Canadian Biotechnology Advisory Committee

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

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Interim Report on Genetically Modified Foods
Canadian Biotechnology Advisory Committee
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Preamble

Canada's current regulatory system has been effective in its primary objective of ensuring the safety of the nation's food supply. As the tempo of development of new food products by genetic modification of plants and animals has accelerated, public interest in the capacity of the regulatory system to keep pace with future developments has grown.

This document is an Interim Report of the Canadian Biotechnology Advisory Committee (CBAC) to the Government of Canada on the regulation of genetically modified (GM) food. It covers the first two phases of a three-phase project that CBAC has undertaken on this important topic. The primary objective of the project is to identify improvements in the structure and function of the regulatory system that would position it to successfully meet current and future challenges.

Phase 1 of the project began in the summer of 2000. It consisted of collecting and analysing information on the regulatory, social, economic, ethical, legal and environmental elements of GM foods. A number of background papers on GM foods were commissioned. Reports of other expert groups including the report of the Royal Society of Canada Expert Panel on the Future of Food Biotechnology were reviewed.

Phase 2 consisted of three key activities, all designed to garner input of Canadians concerning the regulation of GM foods. The first was the release in March 2001 of a Consultation Document soliciting input from Canadians. The second involved a series of multi-stakeholder workshops held in April 2001 in five cities across Canada. Some representatives from civil society, primarily environmental non-governmental organizations, chose not to participate, thus diminishing representation of this group. The third was a review in May 2001 of existing public opinion research reports related to GM foods. Reports on these three activities are available on the CBAC Web site.

Phase 3 of the GM foods project begins with the release of this Interim Report. CBAC is inviting feedback on this report and will be accepting input until January 31, 2002. At the conclusion of Phase 3, following the comment period, CBAC will submit its final report to the Government of Canada.

Further information and documentation on CBAC's activities can be obtained from the CBAC Web site: **www.cbac-cccb.ca** or toll-free number (1-866-748-2222; TTY/ATS: 1-866-835-5380).

Observations, Findings and Draft Recommendations

The Interim Report begins with a brief description of the context for CBAC's project on GM foods and the process by which it has been conducted. This is followed by a summary of Canada's system for regulating GM foods. The ethical context within which CBAC considered the main issues of contemporary interest and relevance is identified.

The phrase "GM foods" refers generally to food produced from genetically engineered plants and animals using recombinant DNA technology. It became evident in our deliberations that while some aspects of food regulation may be particular to GM foods (e.g. some aspects of the risk assessments), many of the issues involved — and many of our observations and recommendations — apply to all plants, crops and animals with novel traits. Indeed, under Canada's regulatory system, GM foods are part of the broader category of novel foods. We support this more comprehensive approach, and we have therefore formulated many of our draft recommendations in the context of novel foods in general. In addition, in some cases, our analysis and recommendations have potential implications for certain general features of the food regulatory system, food policy and environmental regulation. Our recommendations seek to identify the situations where wider application may be warranted.

Ten issues are at the heart of CBAC's analysis, consultations and draft recommendations. They are:

- 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
- labelling
- environmental stewardship
- broader social and ethical considerations.

These issues are discussed under three overarching themes:

- good governance
- information and choice
- social and ethical considerations.

CBAC's current thinking regarding GM foods is presented as draft recommendations. These consist of five general and twenty-four specific recommendations. They target a number of structural and operational features of the regulatory system as well as key challenges related to public information, informed choice and environmental stewardship. We also identify a sixth area in which we intend, as part of Phase 3 of our project, to develop additional insight and recommendations concerning social and ethical issues related to the regulation of GM foods.

The draft recommendations presented below reflect core values and principles for the protection of health and the environment, individual autonomy, transparency, integrity and accountability of the regulatory system, and sustainability of food production. We believe an understanding of the ten issues and effective application of their associated recommendations, once finalized, will contribute to a more accountable, knowledge-based and cautious food regulatory system.

Good Governance

1. Structure, Organization and Operation of the Federal Food Regulatory System

Observations: *The federal food regulatory system relies on a number of regulatory bodies, some being more active on issues pertaining to GM and other novel foods 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. Health Canada and the Canadian Food Inspection Agency (CFIA) function more closely than other parts of the system, but coordination with the other parts appears weak. There is no individual leader or spokesperson for food safety matters at the federal level for either GM and other novel foods or for food in general. GM and other novel foods are currently a small part of the overall food safety systems, but this may change in the near future. The degree to which the regulatory function remains independent from the government's promotional activities is not clearly described.*

Draft 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 clarify 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.*

Specifically, we recommend the following measures:

1.1 Appointing a chief safety officer for GM and other novel foods. This person will become the focal point and spokesperson on all federal GM and other novel food safety matters — related

to human health as well as environmental safety — and will coordinate activities of the individual regulatory bodies. This officer will chair a new assistant deputy minister (ADM) committee on GM and other novel food safety regulation (see below). This person will be appointed *ex officio* member of all rulings committees operated by regulatory bodies within the food regulatory system.

1.2 Establishing a committee at the ADM level to oversee GM and other novel food safety regulation for Canada. Representatives will be from federal regulatory bodies involved in the assessment and approval/registration of products of biotechnology and related inspection and enforcement activities (at a minimum, Health Canada, the Canadian Food Inspection Agency, Environment Canada, and Fisheries and Oceans Canada). The committee's responsibilities will include ensuring effective interdepartmental and interagency coordination and communication, and planning and analysis activities. Specific functions would address:

- Coordination and communication of product assessments as well as proposed and final regulatory decisions.
- Coordination of communication activities and tools aimed at external audiences.
- Elimination of gaps and counterproductive overlaps in the regulatory system.
- Evaluation of the adequacy of the existing guidelines covering experimentation involving recombinant DNA and other forms of genetic modification. This function should be pursued to determine the ability of existing guidelines to ensure health and environmental safety during research and development activities, the extent to which they are applied by researchers in public and private organizations, and whether further action, including greater regulatory scrutiny or a single national standard for research and development is needed to protect health and the environment.
- Management of the government's scientific and technical expertise. The aim would be to ensure that it is maintained and built up where necessary, and is adapted in anticipation of future regulatory needs, following periodic evaluation of new research findings and market trends.
- Preparation and publication of standard operating procedures (SOPs) to clearly describe the delegation of decision-making authority, the strategies in place to insulate officials from inappropriate influence, the procedures and rationale for engaging non-governmental experts and expert panels in regulatory processes, the policies regarding the preparation of decision documents for public review prior to final decision making, and the details regarding rulings committees and other elements of internal reviews.
- Examination of opportunities for ongoing improvement of risk assessment and risk management activities, and of inspection and enforcement capacity in relation to more complex, newer generation products. This function should be conducted with a view to ensuring routine monitoring for

compliance with conditions of approval associated with the production of plants with novel traits or novel foods.

1.3 Ensuring effective independence of regulatory functions from the industry and trade promotion functions of the federal government. CBAC recommends that the federal government carefully scrutinize its internal operations and relationships with stakeholders, and modify them where needed. All communications and communication materials should be assessed, and specific attention should be paid to the involvement of regulators in the negotiation of international policy and trade rules. These measures should be undertaken to ensure the highest degree of integrity and independence in the conduct of regulatory functions, to avoid exacerbating the perception of mandate conflict, and to ensure an appropriate role for regulatory officers in international activities. For those regulatory bodies that do not already have in place a standing committee through which all proposed decisions on GM foods and other novel foods must be vetted, CBAC considers it essential to establish one.

1.4 Having the Auditor General of Canada monitor and publicly report on regulatory bodies involved in assessments and decision making related to foods sold in Canada, with emphasis on the independence of regulatory functions, and the effectiveness of standard operating procedures.

