes in scientific knowledge or society's tolerance for risk.

- **Transparency and accountability:** Openness and transparency are essential to support precautionary decision making, and public involvement should be structured into the review and advisory process as much as possible.

- **Proportionality:** Precautionary measures should be proportional to the potential severity of the risk being addressed and society's chosen level of protection.

- **Non-discrimination:** Precautionary measures should be non-discriminatory and consistent with measures taken in similar circumstances.

- **Cost-effective and efficient:** Precautionary measures should be cost-effective, with the goal of generating (a) an overall net benefit for society at least cost, and (b) efficiency in the choice of measures.

- **Least trade restrictive:** Where more than one option reasonably meets the above characteristics, the least trade-restrictive measure should be applied.

The use of precaution in regulatory decision making was also addressed in the recent Royal Society of Canada Expert Panel Report, which recommended "where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harms" the lack of good experimental data "should not be taken as a reason for withholding regulatory restraint" (Rec. 8.3). In recommendation 8.4, this view was essentially restated within the context of "risk of extensive, irremediable disruptions to the natural ecosystems through emergence of highly aggressive or invasive weed species" or with respect to "serious risks to human health" related to "potential allergens in genetically engineered foods." The Expert Panel was also of the view that "where there are health or environmental risks involving catastrophe scenarios (e.g. the potential effects of global warming), the

greater the case for more conservative safety standards such as 'zero-risk' or low threshold standards, such as that of 'substantial equivalance'"(Rec. 8.5).

In its response to the Expert Panel Report, the federal government confirmed its support for a precautionary approach consistent with the language of Principle 15 of the 1992 Rio Declaration on Environment and Development, and emphasized that it uses this approach in reviewing products for human and environmental safety.

Substantial Equivalence

The concept of substantial equivalence formulated by the OECD in 1993[53] was the result of consultations with some 60 experts from 19 countries on methods to assess the safety of GM foods. As noted earlier, substantial equivalence embodies a comparative approach to risk assessment based on the principle that GM foods can be compared with conventional foods that have a history of safe use employing the same risk factors (for example, toxins, allergens or anti-nutrients) established for the conventional counterpart. Using this approach, risk assessors seek to identify similarities and differences and focus much of their assessment on the differences between the new food and the comparison food in order to ascertain any new risks arising from these differences. Keeping in mind that many conventional foods that are generally considered acceptable may present specific risks depending on what they contain (e.g. allergens or additives) or how they are processed, the intent is not to establish absolute safety but rather to determine whether the new food is "as safe as" its conventional counterpart. Similarly, from an environmental perspective, a risk assessment using substantial equivalence is not designed to measure the full impact of agriculture on the environment but rather to measure the additional impacts, if any, of substituting the GM crop for the traditional crop. In carrying out these assessments, specific tests are conducted to assess health and environmental effects.

Substantial equivalence has been both endorsed[54] as an assessment tool and criticized for being subjective, inconsistent and pseudo-scientific.[55, 56] The term "substantial equivalence" has been used and interpreted inconsistently. In addition to being used as a method of safety assessment, the phrase "substantially equivalent" is sometimes used to declare that a GM food or crop is safe.[57, 58] In Canada, substantial equivalence is also used as part of the definition of a novel-trait in the Seeds Regulations[59] in a way that implies that a determination of substantial equivalence obviates the need for further regulatory assessment. This interpretation prompted the Royal Society of Canada Expert Panel to reject the use of substantial equivalence "as a decision threshold to exempt new GM products from rigorous safety assessments" (Rec. 8.1) and further to recommend that "testing should replace the current

[53] OECD (1993), *Safety Evaluation of Foods Produced by Modern Biotechnology - Concepts and Principles*, Paris.

[54] FAO/WHO (1996), *Biotechnology and Food Safety*, Rome; FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29–June 2, Geneva, Switzerland; OECD (2000), *Report of the Task Force for the Safety of Novel Foods and Feeds*, C(2000)86/ADD1, Paris.

[55] Royal Society of Canada (2001), *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, Ottawa (http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf).

[56] E. P. Millstone, E. J. Brunner and S. Mayer (1999), Beyond "substantial equivalence," *Nature* 401: 525–26.

[57] FAO/WHO (1996), *Biotechnology and Food Safety*, Report of a joint FAO/WHO consultation, Rome, FAO Food and Nutrition Paper 61: "Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (i.e. the food or food component can be concluded to be as safe as the conventional food or food component)."

[58] Decision Document 1999-33: Determination of the Safety of Monsanto Canada Inc.'s Roundup Ready™ Corn (*Zea mays* L.) Line GA21, Canadian Food Inspection Agency (http://www.inspection.gc.ca/english/plaveg/pbo/dd/dd9933e.shtml): "GA21 and corn hybrids derived from it have been assessed and found to be substantially equivalent to traditional corn varieties. GA21 and its by-products are considered to meet present ingredient definitions and are approved for use as livestock feed ingredients in Canada."

[59] "Novel trait," in respect of seed, means a characteristic of the seed that (a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. Source: JUS96-004-01(SOR/DORS): Amendments to the Seeds Regulations — Release of Seed.

regulatory reliance on 'substantial equivalence' as a decision threshold" (Rec. 7.1). It should be noted that to date the CFIA has required environmental safety assessments of genetically modified plants that are to be grown in the Canadian environment.

The most recent FAO/WHO joint expert consultation[60] on GM foods from plants concluded that the proper application of substantial equivalence contributes to a robust safety assessment framework and that it is the best strategy for safety assurance currently available. As well, the Royal Society of London stated in a recent report that "some form of substantial equivalence, starting with a direct comparison of the novel foodstuffs with their unmodified counterparts, appears to be the only practical solution."[61] The Royal Society of Canada Expert Panel expressed a similar view: "invoked as an unambiguous safety standard, it stipulates a reasonably conservative standard of safety consistent with a precautionary approach" (Rec. 8.9).

It should be noted that the baseline data on which the substantial equivalence approach depends — that is, information concerning conventional food sources in terms of natural range and variations in the amounts of key nutrients, anti-nutrients, toxicants and potential allergens — may be lacking. Also, the more complex GM foods expected to appear in the future will make the risk of adverse effects more difficult to assess. These future foods may require that the traditional assessment approaches targeting changes in the levels of specific antinutrients or toxins be supplemented with non-targeted, or so-called metabolic profiling, methods currently being developed.[62] These issues were addressed in the recent Royal Society of London report, which recommended additional research be undertaken to develop and validate various profiling techniques[63] and to define the "normal" compositions of conventional plants. The Expert Panel of the Royal Society of Canada also called for research to establish the knowledge base required for more complete assessments of the DNA structure of novel plants, the expression of the inserted gene and its interaction with host genes, protein profiling, and metabolic profiling, and for more research on the testing of whole foods.[64]

Conclusions

We conclude that the Canadian approach, whereby GM crops and foods are regulated on the same basis as other foods and crops displaying novel or unfamiliar characteristics, represents a standard of regulatory oversight that is unsurpassed internationally and is a sound basis on which to apply the precautionary approach. We endorse the guidelines, under discussion in Canada, for applying the precautionary approach. In particular, we support the concept that mitigating measures, appropriate to the magnitude of risk, are warranted where there is a plausible scientific rationale supporting the possibility of harm, even in the absence of complete empirical data.

The precautionary approach to the health and environmental regulation of GM and other novel foods should be applied at all stages of the development and commercialization of a new product: namely, the research laboratory stage; confined field trails; pre-market assessment for commercial release for use by farmers and in the food chain; and post-market release monitoring and surveillance. Bearing in mind the provisional nature of all scientific knowledge, a precautionary approach to managing risk necessitates the need for a systematic evaluation of new information and reviewing previous regulatory

[60] FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29–June 2, Geneva, Switzerland.

[61] Royal Society of London (2002), Genetically Modified Plants for Food Use and Human Health: an Update, Policy Document 4/02, February (http://www.royalsoc.ac.uk).

[62] H. A. Kuiper, Gijs A. Kleter, Hub P. J. M. Noteborn and Esther J. Kok (2001), Assessment of the food safety issues related to genetically modified foods, *The Plant Journal* 27: 503–28.

[63] Techniques such as micro-array technology for studying messenger-RNA (mRNA) expression, quantitative two-dimensional gel electrophoresis and mass spectrometry for protein analysis, and metabolomic analyses to measure changes in metabolic intermediates and end products.

[64] Royal Society of Canada (2001). Chapter 7, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, Ottawa (http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf).

decisions and risk mitigation measures with a view to modifying them if necessary. The review process should also examine if a particular trait in a specific species should continue to be considered "novel" for regulation purposes. While partially addressing these issues, existing new information requirements for GM crops and other plants with novel traits regulated under the *Seeds Act*[65] do not mandate pre-set future dates to review product approvals. Although a condition to report any new information is contained in each letter of "no objection" issued, it would be clearer if this requirement were listed in the Novel Food Regulations.

New knowledge should also be taken into account in periodic examinations of research standards to ensure they reflect a precautionary approach. Research activities are currently not subject to statutory regulations or authorization; they are governed instead by Canadian Institutes of Health Research guidelines or other institutional biosafety guidelines. It is not clear whether these guidelines are being applied in all research settings, or to what extent compliance is being monitored and enforced. In the case of research leading to the production of GM foods, the lack of standardized guidelines for the propagation of GM plants in greenhouse facilities is a cause of some concern.

Looking ahead, it is clear that future GM foods will require new or refined scientific methods to assess both their direct and indirect potential adverse impacts on health and the environment. In line with a precautionary approach, the best possible analytical tools should be applied to rigorously evaluate safety during the pre-market phase. As well, the knowledge gap surrounding traditional foods — in terms of the variability of key nutrients, antinutrients, toxins and allergens, and in terms of their possible interactions with ecosystems — needs to be filled. In the case of crops where Canada is a leader, such as canola, identity-preserved soybean, durum wheat, flax and malt barley, we have a particular interest in filling these knowledge gaps. Given the global nature of these challenges, Canada should pursue opportunities for increased international scientific collaboration.

Notwithstanding its inherent limitations, we believe the concept of substantial equivalence remains a useful approach to structuring the environmental and food safety assessment of GM foods and crops. While our work did not involve an audit of past regulatory decisions, we did review the operations of the regulatory agencies in some detail and found no evidence to indicate that substantial equivalence has been used as a decision threshold to exempt GM foods from appropriate regulatory oversight. However, as noted earlier, the use of the term "substantial equivalence" in the existing definition of "novel trait" in the Seeds Regulations could reasonably lead to the conclusion that substantial equivalence may be being used as a threshold for regulation and we believe that this ambiguity should be removed.

While some applications of new technology may pose risks, others have the potential to yield methods not only to mitigate risks but also to produce crops in which the risks to human health and the environment may well be lower than their conventional counterparts. For example, scientific developments are expected to result in greater control over when and where genes inserted into crops are active. Many of the conventional foods we currently consume contain allergens or small amounts of toxic material that may pose health hazards. Modern biology has the potential to enhance our capacity to develop foods that are free of, or contain reduced amounts of, these allergens and toxic materials. There is also potential for new GM crops to be designed to present less risk to the natural environment than conventional crops and their associated agricultural practices. In short, it is not unreasonable to look forward to the incorporation of ever higher performance standards into the regulation of the crops we plant and the foods we eat.

[65] JUS-96-004-01 (SOR/DORS), Amendments to the Seeds Regulations: Release of Seed (http://www.inspection.gc.ca/english/plaveg/pbo/96004e.shtml). Similar new information requirements are also a feature of the Feeds Regulations (1983) that control the sale of livestock feeds in Canada (http://laws.justice.gc.ca/en/F-9/SOR-83-593/105837.html).

Recommendations

We recommend:

3.1 That regulatory authorities maintain and strengthen Canada's risk-based approach to the regulation of novel foods and plants with novel traits rather than limiting regulatory oversight to the products of any specific technology, such as recombinant-DNA technology.

3.2 That regulatory authorities take a precautionary approach to all stages of development and commercialization of a GM food (laboratory research, confined field trials, pre-market risk assessment and post-market surveillance) to ensure the application of a conservative safety standard in assessing health and environmental risks related to GM and other novel foods, recognizing that this does not imply "zero risk."

3.3 That regulators use the following guidelines in applying the precautionary approach:

- precautionary decisions should be based on a socially acceptable level of protection
- despite the existence of scientific uncertainty, where there are scientifically credible theoretical or empirical grounds establishing a reasonable case for the possibility of serious harms, the lack of robust experimental data should not be taken as a reason for withholding regulatory restraint
- a highly conservative standard should be applied when there is a plausible risk of catastrophic harm to health or the environment
- precautionary measures adopted should be proportional to the potential severity of the risk being addressed and should take into account the benefits and costs of actions or lack of actions
- precautionary measures should be subject to reconsideration on the basis of the evolution of science, technology and society's views about the acceptable level of protection
- precautionary measures should be non-discriminatory between situations presenting similar risks and should be consistent with measures taken in similar circumstances
- where two or more equally effective options are available to mitigate the risks, the least trade-restrictive option should be given serious consideration
- the administration of the precautionary regime should be transparent, accountable and provide for public involvement.

3.4 That government undertake a study to evaluate the effectiveness of existing guidelines covering experimental work with genetically modified organisms in laboratories and greenhouses, including the extent to which they are currently being applied in public and private research facilities and the degree to which recommended guidelines are applied and enforced, with a view to determining the need for national guidelines or statutory measures.

3.5 That government initiate and fund a broad-based program of long-term research into GM and other organisms that are part of the human food chain, with the objectives of:

- developing new, validated, targeted and non-targeted analytical methods for assessing the health and environmental safety of future GM and other novel foods
- expanding the knowledge base for non-GM foods and crops
- developing strong international connections and access to the world's best research and researchers
- ensuring that the knowledge developed is readily accessible to both regulatory agencies and to private and public sector developers of new GM foods, and other applications involving crops and farm animals.

3.6 That government revise the existing authorization processes for novel foods and plants with novel traits in order to provide for a pre-scheduled (say, 10 years after approval) review of product

approval decisions, taking into consideration new information available in the scientific literature, post-market mitigation measures and other scientific evidence:

- the information for this review should be prepared by the product proponent and made available for scientific peer review and public comment
- the relevant regulatory agencies should then assess the evidence and, if conditions warrant, have the authority to require reassessment of all or parts of the product or to suspend product approval pending further assessment
- the criteria for reassessment or suspension of approval should be laid out in the standard operating procedures
- these measures would be in addition to existing "new information requirements."

3.7 That regular reviews be undertaken, not less than once every 10 years, of the emerging implications of modern biotechnology and other transformative technologies for the continuing adequacy of the regulatory regime, and that the reviews take into account:

- current regulatory practices, including the use of substantial equivalence and the precautionary approaches; and health and environmental performance standards
- the science underpinning the regulatory regime
- the adequacy of the regulatory and coordinating structures and their resource levels
- developments in international cooperation and coordination in scientific activities and regulation.

3.8 That steps be taken to make the regulatory process as efficient and timely as possible without compromising regulatory effectiveness, and that systems be designed to assist small and medium-sized enterprises in coping with the burdens involved in securing regulatory approval, provided these measures can be implemented without limiting regulatory effectiveness.

3.9 That substantial equivalence continue to be used as a guide to identifying the differences between conventional and novel crops so that such differences can be rigorously assessed to determine their implications for health and environmental safety; as knowledge advances, specific scientific performance standards should be developed and applied in the regulatory assessment process to minimize risks to human health and the environment.

3.10 That the definition of "novel trait" within the *Seeds Act* be revised to remove the reference to substantial equivalence; and that the regulations be amplified to provide additional guidance to developers as to when a trait is in fact a "novel trait," or to elaborate an unambiguous process for making this determination.

Recommendation 4. Evaluation and monitoring of long-term health impacts

Observations

GM foods currently in the marketplace have arguably undergone greater regulatory scrutiny than their conventional counterparts. Nonetheless, some people fear that GM foods may pose a danger to health that may only become apparent after prolonged exposure, and they contend that long-term testing should be a prerequisite to the marketing of GM foods. Some go so far as to argue that, even though GM foods meet current safety standards, they should be considered potentially dangerous unless a lack of future harm can be proven, even though science cannot conclusively prove the absence of the possibility of harm.[66]

[66] The absolute safety of any product or process to all individuals in society is unattainable. What makes something safer for one group may pose risks to another group. Consider, for example, the case of automobile airbags or vaccination against disease. A common standard of a safe food is "one which, as far as we know and with the exception of specific individuals who may be peculiarly sensitive or allergic, when consumed in moderation over a period of time, does not result in identifiable harm to the consumer." Based

Post-market surveillance to detect long-term effects, as opposed to pre-market long-term testing, is well established for some types of products (for example, pharmaceuticals). The question arises whether or not it can and should be applied to GM and other novel foods. Under the current system, GM foods that have received pre-market safety assessment and regulatory approval are not routinely subject to post-market surveillance for long-term health impacts. The GM foods already approved are derived mainly from a few crop varieties (in Canada, primarily canola, corn and soybean) modified to be tolerant to a broad spectrum of herbicides and/or insect pests. Except for a very few examples of GM canola and soybean varieties with modified oil compositions, all of these products have compositions that are the same as their conventional counterparts and have been judged to pose no increased risk of untoward effects. The lack of any identified safety concerns arising from pre-market testing and evaluation, together with the absence of any plausible scientific hypothesis for how these foods could otherwise affect human health, based on their "GM nature," has caused some regulatory authorities to "see no scientific justification for the use of post-market surveillance."[67]

The Royal Society of London noted in an update of its 1998 report on GM plants for food[68] that the report of the Medical Research Council expert group[69] concluded that long-term surveillance is impractical and would be of limited epidemiological value. The conclusion was based on the lack of a firm scientific hypothesis about which human health end points GM foods might affect, the difficulty in measuring individual exposure to GM foods, and the currently very low level of consumption of GM foods. In a similar vein, a 2001 Joint FAO/WHO Expert Consultation[70] expressed the view that "the possibility of long-term effects being specifically attributable to genetically modified foods would be highly unlikely." To further investigate this issue, the Food Standards Agency of the United Kingdom has commissioned a two-year study to examine the feasibility of monitoring the consumption of GM foods; its results are expected in 2002.

Several international bodies[71, 72, 73] have advocated the use of post-market monitoring to test specific hypotheses concerning food safety, such as the effects of intentionally altered nutritional composition, the possibility of allergic sensitization or where a single food comprises a significant portion of the diet. In Canada, the Royal Society Expert Panel recommended that, if there are data to indicate their effectiveness, mechanisms should be developed to monitor emerging health risks (for example, unanticipated and unpredictable allergic reactions) related to GM foods incorporating a novel protein (Rec. 4.6). Furthermore, there is a general recognition that future GM food products designed to bring about specific public health outcomes (such as foods containing edible vaccines) will likely require some form of post-market monitoring to establish their value.

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on international consultations on evaluating the safety of GM foods, the following standard of safety has been elaborated: "The safety of food for human consumption is based on the concept that there should be a reasonable certainty that no harm will result from intended uses under the anticipated conditions of consumption. Historically, foods prepared and used in traditional ways have been considered to be safe on the basis of long-term experience, even though they may have contained natural toxicants or anti-nutritional substances. In principle, food has been presumed to be safe unless a significant hazard was identified." OECD (1993), *Safety Evaluation of Foods Produced by Modern Biotechnology – Concepts and Principles*, Paris.

[67] OECD (2000), *Report of the Task Force for the Safety of Novel Foods and Feeds*, C(2000)86/ADD1, Paris.

[68] Royal Society of London (2002), Genetically Modified Plants for Food Use and Human Health: an Update, Policy Document 4/02, February (http://www.royalsoc.ac.uk).

[69] Medical Research Council (2000), Report of a Medical Research Council expert group on genetically modified (GM) foods, London.

[70] FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29–June 2, Geneva, Switzerland.

[71] European Union (1997), 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. Off. J. Eur. Commun. L253, 1-36.

[72] FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29–June 2, Geneva, Switzerland.