2. Evaluation of Long-term Health and Environmental Impacts

Observations: *The federal government conducts research related to GM foods. Work is also under way internationally. However, a number of additional tools and programs are needed to effectively assess and anticipate long-term health and environmental impacts associated with GM and other novel food.*

Draft 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.*

This activity involves the following measures:

2.1 Requiring the inclusion of effective detection methodologies for transgenes as part of the application process for requesting approval of novel products.

2.2 Developing food consumption data in order to improve the risk assessment process. Providing a greater understanding of potential exposure to certain foods would assist in the identification of populations that may be at higher than normal risk and in monitoring for long-term effects of certain food consumption patterns.

2.3 Ensuring that new scientific or technical information is taken into account within a reasonable time frame. This objective could be achieved by including in product approvals a preset deadline before which a reassessment of any new information related to the product or otherwise relevant to its risk assessment is conducted.

2.4 Introducing a broad-based program of long-term research into GM organisms that are part of the human food chain. This task would improve our scientific knowledge of health and

environmental harms as well as benefits of the products in question. Leadership should be shown in studying crops for which Canada is a global leader (e.g. canola, identity preserved soy, durum wheat, flax and malt barley). International collaboration and information sharing as well as programs for developing similar information on other novel foods are also recommended.

3. Transparency

Observations: *While there is a desire within the federal government to be more transparent in its regulatory functions, constraints (and possibly legal impediments) remain. There is insufficient emphasis on transparency. The communication of information related to the regulation of GM and other novel foods has not been highly effective.*

Draft 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.*

We recommend the following measures:

3.1 Continuing to involve the Canadian public in the development of laws, regulations, policies and programs related to the Canadian food regulatory system.

3.2 Improving information and communications about the federal food regulatory system. Decision trees could clearly describe the regulatory authorities, responsibility centres and relevant laws, activities, stages of risk assessments and decision processes, progression through the regulatory system, relevant time lines, mechanisms to resolve differences of opinion, and opportunities for public input at various stages.

3.3 Maintaining a readily accessible public record of the GM and other novel food products currently under review as well as the status of the assessment.

3.4 Communicating GM and other novel food risk assessments and proposed regulatory decisions systematically through published documents. This would include a 45-day comment period for public input on the proposal. This should be followed by a final decision document, amended as appropriate, based on the input received. (Minimum topics to be covered in these documents are listed in the full report.)

3.5 Making publicly available the detailed scientific and technical data reviewed by the government in conducting human health and environmental safety assessments of GM foods and other novel foods. For this purpose, a review should be conducted to ensure an accurate interpretation of existing provisions in the *Access to Information Act.* As well, consideration should be given to any necessary amendments to applicable laws and regulations. The disclosure requirements should not, however, include details such as how to construct and manufacture the product, as this could significantly jeopardize a company's competitiveness. Furthermore:

- The information should be available for products sold in Canada and for products being proposed for market approval.
- Existing provisions in the *Access to Information Act* should not be viewed as requiring the government to keep

confidential any technical or scientific data that have not been kept strictly confidential by the owner of the data (e.g. if the data have been made public or are available to the public as a result of the product being approved in another country).

- Consideration should be given to any necessary amendments to applicable laws and regulations in order to allow the release of the data.

3.6 Re-examining pollen drift and reassessing the buffer zones currently applied to field studies of GM crops and other plants with novel traits. Information on pollen drift should be required in all submissions for approval of plants with novel traits. Growers within five kilometres of a field study involving GM crops should have access to more detailed information, on request, in order to protect 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 because of the risk of damage through vandalism. Further study is needed to better understand the characteristics and risks associated with GM products.

3.7 Publishing, on an annual basis, information on government inspection programs, findings related to compliance with measures concerning GM products, the frequency of non-compliance and measures applied to rectify non-compliance.

3.8 Publishing, on an annual basis, information on the government's research program and research results related to health and environmental safety aspects of GM foods, plants and feed, and other novel products.

Information and Choice

4. Information and Informed Choice

Observations: *Canadians want easy access to reliable and complete information regarding food including GM and other novel foods. The current information sources are criticized for being unreliable, incomplete, overly technical or otherwise ill-suited to the needs of the general public. Canadians also want to be able to choose whether or not to buy GM foods. Consumer choice can be influenced by health and environmental concerns as well as by principles, beliefs and values. Labelling is currently required for such health concerns as the presence of an allergen or a significant nutritional change. Current laws allow voluntary labelling if it is not misleading. However, the absence of a systematic and reliable standard for labelling food regarding whether or not it is derived from genetic modification prevents labelling claims such as "GM free" from being verified. Other countries are putting forth various forms of voluntary or mandatory labelling policies.*

Draft 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.*

We recommend the following measures:

4.1 Establishing a centralized food information service as the primary avenue through which the government provides food-related information, including on GM and other novel foods, to Canadians. The service should reflect effective cooperation among all parts of government with roles related to food regulation, food research, food policy and consumer affairs. The information disseminated for the most part should originate in the federal government, and should always be unbiased. The organization and operation of the service should be based on a comprehensive strategy. Funding for related government communication and information activities should be consistent with the strategy.

4.2 Developing, as part of this strategy, reliable information for use by health care professionals and other intermediates (such as doctors, nurses, nutritionists, dieticians, teachers, community workers, consumer associations, civil society groups and the media).

4.3 Developing a labelling system for foods with GM content and continue to work on an international labelling scheme.

- Develop a set of clear labelling criteria regarding the GM content in food. Further effort could be placed on the ongoing labelling initiative of the Canadian General Standards Board and Canadian Council of Grocery Distributors.
- Ensure that any label statements regarding genetic modification are verifiable, and that programs and techniques are in place to ensure their validity.
- Implement the labelling standard voluntarily, at least initially, in order to test its adequacy and effectiveness, and widely promote its use so that people have real opportunities to make informed choices.
- Continue to work with other countries in international fora to develop a harmonized international approach for labelling regarding genetic modifications.
- Depending on the success of this approach — and especially if it fails to provide Canadians with sufficient choice regarding the food they consume — further consideration should be given to a mandatory labelling scheme.

Social and Ethical Considerations

5. Environmental Stewardship

Observations: *Currently, there are no binding international standards for environmental assessments for GM or other novel foods. Work is under way and progress is being made in identifying "best practices." Nonetheless, CBAC believes there is room for improvement in the current approach to environmental assessments for research into long-term impacts and the degree to which ecosystem effects are being considered.*

Draft 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.*

We recommend the following measures:

5.1 Establishing a well-supported and collaborative national research program to improve knowledge about the long-term effects of GM organisms used in novel foods or used in food production on the natural, agricultural and other ecosystems.

5.2 Exploring over the short term and implementing options for integrating a stronger ecosystem perspective into environmental risk (safety) assessments of GM and other novel foods. A report of options should be developed and released publicly within a year. Key elements would include national and international research collaboration needs and the potential for making better use of ecological expertise.

5.3 Strengthening over the medium term the environmental assessments of novel foods and GM processes used in food production through a stronger ecosystem perspective and peer review of experimental design and data. Independent panels should be utilized to recommend ecologically meaningful experimental protocols for each new class of GM introductions. This task would require building a strong base of expertise to cover key ecological and environmental concerns, such as environmental persistence of GM organisms, effects on biogeochemical cycles, reproductive biology such as pollen flows, harmful effects of horizontal gene transfer, diminution of biodiversity, insect resistance to GM insecticidal products and cumulative effects.

5.4 Taking a precautionary approach to ensure a conservative safety standard for environmental and health concerns related to GM and other novel foods. This does not imply, however, a zero-risk approach. Special concern should be taken with regard to potentially catastrophic kinds of risks. Under circumstances where it is appropriate to use substantial equivalence as a framework to structure the safety assessment of novel foods, it is necessary to ascertain whether the composition of the plant has been changed in any way. Examples are the introduction of new hazards into food, an increase in the concentrations of inherently toxic constituents, a decrease in the expected nutrient content, or the introduction of unwanted characteristics such as antibiotic properties into natural ecosystems.