[73] CODEX (2001), Joint FAO/WHO Food Standard Programme, 24th Session, July 2–7, Geneva, Switzerland; Report of the second session of the CODEX *ad hoc* intergovernmental task force on foods derived from biotechnology, Chiba, Japan, March 25–29, 2001; ALINORM 01/34A, FAO, Rome (ftp://ftp.fao.org/codex/alinorm01/al01_41e.pdf).

There are many challenges in designing a system for post-market surveillance — even one with very narrow objectives — that would have meaningful implications for public health. Chief among these is the identification of "exposed" and "non-exposed" individuals or populations based on a unique exposure characteristic (for example, smoking versus non-smoking). While this approach is generally followed in collecting data on the potential effects of new pharmaceutical products, it is not applicable to GM foods.

Except when they are consumed as "whole foods," GM foods are usually present as ingredients within a processed food product whose composition and ingredient sources may change significantly over time (for example, due to changes in price or availability of source ingredients, changing consumer taste preferences or new processing technologies). These changes, even if they were reflected in labels, will be difficult to track and will likely go unnoticed by consumers. Moreover the lack of a system of traceability and identity preservation for all foods makes it impossible to monitor consumption of GM foods and to link their intake with subsequent health effects. The implementation of such a system is complex and costly.

Other post-market monitoring strategies, such as randomized controlled trials, could in principle be used if properly designed and conducted to gather data on the medium- and long-term effects of GM foods. However, randomized controlled trials can also be costly, are difficult to conduct and in any case would be compromised by confounding variables influencing health outcomes. Such variables include variation in diets and dietary components, variability in genetic predisposition to possible adverse food-related effects, and environmental factors unrelated to diet.[74]

The reliability of self-reported data about food allergies is a significant problem. The incidence of perceived food allergies is probably about 10 times greater than that of actual food allergies.[75] Fewer than 40 percent of cases of self-reported reactions are confirmed when patients are subjected to double-blind placebo-controlled food challenges.[76] Reports of adverse reactions to foods are more frequent following publicity about a specific product.[77]

Internationally, there are no operational post-market surveillance systems for GM foods and the experience with similar programs for non-GM foods has been limited primarily to foods with nutritional or functional claims (e.g. fat replacers such as Olestra™, phytosterol esters or novel sweeteners such as Aspartame™). As a condition of approval for Olestra™,[78] the U.S. Food and Drug Administration in 1996 required specific labelling of all products containing Olestra™,[79] and the implementation of a post-market surveillance program to monitor exposure and frequency of consumption as well as the spontaneous reporting of adverse effects. For Aspartame™, specific labelling was required in order to warn sufferers of the hereditary disease phenylketonuria[80] (PKU), and a surveillance program was implemented to obtain information on actual intakes relative to pre-market projections. The surveillance study, which included surveys of more than 2000 households per year over 14-day periods between

[74] The FAO/WHO Joint Consultation noted: "Observational epidemiological studies would be unlikely to identify any such effects against a background of undesirable effects of conventional foods." See also, FIFRA Scientific Advisory Panel Meeting (2000), Report on Assessment of Scientific Information Concerning StarLink Corn, November 28, Arlington, Virginia.

[75] FIFRA Scientific Advisory Panel Meeting (2000), Report on Assessment of Scientific Information Concerning StarLink Corn, November 28, Arlington, Virginia.

[76] Ibid.

[77] "This product contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added."

[78] Marketed by Procter and Gamble, Olestra is a mixture of polyesters prepared by esterifying sucrose with long-chain fatty acids isolated from edible fats and oils. It has the organoleptic and chemical properties of a fat, but is not hydrolyzed by gastric and peptic enzymes and is not absorbed intact from the gastrointestinal tract. Since it is indigestible, Olestra does not provide any calories and can be used as a fat replacement in a many foods (e.g. potato and corn chips). If Olestra is consumed in significant quantities as a dietary fat replacer, it may result in deficiencies in fat-soluble vitamins (A, D, E and K), for which natural fats act as carriers and aid in absorption.

[79] "This product contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added."

[80] Aspartame was approved as a food additive in the U.S. in 1987. It is a derivative of the amino acid phenylalanine and, for people with the disease phenylketonuria (PKU), consumption of Aspartame can lead to elevated levels of phenylalanine, which can cause brain damage.

1984 and 1992, concluded that Aspartame™ consumption was well below the previously established acceptable daily intake. Another outcome from this work was the conclusion that passive surveillance systems, while useful for detecting rare adverse effects of a food additive, likely have limited utility once the food additive gains widespread use.[81]

The limited availability of data on Canadian food consumption patterns makes estimating the significance of GM foods in the Canadian diet or economy difficult. There are no food consumption monitoring programs, no population-based health surveillance programs specifically linked to the long-term impacts of either conventional or GM foods, and no post-market data on aspects such as sales, use and exports/imports of GM foods, crops or seeds. Health Canada has initiated a Biotechnology Surveillance Project to establish a national surveillance system to monitor the late health effects[82] of bio-engineered foods. This project is still in the formative stages, and details are not yet available.

We have concluded that, for now, generalized surveillance aimed at providing meaningful data on the linkage between consumption of GM foods and health outcomes is not feasible. The same is true of surveillance strategies for other food categories, such as organic foods. However, post-market monitoring to test specific risk hypotheses, such as the effects of changing eating habits or exposure to novel foods on individual susceptibility to food allergies, would provide important information for evaluating the potential allergenicity of new foods. The availability of adequate food consumption data, particularly for population subgroups such as the elderly, infants, nursing mothers and specific ethnic or social subgroups, is an essential component of any system of post-market monitoring.

Recommendations

We recommend:

4.1 That government establish a major long-term program of research designed to test specific hypotheses about the long-term health effects related to the consumption of specific foods and food groups, including GM and other novel foods or food ingredients.

4.2 That government initiate a program to substantially improve the quality and timeliness of food consumption data for conventional foods, GM foods and other novel foods, and to make these data accessible to academic researchers, food producers, epidemiologists and private and public sector technology producers to help develop surveillance methodology and determine potential exposures during pre-market risk assessments.

4.3 That mechanisms be established to facilitate timely incorporation of new information related to food consumption patterns and for reviewing approvals of existing products based on valid post-marketing data.

[81] H. H. Butchko, C. Tschanz and F. N. Kotsonis (1994), Postmarketing surveillance of food additives, *Register of Toxicology and Pharmacology* 20: 105–18.

[82] Health Canada defines human late health effects as those that appear only after a product is released. Typically, late health effects happen a long time after exposure to a biotechnology product or are the result of long-term exposure to a biotechnology product.

Recommendation 5. Environmental stewardship

Observations

Broadly defined, environmental stewardship involves matters of environmental protection, the effective integration of key goals such as the promotion of health and social well-being, and economic prosperity. It requires a long-term, global perspective regarding the impacts of products and technologies, the mobilization of expertise in a broad range of disciplines, significant research investment, international cooperation, and effective linkages between scientific and regulatory bodies.

Environmental stewardship is facilitated by adopting a life cycle approach to assessing the environmental effects of products, processes, technologies and services. This approach is based on the concept that all stages in the development of a product (research, field testing, manufacturing, transportation, distribution, use/reuse and waste management) have potential environmental impacts and implications for quality of life, both positive and negative.

As noted earlier, environmental impacts are considered at two points during the approval process. In applications for confined field trials, plants with novel traits are assessed for their potential impact on adjacent natural ecosystems and on endangered species and species at risk. During the assessment for unconfined environmental release, potential impacts on non-target organisms, consequences of gene flow to other species and the potential for increased weediness are evaluated. Conventional agricultural practices and their associated environmental impacts are used as a baseline.

Agricultural regions are inherently artificial or managed ecosystems. After many hundreds of years of agricultural cultivation, little that is pristine remains in farming regions. Nevertheless, there are vital links between agricultural areas and natural ecosystems. The practice of agriculture, in all its forms and whether practised on a large or small scale, has the potential to harm the environment and affect biological diversity. This is true particularly when agriculture is not practised in a resource-efficient way[83] or when it applies technologies that are ill suited to the soils, topography, and climate of a particular area. Tillage, the intensive application of fertilizers, herbicides and pesticides, and changing land use patterns all have the potential to cause environmental harm. For example, converting agricultural land to urban use puts greater stress on marginal zones, which in turn leads to conversion of forests to agricultural land and the destruction of natural ecosystems. By contrast, the high productivity of modern agriculture reduces the pressures to extend cultivation to new areas that are currently unmanaged.

While some new GM crops may be no better than their conventional counterparts with regard to environmental impact, others offer distinct advantages. Any consideration of the environmental impact of GM crops must examine not only the potential risks but also the potential benefits associated with reducing the "environmental footprint" of existing agricultural practices. This distribution of potential risks and benefits can be illustrated by considering the case of herbicide-tolerant canola, which represented about 81 percent of the 4 million-hectare canola crop in Canada in 2001.[84] Herbicides are used in agriculture to reduce competition between crop plants and weeds so that the crop has maximum access to sunlight, water and nutrients. Although the evidence to date is mixed, the introduction of herbicide-tolerant crops has given rise to concerns of even more widespread use of herbicides. Another possible negative impact is that herbicide-tolerant canola might breed with other non-herbicide-tolerant varieties or with wild weedy relatives,[85] prompting the application of alternative herbicides to control weeds and

[83] Resource efficiency is integral to the practice of sustainable agriculture. It has to do with the efficient use of non-renewable resources, such as water for irrigation, and with practices that promote soil conservation or minimize the impacts of agricultural inputs such as fertilizers and pesticides.

[84] For 2001, the total area of herbicide-tolerant canola consisted of 45 percent glyphosate-tolerant (transgenic), 16 percent glufosinate ammonium-tolerant (transgenic), 20 percent imidazolinone-tolerant (mutagenesis), and 19 percent conventional. Source: Canola Council of Canada.

[85] Related weedy species include *Diplotaxis muralis* (sand rocket), *Raphanus raphanistrum* (wild radish) and *Erucastrum gallicum* (dog mustard).

volunteer plants that have become tolerant to commonly used herbicides. On the positive side, the herbicides to which crops are being made tolerant are less persistent in the environment than some of the herbicides they replace. In addition, the cultivation of herbicide-tolerant canola in the Canadian prairies has contributed to the adoption of "no-till" practices, whereby farmers are able to seed herbicide-tolerant plants directly into the stubble of the previously harvested crop without any prior cultivation. This provides for both soil conservation (topsoil is held in place by the residue of the previous crop) and water conservation (the stubble cover allows for better water retention and inhibits evaporation).

Even though transgenic crops have been grown on more than 175 million hectares worldwide, knowledge of how they might affect agricultural and natural ecosystems in the long term is limited. Assertions of the lack of any adverse environmental effects are unverified, given the lack of any systematic monitoring to detect such effects. The pre-market assessment of environmental risks of GM crops is based on data obtained from small-scale confined field trials[86] that are generally not suited to detecting small or low-probability effects that would become apparent only at larger spatial scales and over extended periods of time. In its report *Environmental Effects of Transgenic Plants*, the U.S. National Academy of Sciences (NAS) recommended that post-commercialization validation testing be used to verify the effectiveness of pre-commercialization risk assessment, and that it be designed to test specific hypotheses regarding the major categories of risk (for example, movement of transgenes, impacts of the whole plant through escape or impact on agricultural practices, non-target effects, and the evolution of resistance).

The U.S. National Academy of Sciences committee also found that broader ecological monitoring was needed following commercialization because ecosystems are complex; the full range of possible ecological effects of a transgenic crop, particularly indirect effects, cannot readily be predicted or replicated in the laboratory or in small-scale field trials. However, the committee also noted that the ability to assess the environmental impacts of large-scale planting of GM crops was hampered by the lack of baseline data on the environmental impacts of agriculture generally. For example, despite the efforts of the U.S. National Agricultural Statistics Service, there are no consistent or comprehensive data available on crop losses due to pests or diseases, nor on pesticide resistance, nor on soil qualities such as salinity, organic matter and compaction. These and others gaps would have to be addressed if monitoring of new agricultural practices, including the use of transgenic crops, is to be seriously considered.

The NAS committee recommended a two-pronged approach to ecological monitoring: the use of existing networks of trained observers (for example, personnel from the Agricultural Extension Service and the Animal and Plant Health Inspection Service), other federal and state resource professionals, crop consultants, and farmers, and the development of biological indicators as sentinels of ecosystem change. The committee did not address the issue of which ecological indicators could be relevant but emphasized that they should be clearly linked to underlying ecological processes based on objective criteria and that agencies, industry, and other stakeholders should be involved in determining them. The committee further recommended that an independent body separate from the Animal and Plant Health Inspection Service develop the monitoring program,[87] that more extensive data be collected on the location and acreage of transgenic crops planted each year, that these and other monitoring data be publicly released, and that new processes be developed to permit clear regulatory responses to findings from environmental monitoring.

[86] For example, in Canada, the current policy on confined field trials of plants with novel traits states that for each crop species × trait combination, trials must be no larger than 1 hectare in size, and that no more than 10 trial sites comprising a cumulative total of 5 hectares are allowed per province (e.g. maximum of 10 × 0.5 hectare trials per crop species × trait combination per province). Exemptions to these limitations are permitted, provided that a sufficient scientific rationale is presented.

[87] The rationale for this recommendation is based on the fact that, currently, the Animal and Plant Health Inspection Service deregulation of a transgenic plant (which also includes all progeny and descendants) is absolute, completely removing the article from the agency's regulatory authority. The Animal and Plant Health Inspection Service cannot require monitoring of any deregulated article.

The NAS also recommended using performance standards to assess and manage potential environmental risks. For example, if little or no *Bt* is expressed in the pollen of a plant, bees and other pollen-using insects will not be adversely affected by the insecticide. Similarly, if a GM plant cannot reproduce, the likelihood of the inserted gene unintentionally spreading the crops gene to related plants or weeds is limited.

In April 2001, the European Union agreed on a new framework governing the environmental release of GMOs. The framework included a new directive requiring that developers provide and implement a plan for monitoring the occurrence and impact of potential adverse effects of GMOs on the environment. The period of post-market monitoring is established at the point of granting commercial approval, and subsequent renewal of commercial approval may be contingent on surveillance data.

Similar views about improving pre-market assessment and post-market monitoring were expressed in the report of the Royal Society of Canada Expert Panel on the Future of Food Biotechnology. The report made several recommendations directed at improving the rigour of pre-market safety assessment and, when warranted due to persistent environmental risks, ensuring that exhaustive, long-term testing for ecological effects be carried out (Rec. 6.2). The Expert Panel urged that Canada develop and maintain baseline data on the biology of its major agro-ecosystems and adjacent biosystems (Rec. 7.4), that a detailed analysis be undertaken of the expertise needed in Canada to evaluate the environmental effects of new biotechnology products and that, if this expertise is lacking, resources be allocated to improving the situation (Rec. 6.4). The report also emphasized the need to ensure that environmental assessments of GM plants consider the impacts not only on agro-ecosystems, but also on nearby natural and undisturbed habitats (Rec. 6.7).

Reducing the impact of agriculture on the environment depends on finding ways to change agricultural practices to ensure adequate safe food production, the livelihood of farmers and the enhancement of biodiversity. In this effort, biotechnology is a tool that can be used wisely or badly and, in this respect, it differs little from other human activities that leave their footprint on the environment.

The GM plants currently on the market tell us little about how future products may affect the environment. The traits expressed as a result of novel genes introduced into crop plants needs to be assessed at the level of both the individual plant and the plant's interaction with the wider environment. We believe that there is room for improvement in the current approach to environmental risk assessment of GM plants and the degree to which ecosystem effects are being considered. The current regulatory framework does not provide for a sufficiently broad stewardship approach.

Research aimed at improving the pre-market environmental assessment and validating risk hypotheses in a post-approval commercial setting is needed. For example, the use of indicator species (originally developed to assess the impacts of chemical and microbial pesticides) for assessing the impacts of future GM crop products needs to be evaluated.[88] Similarly, research on long-term effects, both beneficial and adverse, is required to determine how benefits can be increased and risks minimized.

Both pre- and post-approval risk mitigation measures must be adequate for effective environmental stewardship. It is during the experimental field-testing phase that new GM plants may present the greatest challenge in risk management. Thus, it is essential to ensure the effectiveness of isolation zones or other measures designed to mitigate cross-pollination, and of traceability mechanisms should plant material accidentally escape and enter the livestock animal and human food chains. Similarly, the effectiveness of post-approval conditions, such as insect-resistance management plans for insect-resistant GM crops, needs to be assessed at regular intervals, taking into account new scientific

[88] Typically these include avian species (e.g. quail), aquatic animals (e.g. vertebrates such as channel catfish and invertebrates such as *Daphnia*, which is a bio-accumulator), honeybees and certain other beneficial insects (e.g. ladybird beetles) and soil invertebrates (e.g. *Collembola* and earthworm species).

information and/or changing agricultural practices. In each of these areas, the implementation of effective auditing programs is necessary to ensure compliance.

The credibility of the environmental risk assessment process for GM plants depends on open access to relevant information in order to facilitate rigorous public and peer review. It is also important to ensure access to high-calibre scientific and technical expertise in ecosystem science, both within regulatory agencies and in external independent panels.

Recommendations

We recommend:

5.1 That government establish a continuing program of research to improve knowledge about the long-term effects of GM and other novel plants and crops on agricultural and unmanaged ecosystems, and that this research effort involve a strong international collaboration component. We further recommend that the research focus include identification of specific biological indicator species for use in:
- pre-market environmental risk assessment
- long-term surveillance of potential impacts on agricultural and unmanaged ecosystems.

5.2 That the following actions be undertaken to ensure the effectiveness of the pre- and post-approval management of health and environmental risks:
- the sizes of isolation zones currently applied to confined field trials should be reassessed in light of the latest scientific information regarding pollen drift for various agricultural crops, based on an achievable standard for reproductive isolation
- detection techniques, or other methods for ensuring traceability, should be a requirement to be met prior to the authorization of confined field trials of GM plants, or other plants with novel traits
- audit programs to establish the effectiveness of, and level of compliance with, post-approval risk mitigation measures should be implemented.

5.3 That government strengthen the ecosystem perspective of the environmental assessment of GM organisms used as foods, or in food production, by:
- undertaking a feasibility study, to be published within one year, exploring national and international research collaboration needs and the potential for making wider use of ecological expertise within the risk assessment process
- establishing an independent panel to review and recommend ecologically meaningful experimental protocols, performance standards and monitoring indicators for each new class of GM organism to be introduced.

Theme 3: Information and Consumer Choice

Respect for diversity and autonomy entails allowing consumers to make informed choices regarding the foods they eat based on their principles, beliefs and values, including their concerns for health and the environment. The recommendations pertaining to this theme are intended to enhance the quality and extent of information available to consumers to support informed choice, including the choice of whether or not to buy GM foods.

Recommendation 6. Improved information to support consumer choice

Observations

Canadians need easy access to reliable, complete, balanced, understandable information about GM and other novel foods to make informed choices about the foods they eat. The information should cover the production, regulation, nutritional value, risks and benefits of the products and other relevant matters. Public opinion research[89] indicates that most people wish to be assured that the information they might want is readily available, regardless of whether or not they would use the information.The goal therefore is to identify the best sources of information and the best means to make it available and understandable to those who want it. Achieving this goal entails simplifying complex subject matter while maintaining accuracy, serving the needs of groups with diverse interests and presenting information in an unbiased manner so as to engender trust.

While government departments and agencies are making progress in improving the quality and quantity of information about GM and other novel foods, much remains to be done to achieve optimum levels of readability, reliability, comprehensiveness and accessibility. More extensive, effective use of various media, and materials tailored to suit users with different levels of sophistication, are highly desirable.

The information resources must also be well organized. A centralized consumer information service on food biotechnology is needed to act as a main portal for accessing and navigating among various information sources on topics such as food production, modern food biotechnology, traditional practices in food production and plant breeding, balanced descriptions of the benefits, risks and uncertainties of different types of foods, relevant laws and regulations, scientific knowledge, perspectives on ethical and social issues, research and development activities, and how citizens can contribute to the development of policies.