5.5 Assessing the implications and suitability of recommendations 5.1 to 5.4 above for broader application throughout the environmental regulatory system.

6. Other Social and Ethical Considerations Related to GM Foods

Observations: *The debate over GM foods is polarized between those supporting the application of biotechnology (e.g. rDNA technology) to foods and those against it. The search for common ground between advocates of different views is hindered by the lack of suitable tools to systematically consider and evaluate on an ongoing basis the social and ethical factors that influence public acceptability of specific food.*

CBAC will continue to consider the health and environmental safety, ethical, social, 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.

Introduction

This document represents the first report of the Canadian Biotechnology Advisory Committee (CBAC) to the Government of Canada on the Regulation of Genetically Modified (GM) Food. The purpose of the Interim Report is twofold:

- present to Ministers and regulatory bodies CBAC's draft recommendations regarding GM foods and ten key issues on this topic
- invite Canadians to express their views on the issues and draft recommendations.

CBAC is an independent expert advisory created by the Government of Canada to assist it in the formulation of public policy on a range of biotechnology subjects.[1] It provides its advice to the Biotechnology Ministerial Coordinating Committee (BMCC), which includes the federal ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade. CBAC's Program Plan 2000 describes in detail the committee's organization, operating procedures and program of activities.[2] CBAC's first Annual Report offers further information on the origin and activities of CBAC, its ongoing monitoring and advisory role, advice it has delivered to government to date, and broader perspectives on developments in biotechnology. These documents may be found and obtained through the CBAC Web site (**www.cbac-cccb.ca**) or toll-free telephone number (1-866-748-2222; TTY/ATS: 1-866-835-5380).

In 2000, CBAC initiated a program of research and consultation regarding the regulation of GM foods in Canada. As part of this program, it produced a Consultation Document outlining the ten issues on which it would concentrate initially and various possible options to resolve or address them. This Interim Report outlines our Draft recommendations. It also introduces a new element that is intended to foster a more meaningful dialogue on the acceptability or non-acceptability of certain GM foods. Canadians are invited to comment on any or all of these aspects.

In addition to the draft recommendations, this report:

- provides an introduction to the Canadian food regulatory system and a snapshot of what the term "GM foods" means
- addresses the ethical context in which GM foods can be considered
- clarifies the key issues that CBAC has identified and that have been debated by Canadians during CBAC's consultations
- directs readers to related research studies and technical reports commissioned by CBAC, reports of feedback received during consultations on GM foods, and to other companion documents relevant to the topic and useful to CBAC during its deliberations to date
- describes approaches other countries have adopted for regulating GM foods
- presents a matrix of the recommendations of the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology
- presents an introduction to possible second and third generation GM foods and the questions they raise.

Quite purposefully this Interim Report has focussed on Canada's food regulatory system through the lens of GM foods. CBAC recognizes, however, that many of the issues which have been brought forward are not unique to GM foods but apply as well in other areas of public policy. Insofar as this report seeks to inform and influence the GM foods policy agenda, it does so in the realization that government's course of action in this area needs to be consistent with actions regarding other foods, and that an overall strategy for food safety and security is desirable.

[1] More information on CBAC and its activities including other consultation topics, as well as on biotechnology in general, are available on the committee's Web site: **www.cbac-cccb.ca**. A list of members is provided in Annex A.

[2] In addition to Regulation of Genetically Modified Food, CBAC is currently preparing recommendations to government on Intellectual Property and the Patenting of Higher Life Forms.

The Setting and the Consultation Process

GM crops and foods are being produced and marketed in increasing quantities in Canada and around the world. There may soon emerge new items with novel functional, nutraceutical or pharmaceutical attributes, such as edible vaccines and biopharmaceuticals produced in plants and animals. The implications of these developments for people, animals and the environment are the subject of significant debate in Canada and abroad.

The debate focusses primarily on the safety of GM foods, its possible impact on the environment, ethical implications, effects in the developed and developing worlds, and trade relationships. The debate is highly polarized. There are those who are concerned about GM foods and other GM organisms and who advise further research and strict and reliable controls prior to the approval of any GM product. In contrast, there are those who believe GM foods provide vast opportunities and benefits for Canadians and others around the globe and who believe that the risks associated with GM foods are no more significant than those inherent in foods produced through more traditional methods. This debate has led several governments, think-tanks and international organizations to undertake policy analysis, scientific studies and public consultations regarding the hazards, benefits, social and ethical implications, and regulation of GM foods.

At its inaugural meeting in October 1999, CBAC identified the regulation of GM foods as a priority subject for consideration. It identified three main areas for study: the science base underpinning the regulatory processes; the organization and governance of regulatory systems; and the social, ethical and legal dimensions of GM foods. CBAC decided to focus on the latter two aspects when the Royal Society's Expert Scientific Panel on the Future of Food Biotechnology was created in December 1999 to advise government on the scientific capacity of the regulatory system regarding GM foods. Rather than duplicate the panel's work, CBAC has considered their recommendations. A matrix illustrating the points of intersection of the recommendations of the Royal Society Panel with the key issues CBAC has been focussing on is presented in Annex D.

During the summer and fall of 2000, CBAC undertook Phase 1 of its work. This consisted of collecting and analysing information on the regulatory, social, economic, ethical, legal and environmental elements of GM foods. Work included preparing a number of research papers and technical reports by experts in these various fields, reviewing key existing studies and documentation, and holding discussions with regulators and other experts to learn as much as possible about GM foods regulation in Canada. Based on this work, the committee identified ten key issues on which it would concentrate initially. Bibliographies of CBAC's commissioned reports and other companion documents consulted by CBAC are contained in Annex B.

In March 2001 CBAC began Phase 2 of its GM foods project. Phase 2 consisted of three key features, all designed to garner input concerning the views of Canadians on the regulation of GM foods. The first was the release of a Consultation Document, which focussed on the ten key issues and which invited Canadians to comment on them. The Consultation Document was posted on CBAC's Web site. Several organizations (e.g. producers, environmental and citizen groups, consumers, health professionals and industry) helped with its dissemination. CBAC invited people to send comments via the committee's toll-free telephone number or Web site, or by fax or regular mail.

The second feature of Phase 2 involved a series of multi-stakeholder workshops held in April in five cities across Canada. The purpose of the workshops was to generate a dialogue and receive additional perspectives on the issues, to explore the strengths and weaknesses of the various options for addressing them, and to assess the values and principles related to the issues. The sessions were

designed to achieve a balance of representation from the general public, society, industry, research and academia. However, some representatives from civil society, primarily environmental non-governmental organizations, chose not to participate, thus diminishing the representation of this group. The petition presented by these representatives, as well as CBAC's response, can be found on the CBAC Web site.

In collecting input, CBAC also sought a better understanding of the concerns and preferences of the Canadian public. It undertook a review of existing public opinion research reports related to GM foods.

The results of these three streams of input — the Consultation Document, the multi-stakeholder workshops and the public opinion research — have been summarized in reports, referenced in Annex B, which are available on the CBAC Web site.

Phase 3 of CBAC's project on GM foods begins with this Interim Report. This report reflects the results of CBAC's deliberation on input received during Phase 1 and Phase 2. It contains draft recommendations to address the issues identified. CBAC is making it available to the public and is inviting comments from Canadians through January 2002. The purpose is to ensure that everyone has sufficient time and opportunity to consider the Interim Report and to prepare and submit any comments and suggestions.

CBAC will take into account the feedback from Phase 3 to produce its final report and formal recommendations on the regulation of GM foods. This report will be delivered to government in early 2002.