Such an information service requires a well thought out strategy that identifies the needs of various users (for example, doctors, nurses, nutritionists, dieticians, teachers, community workers, consumer associations, civil society groups, individual consumers and the media), the information that would meet those needs, and the most cost-effective way to deliver the information to each group.

Recommendations

We recommend:

6.1 That the government put in place enhanced mechanisms and allocate additional resources to help Canadians make informed choices about the foods they consume, and allocate additional resources to provide Canadians with accurate and comprehensive information on GM and other novel foods, the food regulatory system, and food standards and regulations.

6.2 That the mechanisms include a centralized food information service as the primary venue through which the government provides information about foods, including GM and other novel foods, to Canadians; that the service reflect effective cooperation among all parts of government with roles related to food regulation, food research, food safety, food policy and consumer protection; and that it be organized and operated within a comprehensive funding strategy that integrates related government communication and information activities.

[89] *Release of the 5th Wave Public Opinion Research into Biotech Issues* is available on the CBS Web site in English (http://biotech.gc.ca/engdoc/opinion.html) and in French (http://biotech.gc.ca/frndoc/opinion.html).

6.3 That reliable information be developed and made available in a form that is appropriate for use by health care professionals and other intermediaries (such as doctors, nurses, nutritionists, dieticians, teachers, community workers, consumer associations, civil society groups and the media).

Recommendation 7. Labelling

Observations

Canada's regulatory system requires the labelling of all foods, including GM products, for reasons of health and safety; for example, in cases of significant nutritional or compositional change, or where allergens are present. The labels must be understandable, truthful and capable of verification, and they must not be misleading. New foods that are assessed to have serious adverse health effects (for example, carcinogenic or toxic potential) are not permitted to enter the market. Currently, labelling of GM foods on the grounds of how they are derived (as opposed to labelling for reasons of known risks to health or safety) is optional. For the most part, Canadians do not know whether or not the foods they buy are derived from GM plants.

Consumer Choice

Our background research, the public feedback we received and public opinion polling results indicate that the central issue around labelling is one of consumer preference or choice. This finding is similar to that of the Royal Society's Expert Panel.[90] The Panel of the Royal Society supported a voluntary labelling system except where health risks or significant nutritional changes are present.[91] Its position is contingent on regulatory agencies implementing its recommendations regarding the effective management and risks of GMOs, including long-term monitoring.[92]

For some people, the question of labelling is simply a matter of principle. They see it as an issue related to autonomy; that is, labelling allows consumers to exercise their "right to know" and to express their values through the choices they make when purchasing foods. Other reasons why consumers might choose to consume or avoid GM foods include perceived or potential health risks or benefits, perceived or potential environmental risks or benefits, a fundamental ethical opposition to genetic modification of any kind, religious beliefs, food quality and price, broader societal concerns (such as globalization, food security issues and concentration of corporate power), and lack of confidence in the regulatory system.

Under the current system, consumers cannot easily choose whether or not to consume GM foods. While labelling is one way to inform them, it does not provide all of the information necessary to make a completely informed choice. Public opinion research shows that many people do not have a clear understanding of GM foods and could be confused or misled by a label indicating GM content. It is therefore necessary that other sources of information supplement the labelling regime.

Much of the labelling debate centres on whether the system for labelling GM and other novel foods for reasons other than health and safety risks should be voluntary or mandatory. Many see mandatory labelling as the only way to ensure that GM foods are identified because they believe that under a voluntary system too few suppliers would actually label their GM products.

[90] Royal Society of Canada (2001), *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, Ottawa, p. 223 (http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf).

[91] Ibid., p. 226.

[92] Ibid., p. 224.

Those who argue against mandatory labelling express concern that consumers may incorrectly associate a GM label as a warning that the food may not be safe, despite having passed regulatory assessments. This could inappropriately damage the market, resulting in losses to farmers and food processors. Opponents of mandatory labelling contend that such a system could increase costs for all consumers, reduce consumer choice if imported goods are withdrawn from the Canadian market and expose Canada to potential trade sanctions. They believe a voluntary system will provide optimum flexibility for consumers, government and industry, and that the market can and will satisfy consumer demands for a sufficient exercise of personal values and choice.

It should be noted that any labelling system — whether voluntary or mandatory — cannot by itself guarantee full consumer choice. Even with a system of mandatory labelling in place, if consumers do not demand "GM-free" products, the market will not supply them. Also, a market in which the majority of products are labelled "contains GM ingredients" may not provide effective choice, as consumers would have difficulty avoiding foods derived from GM plants.

The issue of labelling of GM foods came before Parliament on October 17, 2001, when Bill C-287 (a Private Member's Bill) was tabled and defeated in the House of Commons. The bill proposed mandatory labelling through amendments to the Canadian *Food and Drugs Act*. Two parliamentary standing committees are examining the issue. The Standing Committee on Health, whose mandate includes consideration of the best ways to meet consumers' needs for food information, is still conducting its hearings. The Standing Committee on Agriculture studied the impact of voluntary and mandatory labelling on agricultural producers and the agri-food industry and issued its report in June 2002.[93] The report recommends:

- That the government continue to develop a standard for the voluntary labelling of foods derived from biotechnology. That standard should use the narrow definition of GMOs, as proposed in the draft standard produced by the Canadian General Standards Board.[94]
- That the government intensify research into the benefits and risks to human health and the environment of agricultural products derived from biotechnology, and bring forward a public information program.
- That the government assess the additional costs, particularly for farmers and consumers, of implementing segregation and tracking systems, which are necessary for the labelling of GM foods, and report to the committee and the House of Commons.
- That the government assess the trade implications of mandatory versus voluntary labelling of GM foods, and report the results of this assessment to the committee and the House of Commons.

These recommendations are fully consistent with those offered in this report and the Interim Report of August 2001.

Defining a Meaningful and Effective Standard for Labelling

Deciding what should be labelled as "GM" or "GM-free" is not straightforward. While the labelling of whole foods such as a hypothetical GM fruit or vegetable may be reasonably clear-cut, complexities arise when considering processed foods that may or may not contain ingredients derived from GM plants. In some cases, the ingredient may contain an identifiable GM gene and/or protein. In other cases, such as oils derived from GM plants, there is no detectable GM protein or DNA that would distinguish them from the oil derived from a non-GM plant. Should products containing oil from GM plants be considered genetically modified? Or just those products containing identifiable GM protein or

[93] House of Commons (2002), *Labelling of Genetically Modified Food and its Impact on Farmers*, Report of the Standing Committee on Agriculture and Agri-Food, June 2002.

[94] Ibid. The "narrow definition" would include only transgenic organisms and would exclude products derived from mutagenesis.

DNA? As discussed below, taking the more inclusive approach poses additional challenges. Because it is not feasible to guarantee the total elimination of GM ingredients, a definition of GM is typically based on a threshold level of GM ingredients. Currently, thresholds in other countries range from 1 to 5 percent. The lower the threshold level, the greater the difficulty of monitoring compliance and verifying claims if methods of detection are not sufficiently sensitive or specific.

The Canadian Council of Grocery Distributors and the Canadian General Standards Board[95] are currently developing a Canadian standard for the voluntary labelling of GM foods. They have completed a draft standard with the involvement of a wide cross-section of consumer groups, food companies, producers, interest groups and government, and are continuing to work toward a consensus.

In January 2001, the U.S. FDA announced its draft guidance to industry on voluntary labelling,[96] advising food manufacturers on the acceptability of various types of label claims and reinforcing the fact that labelling must be truthful and not misleading. The FDA reiterated the requirement that manufacturers must be able to substantiate label claims and that, in labelling a food as "not a product of bio-engineering," there should be no connotation of superiority.

Some countries, such as the European Union, Japan, Australia and New Zealand, have announced mandatory labelling requirements for GM foods that contain detectable amounts of novel DNA or protein. While these schemes are similar in intent, there are notable differences with respect to which foods must be labelled (whole foods, processed foods and restaurant foods). Other differences are exemption thresholds for food additives that may have been derived from GM foods as well as thresholds for the unintended presence of GM foods in a processed product. It is difficult to assess the use of these systems because none of these countries has significant amounts of GM foods in the marketplace.

Many countries, including Canada, are working together on an international approach to the labelling of GM foods. Canada is actively working with the international CODEX Committee on Food Labelling to arrive at a common international position on labelling. While any agreed-upon standard would be voluntary (as are all CODEX standards), such voluntary standards have been incorporated by reference into trade agreements, thus making them, in practical terms, a common standard both for goods sold in international trade and in many domestic markets.

Conditions Required for Verification

Producers and the food industry estimate that up to 75 percent of all processed foods in Canada contain corn, soya or canola products. Since the North American supply chain does not generally separate conventional crops from GM crops, these products are mixed. As a result, some estimate that up to 75 percent of processed foods contain material that has come from a GM plant. However, at present, food processors have no way of knowing exactly how much of a processed food is derived from GM material. Moreover, the portion could vary from batch to batch.

Labelling requires a system to segregate GM crops from conventional crops at all levels of production and transportation in order to verify claims. The cost, effort and time required to develop and implement such a system (sometimes called an identity preservation system) would be very significant and would entail among other things sophisticated, expensive information systems. It would also entail additional public costs to enforce the labelling scheme.

[95] The Canadian Council of Grocery Distributors is an organization representing about 80 percent of Canada's major food retailers and is involved in public awareness and education activities for biotechnology. The Canadian General Standards Board is a standards development organization in the federal Department of Public Works and Government Services.

[96] U.S. Food and Drug Administration Center for Food Safety and Nutrition (2001), *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bio-engineering*, Draft Guidance, Washington DC, January 17, Docket Number 00D-1598 (http://www.cfsan.fda.gov/~lrd/../~dms/biolabgu.html).

While a mandatory labelling system would bring additional costs, it is difficult to predict what those would be. The systems in place in other countries have not been operating long enough to determine the full costs and technical problems.[97] The cost and practicality depend in part on the chosen level of tolerance (that is, the content threshold for designating a product as being GM or non-GM).

Finally, who bears the cost of a labelling system requires consideration. Under a mandatory system, additional costs are ultimately borne by all taxpayers and consumers, whether or not they want mandatory labelling. Under a voluntary system, the costs are borne primarily by those who want the information in order to make their food choices. However, mitigating factors may come into play. For example, identity preservation could prove beneficial, not only for labelling purposes but also for tracking contaminated food products, thus enhancing food safety. It could also contribute to the development of niche markets for higher-value-added products that some say will mark the future of Canadian agriculture. These additional applications would allow the cost of developing and operating identity preservation systems to be absorbed over a broader range of food products than GM products alone.

The capacity to verify the integrity of the identity preservation system is critical to enforcing the accuracy of a GM label. While tests do exist to identify some GM crops and ingredients, these tests require the presence of molecular markers (DNA or protein) specifically resulting from the genetic modification. At present, no tests are available to identify products derived from GM plants in the absence of these or other markers. This limitation is particularly significant in the case of oils and other products commonly used as ingredients in most processed foods. The absence of effective tests to detect GM content will necessitate establishing both an effective management process standard to ensure the separation of GM and non-GM products throughout all stages of the process, as well as effective audit systems to test for compliance.

Labelling and Health

As noted earlier, the current regulatory system already requires labelling of all foods for reasons of health and safety, whether derived from GM plants or not.

It has been argued that the mandatory labelling of GM foods is a necessary component of a monitoring system for long-term health effects. However, the kinds of consumer-oriented labels being called for are neither necessary nor sufficient to provide the information required for this kind of monitoring.[98] Epidemiological studies to determine such effects require databases that provide more specific and significantly more complete information related to the formulation of a product.

Trade

Canada is a major importer and exporter of primary, intermediate and final food products. It is therefore prudent to consider the effect that mandatory labelling might have on our international trade commitments, on our relations with our major trading partners, on the free flow of food products and on enhancing opportunities for trade.

Trade agreements allow countries to mandate labelling for reasons of health and safety and to disclose the nutrient content of the product. Labelling for other reasons may be considered a non-tariff barrier to trade. Canada, the United States and other countries have raised questions in the World Trade

[97] P. W. B. Phillips and H. McNeill (2001), A survey of national labelling policies for GM foods, *AgBioForum* 3(4): 219–24 (http://www.agbioforum.org).

[98] Leonard Ritter, *Long-term Monitoring of Health Effects*, a report prepared at the request of the Canadian Biotechnology Advisory Committee, Ottawa.

Organization's (WTO's) Technical Barriers to Trade/Sanitary and Phytosanitary Committees regarding the compatibility of the European Union's recently proposed labelling regulations. This is now a matter of contention between the United States and the European Union. Negotiations are taking place to resolve the matter but, in the absence of an agreement, it may be brought to the WTO for resolution. Mandatory labelling of GM foods may contravene Canada's international trade agreements and leave us open to a WTO or North American Free Trade Agreement (NAFTA) challenge and to potentially significant penalties, whereas a voluntary system would not.

Even without trade action, a mandatory labelling system could disrupt the free flow of food products. This is because our trading partners might have either no system of mandatory labelling in place or a different standard, and producers might choose to bypass the relatively small Canadian market rather than bear the increased costs associated with labelling. This is significant from an economic perspective because our agricultural and food processing sectors are highly integrated with those of the United States. Mandatory labelling could diminish this integration with resulting impacts on the economy. From a consumer perspective, this might have the effect of reducing consumer choice if the products they demand are no longer available in Canada. However, a mandatory labelling system and proper segregation of products could enhance trade opportunities for Canadian producers with international clients that want to provide more choice for their customers or with countries that have or are moving toward either an outright ban on certain GM foods or mandatory labelling. The development of an international labelling standard, accepted by all of Canada's trading partners, is the surest way to obviate the negative consequences of mandatory labelling while providing meaningful consumer choice. It would be highly advantageous for Canada to actively promote the development of such a standard.

Conclusion

Annex 5 provides a matrix that summarizes the impacts of three labelling scenarios: status quo, voluntary labelling and mandatory labelling. We have concluded that an effective standard for labelling, broadly supported, is a prerequisite for either a voluntary or mandatory labelling scheme. Moreover, a single internationally accepted standard is highly desirable and perhaps essential in the longer run. Until an agreed-upon Canadian standard is developed and tested, it would be premature for Canada to impose a mandatory labelling system. Moreover, without an agreed-upon standard, even a voluntary system could be misleading and therefore emphasis should be placed on the development of an effective standard.

All but one of the members of CBAC believe Canada should begin implementing this standard through a voluntary labelling system:

- to allow time to test its adequacy and efficiency and to develop an international standard and consensus, hopefully through Canadian leadership
- to provide consumers who wish to purchase GM-free products with the ability to identify them
- to limit costs
- to avoid trade action in the event a mandatory labelling scheme contravenes trade agreements.

In order for consumers, civil society groups, industry and government to assess fairly and openly the success of a voluntary labelling system, a clear set of measurable criteria would have to be established. These measures should address whether the availability of labelled GM-free products is reasonable, the consumer acceptance of such products, the consumer understanding of these labels, and the fairness and effectiveness of the system for the verification of claims.

The dissenting member, Anne Mitchell, believes Canada should move directly to a mandatory labelling regime for GM foods; she notes the high level of support for this position among citizens responding to our Interim Report.

Recommendations

We recommend:

7.1 That Canada establish a voluntary labelling system for foods with GM content based on a set of clear labelling criteria, derived from a broadly accepted standard. It is essential that any label statements regarding genetic modification are verifiable, and that programs, processes and methodologies are in place to ensure their validity.

7.2 That this voluntary system be assessed on the basis of its adequacy and effectiveness; that early consideration be given to the criteria and methodology to be used to evaluate whether the voluntary labelling regime has provided adequate choice to consumers; that a review be undertaken five years after implementation to determine if the system has provided Canadians with sufficient choice regarding the foods they consume; and that, if it has not, other approaches, including mandatory labelling, be considered.

7.3 That the voluntary system be widely promulgated and promoted.

7.4 That Canada enhance its continuing effort, in concert with other countries, to develop a harmonized approach to labelling in regard to GM foods with special emphasis on the development of an internationally accepted labelling standard.

Theme 4: Social and Ethical Considerations

The earlier observations and recommendations in this report reflect some of the social and ethical aspects of the regulation of GM and other novel foods. Under Theme 4, we examine some of these aspects from a broader perspective.

Recommendation 8. Other social and ethical considerations related to GM foods

Observations

The regulation of GM and other novel foods takes place in the context of a variety of social values and ethical principles, largely those relating to beneficence and autonomy. Also important are questions related to the intrinsic morality of genetic engineering, justice and cultural diversity.

Ethical Acceptability

There is a wide spectrum of opinion regarding the ethical acceptability of genetic modification. At one end of the spectrum are those who believe genetic modification is intrinsically wrong and should not be pursued under any circumstances. At the other end are those who see the exploitation of genetic modification for the benefit of humanity as a moral duty.[99] In between are individuals for whom genetic modification is a problem only when it involves breaching the species barrier, and others who believe that genetic modification is unnecessary because its objectives can be achieved in other ways or because its benefits are illusory. Still others believe that the technology generates considerable benefits and that these benefits justify its pursuit.

[99] See for example, *Nature Genetics* 28 (2001) Editorial: Defining a new bioethic, August, p. 297; United Nations Development Program (2001), *Human Development Report*; Peter A. Singer and Abdallah Daar (2001), Harnessing genomics and biotechnology to improve global health equity, *Science* 294 (October 5).

Traditional Knowledge and Resources

Many societies around the world are rich in resources and knowledge that would be beneficial for the development of new GM foods. By using these resources and this knowledge, new genetic combinations can be produced that are well suited to a given purpose or environment. However, when corporations, research institutes, universities or individual inventors hold patents on these new items, the individuals and societies who contributed to them may not share in the financial and other benefits. This lack of benefit sharing may be considered even more egregious when these new products — for example, improved seed and plant varieties — are sold back to the source societies and farmers at substantial profit. While such matters are of concern to some, they are less troublesome to others who believe that the growers and consumers in these societies derive substantial value from the new products. Discussions about these issues are becoming more common in international fora, and signs are emerging through the media that companies may be starting to consider and implement benefit sharing.

Power Imbalance and Vulnerability

As with the introduction of many new technologies, the development of GM foods raises the issue of a possible imbalance between those who will benefit the most from it and those who will bear the greatest risk. Currently, the greatest benefit is often seen as one of productivity and financial gain shared among a few (the developers of new products and farmers), while negative impacts on health or the environment would befall the much larger population of consumers. In response to this, some people advocate focussing more effort on achieving a better balance, with greater benefits for consumers. Others believe that the benefits are in fact broadly shared through such positive effects as job creation, economic expansion, less pesticide use, more nutritious foods and more efficient land use.

At present, a relatively small number of companies hold the vast majority of plant biotechnology patents and an increasing share of the GM food market. This market dominance and concentration of economic power is seen by some as a source of diminished self-sufficiency in food production and a threat to the sovereignty of some underdeveloped countries. Others regard this industrial structure as a necessity due to the time and expense involved in developing products from the research stage through regulatory approval.

Introducing new technologies and capital into countries with agrarian economies and traditional farming systems can significantly alter local agricultural practices and societies. In the context of GM foods, some fear that this might destabilize the society's traditional way of life and increase the vulnerability of poor farmers. Conversely, some believe that food biotechnology can help to stabilize vulnerable societies. They contend that, subject to appropriate regulation to manage potential risks to human health and the environment, biotechnology can make a significant contribution to food security and improved nutrition in the developing world,[100] to feeding a burgeoning world population and to addressing the problems of a shrinking agricultural base as well as diminishing water supplies, without degrading the environment. They typically support a cooperative approach that focusses on meeting the specific needs of less developed nations. Such benefits will accrue, however, only if scientific research focusses on the problems and opportunities in the developing world and if the technology is either generated by the developing countries or transferred to them at an affordable price and in a form that is readily usable in the local society.