To assist in its activities on GM foods, CBAC created a reference group of individuals affiliated with various stakeholder groups to comment on the committee's research reports, key issues, consultation approach, Consultation Document, feedback received and communication materials. The Group held three meetings from December 2000 to May 2001. CBAC also engaged numerous academics and other experts throughout its GM foods project to review and advise on various technical stages of its work. Neither the members of the reference group nor other experts engaged by CBAC were tasked with achieving consensus decisions. They do not necessarily endorse CBAC's work, the reports or analyses undertaken, its Consultation Document, or this Interim Report to government. CBAC would like to thank all members of the reference group and all other academics and other experts for their valuable contribution to the committee's work through their analyses, insights, observations and suggestions.

Anyone wishing to comment on this report should do so by January 31, 2002. Comments may be submitted either through the Web site at **www.cbac-cccb.ca**, by fax at (613) 946-2847, or by mail to CBAC, 240 Sparks Street, Room 570E, Ottawa, Ontario K1A 0H5.

GM Foods, Other Novel Foods and the Canadian Regulatory System

As it is commonly understood, the term "genetically modified" (GM) food refers to food that has been produced using recent advances in gene technology, such as gene cloning, gene splicing and the introduction of single genes into plants (or animals) through a process called transformation. These and other techniques are often collectively referred to as recombinant DNA technology, or modern biotechnology, and they define a set of tools for "genetically engineering" organisms (e.g. plants, animals and bacteria) to possess predictable, defined characteristics. For this reason, GM foods are also referred to as "genetically engineered" (GE) foods.

As we shall see later, Canada's regulatory system was not designed to focus specifically on GM foods or GM crops, but rather has used existing legislation to deal with these products within the broader categories of novel foods and plants with novel traits, respectively. Although this Interim Report uses the terminology of "GM foods," it is recognized that, within the context of Canadian regulations, all GM foods are novel foods, but novel foods can also include foods produced by means other than genetic engineering as defined above.

The technologies for genetically engineering plants were first established using tobacco model systems in the early 1980s. They have been refined over time so that it is now possible to introduce specific genetic modifications into all of the major food crops. GM foods have been subjected to scientific and regulatory scrutiny aimed at ensuring their safe introduction into the marketplace. In Canada, GM foods have been available since 1995 and they now include a range of products that are predominantly produced from corn, soybean, canola and cotton. A number of other GM crops, such as varieties of flax, potato, tomato, squash and sugar beet, have also been approved for food use in Canada, but their contribution to date to the Canadian diet has been minor. The genetic modifications introduced into these crops include herbicide tolerance, resistance to insect pests and to diseases caused by plant viruses, improved shelf life (in the case of tomatoes) and modified oil composition.

Based on current research and development activities, the future may include crops with increased tolerance to salinity and drought, improved disease and pest resistance, enhanced yield potential and modified nutritional qualities as well as crops that can act as delivery vehicles for vaccines and therapeutic proteins. These foods with new functional, nutraceutical or pharmaceutical attributes are anticipated to exhibit more complex traits that in many cases will blur the boundary between foods and therapeutics. Some examples of these include potatoes that express a vaccine against Norwalk virus (responsible for viral gastroenteritis, which makes up about 25 percent of the cases of "travellers' 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 herpes virus, or the production of biodegradable polymers as substitutes for plastic. These foods are described in more detail in Annex E of this report.

The first phase of a biotechnology revolution in agriculture is already under way. In 2000, 44.2 million hectares (109.2 million acres) worldwide — an area almost twice the size of the United Kingdom — were being cultivated with GM crops.[3] This represents an increase of 11 percent over the 1999 area and more than four times the area cultivated in 1997. Four countries — the United States, Argentina, Canada and China — accounted for 99 percent of this area (68 percent, 23 percent, 7 percent and 1 percent, respectively). Nearly all of

[3] C. James, "Global status of commercialized transgenic crops: 2000," in *ISAAA Briefs No. 21: Preview* (Ithaca, NY: ISAAA, 2000).

this area was devoted to four GM crops, namely, soybean (58 percent), corn (23 percent), cotton (12 percent) and canola (7 percent).

For a number of reasons, some of which are highlighted below, GM foods have surfaced as a topic of much debate in a number of nations and is the focus of attention in several international fora. As a result, many countries and international organizations are conducting scientific studies and seeking the views of the public regarding the safety and appropriate regulation of GM foods.

Benefits and Concerns

As with any new enabling technology, the potential benefits of applying biotechnology and genetic engineering to food production are balanced by concerns about potential negative effects. People have different views on how biotechnology developments could affect humans, animals and the environment.

Many scientists believe that producing new foods through biotechnology is no riskier than other means of production. Their view is that, while science can rarely provide guarantees, our system of risk assessment and regulatory oversight is reliable in terms of both health and environmental safety. Others, however, are concerned that the regulatory system cannot deal effectively with the health and environmental safety aspects of GM foods, particularly in the long term and especially with regard to the second-generation products that may soon emerge.

Differing viewpoints exist concerning the environmental benefits and risks of GM crops. Proponents believe the genetic modification of crops to be more resistant to pests and disease, with potentially less reliance on the use of pesticides and herbicides, greater environmental sustainability, less groundwater contamination and potentially fewer cases of pesticide-related farm worker illness or injury. Some believe the introduction of these new varieties will aid farmers in both the developed and developing countries. Some also believe GM crops will in fact be instrumental in addressing social and ethical concerns such as contributing to improved food security in developing countries.

Contrarily, there are concerns about the long-term environmental impacts of GM crops. These include concerns that plants producing their own pesticides to combat insects could accelerate the development of resistant insect populations, thus reducing the effectiveness of these pesticides for other agricultural applications. There are also fears that outcrossing (that is, the movement of engineered traits) between herbicide-tolerant crop plants and closely related weeds could result in the creation of "superweeds." There are also concerns that animals and insects consuming GM plants will be harmed and that biodiversity will be diminished.

Some individuals and organizations are concerned with broader social and ethical questions raised by the production and consumption of GM crops and foods. These include fundamental opposition to the artificial manipulation of plants and animals (playing God with nature), the belief that global justice and beneficence (that is, doing or producing good) are not being served with this technology, the concern that citizens cannot make informed choices about their food in absence of labelling of GM products, and the economic implications of increased globalization and concentration of power in the hands of a few multinational corporations. There are also concerns over the Canadian government's dual role of promoting and regulating GM foods, the boundaries between commercial secrecy and the public's right to information, and the fact that the federal regulatory system is science-based and is not mandated to address social, ethical or economic concerns as part of the risk assessment and decision making process.

The Advent of Food Safety[4] Assessments

For 10,000 years, agriculture has relied on plant and animal breeding to improve the yield and quality of the products we grow and the foods we eat. Until about 100 years ago, most breeding was done on a trial-and-error basis. Plants, for example, were selected based on healthy appearance, vigorous growth, higher yields and desirable appearance, taste and smell of the edible plant parts. In the late 1800s and early 1900s, plant breeding evolved from a qualitative art to a quantitative science. Breeders applied new technologies to expand the genetic variability of plants and animals. In the 1930s, accelerated mutagenesis was first introduced as a means of deliberately changing a plant's DNA. Chemicals or radiation are applied to seeds to create random changes in the plant's genetic structure that can result in desirable traits that are selected by breeders. Plants produced by accelerated mutagenesis have been commercialized since the 1950s. 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.[5]

In the past 20 years, the use of recombinant DNA technology has allowed the production of plants and animals with traits that could not have been introduced through traditional breeding techniques. Genes for sought-after traits can be isolated and cloned from plants, microorganisms or animals and then incorporated into a plant's genome.