[100] See, for example, the statements on biotechnology by the Food and Agriculture Organization (http://www.fao.org/biotech/stat.asp); by the World Health Organization (2001), Food Derived from Biotechnology (http://www.who.int/fsf/GMfood.htm); G. J. Persley and M. M. Lantin, eds. (1999), *Agricultural Biotechnology and the Poor*, Proceedings of an International Conference, Consultative Group on International Agriculture Research, Washington DC, October 21–22.

Environmental Ethics and Economics

Environmental ethics dictate that it is wrong for individuals, companies or societies to behave or develop in a manner that undermines the long-term health of the environment and its natural diversity of plant and animal species. Adhering to this ethic requires greater attention to environmental economics; that is, taking into account the costs and benefits of any actions that could affect the environment. In the case of a company, for example, it would require that the impacts of its activities on the environment — both positive and negative — be included in the firm's cost structure and thereby into its business decisions. Financial incentives such as subsidies or disincentives such as taxes are measures that would encourage an entity to make environmentally sound decisions.

Application of Ethics to Decision Making

Food regulatory processes generally do not involve considering the kinds of issues outlined above. Some observers therefore conclude that these matters have less influence on policy than the more traditional factors that rely on science-based evaluations. However, these issues are certainly not absent from public debate as the recent controversy surrounding the potential introduction of GM wheat into Canadian farms indicates. However, the absence of formal procedures to take such matters into account does make it more difficult to ensure that they form part of the decision-making process. A central issue, then, is when and how ethical concerns ought to be built into decision-making processes regarding GM Foods.

Several questions arise. How should government and others engage to consider and resolve such conflicts? Under what conditions should legislative or regulatory instruments be considered and how should they operate? Are there other mechanisms that could resolve these matters? When is the most appropriate time to consider these issues — at the development stage, the research stage or the commercialization stage?

Recognizing that the current paradigm for regulatory decisions pertaining to health and the environment is based on scientific evaluations and risk assessments, a key question is whether or not the current regulatory system could or should be modified to add broader social and ethical considerations to case-by-case, product-level regulatory decisions. Some fear that this could lead to abuse by those who seek to undermine current regulatory processes for political reasons; or that it would reduce the predictability of the regulatory process; or that including social and ethical considerations in assessments would modify their basic purpose, thus possibly putting the country's policies at odds with its international obligations and with the thrust toward international harmonization. Others note that Canada has an array of laws, policies and programs that are better suited to address these issues than is the regulatory system.

Given the nature of social and ethical values and the need to resolve differences in priorities among different groups in society, it is important to consider whether these matters might more appropriately be addressed by the political process — that is, by government and/or Parliament — than by an administrative agency. Typically, it is the responsibility of elected representatives to address new policy issues that have broad social impacts. Moreover, the question of which agency should be responsible for addressing social and ethical issues may depend on the particular issue at hand. In the absence of clarity about the values involved and the implications of the various options, it is difficult to transfer such matters to administrative bodies or to entice them to champion their resolution. Accordingly, a further policy analysis should be undertaken to better define the broader social and ethical issues relating to GM foods and to identify the options for addressing these matters and assessing the implications of the options.

In its Interim Report, CBAC introduced a consultation tool called the Acceptability Spectrum. The Acceptability Spectrum is a framework intended to facilitate a dialogue on GM foods, classes of products or applications of genetic modification, as well as on the values and principles that underlie the Canadian public's attitudes toward these foods. It is based on the premise that different kinds of GM foods or different types of application could be considered as being more or less acceptable, according to a variety of criteria. These include: health, environmental safety, socio-economic factors, ethical issues (such as a view that combining animal and plant DNA is unethical) and broader social and international implications.

Since the publication of the Interim report, an Exploratory Committee has been established to guide a special pilot project to assess the validity and usefulness of the Acceptability Spectrum and to improve its design and the methodology for its potential uses. The Exploratory Committee consists of individuals from non-governmental organizations and industry. This is explained in more detail in Annex 6.

It seems evident that no single approach can address the wide range of social and ethical issues raised by transformative technologies such as biotechnology. Further study and analysis are needed to identify the repertoire of approaches available in developing public policy to deal with the ramifications of particular technological advances.

Organizations with Mandates Involving Social and Ethical Implications of Biotechnology

Ethical Acceptability: When Genome Canada was created, each Genome Centre was required to incorporate into their programs the ethical issues that might arise from the science conducted in the centre. Similarly, CBAC's mandate empowers it to examine issues from a broad perspective that includes the social and ethical aspects of the issues it addresses. The Canadian Council on Animal Care maintains guidelines for the protection and humane treatment of animals used in research. Laws governing the treatment of animals and Humane Societies protect all animals from abuse, whether in research or agriculture.

Traditional Knowledge: Canada supports and participates in several international negotiations to clarify, define and give meaning to traditional knowledge and mechanisms for fair benefit sharing. These include the recently approved International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Voluntary Guidelines on Access to Genetic Resources and Benefit Sharing. Canada is also working in the World Intellectual Property Organization working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether and how a new form of intellectual property can be created for traditional knowledge.

Power Imbalances: Canadian Competition Laws address the power imbalance issues that arise in commercial markets and other laws govern the relationship between employers and employees and customers. On the international front, Canada maintains and supports the Canadian International Development Agency and the International Development Research Centre to assist developing nations with a wide array of development challenges, including food and agricultural support. It also supports capacity building to enable developing nations to more effectively participate in international negotiation, and to develop effective domestic capacity to overcome power imbalances.

Environmental Ethics and Economics: All provincial governments and the federal government have departments of environment that develop and implement laws for the protection of the environment. Other instruments such as the use of tax law to create incentives for the use of more environmentally friendly technology are in place and additional measures have been recommended. Canada participates in the international treaties that are intended to protect the environment, such as the Biosafety Protocol and the Convention on Biodiversity.

Recommendations

We recommend:

8.1 That the government facilitate further study and analysis to identify effective ways to address the social and ethical issues related to biotechnology by supporting such study and analysis within government and its advisory bodies and by non-governmental stakeholder groups. In this regard, the government may wish to pay particular attention to the outcome of CBAC's pilot project on the development of a consultation tool — the Acceptability Spectrum — and methods for its use as a suitable approach to addressing these issues.

8.2 That the government work with domestic and international agencies to develop the capacity of developing countries to protect and exploit their traditional knowledge and resources; such efforts should build upon the progress already made through the International Treaty on Plant Genetic Resources for Food and Agriculture as well as through the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization.

8.3 That the government achieve the objective of recommendation 8.2 above in part by establishing a program, through the Canadian International Development Agency, to assist developing countries in:

- using modern biotechnology where appropriate to achieve their objectives with respect to agricultural productivity, improvements in the nutritional qualities of domestic crops and protection of their environment as well as to prevent or treat diseases prevalent in the developing world
- establishing or strengthening regulatory processes to protect against potential risks of modern biotechnology.

The program would work with other national development agencies and international agencies, such as the United Nations Development Programme, the Food and Agriculture Organization, the World Health Organization, the United Nations Environment Programme and the Consultative Group on International Agricultural Research (CGIAR), as well as with local non-governmental, academic and business groups.

Conclusion

This report marks the completion of our original project plan pertaining to the regulation of GM and other novel foods in Canada. However, we will continue to take an active interest in matters pertaining to GM foods, including developments in the areas of regulation, the monitoring of long-term health and environmental effects, labelling, and integration of social and ethical considerations into public policy discussions and decision making. We will report on these matters as the need arises. We will also:

- meet with interested parties, both inside and outside government, to discuss and explain our recommendations concerning the regulation of GM and other novel foods
- cooperate with federal agencies on their work programs to address our recommendations
- continue to facilitate the Exploratory Committee's work on the pilot project on the Acceptability Spectrum, including the refinement and testing of the tool, the methodologies for using it and examining its scope for application in wider consultation settings
- undertake a watching brief on national and international matters pertaining to the regulation of GM foods
- monitor public opinion research concerning GM foods
- continue to sponsor research and background studies on specific topics pertaining to GM foods
- report on important developments, including progress in the implementation of our recommendations
- closely monitor developments in the labelling of GM foods and, in particular, should a voluntary labelling scheme be adopted, whether or not the scheme provides consumers with a reasonable range of choice in the foods they purchase.

As we have emphasized throughout the report, GM foods will continue to evolve and take on new dimensions that offer both promise and possible risks. Our recommendations are designed to maximize the former and minimize the latter. We look forward to the government's response to our findings and recommendations.

Annex 1. CBAC Publications, Commissioned Reports and Companion Documents[101]

CBAC-commissioned Reports Related to GM Foods

Analysis of Relevant Canadian Legislation, by Donald J. MacKenzie, Executive Vice-President, Agriculture and Biotechnology Strategies (AGBIOS) Inc.

Biotechnology, Ethics and Government: A Synthesis, by Michael McDonald, Director, Centre for Applied Ethics, University of British Columbia.

Comparison of International Regulatory Regimes for Food Products of Biotechnology, by Donald MacKenzie, Executive Vice-President, Agriculture and Biotechnology Strategies (AGBIOS) Inc.

Food and Agricultural Biotechnology: Incorporating Ethical Considerations, by Paul Thompson, Distinguished Professor of Philosophy, and Joyce and Edward E. Brewer, Chair of Applied Ethics, Purdue University, West Lafayette, IN.

Inside the Canadian Biotechnology Regulatory System: A Closer Exploratory Look, by Bruce Doern, School of Public Administration, Carleton University, and Politics Department, University of Exeter.

International Approaches to Non-science Issues in Regulating the Products of Biotechnology, by Ozzie Silverman, Consulting Partner, Secor Conseil Inc.

Labelling of GMO Products: Strategic Trade Policy Considerations for Canada, by Ramesh Chaitoo, Senior Trade Policy Analyst, Centre for Trade Policy and Law, Carleton University, and Michael Hart, Simon Reisman Chair in Trade Policy, Norman Paterson School of International Affairs, Carleton University.

Meeting the Public's Need for Information on Biotechnology, by Edna F. Einsiedel, Professor of Communication Studies, Faculty of Communication and Culture, University of Calgary.

Regulators and Promoters of Genetically Modified Foods in the Government of Canada: An Organizational and Policy Analysis, by Michael Prince, Lansdowne Professor of Social Policy and Associate Dean, Faculty of Human and Social Development, University of Victoria, British Columbia.

Report on the Precautionary Principle, by Marc Saner, Managing Director, Ethics and Policy Issues Centre (EPIC), Department of Philosophy, Carleton University.

Secondary Analysis of Public Opinion Research Regarding Genetically Modified Foods and Related Biotechnology Issues, by Environics Research Group, June 2001.

Taking Stock: The Benefits and Costs of Genetically Modified Crops, by Richard Gray et al, Professor, Department of Agricultural Economics, University of Saskatchewan.

Towards an Adequate Ethical Framework for Setting Biotechnology Policy, by Susan Sherwin, Munro Chair in Philosophy, Department of Philosophy, Dalhousie University.

[101] All reports listed are available on the CBAC Web site (www.cbac-cccb.ca).

CBAC Publications on GM Foods

Regulation of Genetically Modified Foods, Consultation Document, February 2001.

Workshops on GM Food: Stakeholder Sessions, Summary Consultation Report, June 2001.

Written Input on Genetically Modified Foods , Summary Consultation Report, June 2001.

Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada, Interim Report to the Government of Canada Biotechnology Ministerial Coordinating Committee, August 2001.

Written Input on CBAC's Interim Report on Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada, Summary Consultation Report, May 2002.

Annex 2. Summary of the Written Input to the Interim Report

The Interim Report contained six major and 24 specific recommendations based on 10 issues, as listed below.

- **transparency**
- **separation and independence of regulatory functions**
- **ensuring safety during research and development activities**
- **opportunities for public involvement**
- **post-market monitoring for risks and benefits**
- **capability and capacity in the regulatory system**
- **information provision to support consumer choice**
- **labelling**
- **environmental stewardship**
- **broader societal and ethical considerations.**

Respondents were invited to provide input on each recommendation or on any one of particular interest to them.

Respondents

CBAC received 160 submissions in response to its Interim Report. The responses were classified according to the respondent's perspective as a consumer, industry representative, government official, etc. The perspectives and the number of responses received were as follows:

Respondent category	No. of responses
Consumers and interested citizens	127
Industry representatives	9
Representative of a non-governmental not-for-profit organization	8
University research scientist or other academic	9
Government official	7
Total	160

Some respondents addressed each recommendation in the Interim Report, while others addressed specific recommendations of interest or concern to them.

Analysis Conducted

CBAC reviewed the responses and prepared a summary table of responses to each recommendation. For those who did not refer to a specific recommendation in their response, CBAC has either included the information alongside the most appropriate recommendation or captured the information under "other views." Based on this summary, CBAC extrapolated the key patterns and messages observed (e.g. the main types of responses and reasoning, related to a given recommendation and among the "other views").

To ensure as fair and accurate an interpretation and representation as possible of the responses received, CBAC commissioned two reviews of its work by academics from Canadian universities. These reviewers were provided with all of the responses received, and were asked to review and provide suggestions to help improve the accuracy of the summary table and the description of key patterns and messages observed. CBAC then revised this report.

This report is intended to be a reflection of the views of those submitting input to CBAC's consultations on GM foods, drawing out key patterns and messages in a qualitative rather than a quantitative manner. The views should not be considered consensus views of respondents, nor should they be construed to reflect the views of CBAC. Likewise, this report should not be considered to represent the views of the reviewers commissioned to assist CBAC in the preparation of this report, as the reviewers may not necessarily agree with the report or with the views it contains.

Patterns Observed

The comments pertaining to each recommendation are broadly summarized below. It is important to note that many respondents made comments that did not directly pertain to the recommendations as written in the Interim Report. These comments are summarized in a final subsection under the heading *Other Comments*.

Recommendation 1

CBAC recommends that the federal government enhance the structure, organization and operation of the federal food regulatory system for GM and other novel foods. It should adopt a series of measures to further systematize and integrate its different regulatory bodies, and to darify the separation of government's regulatory role from its promotional activities. We also recommend that an assessment be undertaken to determine whether it would be advantageous to apply this recommendation more widely to the entire Food Safety System.

Respondents addressing this recommendation:

Respondent category	No. of responses
Consumer/interested citizen	29
Non-governmental organization	4
Government	4
Academics	5
Industry	7
Total	49

In general, a majority of respondents from all interests supported improving the structure and function of the regulatory bodies and further integrating them. Many also agreed that an adequate separation of regulatory functions from promotional functions needs to be ensured. However, most industry respondents noted that this separation had already been achieved and that the problem was that the roles and responsibilities were not adequately communicated to the public. Some respondents stated that government should simply not be responsible for both activities at the same time.

A number of concerns were expressed, particularly from non-industry interests, regarding perceived corporate influence on government and regulatory agencies. Respondents noted that there should be independent testing, monitoring, reporting and regulating within the regulatory agencies. It was noted that CBAC should highlight the need for independent parties to assess the impacts of GM crops. In general, these respondents were concerned that government and regulatory agencies were not independent enough from corporate influences.

Many respondents from industry noted that the creation of a Chief Food Safety Officer (CFSO) and an Assistant Deputy Minister's (ADM's) committee would add another layer of bureaucracy to the regulatory system without added benefit, and possibly add delays. Some of these respondents argued that these roles are already established within the government (e.g. that the CFSO is the Minister of Health or the President of the Canadian Food Inspection Agency). It was suggested that rather than adding more management levels, the existing scientific capacity to review applications should be increased.

Respondents who supported creation of a CFSO noted that CBAC should outline the procedures for the nomination of candidates to ensure that a qualified person, with no conflict of interest, occupies the position. Respondents supporting the establishment of an ADM's committee suggested that a peer review process be established to advise the ADM's committee on GM and other novel foods, to screen candidates and to advise on appointments to the CFSO position. Several respondents noted that peer review should involve a diverse range of expertise and disciplines.

Among those who addressed the issue of Standard Operating Procedures (SOPs), there was general agreement with the publication of SOPs and with monitoring by the Auditor General. Some respondents noted that monitoring by the Auditor General already occurs.

All respondents agreed that the regulatory system needed to be more transparent and that information should be provided. It was noted that the government has a paramount role in providing information to Canadians on the regulatory process. Some respondents remarked that increased information would enhance consumer confidence in the regulatory process.

Respondents suggested some elements that they thought are missing in CBAC's recommendation:

- methods of assessment, particularly the use of substantial equivalence
- government testing of data submitted by developers
- public access to the decision-making process
- the costs of implementing the recommendation
- issues of accountability and liability
- standards for greenhouse testing.

Recommendation 2

CBAC recommends that the federal government launch a significant effort related to the monitoring of long-term health and environmental impacts associated with GM foods and other novel foods.

Respondents addressing this recommendation:

Respondent category	No. of responses
Consumer/interested citizen	22
Non-governmental organization	5
Government	4
Academics	5
Industry	7
Total	43

Virtually all respondents from the consumer/interested citizen group fully supported long-term testing of GMOs. However, they were very concerned that GMOs are currently in the market. Many noted that this type of testing has to be done before introducing a food for general consumption. These respondents thought that the tests done on GM foods currently on the market were not long enough or that the results were not conclusive enough to demonstrate GMO safety. Many of these respondents stated that there should be an immediate ban on GM products until further long-term testing is completed.

Respondents from non-governmental organizations said that GM foods are underregulated and expressed concerns about the data that were submitted to regulators on behalf of a product. Respondents remarked that the data were of poor quality and not adequate to pass a peer review process. A respondent noted some specific problems with testing and regulation, including the inability of scientists to use proper experimental controls, a misunderstanding of the precautionary approach and a lack of foresight regarding potential impacts. One respondent suggested establishing two independent panels with expertise in ecology and in human and animal epidemiology, while another suggested that safety reviews should be conducted by scientists, farmers and consumers. These panels should be empowered to revise CFIA regulatory directives, guidelines and protocols. It was also noted that there are challenges to post-market monitoring, such as mandatory segregation, traceability and the authority to enforce, that will need to be addressed before this recommendation could be effective.

A respondent from government noted that the cost of implementing this recommendation would be high and that the focus should be on pre-release testing rather than on post-market monitoring. This respondent thought that long-term monitoring was of questionable value because GM crops are grown in rotation with other crops and because cause-and-effect relationships for health impacts are difficult to determine. Some government respondents also suggested that it is essential to develop national programs and improve capacity to identify the source of foods, including GM ingredients, so that they can be traced if there are problems. Further, it was noted that enhanced methods to predict and test allergenicity and toxicity of novel proteins, and effective detection methods for new proteins, are essential. Failure of the government to provide sufficient funds to develop such methods would be a major public health concern and a disservice to the Canadian population.

Respondents from the academic and consumer groups noted the incompleteness of the scientific knowledge of genes in living organisms and of the impacts of GM crops. Concerns were expressed that

GM processes could introduce unexpected changes that could cause health or environmental impacts. These risks are not identified in the regulatory system. A respondent noted that post-market monitoring assumes that unintended effects of GMOs will be controllable or reversible and that CBAC should address this assumption. A respondent expressed concerns that CBAC had not addressed certain assumptions about the scientific basis of genetic engineering, but had instead deferred these questions to other processes such as the Royal Society. Respondents noted that before GM crops are released there should be strict and repeatable research on health effects, including intergenerational effects, and that a moratorium on GM foods is scientifically defensible until such effects are known and until our ability to predict gene function improves. It was also noted that CBAC should advocate for process-based regulation over the current practice of product-based regulation.

A number of industry respondents disagreed with specific parts of the recommendation, primarily the recommendation for developing food consumption data and the recommendation for including in product approvals a preset deadline for reassessing any new information related to the product or its risk assessment. These respondents thought that Health Canada already collects adequate food consumption data, that it is not necessary to do more in this regard and that the ability to reassess products already exists within current legislation. It was noted that routine reassessments are not needed, especially if they withdraw resources from conducting new product evaluations. It was suggested that improving the regulatory system is a key way to make the evaluation of long-term health and environmental impact more credible, and that research must be done independently of interested parties. Several industry respondents supported long-term research as an important component of the regulatory process, although several also expressed concern about the cost and validity of such research. Many emphasized the need to maintain a strong scientific basis for regulations.