The products of traditional breeding and selection have received little, if any, regulatory scrutiny. New plant varieties and the food products derived from them have regularly been introduced into commerce without a formal safety assessment, largely because the methods used to produce them have a long history of safe use. The advent of crops and foods derived from modern biotechnology has challenged this convention. The use of recombinant DNA technologies to produce genetically engineered plants and foods has led to governmental and institutional regulations around the world that are specifically applied to assessing the safety of these plants and foods.

In 1993, the federal government announced a regulatory framework for biotechnology as established through agreement among federal regulatory bodies. The need for an investment in this regulatory strategy to meet new challenges was recognized when the Canadian Biotechnology Strategy was renewed in 1998. The principles from this strategy, which are still in place, include reflecting Canadian values; engaging Canadians in open, ongoing, transparent dialogue; promoting sustainable development, competitiveness, public health, scientific excellence and an innovative economy; and ensuring responsible action and cooperation domestically and internationally. These principles established that the practical benefits of biotechnology products and processes would be balanced with the need to protect health, safety and the environment.

[4] For the purposes of CBAC's project on GM foods, the term "food safety" comprises aspects of human health as well as environmental safety. However, in the discussion of the various components of the regulatory system, the safety assessments can refer to health issues, environmental concerns, or both, as described in the text.

[5] M. Maluszynski et al, "Officially released mutant varieties — the FAO/IAEA database," in *Mutation Breeding Review No. 12.* (Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and FAO/IAEA Agriculture and Biotechnology Laboratory, 2000.)

The Regulatory System

A key feature of the Canadian regulatory system is the principle that it is the nature of the product that determines the nature and level of associated risk; it is not the novelty of the science used in its production. Numerous expert consultations have stressed that it is the safety of the end product that must be assessed, regardless of how a genetic change was induced,[6] including but not limited to recombinant DNA techniques, artificial mutagenesis (random genetic change caused, for example, by chemical agents), and artificial wide crosses among species created using sophisticated laboratory methods. Using this principle, all agricultural commodities and food products, whether they are produced using conventional technologies or biotechnologies, are governed under the same laws. In practice, this means that any plant or food with novel characteristics proposed for the market, irrespective of the technique by which they were developed, is subject to regulation and mandatory safety assessment under Canadian law. Crops that have been genetically altered to express novel traits must be thoroughly assessed to ensure their safety for human and animal health as well as for the environment before they can be grown in Canada or used in foods marketed in Canada. This regulation is more comprehensive than that in other countries, where it is the process of genetic engineering that acts as a trigger for regulatory oversight.

Because 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. As defined in the regulations, a novel food is 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 which causes a significant change in the properties of the food. Novel foods include all GM foods but can also include other foods, such as novel sources of dietary fibre, for example. Similarly, a plant with a novel trait can be any plant whose characteristics are unfamiliar or not comparable with similar traits in other plant species. This definition can include plants produced through genetic engineering as well as plants produced through accelerated mutagenesis, cell fusion or even conventional cross breeding.

In Canada, the regulation of GM plants and foods is coordinated among Health Canada, the Canadian Food Inspection Agency (CFIA) and Environment Canada.[7] 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 as well as prescribing basic food labelling and advertising requirements. Environment Canada is responsible for performing environmental risk assessments of substances including organisms and microorganisms produced through biotechnology. The Department of Fisheries and Oceans is currently developing draft regulations on transgenic aquatic organisms. Until these are in

[6] 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."

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 Companion Documents for bibliographies.)

[7] 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**

force, any applications for the commercial development of transgenic fish would require an environmental assessment by Environment Canada.

Scientists developing products of biotechnology do their work in labs, growth chambers and/or greenhouses. In these settings, the products are contained and should not come in contact with the environment. These activities are not currently regulated under the federal system. The Canadian Institutes of Health Research have guidelines for working with genetically modified organisms. Most research institutions — both public and private — also have their own codes of conduct and oversight committees for biotechnology research.

The Canadian Food Inspection Agency

Plants produced through biotechnology are examined under contained conditions. Those that look promising are then evaluated in research field trials under conditions of reproductive isolation. The conditions for confinement are mandated by the CFIA and were developed with the intention of severely restricting the interaction of the plant with the larger environment. This means that plants produced through biotechnology are grown under conditions aimed at preventing the transfer of pollen to other plants; they are monitored by the experimenter and CFIA field inspection staff; and the trial site is subject to post-harvest, land-use restrictions and further monitoring. 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*. Novel plants are typically evaluated in confined field trials over a number of years. Those that appear to have commercial promise are then subject to environmental, livestock feed and human food safety assessments before being granted approval to enter the marketplace.

No plant produced through biotechnology can be grown outside confined field trials unless it has been assessed by the CFIA. CFIA science evaluators 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 its biology as well as its environmental impact. Plants produced through biotechnology are compared with their conventional counterparts to see if the new trait(s) they contain have changed the plant's environmental influence. For example, the consequence of gene flow from a novel plant to other species, its impact on non-target organisms and on biodiversity are among the environmental criteria that are assessed, as described in Regulatory Directive 94-08: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*. An authorization for an unconfined release is granted only when the CFIA has determined that any environmental risks associated with the release of any novel plant are acceptable and/or manageable.

The CFIA also regulates plants produced through biotechnology as well as their by-products used in experimental animal feeding trials, and 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 stability of the novel feed, its environmental fate and a determination of whether the gene products and by-products of the feed will reach the human food chain. Novel feeds cannot be used unless duly assessed and authorized by the CFIA.

Canada has a system of variety registration for newly developed crop varieties designed to ensure that only those varieties with proven merit are sold. Varieties are assessed in regional field trials, and

those selected and supported by national recommending committees move forward for registration. In addition to meeting the standard requirements for variety registration, plant varieties produced through biotechnology cannot be registered and sold in Canada until they have the necessary environmental, livestock feed and food safety authorizations.

Health Canada

Health Canada is solely responsible for assessing the human health safety of foods, including GM foods and other novel foods, and for allowing them to be sold in Canada. It is responsible for the *Food and Drugs Act* provisions that relate to public health, safety and nutrition; for establishing policies and standards for the safety and nutritional quality of food sold in Canada; and for assessing the effectiveness of CFIA activities related to food safety (e.g. 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, seeks to establish the relative safety of the new food product such that there is a 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 defined differences inherent in the new food and requires a critical assessment of molecular, compositional, toxicological and nutritional data. Concerns related to 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 into a comprehensive report, which is subject to a review by an oversight committee.

Approvals of GM crops or foods are eventually published in summary form by the CFIA and Health Canada and can be accessed on their respective Web pages. 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 Regulations and for performing environmental risk assessments of substances to determine if they are toxic, as defined under CEPA. The regulations cover organisms and microorganisms that may have been produced through biotechnology. The New Substances Notification (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 prior to their import into or manufacture in Canada. 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.

The NSN Regulations under CEPA, 1999 ensure regulatory oversight of new substances for uses that are not regulated under any other federal act and regulations. They provide for notice and assessment of potentially adverse effects on the environment and human health prior to manufacture, import or sale.

The Department of Fisheries and Oceans is currently developing draft regulations on transgenic aquatic organisms. Until these are in force, any application for the environmental release of transgenic fish is assessed under CEPA. There have been no such applications to date.

International Aspects of Regulation

There currently are nine international bodies vying to contribute to the coordination and regulation of products of biotechnology. Conceptually they represent a progression from institutions that are largely science-based (the International Plant Protection Convention, the International Office of Epizootics, Codex Alimentarius and the World Health Organization) to ones that have broader objectives such as food security, trade facilitation, environmental protection, and other social and political goals (the Food and Agricultural Organization, the Organisation for Economic Co-operation and Development, various bilateral and regional initiatives, the World Trade Organization and the nascent Cartagena Protocol on Biosafety). The science-based organizations mostly seek to contribute to the development of standards and procedures for identifying and assessing the risks of GM foods, while the broader-based organizations concentrate on developing international consensus on the procedures for coordinating assessments, adjudicating disputes and building mechanisms to distribute the benefits of new products. Canada is a significant actor in all of the entities, at times leading the efforts to develop international consensus and contributing very positively to the development of science, governance or policy.