Recommendation 3

CBAC recommends that the federal government become more effective and transparent in communicating all features of the GM and other novel food regulatory system, including the scientific basis for regulatory decisions related to human and environmental health and safety.

Respondents addressing this recommendation:

Respondent category	No. of responses
Consumer/interested citizen	12
Non-governmental organization	3
Government	5
Academics	3
Industry	7
Total	30

Almost all respondents supported the full recommendation. Respondents specifically expressed support for transparency of all of the government's processes, including those of the regulatory bodies. Respondents supported decision trees, and some suggested using case studies as ways to achieve more transparency. Also, many respondents supported the recommendation to publish the detailed scientific data about health and environmental safety assessments prior to the release of a GM product.

Some industry respondents cautioned that this release of information should respect confidential business information, while some respondents from other interests thought that the current level of privacy granted to a company's business information is unnecessary and should not be used as a barrier to transparency or public involvement. The value of releasing detailed studies to the public was questioned and a respondent suggested publishing regulatory decision documents that provide the regulator's basis for approval as well as summary comments on the data supplied in support of the submission. Also, it was suggested that a 45-day public comment period on proposed product approvals would cause unnecessary delays and cost more for both industry and government.

Some industry respondents indicated that the detailed location of field trials should not be released due to the risk of vandalism and to protect the safety of workers. One respondent suggested that all of the implications of disclosing this information should be considered before doing so and that it should be communicated that farmers who conduct these trials are guided by standards of practice.

Some respondents made specific recommendations:

- CBAC should more clearly define what it means by "information on pollen drift must be provided." Ideally, CBAC would indicate that when there is a lack of direct research data to indicate otherwise, the minimum restrictions under confined testing must take into account the worst scenario and provide a margin of safety. Another respondent suggested that the decision to increase or decrease the buffer zones should be made on a case-by-case basis when it is scientifically justifiable (although one respondent noted that buffer zones are already re-evaluated as new scientific information becomes available).

- CBAC should recommend the establishment of a public database for all GM crops and foods approved for commercial cultivation and use that provides comprehensive historical information about how the product was evaluated. The database should also contain information about the long-term health and environmental impacts of the product.

- Some respondents noted that the CBAC recommendations fail to address the consequences of pollen drift and gene escape for neighbouring farms and particularly for organic farmers. Some also argued that CBAC failed to address the protection of farmers against allegations of patent infringement.

- One respondent felt that existing regulations were developed with sufficient public involvement and transparency. Another respondent felt that improved communication could be achieved through existing vehicles such as the Food Biotechnology Communications Network.

Recommendation 4

CBAC recommends that the federal government put in place mechanisms to help Canadians make informed choices about the foods they consume. The government should allocate new and additional resources for providing Canadians with a centralized service for accurate and comprehensive information on GM and other novel foods, the food regulatory system, and food standards and regulations. The government should also ensure the development of an approach to labelling foods regarding genetic modification that, combined with the information service, is effective in helping Canadians make informed food choices.

Respondents addressing this recommendation:

Respondent category	No. of responses
Consumer/interested citizen	95
Non-governmental organization	7
Government	5
Academics	6
Industry	8
Total	121

Respondents to this issue fell into two distinct categories: those who want mandatory labelling of GM foods and those who want a voluntary system of labelling. The vast majority of respondents from the consumer/interested citizen, academic and non-governmental organization interests wanted a mandatory labelling system, while the vast majority of industry respondents supported a voluntary system. Government respondents were essentially split (two for mandatory and three for voluntary).

The most common reason provided for supporting a mandatory system was to allow consumers to exercise their right to make an informed choice. It was repeatedly stated that consumers have the right to know if foods have been genetically modified, so they can decide whether or not to buy GM products. Several respondents said they had difficulty trying to avoid GM foods in the current marketplace. These respondents stated that if there were mandatory labelling of GM foods, they would be able to choose their foods based on whether or not there were GM ingredients. Many thought that they were effectively being forced to eat GM foods.

Respondents were concerned about the long-term effects of GM products and, because they could not choose whether or not to eat these products, they claimed that they were being used by the government as guinea pigs. Some respondents indicated that they chose to eat foods based on factors such as moral convictions stemming from religious beliefs and that their freedom to exercise these beliefs did not exist because GM foods are not labelled.

Respondents expressed disappointment that CBAC had not recommended mandatory labelling. They did not think that a voluntary labelling system was adequate because they thought that manufacturers would choose not to label. Several respondents also stated that the majority of Canadians wanted mandatory labelling and that the government should acknowledge this preference.

Some supporters of mandatory labelling also expressed concern about who would bear the cost of labelling systems and that this should not be passed on to consumers or farmers.

Supporters of a voluntary system claimed that this system would provide optimum flexibility for consumers, government and industry. One respondent suggested that labels should be for content and not process, and that labelling for value and choice was a personal preference and should be at the discretion of the industry in response to consumer demand. Some respondents expressed concern that mandatory labelling would reduce consumer choice, increase costs and create trade implications. It was noted that labels should be informative, understandable, verifiable and not false or misleading. Some responses noted that education should be part of a voluntary labelling system. Many industry respondents felt that the current system of mandatory labelling for changes in nutrition and composition was adequate.

Regardless of whether mandatory or voluntary systems of labelling were supported, respondents agreed that labelling had to be clear, straightforward and unbiased. It was further stated that the government should determine how to regulate, implement and ensure proper labelling of GM foods. Several of the respondents stated that the government should be a source of centralized food information for consumers.

Several respondents, particularly from industry, noted that Canada should continue to work toward a harmonized standard internationally. One respondent stated that the objection to mandatory labelling due to its effect on international trade was invalid in light of current labelling policies.

Recommendation 5

CBAC recommends that the federal government strengthen its environmental stewardship over GM foods, other novel foods and the organisms from which foods are derived. A comprehensive national research program related to long-term impacts, improved environmental assessments of regulated products and the use of conservative standards of safety as the basis for product approvals is needed.

Respondents addressing this recommendation:

Respondent category Consumer/interested citizen	No. of responses 43
Non-governmental organization	5
Government	6
Academics	1
Industry	5
Total	60

There was broad support from all respondents for a national research program to improve knowledge about the long-term effects of GM organisms. Industry respondents generally supported an ecosystem perspective but many commented that GM technology should not be singled out for more rigorous regulatory review, and that the risks and benefits of GM crops should be assessed in comparison to conventional or alternative products and practices. It was suggested that this research should be a joint effort of government, industry and researchers. Most industry respondents expressed support for the concept of substantial equivalence and the precautionary approach as currently used in Canada (i.e. a science-based approach that weighs risks and benefits but does not aim for zero-risk).

Most respondents from other interests said that not enough research had been done on GM crops and that there was an urgent requirement for a national research program. This research program should determine acceptable detection methodologies for GM and novel foods as well as serve as a national monitoring program of the long-term health and environmental impacts associated with GM foods. Respondents commented that the concept of substantial equivalence should be replaced with rigorous scientific assessment of GM impacts on health and the environment.

Some respondents noted that we should take a precautionary approach to GM products, but there were differing views on what a precautionary approach might entail. One respondent indicated that this approach was poorly defined in the CBAC report and should be tightened and clarified. Another respondent suggested that a precautionary approach must begin not at the risk management stage but with the very design and statistical treatment of scientific studies. One respondent noted that a precautionary approach does not mean a zero-risk approach. Yet another argued that CBAC's position was incompatible with a precautionary approach because it supported voluntary labelling and did not question the need for GM foods; this respondent also noted that the concept of substantial equivalence was in direct conflict with a precautionary approach.

Several respondents expressed concern about the cost of Recommendation 5 and asked who would cover these costs.

Recommendation 6

CBAC will continue to consider the health and environmental safety, ethical, social (including economic) and broader societal considerations that influence people's acceptability of different kinds of GM foods. Attention will be focussed on developing methods to enable meaningful dialogue on these factors and to better identify the criteria and values at play in people's evaluation of specific foods. Guidance in relation to this aspect of the GM foods debate — in particular, a mechanism for addressing social and ethical factors that influence the public's acceptability of specific foods — is being developed for CBAC's final report.

Respondents addressing this recommendation:

Respondent category	No. of responses
Consumer/interested citizen	4
Non-governmental organization	1
Government	1
Academics	4
Industry	3
Total	13

Many respondents expressed concerns regarding the Acceptability Spectrum. Primarily, there were concerns that it is an arbitrary method of quantifying subjective information and that it is a static approach to an open-ended problem — that is, the Acceptability Spectrum attempts to assign a level of acceptability to a product but this acceptability will often shift based on societal values and beliefs, information flow and individual consumer preferences. It was also noted that there was no authority, guidance or set of tools currently that could be used to implement the Acceptability Spectrum, and that

our policies and institutions must be flexible enough to anticipate trends. Other concerns and questions regarding the Acceptability Spectrum include:

- This is a bookkeeping device and not a solution to the problem of decision making; no scheme can substitute for human ethical judgments.
- There is no indication of how the Spectrum will be used in decision making.
- Who among the Canadian population is to judge acceptability?
- How can agreement on acceptability be reached?
- How is the judgment about acceptability to be made?
- How are categories to be weighed?

One respondent expressed concerns that there were no specific recommendations on incorporating social and ethical issues into decision making; that the ethical principles or guidelines displayed on page 21 of the Interim Report were not referenced or evoked in the draft recommendations; and furthermore, that there are contradictions between the draft recommendations and these ethical principles.

The establishment of an ethical panel to evaluate breakthrough science for the biotechnology industry was suggested as a means of addressing social and ethical issues. It was also suggested, particularly from industry respondents, that these issues should be addressed not at the regulatory stage but at the research stage.

Other Comments

Respondents commenting on other related issues:

Respondent category	No. of responses
Consumer/interested citizen	78
Non-governmental organization	7
Government	4
Academics	8
Industry	7
Total	104

Many respondents commented on issues that did not pertain directly to CBAC's specific recommendations. These comments are summarized below.

Inherent Indeterminacy and Complexity of Socio-ecological Systems

Consumer respondents frequently cited the complexity of ecosystems and the inherent inability of science to provide enough information to manage ecosystems or sufficiently predict outcomes. Frequent reference was made to previously failed science-based "miracle cures" such as DDT, thalidomide, cane toads, asbestos, prescription drugs that have proved to have toxic side effects, and release of endocrine disruptors into the environment. This reasoning was provided to support a number of arguments (bans, long-term testing, precautionary approaches and independent scientific panels), and was prevalent throughout the "other" section.

Establishing a Moratorium or Ban on GM Foods

Many of the consumer respondents stated that genetically modified foods (made by rDNA technology) are different from foods made by other processes. Because of this difference, they were concerned that as yet unforeseen negative effects on human and environmental health might ensue. Some respondents were particularly concerned about the possible negative effects on children who eat foods derived from GMOs. Respondents frequently cited the lack of long-term health and environmental impact studies as a key concern around GM foods. For these reasons, many respondents were concerned that the Interim Report assumed that GM foods were here to stay and had to be regulated. A number of respondents proposed that this assumption itself should have been questioned and explored by CBAC. In fact, many respondents suggested that there should be an immediate moratorium on GMOs until further long-term studies conclusively prove their safety for humans, animals and the environment.

Corporate Influence on Governance

Respondents frequently indicated that they did not think that the government really had an interest in their concerns or thoughts regarding GMOs. They expressed frustration that they were not consulted in the process of developing and marketing these products. Many of these respondents thought that there was undue corporate influence on the government to approve these products. Respondents expressed distrust in corporations that develop and market GMOs and voiced concern that large multinational firms were exerting undue control over farmers, farming practices and food supply both domestically and internationally. Respondents also stressed that they wanted government to be independent of corporate influence and to listen to what Canadians wanted regarding GMOs.

Comments on CBAC and the Interim Report

Some respondents noted that the CBAC Web site was difficult to find and that CBAC's outreach was inadequate. One respondent indicated that the public cannot have adequate input if there is no publicity and suggested that CBAC should have posted notices in grocery stores.

Some respondents thought that CBAC itself was not a neutral body or that the committee lacked membership from particular sectors, specifically people with backgrounds in environmental and sustainability issues.

It was noted that the language and format of the Interim Report was frustrating. Some were concerned that there was a pro-biotechnology bias writing in the report.

There were also several repeated concerns that fall outside the above categories:

- concerns about patenting life forms, and particularly the effects of patenting on farmers, indigenous peoples and biodiversity
- concerns that the risks and benefits of GM foods are not distributed fairly, but that developers benefit more than consumers and farmers, who must bear the risks
- broader ethical concerns such as social justice issues and violation of ethical or religious codes have not been addressed
- economic issues (such as marketability of GM crops) and legal issues should also be addressed.

Many respondents also expressed general support for the Report of the Royal Society of Canada.

Annex 3. The Future of Food Biotechnology[102]

Our consideration of the regulation of GM foods would not be complete without attempting to project into the future and anticipate food products of biotechnology that may emerge over the coming years.

The evolution of GM crops can be viewed in three distinct waves or generations. The first generation has generally involved altering crops to make them virus or insect-resistant or herbicide-tolerant. As mentioned earlier, this generation of GM crops is already well established, with about 53 million hectares of herbicide-tolerant soybean and insect and herbicide-resistant maize, cotton and canola under cultivation worldwide.

In recent years, the genetic alterations in new plant varieties under development have become more complex, with more genes involved and with an increasing tendency to alter existing metabolic pathways (chemical processes that determine plant physiology and growth) or even introduce new ones. These new products will form the future generation of GM crops. The second generation will likely involve plants that have new nutritional characteristics (e.g. increased vitamin levels). The third generation may be plants that act as factories for the production of pharmaceuticals or as delivery vehicles for vaccines.

Unlike the first generation of GM food crops, which were not intended to have altered nutritional properties and whose single-gene traits were relatively straightforward to assess for safety, future generations of products may require additional regulatory measures by government and may even be the subject of broader public debate to determine social acceptability.

This annex is not meant to provide a comprehensive review but simply a few examples of how biotechnology may affect food production over the coming years.

Non-GM Foods from GM Plants

Many of the perceived hazards associated with GM plants are related to concerns over the presence of transgenes and the proteins they encode in food products or in specific plant tissues such as pollen. For example, there are concerns around the spread of herbicide-tolerance traits from GM plants to non-GM varieties by cross-pollination, and the potential transfer of antibiotic-resistance marker genes that are present in some GM plants to other organisms.

In the earliest transgenic plants, the inserted genes and the proteins they encoded were present in all plant tissues. Through the use of tissue-specific regulators of gene expression, it is possible to produce plants in which the new proteins are produced only in certain tissues, although the introduced genes are still present in all tissues. Other strategies to remove marker genes from plants have employed site-specific recombinases[103] as a gene deletion technology.

A recently proposed strategy combines tissue-specific (or chemically inducible) promoters with a site-specific excision mechanism to specifically remove all of the transgenes from certain tissues of a GM plant or from the whole plant following application of a triggering chemical.[104] As proposed, these "partially transgenic" plants have the advantage that the foods derived from them would not contain any GM material, which could alleviate some consumer concerns. Also, implementation of such a transgene

[102] This article first appeared in our Interim Report and has been updated and modified slightly since then.

[103] J. Zuo, Q. W. Niu, S. G. Moller and N. H. Chua (2001), Chemical-regulated, site-specific DNA excision in transgenic plants, *Nature Biotechnology* 19: 157–61.

[104] R. J. Keenan and W. P. C. Stemmer (2002), Nontransgenic crops from transgenic plants, *Nature Biotechnology* 20: 215–16.

deletion strategy could eliminate the need for costly identity preservation systems that are now being proposed to satisfy consumer choice.

Pest and Disease Resistance

Breeding and selecting for crops with increased resistance to pests and disease have been primary objectives throughout the history of agriculture. Genes identified in wild germ plasm or recovered as spontaneous or induced mutations have been incorporated into cultivated varieties of many major crop species. This process now is being supplemented by the techniques of genetic engineering.

The first cases of engineered disease resistance were to protect against infection by plant viruses. The introduction of plant virus sequences into plant genomes as a means of conferring "pathogen-derived" resistance to diseases caused by these agents now is well established, and there are commercial varieties of potato, squash and papaya that have been developed in this manner. This remains a very important approach that has great potential, particularly against some significant crop diseases in the developing world. Two relevant examples concern efforts to produce virus-resistant varieties of cassava, as staple food for more than 500 million people, and sweet potato. In the case of cassava, crop yields can be reduced by up to 80 percent following virus infection.

Plants are able to defend themselves against disease in several ways, some of which include the production of specific chemicals or proteins. These defence-related compounds can be specific for individual pathogens or general and, in many cases, their production leads to localized cell death around the point of pathogen entry which results in "walling off" the disease agent and preventing its further spread. As our understanding of natural host defence mechanisms improves, there is the potential to enhance these processes or to transfer resistance from one species to another using genetic engineering.

Two examples of how fungal resistance in plants has been increased by transferring or modifying plant defence capabilities include: tomatoes expressing an enzyme, stilbene synthase,[105] from grapevines that have enhanced resistance to *Phytophthora infestans* (the agent most commonly known as being responsible for the Irish potato famine in 1845–46); and cucumber with improved resistance to grey mould (*Botrytis cinerea*) because of a chitinase gene from rice.[106]

Other examples include the expression of anti-bacterial peptides and proteins, resistance against fungal toxins introduced into cereals, and protection against soil nematodes that attack the roots of plants and also spread disease. The recent cloning of a "master-switch" gene, which is responsible for regulating the production of many pathogenesis-related proteins in *Arabidopsis thaliana* (a common weed in the mustard family), presents the possibility that crop plants with durable and broad-spectrum resistance against many destructive diseases can be developed using just one gene.

Environmental Stress

In our quest to achieve ever-increasing food production, one inescapable reality is that the amount of arable land available for agriculture is very limited. Much of it is inhospitable to farming because of conditions of high salt, lack of water, frigidity or contamination with heavy metals. Even large tracts of land currently under agricultural cultivation suffer from these problems that limit crop productivity, which

[105] J. E. Thomzik et al (1997), Synthesis of a grapevine phytoalexin in transgenic tomatoes (*Lycopersicon esculentum Mill.*) conditions resistance against *Phytophthora infestans*, *Physiol. Mol. Plant Pathol*. 51: 265–78.

[106] Y. Tabei et al (1998), Transgenic cucumber plants harbouring a rice chitinase gene exhibit enhanced resistance to grey mould (*Botrytis cinerea*), *Plant Cell Rep*. 17: 159–64.

could be increased by producing plant varieties with increased tolerance to these environmental stresses.

High salinity affects about 20 percent of agricultural land overall and about 40 percent of irrigated land in particular. Most crop plants cannot tolerate high concentrations of salt, which leads to a decline in photosynthesis and an accumulation of deleterious metabolites. The adaptability of some plants to drought or high salt conditions is the result of numerous gene products acting in concert, which has made the introduction of these traits, either via traditional breeding or modern molecular biology, quite intractable. Nevertheless, some progress is being made by engineering plants to have elevated levels of compounds such as glycinebetaine,[107] which protects plant cells against the ravages of salt by preserving osmotic balance and stabilizing protein structure. Other approaches that have focussed on increasing the rate at which sodium ions can be "pumped" out of plant cells have increased the salt tolerance of tomatoes.[108] Using another approach, in which sodium ions are pumped into storage vacuoles within the leaves, transgenic tomatoes have been developed that not only grow in 40 percent salt solution but are able to remove salt from the soil, thus combining the potential of increased food production with environmental bioremediation.[109]

High acid soil conditions result in the release of aluminum, which is toxic to the roots of most crops and is a problem in 30–40 percent of the world's arable land, especially in the tropics. For example, the yield of corn is reduced up to 80 percent when grown on acidic soils. Plants that are naturally tolerant to high aluminum concentrations in the soil secrete malic or citric acid, which act to sequester aluminum ions, preventing their absorption by roots. The introduction of a bacterial citrate synthase gene into papaya made them more tolerant of aluminum,[110] but it is not clear what effect the extra citrate production may have on plant physiology.

Yield Improvement

While some of the existing commercialized GM crop varieties, particularly those with resistance to disease or insect attack, have raised actual yields, they have not increased the yield potential of the respective crops. A number of parameters, such as water use efficiency, starch synthesis, seed weight and nitrogen metabolism, determine the potential yield of a crop plant and these are all being addressed through biotechnology approaches.

Genetic manipulation of the metabolic pathway from sucrose to starch by introducing specific genes to accelerate or bypass intermediary steps has resulted in potatoes with significant increases in starch content.[111] The higher starch content results in lower moisture content and thus higher energy yield per unit weight, but also results in less fat absorption on frying and improved texture.

All plants require a source of "fixed" nitrogen in order to grow. For leguminous crops like soybean, alfalfa and pea, this is provided through a symbiotic relationship with nitrogen-fixing *Rhizobium* bacteria, which are associated with root nodules. For other crops such as cereals, it is supplied by fertilizers. Two approaches to increasing the availability of nitrates and ammonia that are being pursued include the

[107] H. Hayashi et al (1997), Transformation of *Arabidopsis thaliana* with the coda gene for choline oxidase: Accumulation of glycinebetaine and enhanced tolerance to salt and cold stress, *The Plant Journal* 12: 133–42.

[108] I. Arrillaga et al (1998), Expression of the yest HAL2 gene in tomato increases the in vitro salt tolerance of transgenic progenies, *Plant Science* 136 (2): 219–26.

[109] H.-X. Zhang and E. Blumwald (2001), Transgenic salt-tolerant tomato plants accumulate salt in foliage but not in fruit, *Nature Biotechnology* 19: 765.

[110] J. M. de la Fuente, V. Ramirez-Rodriguez, J. L. Cabrera-Ponce and L. Herrera-Estrella (1997), Aluminum tolerance in transgenic plants by alteration of citrate synthesis, *Science* 276 (5318): 1566–68.

[111] J. R. Lloyd et al (1999), The influence of alterations in ADP glucose pyrophosphorylase activities on starch structure and composition in potato tubers, *Planta*. 209: 230–38.

genetic modification of *Rhizobium* species to enhance their propensity to form root nodules,[112] and the introduction of a nitrogen-fixing trait from bacteria into plants. This latter tactic would require the introduction of up to 16 genes and maintenance of the nitrogen-fixing system in an oxygen-free environment, a feat yet to be accomplished.

It is possible that a plant's oxygen supply might also be manipulated in a manner beneficial to the plant. Introduction of a bacterial hemoglobin gene into tobacco plants resulted in plants that germinated three to four days earlier and developed faster, accumulating 80–100 percent more fresh weight after 35 days.[113] The exact mechanism by which the bacterial hemoglobin functions in the tobacco system is not clear, and it remains to be seen whether the reported enhanced productivity can be repeated in other crops or how this would be translated into increased yields under field conditions.

Livestock Feeds

Existing practices of livestock food production have the potential to negatively impact on the environment. For example, pigs are normally reared on phosphate-supplemented feeds, as they are unable to digest phosphate from plant sources because it is bound in a chemical form called phytate.[114] As pig farming becomes more intensive, one consequence of this practice has been the increasing contamination of agricultural soils with high concentrations of phosphate resulting from the spreading of pig manure. There have been different approaches to this problem. In one approach, transgenic pigs have been produced that express a microbial-derived phytase enzyme in their saliva, which acts to break down phytate in the feed, thus eliminating the need for phosphate-supplemented feed while reducing the level of phosphorus in the manure by 75 percent.[115] Alternative approaches have included the incorporation of commercial preparations of phytases within livestock feeds, and the production of transgenic feed crops such as soybean to express phytases.[116]

Nutraceuticals

In addition to providing essential vitamins and minerals, plants also synthesize tens of thousands of secondary metabolites, some of which may have significant positive consequences for human health. Nutraceuticals are foods or parts of foods that are believed to have medicinal value. One example is sulforaphane, found in broccoli,[117] which has been shown to reduce the incidence, multiplicity and rate of development of mammary tumours in mice.

One way of increasing dietary intake of micronutrients and other nutritionally beneficial substances is to manipulate their levels in plant foods. For example, elevating the levels of ßcarotene (a provitamin A molecule) in commonly consumed food crops could alleviate the problems related to vitamin A deficiency in some parts of the world. In South East Asian countries, where rice is a staple food, vitamin A deficiency affects about five million children each year, causing an eye disease called xerophthalmia,

[112] J. M. Barea et al (1996), Effect of a genetically modified *Rhizobium meliloti* inoculant on the development of arbuscular mycorrhizas, root morphology, nutrient uptake and biomass accumulation in *Medicago sativa*, *New Phytologist* 134 (2): 361–69.

[113] N. Holmberg et al (1997), Transgenic tobacco expressing *Vitreoscilla hemoglobin* exhibits enhanced growth and altered metabolite production, *Nature Biotechnology* 15: 244–47.

[114] Seeds store phosphorus needed for germination in the form of phytate, a sugar molecule containing six phosphate groups. Because phytate also strongly binds iron, calcium, zinc and other mineral ions, it acts as an anti-nutrient in the human diet (as well as the diet of livestock animals), making these substances unavailable for uptake.

[115] S. P. Golovan et al (2001), Pigs expressing salivary phytase produce low-phosphorous manure, *Nature Biotechnology* 19: 741–45.

[116] D. M. Denbow et al (1998), Soybeans transformed with a fungal phytase gene improve phosphorus availability for broilers, *Poultry Science* 77 (6): 878–81.

[117] J. W. Fahey et al (1997), Broccoli sprouts: An exceptionally rich source of inducers of enzymes that protect against chemical carcinogens, *Proceedings of the National Academy of Science* 94: 10367–72.

which for 250 000 of them leads to eventual blindness. Improved vitamin A nutrition could also prevent up to 2 million infant deaths because vitamin A deficiency predisposes them to diarrhea and measles.

Many flowers and fruits owe their bright colours to carotenoid pigments, the best known of which is ß-carotene, which is responsible for the orange colour of carrots and sweet potatoes. Milled rice kernel (endosperm), a staple source of carbohydrate for nearly half the world's population, does not contain any ß-carotene or its carotenoid precursors such as phytoene. In a highly publicized case, three genes — two from daffodil and one from a bacterium — were introduced into rice in order to stimulate the biosynthesis of ß-carotene in the rice endosperm.[118] The potential for this so-called "golden rice" to alleviate vitamin A deficiency has yet to be evaluated as neither field trials nor feeding studies have been completed.

Similarly, tomatoes have been modified to contain up to four times the normal level of lycopene,[119] a carotenoid pigment that is a precursor to ß-carotene and whose intake has been correlated with a reduction of coronary heart disease and certain types of cancer.

Vitamin E is the most important fat-soluble anti-oxidant in our diet and has been associated with a decreased risk of cardiovascular disease and some cancers. Natural sources of vitamin E are oil seeds such as canola and soybean, in which it is present as a mixture of tocopherol molecules, each with a different degree of vitamin activity. Alpha-tocopherol is the most beneficial, but the majority of tocopherol quinones in products such as soybean oil are g-tocopherol (70 percent), with only a small proportion of a-tocopherol (7 percent). The relative proportion of the more active a-tocopherol in seeds of the canola relative, *Arabidopsis thaliana*, has been increased to more than 95 percent by introducing a gene that aids in the conversion of g-tocopherol to a-tocopherol.[120]

Iron deficiency is one of the most common dietary deficiencies worldwide and affects an estimated one to two billion people. Decreased blood hemoglobin or anemia is the most common symptom of iron deficiency, but it has also been associated with impaired learning ability in children and increased susceptibility to infection. In addition to dietary supplements, attempts to increase dietary iron intake have advanced on two fronts, increasing the content of iron storage proteins (ferritins) in food crops and reducing the impact of anti-nutrient compounds that interfere with iron uptake. Introducing an iron carrier protein from soybean has produced genetically engineered rice that contains three times more iron than conventional varieties.[121] It has been estimated that a meal-size portion of this transgenic rice would provide 30–50 percent of the daily iron requirement.

Seeds store phosphorus needed for germination in the form of phytate, a sugar molecule containing six phosphate groups. Because phytate strongly binds iron, calcium, zinc and other mineral ions, it acts as an anti-nutrient in our diet (as well as the diet of livestock animals), making these substances unavailable for uptake. One approach to countering the anti-nutritional properties of phytate in rice has been to introduce a gene from the fungus *Aspergillus niger* that encodes a phytase, an enzyme that breaks down phytate.[122] Commercial preparations of phytases are often added to livestock feeds to improve the dietary availability of phosphate. Genetically engineered soybean expressing a fungal phytase can substitute for phytase treatments or supplementation of poultry feed with inorganic

[118] X. Ye et al (2000), Engineering the provitamin A (beta-carotene) biosynthetic pathway into (carotenoid-free) rice endosperm, *Science* 287 (5451): 303–05.

[119] R. L. Ausich (1997), Commercial opportunities for carotenoid production by biotechnology, *Pure and Applied Chemistry* 69 (10): 2169–73.

[120] D. Shintani and D. Della Penna (1998), Elevating the vitamin E content of plants through metabolic engineering, *Science* 282 (5396): 2098–2100.

[121] F. Goto (1999), Iron fortification of rice seed by the soybean ferritin gene, *Nature Biotechnology* 17 (3): 282–86.

[122] I. Potrykus et al (1999), Research Abstract: Contributions to food security by genetic engineering with rice, Rockefeller Foundation (http://www.rockfound.org/rocktext/t_news/t_072699_rice.html).

phosphorus,[123] which has the potential not only to decrease production costs but also to reduce phosphorus pollution.

Oral Vaccines

Plants have long been a valuable source of medicinal compounds for the treatment of human disease. In recent years, much research has been focussed on using genetic engineering techniques to manipulate plants to produce a range of compounds from vaccine antigens and monoclonal antibodies to pharmaceutical products.

The engineering of harmless antigens (agents that stimulate a protective immune response) from human disease pathogens into food plants allows for the production of oral vaccines. The potential benefits of oral vaccines include ease of delivery without health care professionals, no requirement for refrigeration, longer retention of protective immunity through repeated intake, and elimination of risks from needle injections, which are a significant factor in the spread of hepatitis B and C.

Enterotoxigenic *E. coli* (ETEC) and *Vibrio cholerae* (cholera) are the primary agents responsible for severe diarrhea, which causes nearly 2.5 million infant mortalities per year and for which there is no effective vaccine. When potatoes engineered to express a portion of the ETEC toxin were fed to mice, the mice developed an immune response to the vaccine protein.[124] Although it is still early in the evaluation process, initial human trials with this "edible" vaccine are promising and have raised hopes that this technology may help solve many of the problems associated with delivery of safe, effective vaccines in developing countries.[125] Other examples include the development of "edible" vaccines against hepatitis B virus,[126] *Norwalk* virus[127] (responsible for viral gastroenteritis, which makes up about 25 percent of the cases of "traveller's diarrhea"), and rabies virus.[128]

Rather than stimulating a protective immune response by expressing disease antigens, the expression of specific proteins in plants can also be used to help prevent the development of deleterious immune responses such as occur in auto-immune diseases like insulin-dependent diabetes. When mice were fed potatoes engineered to express a fusion protein of cholera B toxin and pro-insulin, they developed high levels of circulating antibody that suppressed the auto-immune response that would normally have destroyed the insulin-producing cells in the pancreas.[129]

Plants as Factories

Increasingly, food crops are being engineered for non-food purposes in order to realize economies of scale in the production of industrial proteins, pharmaceuticals and other products.[130] Briefly, some examples include the production of the anti-microbial protein lysozyme in tobacco plants, the expression

[123] D. M. Denbow et al (1998), Soybeans transformed with a fungal phytase gene improve phosphorus availability for broilers, *Poultry Science* 77 (6): 878–81.

[124] H. S. Mason et al (1998), Edible vaccine protects mice against *Escherichia coli* heat-labile enterotoxin (LT): Potatoes expressing a synthetic LT-B gene, *Vaccine* 16 (13): 1336–43.

[125] T. S. Mor and C. J. Arntzen (1999), Pharmaceutical foodstuffs: Oral immunization with transgenic plants, in *Plant Biotechnology and in Vitro Biology in the 21st Century*, edited by A. Altman, M. Ziv and S. Izhar (Dordrecht: Kluwer), pp. 17–20.

[126] L. J. Richter et al (2000), Production of hepatitis B surface antigen in transgenic plants for oral immunization, *Nature Biotechnology* 18: 1167–71.

[127] H. S. Mason et al (1996), Expression of *Norwalk* virus capsid protein in transgenic tobacco and potato and its oral immunogenicity in mice, *Proceedings of the National Academy of Science* 93 (11): 5335–40.

[128] A. Modelska et al (1998), Immunization against rabies with plant-derived antigen, *Proceedings of the National Academy of Science* 95 (5): 2481–85.

[129] T. Arakawa et al (1998), A plant-based cholera toxin B subunit-insulin fusion protein protects against the development of autoimmune diabetes, *Nature Biotechnology* 16 (10): 934–38.

[130] G. Giddings, G. Allison, D. Brooks and A. Carter (2000), Transgenic plants as factories for biopharmaceuticals, *Nature Biotechnology* 18:1151–55.

of growth factors and interleukins, the introduction of hydroxyproline-rich proteins from mussels into plants as a source of medical glue, the production of biodegradable polymers as substitutes for plastic, and the production of modified oils for use in manufacturing or to formulate coatings and paints.

The large-scale production of therapeutic single-chain monoclonal antibodies in plants is also possible through genetic engineering. These so-called plantibodies consist of the antigen binding regions from an antibody linked together as a single protein molecule that can retain activity when expressed in plants. One example of a plantibody for use in human therapy is for combatting the dental bacterium *Streptococcus mutans*, which is involved in plaque development and hence dental caries.[131] Another example is the expression in soybean of a complete "humanized" monoclonal antibody against genital herpes virus.[132]

Animal Biotechnology

Manipulating animal reproductive physiology to control breeding has a long history, dating as far back as 1891 with the first report of embryo transfer in rabbits. This work forms the basis of modern artificial insemination techniques that allow for the propagation of selected lines of many animal livestock species from banks of frozen embryos.

Experiments in the 1970s with nuclear transplantation into developing frog embryos laid the groundwork for modern animal cloning, which was most publicly exemplified by the cloning of Dolly the sheep in 1997. Micro-injection techniques that permit the introduction of isolated genes into the pronucleus of a recently fertilized egg have allowed for the production of "transgenic" animals that express new or altered traits. These and other genetic engineering techniques have now been applied to a number of livestock animals, including cattle, pigs, sheep and goats as well as chickens and many species of fish.

Transgenic animals have many potential applications in medical research, such as the creation of models to study human disease, development, aging and gene function. The ability to express pharmaceutical proteins in the milk of transgenic animals provides a means of producing important therapeutic agents that cannot otherwise be isolated in sufficient quantities from natural sources, or produced in active form in other systems such as genetically engineered micro-organisms or plants.

Although recent advances in medical science have made heart, kidney and liver transplants a routine occurrence, there is a chronic shortage of suitable organs that limits these life-saving procedures. The ability to genetically engineer animal organs with a reduced potential for transplant rejection has been proposed as a possible solution to this problem. The use of such xenografts (between-species transplants) raises a number of concerns both ethically and scientifically. These latter concerns include the possibility of transmitting animal diseases to human patients.

The first GM food from animal origin that will be submitted for regulatory approval in Canada is likely to be Atlantic salmon that have been genetically engineered to grow faster. These transgenic fish produce higher concentrations of growth hormone, causing them to increase their size and weight up to six times faster than conventional salmon. Their final size is equivalent to normal Atlantic salmon, but they achieve that size in a shorter period of time.

[131] J. W. Larrick et al (1998), Production of antibodies in transgenic plants, *Research in Immunology* 149 (6): 603–08.

[132] L. Zeitlin et al (1998), A humanized monoclonal antibody produced in transgenic plants for immunoprotection of the vagina against genital herpes, *Nature Biotechnology* 16 (13): 1361–64.

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Annex 5. Policy Analysis Matrix – Labelling of GM Foods

Labelling of GM foods is the issue that attracts the greatest public interest in the overall debate on GM foods. The purpose of this Annex is to provide a summary of the major policy considerations and the consequence under each of three scenarios:

- Status Quo — no labelling standard, no requirement to label for either GM content or derivation
- Voluntary Labelling — a consensus standard for positive and negative labelling[133] (such as the CGSB standard presently under development), food suppliers have the option whether to use the standard
- Mandatory Labelling — a consensus standard for both positive and negative labelling and the law requires its use.

The are several policy considerations:

- **Enabling Consumer Choice** — The prime reason for labelling is to enable informed choice; that is, to allow consumers to choose whether or not to consume foods derived from genetically modified plants. Labelling is generally viewed as the means to this end. At issue, is the degree to which the information provided to consumers under each scenario is sufficient to enable them to exercise informed choice.

- **Monitoring of Long-term Health Effects** — There are no known adverse health effects arising from the use of approved genetically modified foods. Nevertheless, there are concerns that some health effects might appear in the long term. At issue is whether or not labelling will assist in monitoring potential long-term health effects (such as allergenicity) associated with GM foods.

- **Enhanced Opportunity for Trade** — At issue is whether the labelling of GM foods could assist in expanding trade opportunities, especially in those countries that do or will require labelling of GM foods.

- **Compliance with Existing Trade Agreements** — In the view of some, mandatory labelling for reasons other than health and safety may contravene existing trade agreements. At issue is the degree to which each of the scenarios could expose Canada to the potential of retaliatory trade actions.

- **Conditions Required for Verification** — Labelling requires a system to segregate GM crops from conventional crops at all levels of production and transportation in order to verify claims. At issue is the feasibility of segregation and the degree of burden imposed under each scenario.

- **Cost Burden** — At issue is the impact on food costs attributable to the labelling standards, including cost to government to enforce the regime and determining who would bear it.

- **Enforceability** — At issue is how the standard is enforced and how challenging it will be to ensure that voluntary standards are truthfully applied, or to enforce a legislated mandatory standard.

The following matrix is not intended as a rigorous policy analysis. Rather it is intended as a summary of the considerations that the Committee took into account in making its recommendations.

[133] That is, does or does not contain GM ingredients or processes.

Policy Objective	Status Quo	Voluntary Labelling	Mandatory Labelling
Enabling Consumer Choice	Consumers have little information other than organic labels on whether or not they are eating GM foods and cannot make a fully informed choice.	Will depend on the uptake of the standard. If the uptake is reasonable, consumers will have choice. If not, consumers will have only limited choice.	Broad consumer choice subject to the parameters of the standard (e.g. level of tolerance, for instance 1% or 5%), the definition of GM content, and the availability of supplementary information.
Monitoring of Long-term Health Effects	Monitoring must use data sources other than labelling.	May allow limited monitoring through labelling, depending on the degree of uptake of the standard. It is questionable whether labelling is useful for scientific monitoring purposes. Other data sources are needed.	Allows for potential monitoring through labelling. However, it is questionable whether labelling is useful for scientific monitoring purposes. Other data sources are needed.
Effect on Trade Opportunities	No immediate change. In the long run, it may diminish trade opportunities in those countries requiring labelling, unless private suppliers organize themselves to meet that market's standard.	May increase trade opportunities for products labelled GM-free. Canadian standard could become a precedent for trade agreements, giving Canada a competitive advantage.	May increase trade opportunities in countries requiring labelling. May restrict food imports from countries where labelling is not required or where the standard differs from the Canadian standard.
Effect on Trade Policy Obligations	None — there are no obligations to label.	None — voluntary labelling does not contravene trade agreements.	Mandatory labelling for a non-safety product process may contravene trade agreements and could expose Canada to retaliatory measures. However, this will ultimately be decided by future rulings from trade bodies such as the WTO.
Conditions Required for Verification	No change to existing system.	A system will be required to ensure that GM-free plants or ingredients are not contaminated by GM material.	Comprehensive systems will be required to ensure that GM and conventional plants or ingredients are kept separate at all levels of production, transportation and sale.
Enforceability	Not applicable.	Likely through third-party audit of a voluntary standard — not through direct regulation. Grocer associations will be monitoring for compliance. CFIA will ensure that labelling is not misleading as per the appropriate labelling standard. Voluntary labelling would be subject to truth in advertising laws.	Likely direct regulation through a government regulatory agency such as CFIA. Enforcement will be complicated by the fact that not all genetic modifications are detectable. An audit system will be needed.