Since the first authorization of a novel food in 1994, 50 novel foods to date have been approved for commercialization in Canada, and 43 plants with novel traits have been authorized for environmental release. Without exception, all GM foods approved in Canada to date have been the result of incorporating or selecting for one or two simple single-gene traits into plants. Most of these traits involve resistance to insects and/or viruses or tolerance to a range of herbicides, and were designed to be comparable in composition and nutritional quality with their traditional counterparts.

Implications of Future Foods for the Food Regulatory System

It is expected that over the coming years there will be a newer "second generation" of GM foods proposed for market introduction. These foods are described in detail in Annex E of this report, and some of their implications are reviewed here.

Plant biotechnology products under development will present an increased range of novel traits and complexity relative to GM foods that have been commercialized to date, which primarily involve single-gene insertions. The introduction of multi-gene traits that either produce entirely new metabolic pathways or significantly alter existing ones 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), which can give rise to toxic effects if ingested in sufficient quantities.[8] 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.

[8] 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.

A key limitation to a targeted approach for assessing truly unanticipated consequences is that it relies on prior knowledge of what to measure, and that it can reveal such effects only if they are anticipated or occur by chance. 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.[9] While promising, none of these metabolic profiling methods is sufficiently well advanced and validated to be routinely included in a food safety assessment at the present time.

Although there have been 50 novel foods approved for use in Canada as of July 2001, these foods represent a narrow range of traits characterized by the expression of a small number of new or modified proteins. 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, which 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 a source of allergenic reaction 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 introduced novel 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 non-allergens (for example, if they have no sequence similarity to known allergens) and also of allergens (for example, if they are stable to digestion). In order to 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 in order to ensure that these products do not enter the human or livestock food chains. This raises the questions of whether such plants should ever be grown outside contained facilities, or whether segregation systems can effectively ensure adequate separation.

Although the Canadian food regulatory system has a number of strengths, many — including CBAC — believe that the system should be further refined. The evolution of the system should reflect current trends for information and public involvement, features that are desired by many in relation to the foods currently being brought forth for approval. More importantly, however, refinements such as these should be applied prior to the time when the system will be used to assess and make judgments on the acceptability of the newer and more complex second-generation GM foods.

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

The Ethical Context

CBAC views **the primacy of the public interest** as the primary criterion for the development of sound government policies and programs. The public interest comprises, for instance, the health of Canadian citizens, the quality of life of Canadians, the health of the environment, the prosperity of the Canadian economy and a sustainable, peaceful global community. The primacy of the public interest calls for good governance, which in turn requires integrity and transparency of operations, independence from inappropriate influence, openness to the views of Canadians, responsiveness to their concerns and effective integration of the diversity of interests and priorities of the people of Canada.

CBAC believes that public policy recommendations ought to be formulated in this ethical context. As described by Thomas Hurka, ethical judgments are not "stand-alone" judgments; rather, they are "all things considered" judgments that take into account economic, political, legal, scientific and other factors.[10] CBAC's task in developing recommendations on biotechnology is to integrate these various factors and to develop a set of recommendations that best serve the greater good and overall public interest.

To reflect its commitment to serving the public interest and supporting good governance, CBAC identified the following **ethical principles and values** for its initial consultations and discussions with Canadians during the winter of 2001. The Committee outlined these principles and values in its Consultation Document and presented them to participants of the GM foods multi-stakeholder workshops in Phase 2 in order to initiate discussion of the kinds of parameters that should guide regulatory systems and policy decisions regarding GM foods.

The feedback received to date on principles and values is summarized in Annex C. The concept of having parameters to guide regulatory systems and policy decisions in relation to GM foods — whether they are values, principles, or other statements of what matters most to Canadians when it comes to how GM foods are handled by government — is central to CBAC's work. CBAC believes that the recommendations it makes to government must be firmly embedded in what really matters to Canadians. In its continuing work during Phase 3 of the GM foods project, CBAC will endeavour to ensure that this goal is achieved.

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 informed choice. A commitment to promote the conditions necessary to allow Canadians to pursue their fundamental values and interests.*
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.*

[10] M. MacDonald, *Biotechnology, Ethics and Government: A Synthesis* (Ottawa: CBAC).

Key Issues Related to the Regulation of GM Foods

During the course of its issue analysis, CBAC identified ten key issues regarding the regulation of GM foods. These issues, grouped under three broad themes as shown below, formed the basis of the Consultation Document and, with a slightly different thematic grouping, they provided the focus for discussions during CBAC's multi-stakeholder workshops.

These ten issues have been carried forward to this Interim Report as well. In the following pages, the key challenges identified in relation to each issue and the options originally put forth by CBAC in the Consultation Document are outlined, and international approaches to the issue are presented. Following the discussion of each issue in a theme, CBAC presents its draft recommendations in relation to that theme. It is CBAC's view that, taken together, these recommendations contribute to a more accountable, knowledge-based and cautious food regulatory system.

Quite purposefully, this Interim Report has focussed on Canada's food regulatory system through the lens of GM foods. CBAC recognizes, however, that many of the issues which have arisen as a consequence of the current debate on GM foods are not unique to GM foods but apply to the regulation of novel foods and potentially to other elements of the food regulatory system as well as other areas of public policy.

As part of its research into these issues, CBAC commissioned several reports that may be consulted for additional information and perspectives. Bibliographies of CBAC's commissioned reports, other companion documents consulted by CBAC, and CBAC publications on GM foods are contained in Annex B. This includes three reports summarizing the input and views of Canadians taken into account in the preparation of the enclosed draft recommendations, namely:

- *Summary Consultation Report — Workshops on Genetically Modified Food*
- *Summary Consultation Report — Written Input on Genetically Modified Food*
- *Secondary Analysis of Public Opinion Research — GM Foods.*

Copies of these reports and publications are available on-line at **www.cbac-cccb.ca**, or through CBAC's toll-free number at 1-866-748-2222; TTY/ATS: 1-866-835-5380.

Themes	Issues
Good governance	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 and choice	Information provision Labelling
Social and ethical considerations	Environmental stewardship Broader social and ethical considerations

Theme 1: Good Governance

As indicated, CBAC views **the primacy of the public interest** as the primary criterion for the development of sound government policies and programs. The primacy of the public interest calls for good governance, which in turn requires integrity and transparency of operations, independence from inappropriate influence, openness to the views of Canadians, responsiveness to their concerns, and effective integration of the diversity of interests and priorities of the people of Canada. CBAC has analysed six specific issues in the context of good governance and has developed three broad recommendations aimed at maintaining the federal regulatory system's current strengths, while enhancing a number of features that define how it works to serve Canadians.

Issue 1 — Transparency

What This Issue Is About

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. Transparency is essential in fostering people's trust in their public institutions and, as such, is a key element of good governance.

Responsible transparency may also require a balance between openness, confidentiality of certain information, and excess information.

In the context of GM foods, the debate on transparency focusses on the government being open and accountable for decisions made as well as sharing information on its risk assessments and decision-making processes, including the scientific data on which they are based, as well as the conclusions and decisions that have been reached.