Annex 6. Facilitating a Policy Dialogue on Genetically Modified Foods and Feeds[134] in Canada

Developing a New Analytical Tool and Innovative Approach to Policy Engagement[135]

Context

Biotechnology development and use in GM foods and feed products has grown rapidly in the 1990s. The impact of Genetically Modified Foods and Feed (GMFF) on public policy and the related regulatory regimes of countries has been particularly challenging.

In the past decade in Europe, the GMFF question has catapulted into prominence with deeply divisive debates in the United Kingdom, France and Germany. In some cases, the issue was contested in the context of globalization and multinational corporations; in other cases, it was concern for the lack of controls, inadequate risk management, transparency and accountability; and for still others, it was a question of the consumer's right to know and choose. The climate for debate on GMFF was not aided by government actions in other areas of food safety, such as the initial United Kingdom approach toward bovine somatotrophic encephalitis (BSE) and other problems such as salmonella in eggs, which damaged public confidence in how food safety is regulated, and in the role of science in the assessment of risk. This occurred amid conflicting views and debate on the scientific evidence related to GMFF. Furthermore, government actions to promote this growing science as an industrial and economic growth engine and yet regulate and control it as a potential health and safety risk area were seen as insufficiently separated. Hence, they were subject to conflict-of-interest claims. The accumulated effects tended to discredit some governments in their role as the objective voice on behalf of the public and as the policy broker.

Meanwhile the corporate sector (especially multinational corporations) and the non-governmental organization (NGO) community struggled to express their often contrary views. Both held strong beliefs in the rightness of their cause and path, and both attempted to discredit the values, tactics and evidence of the other.

This has made for a highly polarized and heated debate on the introduction of GMFF in the United Kingdom and elsewhere in Europe. With no credible third party to convene or facilitate the debate, the sense of uncertainty, risk and confusion grew. In this atmosphere, the public has become unsure about who can be trusted, and the possibility of a reasoned dialogue among stakeholders has diminished considerably.

The regulatory and policy response has been defensive, leaving the policy environment with unanswered questions and unprepared for the new variations expected in the next waves of biotechnology innovation.

[134] For the purposes of this policy dialogue initiative, the focus is on genetically modified crops and livestock for food and feed, either as individual products or classes of products. This has been shortened to genetically modified food and feed and, in this document, will be represented by the acronym GMFF. This includes all forms of genetic manipulation, including recombinant DNA, genetic re-engineering, and mutagenesis.

[135] This is a condensed version of a report prepared for the Canadian Biotechnology Advisory Committee by Lyle Makosky, facilitator to the Exploratory Committee. The full version of the report can be found on the CBAC Web site (www.cbac-cccb.ca).

The Opportunity

In North America, the public debate in GMFF has been less heated and more narrowly based. There have nonetheless been concerns raised by some academics, NGOs and consumer groups, but not to the same extent.

A different environment exists in Canada. Canadians have historically had confidence in the federal government's regulatory role and in its concerns for the health and safety of Canadians. Furthermore, Canadians generally feel that their foods are safe and that there is a competent control system in place.

While the questions and issues about GMFF continue, the debate has not polarized in the public's and policy makers' minds. While some stakeholder groups have been seized with the crux of the issue and are challenging the efficacy and comprehensiveness of the policy framework and regulatory regime, this challenge is more in the way of a wake-up call for all participants, not least the federal government.

In short, the public policy environment and public views and beliefs are not so polarized and entrenched as to prevent the potential for a reasoned, constructive dialogue.

The Challenge

To proceed on a fruitful path for discussion and debate on the future for GMFF (in Canada at least), there is a need to address the following challenges:

- enable a constructive, reasoned dialogue on the key issues, fostering informed participation, but before views have become entrenched and overly polarized
- incorporate science-based knowledge of this area as one starting point, but not to be limited by it, or to it, as the only form of knowledge to inform deliberations
- find common ground upon which to build a direction for Canadian society
- frame the challenges to help identify constructive approaches to fundamental issues and to enable core beliefs and values to be expressed
- steward the process as the dialogue widens to include an appropriate representation of stakeholders and citizens without forcing irreconcilable positions to be taken
- situate the dialogue within a Canadian context while remaining cognizant of the global factors and international context and Canada's international objectives and commitments.

A Canadian Approach

The approach that has evolved to this point within the Canadian context is built upon the following actions:

- designing a tool for policy dialogue called the Acceptability Spectrum, which enables participants to identify all the critical issues related to GMFF and to discuss them within a holistic view (With more development, the tool could enable the user to develop an overall perspective on the advisability of proceeding ahead with a proposed GMFF idea, product or research.)
- creating a small, diverse and well-informed multi-stakeholder steering group called the Exploratory Committee at arm's length from government to pursue the development of the Spectrum tool and to design and steward the process of engaging people in a dialogue using the tool (The committee's profile reflects the range of stakeholder interests and views, including those holding opposing views.)
- engaging critical stakeholder groups, initially within common interest meetings, to help improve the tool, thus incorporating each stakeholder's key interests and enabling each group to test the tool in an initially non-conflictual environment

- supporting the Exploratory Committee process and dialogue sessions with expert, objective facilitation, effective process design and consideration of group consultation and citizen engagement methods, along with logistics, administrative and financial support
- expanding the circle of dialogue carefully and incrementally, with retooling and tailoring at each stage of larger inclusion.

How the Canadian Approach Evolved

A Canadian Advisory Body is created

In 1998, a federal Task Force on Biotechnology recommended the creation of an independent national advisory body of Canadians drawn from related fields of expertise and experience as well as lay people to advise the government on issues and policy directions affecting biotechnology. In 1999, the Canadian Biotechnology Advisory Committee (CBAC) was formed with a mandate to advise the federal government on the related areas of biotechnology.

Among the several areas CBAC charted for their work plan was the highly challenging and contentious subject of the regulation of genetically modified foods. From the beginning, CBAC intended that its considerations would be thoughtful, open to all views and suggestions, and transparent, and would keep the public interest uppermost as its primary principle.

CBAC engages a consultation but not everyone will participate

After collecting and analysing information on the regulatory, social, economic, ethical, legal and environmental elements of GMFF, CBAC prepared a consultation document titled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*, in which it solicited input from Canadians. In addition, CBAC held a series of multi-stakeholder workshops in April 2001 in five cities across Canada. The workshops were based on the consultation document and were designed to facilitate an open dialogue on a wide range of GMFF topics and proposals or options for possible policy directions. Participants included the bio-tech industry, producers and retailers, consumer groups, faith groups, health professionals and other members of civil society.

Approximately 50 Canadian NGOs (especially environmental NGOs or ENGOs) did not participate in the CBAC stakeholder consultations. They instead chose to issue a Petition to the Government of Canada stating their concerns. The ENGO community indicated that it would prepare a consolidated comment on the CBAC consultation paper on genetically modified foods, but did not do so. Their stated concerns related in large part to the perceived lack of independence of CBAC and the consultation process, and whether it would have any real impact on government policy. CBAC expressed its regret and looked for other vehicles through which this group might provide its views.

The ENGO community has not had an opportunity to meet together to discuss these issues. CBAC created its own stakeholder advisory group, called a Reference Group, to comment on and recommend approaches to consultation and study. At the last meeting of the CBAC GM Food Reference Group, a number of individuals from a range of stakeholder interests recommended that a further attempt should be made to engage the ENGO community before CBAC submitted its final report and recommendations on the regulation of genetically modified foods to ministers in early 2002.

An opportunity emerged to bring these different views to a common table with other stakeholders, although the exchange was expected to include very difficult and opposing beliefs and positions.

A new concept emerges from the consultation

At the outset of its consideration of the issues around the current GMFF regulatory system in Canada, CBAC identified the desirability to have stakeholders engage in dialogue on social and ethical factors beyond the risk-based health and environmental assessments associated with the current regulatory approach.

During its consultations, CBAC heard that whether GMFF should be part of our collective future warrants discussion, as does the issue of the line to be drawn between GMFF products that Canadians consider acceptable and those they do not.

Inspired in part by the potential for this concept of acceptability to facilitate a meaningful policy dialogue, a new conceptual framework emerged in the early stages of the consultation round. This concept was discussed and enlarged at each subsequent consultation event. This framework was notionally called an Acceptability Spectrum. The early consultation confirmed its potential to facilitate a discussion of the acceptability or unacceptability of GMFF, and the conditions that affected its acceptability.

The framework was based on the premise that different kinds of GMFF could be classified along an Acceptability Spectrum as being more or less acceptable, according to a variety of criteria. The Acceptability Spectrum, as shown in the following graphic, consists of four categories: acceptable; acceptable with certain conditions; unacceptable at the present time and until more is known or a given standard is met; or not acceptable under any circumstances. GMFF considered not acceptable under any circumstances could be recommended for an unconditional prohibition (banned). Those unacceptable at the present time could be placed under a moratorium.

Using this framework, it could be feasible to assign either groups or classes of food or individual products to a position on the Acceptability Spectrum. These could move along the Acceptability Spectrum as knowledge improves, as society's views change or as certain standards are met.

Acceptable	**Acceptable with conditions**	**Not acceptable until more is known or certain standards are met (i.e. moratorium)**	**Not acceptable under any circumstance (i.e. ban)**

The framework evolves

During the consultations, participants suggested criteria for assessing a GMFF product. These criteria were grouped into four themes: health and environmental safety, social considerations, ethical considerations, and broader societal considerations. Subsequently, a further theme was added: environmental considerations, to address potential impacts on biodiversity, for example, that were beyond concerns of environmental health. The first theme was then refocussed on health. The resulting framework several months later developed to the state portrayed in Annex A, with the thematic considerations grouped as below.

Thematic Considerations	
Health considerations criteria incorporated the existing assessments for human health carried out by the Canadian government's regulatory system (mainly the Canadian Food Inspection Agency and Health Canada), which is based on assessing risk using scientific analysis.	Environmental considerations incorporated the existing assessments of environmental safety carried out by the Canadian government's regulatory system (mainly the Canadian Food Inspection Agency), including whether the GMFF is safe for the environment in terms of its development, potential to be invasive of natural habitants, gene flows, impact on interacting species, as well as broader considerations such as impact on biodiversity.
Social considerations, renamed socio-economic, included issues of economic justice, such as distributive effects, equity or power imbalances, as well as productivity and competitiveness issues.	Ethical considerations included the values or moral choices of transgenic manipulation (i.e. playing God or views of the relationship between nature and humans), impact on animals and animal welfare, effect on consumer autonomy and choice, impact on human rights and transparency, and participatory decision making.
Broader societal and international considerations were intended in part to provide a place for those issues that are part of the context and the broader debate but cannot be readily addressed in a GMFF policy framework. These include globalization, multinational enterprises, impact on developing countries, intergenerational issues, and international trade and trade agreements.	

As the Spectrum developed further, governance questions were also raised and grouped into a review list to be used depending on the purpose of the review. These included the following issues:

- how decisions are made and who makes them in the use of the Spectrum
- transparency in the use of and access to information related to the Spectrum
- responsibility and accountability in the sense of who is accountable if something goes wrong at various stages in the life cycle of the GMFF
- influences on decision makers and conflict of interest (e.g. shared responsibility for regulation, evaluation and promotion of a technology)
- building of trust in the system.

The central idea of the Spectrum was to create a tool for policy dialogue on GMFF, which permitted the subject to be examined and discussed through a holistic view that included the many issues to be found in the five Consideration Themes. The dialogue would be reviewed against questions or criteria that reflected the issues/areas of concern. Ultimately, the analysis could be accumulative, allowing for an overall summary perspective that could take the form of considered advice on the relative advisability of continuing the dialogue or accepting the GMFF and, if so, on what conditions. Each set of thematic considerations would address the risks or adverse impacts as well as the benefits or positive impacts, plus a review of whether there was a need for the product and whether alternatives existed. These impacts and implications would be weighed together to provide a collective assessment for that thematic area. (An example of a consideration column guide to discussion is found in Annex B.) Finally, all the thematic summaries would be considered together against an agreed set of central criteria, values or principles to yield a summary perspective and recommendation.

During later consultations, the dimension of time was added to the Spectrum tool to illustrate the following themes:

- use of the Spectrum used during a multi-stage product life cycle (a GMFF idea evolving from concept to research, to development and production, to retail and consumption, and to use over time)

- changes in the knowledge and understanding of this field over time that could change the basis and criteria of application of the Spectrum
- changes in policy governance as the Spectrum affected the different stages of policy development and implementation over time.

How the Spectrum Tool Was Developed for Dialogue

CBAC empowers and facilitates the work of a multi-stakeholder steering committee

When the results of the 2001 CBAC consultations were in, CBAC reviewed the content and the process. At the last meeting of the CBAC GM Food Reference Group, a number of individuals from a range of stakeholder interests felt that a further attempt should be made to engage the ENGOs who had boycotted the earlier consultations. This view had been reinforced in informal discussions between CBAC and stakeholder groups, including those from the ENGO community, the biotechnology and food industries, and consumers' groups. Although CBAC encountered difficulty in bringing individuals from all of the stakeholders to the table, and although the expected differences in views ensued in the sessions, the absence of a full range of stakeholder input was also noted and regretted by other participants during the consultations.

Meanwhile, the Acceptability Spectrum idea had received generally encouraging reviews (albeit with many qualifiers) in the cross-Canada 2001 consultations, suggesting that further development was warranted.

CBAC was also conscious of the European experience and the value to society of a constructive public dialogue before discourse became irreparably paralysed.

From these ingredients was born the idea of further advancing the Spectrum as a dialogue and policy tool by creating an arm's-length steering committee composed of individuals drawn from a wide range of interested communities. The committee's mandate was to develop, expose and steward the tool through a path of development, improvement, testing and eventually hoped-for use in the Canadian policy environment.

CBAC deliberated on whether to create the steering group in an advisory role or to give it significant leeway to develop its own approach. CBAC decided to act boldly. It undertook to extend invitations to participate in the steering group (called the Exploratory Committee) to individuals from constituencies that represented the main impacted and interested stakeholders who characterized a divergent and wide range of views. CBAC then supported the group to pursue the issues and dimensions of GMFF deemed most important, with the freedom to design and guide the testing and dialogue around the Spectrum tool as the committee saw fit.

CBAC suggested the initial broad structure of a three-stage process. The Exploratory Committee was empowered to design and implement the process, including taking decisions on whether and how to proceed at each step and focussing on the topics and dialogue deemed most relevant to each stakeholder group (and in the last stage, most relevant to all stakeholder groups). The scope would focus on the Acceptability Spectrum as well as on the methods and procedures for its development and use. Within this broad framework the committee was allowed to pursue other dimensions of GMFF issues as the Exploratory Committee and individual stakeholder sessions determined.

The subcommittee co-chairs would be active participants in the process, reporting regularly to CBAC, but they would not control or dictate the process or its recommendations. The process would be self-managing through the weight of group will and agreement, and would be based on adherence to an agreed set of objectives and principles, defined early in the process by the Exploratory Committee. The

committee and dialogue events using the Spectrum tool would be facilitated by skilled moderator(s) and supported by a secretariat.

CBAC outlined its expectations for self-managing principles to guide the process.

• The Exploratory Committee would operate by general agreement of all its members, and would undertake best efforts to define and guide the process to achieve success against the agreed objectives.

• The existence, focus and approach to the project would be publicly known, with findings and results available on the CBAC Web site.

• The Exploratory Committee would set the objectives for each individual stakeholder session within an agreed set of overall objectives for the project.

• All major design elements and the topic focus for each and all sessions must meet the objectives and tests for relevance as defined and judged by the whole Exploratory Committee.

• The Exploratory Committee would outline selection criteria to guide selection of participants for each of the stakeholder sessions.

• The Exploratory Committee would define its own set of ground rules (code of conduct) as well as related ground rules for the individual stakeholder dialogue sessions it creates.

Stage 1: The Exploratory Committee is formed

The Exploratory Committee consists of 13 individuals from non-governmental organizations (including environmental NGOs, health, faith/religion), consumers, GM biotechnology developers, supply chain organizations (farm producers, food manufacturers and distributors), and CBAC representatives (secretariat staff and facilitators are additional). The Exploratory Committee carried out its critical work by electronic exchange and conference calls, convening from time to time for day-long, in-depth planning sessions.

In the early developmental period, the Exploratory Committee carried out the following activities.

- **Explored the Spectrum tool and its potential use.** It was important to develop a shared appreciation of the Spectrum and its potential use. This led to a statement of scope of use of the Spectrum.

Scope of Use of the Spectrum

• To inform and guide high-level policy discussion, broad policy development, and decision making on national policies affecting GMFF products, especially early in the development of policy or the development of potential GMFF, for example:
  – identify the policy gaps and key issues to be addressed
  – provide a broader scope for decision making in the policy environment
  – ensure incorporation of socio-economic and ethical considerations, and provide the context in which economic and social issues shape policy.

• To engage and support public dialogue and to assess public will, values and priorities with regard to broad types of new technologies or products such as GMFF.

• To inform and support individual stakeholder groups in consideration of their own policy making and direction, for example:
  – identify research and development priorities
  – develop a basis for codes of practice.

• To educate the public on the field of GMFF, the issues, and current policies in place and where there are gaps to address, for example:
  – increase understanding of GMFF among the public.

- **Clarified its role.** It was important for the Exploratory Committee members to be clear on, agree and be comfortable with the terms of its mandate and the scope of its empowerment. The role that was agreed upon included the following activities:
  – seek agreement on the objectives for the project
  – create a design for the overall process and a general model for individual stakeholder sessions
  – outline principles and ground rules for the conduct of the project and sessions (incorporating a code of conduct)
  – identify GMO/GMFF case studies or stylized examples of GM foods or products and develop example assessment criteria to be used in the dialogue and examination of the Acceptability Spectrum
  – outline participant selection criteria for the stakeholder sessions, and develop and implement a strategy to invite and engage stakeholders in stakeholder sessions
  – consider the results of the stakeholder sessions and advise on whether a subsequent multi-stakeholder session would be useful and productive
  – consider the results of the Acceptability Spectrum review, and advise on whether and in what ways the learning, Spectrum model and tools (principles, criteria, case examples, etc.) should and could be made more available to other groups and to the public to promote better understanding, and to further assess and improve their viability and usefulness.

- **Defined the objectives and desired outputs from the project.** It was important to set clear goals and achievable outputs for the project.

Objectives of the Project

• To create a space that facilitates a dialogue among key stakeholders on key issues in GMFF, and to assess the viability of extending the space and dialogue for future deliberations in GMFF.

• To test the relevance, viability and usefulness of the proposed Acceptability Spectrum among stakeholders with a wide range of views, and to assess the ability to explore key issues, underlying principles and values questions using the Spectrum.

Desired Outputs from the Project

• A more defined Acceptability Spectrum with an initial range of criteria/guidelines and stylized example GM products to characterize the Spectrum, along with a common terminology/vocabulary for this field of genetically modified organisms.

• An assessment of the relevance, viability and usefulness of the Spectrum, the likely conditions under which it could be successful, and the further development that should be pursued if it is to be applied to policy making.

• An assessment of the ability to create a space that facilitates a dialogue on GMFF toward common ground, and the viability of extending the approach into the future policy environment.