Health Canada and CFIA provide information on various aspects of the regulatory system, including those pertaining to GM foods, through the Internet, in publications, and in public presentations. Environment Canada and Industry Canada also make biotechnology information available. The recently created BRAVO is a Web site that provides information on all regulatory requirements for biotechnology products.[11]

The question of commercial secrecy also arises in the debate over the government's transparency. The desire of companies to maintain the confidentiality of data or information that they consider "commercially sensitive" has some impact on the degree of detail the regulator can provide in communicating information to the public. It also raises the question of who should determine what is commercially sensitive information.[12]

Some of the Challenges Identified

There is a lack of clear and readily available information for Canadians on key features of the food regulatory system for GM and other novel foods. The shortfall includes the activities of the various government bodies involved in regulating foods, how decisions are made to allow a novel product onto the Canadian market, and what information is considered by the government during this process. CFIA and Health Canada have been criticized for not effectively communicating their roles regarding the regulation of GM foods. In fact, CBAC was unable to locate what it considered to be a clear description of the steps that new GM and other novel foods follow as they progress through the regulatory system.

[11] Further information is available at the following Web sites: Health Canada (**http://www.hc-sc.gc.ca/english/food.html#novel**); Canadian Food Inspection Agency (**http://www.inspection.gc.ca/english/toc/bioteche.html**); Environment Canada (**http://www.ec.gc.ca**); Industry Canada (**http://bravo.ic.gc.ca**).

[12] Ibid.

Some of the following information related to GM and other novel foods is not fully communicated at this time, although Canadians have expressed an interest in having access to it:

- Detailed information related to government assessments, particularly the technical health and safety information.
- The data evaluated by government risk assessors. This information is generally considered commercially confidential; that is, belonging to the company that submitted it.
- The list of products currently undergoing review.
- Full information on tests conducted on GM and other novel crops in the field prior to the product's approval. Lacking are complete data on the product being tested and details on locations of the tests.
- Summaries of decisions regarding a product's approval. These documents briefly describe the product's characteristics, the safety issues addressed by the developer and the rationale for the regulatory decision. While these are published, it can often take a year or more, and there is no clear reason for the delay.

With regard to the question of whether a company's technical information on its products can and should remain confidential, regulatory officials often refer to legal limitations related to releasing third-party information, such as those in the *Access to Information Act*, as the reason for not sharing test data on a product.

Another challenge concerns what appears to be a lack of standardized procedures for dealing with certain situations such as how to resolve differences of opinion that might arise internally between regulatory officials, or between regulatory officials and the companies requesting approval of a new GM or other novel product. This can raise questions about the fairness of the system — how decisions are really made — and could potentially undermine public confidence in the government's regulatory bodies.

Some of the Options Considered

The following ideas were among those originally put forth by CBAC to discuss possible solutions to this issue.

Improving communications concerning the regulatory system: The government could develop and make readily accessible information that is, easy to understand, with diagrams or decision trees, about the regulatory bodies and respective laws as well as the steps and criteria involved as a GM or other novel product moves through the regulatory system.

Developing formal processes: Regulatory bodies could develop more formal processes for various aspects of their operations related to GM and other novel foods, such as procedures for dealing with differences of opinion that occur internally or between regulatory officers and the product's proponent. This would help make the system's operations more transparent.

Communicating product decisions and supporting data: CFIA and Health Canada could publish decision summaries either upon a product's approval or in advance in draft form (see below *Issue 4 — Opportunities for Public Involvement*). They could also adopt a pre-notification system listing the GM and novel products currently under review.

Several options exist regarding the broader disclosure of information related to product safety studies of GM and other novel foods (and any requests for data that underlie the decision document). Government could release this information because it believes it to be overwhelmingly in the public interest. It could seek to secure agreement from the developer to release portions or summaries of the data. Or it could undertake its own environmental and/or human

health and safety testing and release the results. Criteria could be developed so that companies could ask to be excluded from releasing the data when they feel that the disclosure would significantly affect their business competitiveness.

Revealing the location of regulated field tests: The two most basic options regarding revealing the location of field tests of GM and other novel crops are disclosure, which is more compatible with transparency, and non-disclosure, which is more respectful of the grower who risks possible acts of vandalism, even though government permission has been obtained and laws are being followed. A third option is to continue the *status quo* whereby regulatory agencies provide general information upon request, such as the number of trials taking place and the region, but not the specific location in which they are occurring. The government could also consider developing criteria for requesting and authorizing full disclosure or non-disclosure, as the case may be. This would allow requests for departing from the default policy. The criteria would assist in their being considered carefully, consistently and on transparent grounds.

International Approaches to This Issue

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, have established systems that require both public notification and an opportunity for public comments prior to a final regulatory decision on GM foods. In Australia, the pre-notification process applies to confined field trial applications (i.e. field research tests), applications for general environmental release (i.e. equivalent to the application for unconfined release in Canada) 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, properties of newly expressed proteins, nutritional quality, and the potential for toxic or allergenic effects associated with GM foods.

In 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 (FDA) voluntary consultation process with industry. This latter situation will be affected by the FDA's recently proposed rule[13] requiring that developers submit a scientific and regulatory assessment of the bioengineered food 120 days prior to marketing. In the proposed rule, the FDA announced its intention to increase the transparency of the process by which it evaluates foods derived through biotechnology. For example, under the proposal, 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 45 voluntary industry consultations regarding GM foods and has recently published information on the relevant safety and nutritional issues for each of these products.[14]

In February of this year, the European Parliament adopted a new directive concerning the deliberate environmental release of genetically modified organisms (GMOs). This new directive, 2001/18/EC, repeals the previous Council Directive 90/220/EEC and among other changes makes new provisions for increased transparency. These changes establish a mandatory requirement for public notification, including the release of assessment reports, and a period of public comment prior to the conduct of research field trials and the granting of market approval for a GMO. While respecting the principle

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

[14] U.S. Food and Drug Administration, "List of completed consultations on bioengineered foods": **http://vm.cfsan.fda.gov/~lrd/biocon.html**

of protection of confidential business information, the new directive specifically excludes from such protection information pertaining to a general description of the GMO, name and address of the notifier, purpose of the release, location of the release, methods and plans for monitoring of the GMO, and the environmental risk assessment.

Issue 2 — Separation and Independence of Regulatory Functions

What This Issue Is About

The federal government has several responsibilities related to biotechnology and food. These include: regulation; scientific research in support of basic scientific knowledge, regulation and risk analysis; policy development and law making (domestically and internationally); facilitating the responsible use of biotechnology; industry and trade promotion; developing new agricultural crops and practices to support domestic food production; and informing people about government roles, policy decisions and risk. A critical consideration is how the government can fulfil these diverse obligations and ensure that regulatory functions are not unduly influenced by economic or market development pressures.

Some of the Challenges Identified

While Health Canada, Environment Canada, the CFIA, and Fisheries and Oceans Canada (with the preparation of their new regulations) all play roles in the regulatory regime, most of the discussion concerning the separation and independence of regulatory functions has focussed on the CFIA.

The CFIA is responsible for regulating GM crops, plants, animals, feeds, fertilizers and veterinary biology. Agriculture and Agri-Food Canada is responsible for promoting agricultural technologies that improve Canadian competitiveness and international trade in agricultural commodities produced in Canada, including GM foods. Both the CFIA and Agriculture and Agri-Food Canada report to the Minister of Agriculture. This means that, although the two government organizations are separate, they report to Parliament through one Minister. Some people suggest that this could create a real or perceived conflict of interest. They suggest that the government's regulatory functions should be completely separate from its promotional activities and from the political process. Others emphasize that the CFIA and Agriculture and Agri-Food Canada are separate entities, and that Agriculture and Agri-Food Canada has no authority or influence over the CFIA's regulatory decisions.

This is also a communications issue in that the government may not always make clear to Canadians the separation and independence of its regulatory and promotional activities, and how potential mandate conflicts are dealt with. As well, those who regulate appeared to some to promote rather than provide unbiased information about GM foods. While these materials may have been intended to impartially inform Canadians, they may instead have undermined the government's credibility as a neutral evaluator and regulator of food and other products of the technology.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

New reporting relationships: Some suggest changing departmental/agency reporting relationships so that CFIA reports to the Minister of Health, or to a separate Minister or to Parliament directly.