• An indication of the state of the debate on GMFF, among key stakeholders, perhaps at its most intense level, and hence an indication of the potential direction of future debates.

- **Defined a code of conduct for the committee.** It was important that members agree on and be mutually bound by the ground rules of their approach. Discussion and definition of these ground rules set the tone and pattern for how the Exploratory Committee members would work together. The agreed code is attached as Annex C.

In summary, it was evident that the Exploratory Committee will be successful if it is able to achieve the following results:

- good will among participants during proceedings
- agreement on the objectives, principles and ground rules
- common ground on the desired qualities, tone and atmosphere of the process
- trust among the group
- trust in the process and agreement to stay with the agreed process to its completion.

Stage 2: The Exploratory Committee designs and conducts separate stakeholder sessions to review and improve the Spectrum tool

The Exploratory Committee undertook to prepare separate stakeholder sessions. In so doing, the committee worked with certain key process or dialogue considerations and built design elements around them as shown below.

Key Process/Dialogue Actions	Design Element Actions for Stakeholder Sessions
Outline the context, the central challenge (what needs to be addressed), and the assumptions on which the new enabling tool is based	• Used a context summary and CBAC Interim Report • Defined design and planning assumptions for the Spectrum (see Annex D)
Identify foundation ideas that underpin the approach on which to build further elements	Created principles as "qualities that the Spectrum would exhibit" and other principles as "beliefs that underpin the concept and approach" (see Annex E)
Build an analytical approach to the Spectrum tool in a logical, incremental fashion	Created a discussion logic and flow for each column, allowing the sequencing of columns to be at choice of reviewers
Portray balance and fairness in the treatment	Structured the discussion logic and flow for each thematic set of considerations to include both adverse and beneficial impacts, as well as the population groups most impacted and whether there was a need or alternatives existed for the proposed GMFF
Ensure a holistic approach	Called for all participants to work through all issues and dimensions of a GMFF proposal; that is, all critical issues would be mapped and reviewed somewhere in the Spectrum tool
Provide guidance to participants	Created a workshop guide to parallel the agenda to guide people through the review
Make the review realistic and practical	Identified examples and cases to use to illustrate issues and tensions
Compel people to consider and weigh all aspects independently and then together	Structured the discussion logic and flows to include weighing the combined reviews of issues all together for each consideration theme area and then overall, combining all themes
Facilitate the identification of shared values and criteria on which choices/recommendations could be made	• Outlined a process to help define key issues and translate into choice criteria • Designed the process to identify the qualities that would be required for a proposed GMFF to be more or less acceptable and then translated these into "what this says about what we value" (producing value statements or criteria)
Avoid polarization and paralysis in the dialogue	• Sought common ground at the principles and values level on which further areas of agreement could be pursued • Acknowledged differences and used them to strengthen the quality, focus and fairness in the issue questions and choice criteria

There were six stakeholder sessions conducted among the following constituencies:

- faith/religion group
- supply chain (farmers, producers, retailers) group, with some health representatives
- consumers and health groups
- bio-tech developers group
- consumers group (Québec)
- civil society/NGOs/ENGOs group.

The following areas of general convergence arose from the findings of the six sessions.

- Multi-stakeholder dialogue is valued and their participation is an important dimension of policy development.

- The Acceptability Spectrum overall is useful for certain purposes, including:
  - informing and engaging public debate
  - helping to shape broad public policy.

- Working through the specifics of the Spectrum workbook is useful and educational and can lead to a range of helpful proposed improvements from each group.

- A short high-level set of principles is important at the front of the Spectrum to help orient its use.

- By and large, the range of acceptability levels is useful, recognizing that what is acceptable for society may change over time.

- The set of structured columns of considerations is considered helpful to animate discussion

- The approach of working through a key set of questions, then elaborating risks and benefits, and finally considering alternatives and trade-offs is useful.

- Identifying example as well as real GMFF cases to illustrate and/or test across the Spectrum in the course of deliberations is useful.

The deliberations during the six sessions also developed the following lessons.

- Weighing the qualities and indicators for a GMFF, as well as considering trade-offs or conditions under which a GMFF might be acceptable, is an important and necessary need/construct stage in the Spectrum review process. The Spectrum helps define the key considerations that will be the basis for the weighing and trade-offs. Ultimately, there will be a degree of judgment to reach a conclusion. The weighing of qualities and indicators depends on the purpose of the review (e.g. mapping the profile, providing general advice, providing a considered opinion or taking a decision) as well as who is doing the review and who takes the decision (if a decision is the goal).

- Further developmental and testing work was recommended to improve the tool before applying it in a more formally constructed policy dialogue or process. The enhancements should concentrate on:
  - portraying the matrix nature of the model (acceptability categories as the rows, and thematic considerations as the columns)
  - clear definitions of the acceptability categories (rows) and areas of consideration (columns)
  - clear criteria for each cell of the Spectrum to guide review of what would be acceptable or not and under what conditions
  - good cases or examples to illustrate the issues and decision points in each area
  - identifying what qualities would move a proposal into a more or less acceptable position and what this says about what we value in our society (and in turn using these value indicators to refine the Spectrum criteria to reflect societal will)
  - methods for weighing and comparing both the positive and adverse qualities and impacts of a proposed GMFF idea
  - methods for adding up all considerations related to a proposal in order to provide considered advice.

Stage 3: Multi-stakeholder meeting(s) are conducted

As the six stakeholder sessions were completed, notes from each were provided to the participants. They incorporated key findings, improvements to the Spectrum tool, suggestions on how it might be applied and ideas for the way ahead.

The Exploratory Committee used the learning from these sessions to undertake further improvements to the Spectrum tool, to prepare it for the more challenging multi-stakeholder review, and to design the approach for such a multi-stakeholder session. These include testing the Spectrum tool with a substantial policy issue to explore the full range of considerations and impacts available in the model.

In its report to CBAC, the Exploratory Committee noted that the Spectrum tool had yielded positive reactions from the individual stakeholder sessions, had demonstrated the potential to create a space for dialogue on this very complex and diverse subject of GMFF, offered a promising aid to dialogue on policy in this area, quite possibly offered an approach that could assist other policy issues in Canada, and merited further development, testing and exposure to a wider audience. CBAC responded proactively and asked the Exploratory Committee to carry out this further developmental work. The Exploratory Committee has embarked on a path of further development and testing and will be conducting a multi-stakeholder session in the fall of 2002. As well, the committee intends to increase awareness, recognition and commitment from government and political officials regarding the value of this process and tool and its potential use in the policy environment.

As the path unfolds and lessons are learned, they will be shared with those who are interested in:

- constructive policy development
- experimentations in governance
- processes that engage citizens and stakeholders in dialogue that enables a search for solutions and choices that reconcile society's values and principles with the opportunities and risks that derive from rapidly moving developments that affect the public interest, whether or not they are technology driven.

Summary Lessons from the Acceptability Spectrum Pilot Project

- The Acceptability Spectrum as a tool for enabling dialogue, informing and even shaping policy looks promising in the Canadian context. It will be interesting to determine whether it can serve as an enabling tool for a more inclusive dialogue at the international level.

- The Acceptability Spectrum tool merits further investment, testing and eventually application in a policy context with real cases.

- This experience suggests that it is possible to create a space for dalogue on this (and perhaps other) complex issues, if the conditions are designed to encourage willing participation around an enabling tool that:
  - provides a holistic view of the proposal, so that all critical related issues and all dimensions can be considered
  - frames the related issues in neutral terms
  - helps translate the issues into test criteria/questions that can be used to prompt and lead focussed discussion
  - uses test criteria/questions designed to reveal answers that portray the characteristic qualities and impacts of the proposed GMFF, which in turn can be collectively valued and assessed

  - incorporates both positive and negative impacts (e.g. costs and benefits, pros and cons) along with indications of which population groups are most impacted in order to realize the scale, depth and consequences of the impact
  - helps participants using the tool to add up and weigh the impacts against a set of societal criteria in the form of values, principles and priorities
  - provides the possibility for a range of assessment conclusions or judgments, with attached conditions where applicable
  - encourages the involvement of individuals from a cross-section of interests who believe in the value of dialogue as a vehicle to advance policy and who are prepared to commit time and effort to the process.

- There is merit in empowering a group of most affected and interested multi-stakeholders to steward the concept and process. It is desirable to incorporate a wide range of divergent and even conflicting interests in the makeup of such a group. This selection provides an early space to explore contentious questions and to estimate and address the strong views, differences and areas of possible agreement that may be expected in full dialogue among participants as the development proceeds. With empowerment must come the terms of self-management, including a shared commitment to define and work toward a code of conduct, and to strive for results that enhance understanding, are constructive, and improve the effectiveness and confidence in the policy environment.

- The qualities of a constructive and fair dialogue should inform the design, ensuring it incorporates fact and evidence-based information where available, fairness in portrayal of the issues and the proposal, participatory democracy in the guided interactions, transparent and accessible reporting of results, respect for the motivations and beliefs of all participants, and neutral facilitation.

- It is important for participants at each stage of stewardship of the development and testing to agree on the ground rules for their dialogue/interaction as well as to formalize and agree to abide by them as a shared code of conduct.

- The presentation and explanation of the enabling dialogue tool (in this case, the Acceptability Spectrum) will depend on good graphic design, clear understandable explanations, a logical flow in the analytical use of the tool, and a practical means of aggregating and summarizing the results of each step.

- Illustrative cases and specific examples, drawn from experience or realistically estimated, will help provide tangibility, real-world impact and focus.

- Given the nature and history of this subject, controversy and conflicting views can be expected. The differences will have to be acknowledged and used to strengthen the depth and rigour of the review and test questions. Where differences appear to create an impasse, previous steps will have to be revisited to find common ground in shared values and principles and/or to seek alternate criteria for a successful solution to which all participants can agree.

- The stewardship and dialogue processes can both benefit from capable, skilled facilitation to help keep the process on track, assist with contentious points or steps and provide objective third-party advice along the way. Solid administrative support is critical for logistics management, communications, record keeping and clear reporting of results.

- People must be encouraged to "trust the process." While the approach must be flexible enough to accommodate innovative steps and preferential focus at any stage, it is important to apply the conceived ideas and process far enough to truly test the design thinking and assumptions.

Departing from a process too early (with the odd exception) often leads to personalized or fragmented experimentation that is, in the end, no more satisfying to the collective and provides no feedback to know whether the original thoughtfully considered approach and underlying assumptions had merits.

Those guiding this project will want to stress that this is an analytical and dialogue tool and that it is still in development, with a promising but still-evolving dialogue process. The project and its potential should therefore be seen as a work in progress, albeit with encouraging advances and benefits already experienced.

Attachment 1. Acceptability Spectrum

	Health considerations	Environmental considerations	Socio-economic considerations	Ethical considerations	Broader societal interests and international considerations
Acceptable					
Acceptable with considerations					
Not acceptable until more is known or certain standards are met					
Not acceptable under any circumstance					

Attachment 2. Code of Conduct for the Exploratory Committee

Members of the Exploratory Committee have agreed to abide by a code of conduct to guide their approach and relationship in this project. The code includes the following operating principles:

Collaboration

The participants agree:

- to proceed in a spirit of mutual respect, openness, and collaboration, striving to achieve the required objectives
- to create a thoughtful, open, candid, and constructive exchange
- to ensure that the process evolves in a timely fashion
- to respect the motivations and beliefs of the other participants
- to aim toward a consensus, with the goal of producing a unanimous report that will identify the points of agreement, differences in principles and unresolved matters
- in cases of severe differences, to allow a participant to include his or her objection in the report
- to record in the minutes of the meetings the decisions of the committee, actions to be taken and any objections raised by members
- to refrain from publicly denouncing other participants or the process or attempting to apply outside pressures on the committee.
- considering the collaborative foundation of the Exploratory Committee, to take steps outside the normal conduct of full committee interactions that will favour the actions of the committee, such as personal meetings, private consultations, small group discussions, etc., and to inform the committee of these events.

Representation

The participants agree:

- to proceed according to their conscience in the pursuit of the objectives, mindful that participation in the committee implies a desire of each participant to contribute actively toward the success of reaching the objectives
- to speak from their own experience as well as to draw upon the knowledge base and interests of the constituency/organization they represent (on behalf of consumers or as representatives of an enterprise, a government authority, a university, a sector association, or of a public interest group/NGO); to consult with the respective enterprise, government authority, university, association or organization to determine one's exact mandate, ideally before or early in the process; but not to be seen as representing the official, comprehensive or conclusive views of their constituency/organization, as this is not a formal stakeholder negotiation; and to work "in the moment" without outside reference
- in exceptional circumstances, to consult with their enterprise, government authority, university, association or organization before making a final decision on a given point, without unduly slowing the pace of the committee work
- to respect the rules of confidentiality from the beginning of the committee's work and to use discretion in representing the interactions and individual opinions of others, refraining from attributing views by name outside the committee
- to make information about the project and the terms of reference publicly available, including the objectives, the membership of the Exploratory Committee, the code of conduct and the Acceptability Spectrum itself
- to name a public spokesperson for the project as necessary who will speak publicly about committee matters after consultation with the Exploratory Committee; until a representative

is named, to have the Executive Director of the Canadian Biotechnology Secretariat provide factual information on request about the pilot project; and to discuss the terms of reference for the project (objectives, desired results, role of the committee, this code), the Acceptability Spectrum itself, the process and nature of the participation, and/or to express opinions on points already reached and agreed within the framework of the committee, without representing these as the current or official discussions of the committee.

Assumptions

The participants agree:

- that the established process of collaboration brings to the committee people who are involved with the subject and who have diverse interests in a climate of confidence and trust
- that flexibility will be allowed and encouraged to accommodate changing needs, and also that it is also important to trust the process and to stay involved until completion
- that all information, including documents deposited by participants, are public, unless confidentiality is required for justifiable reasons and is made explicit by the person who is the source of the information
- that committee meetings are private to favour the development of confidence and mutual understanding
- that committee members will respect the agreed confidentiality and will follow it both inside and outside the working committee
- that all studies undertaken by the committee will be made public after their deposit, either in a press release, through a designated spokesperson or on the CBAC Web site, after agreement with the Exploratory Committee
- that only the persons delegated with the responsibility will have the authority to speak on behalf of the committee
- that press releases concerning the committee should be released by the Canadian Biotechnology Secretariat after examination and acceptance by the committee.

Administrative process

Logistics and administrative support will be supplied by the Canadian Biotechnology Secretariat. The committee is responsible for keeping pace with its agenda and its work.

Internal operating procedure

- The facilitator guides the meetings and associated work, unless the committee determines otherwise.

- In the case of the absence of the facilitator, the alternate co-facilitator will guide the meetings.

- A member cannot choose a replacement with someone else to participate in the committee. In the cases of prolonged or repeated absences, the facilitator of the committee will meet with the person in question to determine whether it would be appropriate to suggest to the respective enterprise, government authority, university, association or organization that the member be replaced by another representative.

Attachment 3. Principles for the Spectrum

- **Objective** — The Spectrum must be used in an objective manner.

- **Verifiable** — The results of a Spectrum review should be able to be verified, using factual and measurable information wherever possible. The evidence presented on behalf of a GMFF should meet a test of confidence, with a level of rigour or standard that is appropriate to the potential conclusion.

- **Balanced** — Both the potential positive and adverse qualities and impacts need to be considered in assessing a GMFF. The criteria or tests for impact of a GMFF need to be weighed in a proportional manner — that is, to consider the extent and level of benefits and how they are valued — in proportion to the level and extent of risks (note: these are not restricted to a cost benefit framework; they also need to address distributional questions such as Who benefits? Who bears risks?).

- **Applied judgment** — Weighing the qualities and indicators for a GMFF, and considering the trade-offs or conditions under which a GMFF might be acceptable or unacceptable, will require a degree of judgment to be applied.

- **Consistent** — The Spectrum must be applied with rigour and consistency.

- **Practicable** — The Spectrum should be clear, understandable and practicable.

- **Flexible and adaptable** — The Spectrum should be flexible and adaptable to incorporate both current values and understanding of technology, and still accommodate their changing nature over time.

Principles as beliefs that underpin the concept and approach

- **Knowledge-based** — The Spectrum approach must incorporate and make transparent all the knowledge necessary to support the review.

- **Informed by science** — The review must utilize the best available scientific knowledge of the GMFF policy questions related to health and environmental impacts as the foundation for any further analysis.

- **Shaped by values and ethics** — Canadian societal values and ethical considerations must be part of the analysis, while recognizing their dynamic and evolving nature.

- **Right to informed dialogue on policy** — The right of Canadians to be informed about the critical factors affecting foods and the food supply, and to provide their input through accessible, informed policy dialogue must be respected.

- **In the public interest** — The Spectrum must view Canadian society as the ultimate beneficiary of improved policy and policy dialogue about food/food stock and GMFF. The Spectrum approach must give the public interest primacy.

- **Respect diverse views** — The Spectrum approach must respect a diversity of opinion.

- **Transparent process** — The Spectrum review process must incorporate an appropriate degree of transparency, and must provide an opportunity for interested citizens and stakeholders to engage in its application.

Annex 7. Letter to CBAC from the Exploratory Committee

Dr. Arnold Naimark
Chair, Canadian Biotechnology Advisory Committee
240 Sparks Street, 5th Floor, West Tower
Ottawa ON K1A 0H5

June 6, 2002

Dear Dr. Naimark,

Last year, CBAC created the Exploratory Committee to pursue development of the Acceptability Spectrum, and the procedures for its application, in order to create a space for dialogue on GM foods issues. The Exploratory Committee consists of 11 individuals drawn from a variety of affected and interested stakeholder communities including non-governmental organisations (consumers groups, the faith community (range of religious groups), environmental), public health, as well as biotechnology developers, and the supply chain (farm producers, food manufacturers, and distributors/retailers).

CBAC has supported the Exploratory Committee in its development of the Acceptability Spectrum Pilot Project, a three-stage process to design and guide testing of the Spectrum dialogue tool and process. The primary objective of the pilot has been to create and assess a tool that would facilitate a dialogue among key stakeholders on key GM foods issues. The pilot sessions also explored how the tool could be improved to aid future dialogue and considered the viability of extending the process and of using the tool to facilitate future deliberations on GM foods.

As we embark on Phase 3 of this project, which was originally planned to involve a multi-stakeholder process, we would like to offer the following key points for CBAC's consideration:

- We commend CBAC for its willingness to support this initiative to date and encourage the Committee to continue to recognize the value of this exciting and progressive process.

- We believe that the Acceptability Spectrum is an innovative tool with the potential to make a significant contribution in advancing the dialogue on genetically modified food and feed, biotechnology in general, and other policy issues in Canada.

- Further, we believe that the ultimate potential will only be realized if the Government of Canada is able to utilize the tool to facilitate dialogue. In the near term, it is our view that this requires an increased awareness, recognition and commitment from government and political officials regarding the potential contribution and value of this process and tool.

- Consequently, we are proposing that as part of Phase 3 of the pilot, the Exploratory Committee and CBAC actively work together to expose and explain the Acceptability Spectrum to key decision makers in the public sector context and to enable the results of this pilot to move to the next stage of application.

As members of the Exploratory Committee, and representing the views of a variety of stakeholder communities, we commit to:

- participating in and leading the design and implementation of Phase 3;

- continuing to pursue the involvement of our constituencies in the process, both through implementation of Phase 3 and by working through our own networks; and

- exploring the Acceptability Spectrum further and providing our best advice and active support to CBAC in further promoting the Spectrum as a dialogue tool and in engaging a wider circle of Canadians.

Thank you for your continued support of the Exploratory Committee and the Acceptability Spectrum pilot project.

Sincerely,

Exploratory Committee Members

Herb Barbolet

Ellen Desjardins

Denise Dewar

Conor Dobson

Robert Friesen*

Jennifer Hillard

Martin Jamieson

Joy Kennedy

Elizabeth May

Nathalie St-Pierre

Geoff Wilson

* While I support the continuation of a broad discussion on the Acceptability Spectrum, I emphasize that science and market acceptance must remain the predominant criteria in the regulatory system.