Standardize procedures: As discussed above under Issue 1 — Transparency, government regulatory bodies could further standardize their internal procedures, which would help alleviate questions about how government works.

Better public information: Government regulatory bodies could provide better information both on the

regulatory system in general and on specific aspects of it, such as how their functions are distinct from other government activities and how the integrity of their assessments and decisions is maintained.

Education program: Recognizing that there is a need for the government to provide Canadians with information and educational materials about the foods sold in Canada, some think it is essential for communications of this nature to be part of a broader, systematic educational program that informs on a range of food (including GM and novel food) technologies. One might also consider whether this task should be the responsibility of regulatory or non-regulatory government bodies.

International Approaches to This Issue

The regulation of GM foods within departments and agencies with both promotional and regulatory responsibilities is not unusual. In the United States for example, the Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the environmental release of bioengineered crops, while the Agricultural Research Service (ARS) within USDA engages in technology promotion. The USDA-ARS, like the Research Branch of Agriculture and Agri-Food Canada, has a mandate to undertake basic agricultural research, including the development of new biotechnologies, and to facilitate the transfer of its technologies to the private sector. Separation of the roles of APHIS and ARS is achieved through institutional codes of conduct and, more importantly, through a transparent product review and approval process.

The United Kingdom has taken a different approach by establishing an independent scientific committee to review all applications for the environmental release of a GM organism (GMO). The Advisory Committee on Releases to the Environment assesses the potential implications of proposed GMO products, including potential allergens and toxins and possible environmental impacts. The committee then advises the Minister of the Environment on whether or not approval should be granted. Because the committee is independent of government, it is inherently separate from any promotional activities related to biotechnology that the government undertakes.

Issue 3 — Ensuring Safety During Research and Development Activities

What This Issue Is About

This issue concerns the possible need to establish standards and/or regulations to ensure that all research programs, from their earliest stages, are conducted in a way that minimizes any negative impacts on health or the environment. Within research laboratories, the early stages of research and development leading to production of GM foods do not fall within the regulatory mandate of Health Canada or the CFIA. Moreover, the existing guidelines and standards are generally not legally binding and may not capture all research programs.

Among the guidelines that currently exist to ensure health and safety are the *Laboratory Biosafety Guidelines and Guidelines for the Handling of Recombinant DNA Molecules* and *Animal Viruses and Cells*. They were initially established by the Medical Research Council and adopted by the Canadian Institutes for Health Research (CIHR), and they apply to work with genetically modified organisms. Internationally recognized standards for *Good Laboratory Practice* are also commonly applied, as are the codes of practice established by research institutions. Federal funding agencies such as the CIHR, the Natural Sciences and Engineering Research Council and the National Research Council require adherence to these guidelines, and university or institutional biosafety committees monitor laboratories' compliance.

Some of the Challenges Identified

Some are concerned that early research and development may not always follow measures to minimize possible adverse impacts on health or the environment. Others are concerned that, where measures are applied, it is unclear **which** methodologies and safeguards have been used. A third concern is that the degree to which researchers comply with the guidelines is not always clear, and that the means of ensuring compliance may not be sufficient if the guidelines are not entrenched in law.

Some also believe that further regulation of this technology will make it more difficult for small companies and university researchers to develop new products. Some point out the lack of evidence demonstrating that current research and development activities have resulted in harm to human health or the environment, and suggest that no additional regulatory requirements are needed.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Develop and implement standard: One option is to develop a single, performance-based standard for recombinant DNA experimentation that minimizes human health and environmental concerns. The standard could remain voluntary, or specific legislation and regulations could be created. Such regulations could be absolute or could permit exemptions on a case-by-case basis for specific facilities or low-risk activities, or for other approaches that meet the standard.

International Approaches to This Issue

In the United States, the National Institutes of Health (NIH) within the Department of Health and Human Services plays a role analogous to that of the CIHR. It has published biosafety guidelines, in place since 1976. These guidelines are similar in intent and implementation as those published in Canada by the CIHR, and describe safety protocols that must be adhered to by government and university researchers. The United States is also examining the issue of potential problems associated with the waste stream from labs. Some countries such as Argentina, Australia and the United Kingdom have addressed laboratory biosafety issues through regulation and have provided a mechanism for some level of review of all experimentation involving genetic manipulation and genetically modified organisms. Even in these countries, research involving the genetic modification of higher plants is treated as low risk, with exemptions or minimal review requirements for many types of experimentation.

Currently in Canada, neither the regulatory system nor the voluntary CIHR guidelines specifically provide standards covering the greenhouse propagation of GM crops. The first point of contact with the regulatory system is upon application to grow GM crops out-of-doors in confined field trials (e.g. research test plots).

Issue 4 — Opportunities for Public Involvement

What This Issue Is About

Opportunities exist for Canadians to express their views on some aspects of the regulatory system. An example is on regulations that are being amended or developed and on policy matters related to the regulatory system. However, similar opportunities do not exist when novel foods or plants with novel traits are approved. Canada's regulatory regime does not provide opportunities for individual Canadians to comment on the risk assessment of a specific GM food. These discussions are generally held between the government risk assessors and the company or

individual seeking approval, with no formal opportunities for external scientific bodies, individual experts, the public or others to contribute.

Some of the Challenges Identified

Some consider the lack of opportunity for public input into individual regulatory decisions on GM and other novel foods to be a weakness of the system. It excludes to some degree the thorough consideration of relevant knowledge and views, and therefore hinders the transparency of the system. Others believe that the decisions warrant the public's confidence without additional input, as all reviews are conducted and the decisions are made by independent government regulators using assessment methods established with public input that integrate internationally accepted approaches.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Releasing documents before decisions are made: As mentioned in the discussion on transparency, both Health Canada and CFIA publish decision summaries explaining GM and other novel food regulatory decisions and the scientific rationale behind them, but do so too late for public comment. To allow individuals to express their views, preliminary decision documents could be produced and released before the final decision is made and serve as the basis for soliciting comments for a given period (for instance, 30 or 60 days). These comments would then be taken into account in the final decision.

This approach is used in the registration of new pesticide active ingredients under the *Pest Control Products Act* and for 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 of the product safety data approved by the proponent. Canadians may comment on the proposed decision for 45 days, after which PMRA publishes a final decision document that includes its consideration of the comments received.

Maintain status quo: Another option is to maintain the current status, with input on the development of policies and legal requirements but not on individual decisions.

International Approaches to This Issue

This issue is twinned with the earlier discussion on transparency of the regulatory decision-making process. Generally, a hallmark of regulatory systems that afford high levels of openness and information disclosure is the existence of some mechanism for soliciting and taking into consideration the views of ordinary citizens. For example, both U.S. and Australian legislation requires environmental reviews of GM crops to allow for a period of public comment. In Australia, a food safety review must also be performed. Aside from meeting a legal requirement, it is the view of many that allowing for public input provides an additional avenue for considering other sources of safety-related information (e.g. individuals, scientific societies, other stakeholders) and promotes confidence in the risk assessment process.

As mentioned already, changes proposed by the FDA in the United States, as well as provisions within the recently approved European Parliament Directive 2001/18/EC governing environmental release of GMOs, provide new opportunities for public input in these jurisdictions.

Issue 5 — Post-market Monitoring for Risks and Benefits

What This Issue Is About

Post-market monitoring for potential long-term health or environmental impacts of GM foods is dictated by caution. The need for specific post-market conditions or monitoring activities is considered during pre-market safety assessments, and currently this applies only to *Bt* crops.[15] In Canada, as in most other countries, the responsibility for post-market surveillance rests with the developer. The developer is expected to monitor for existing and emerging risks and to notify the regulatory authorities if new information is uncovered.

Under the current system, GM and other novel foods that have received pre-market safety assessment and regulatory approval are not routinely subject to post-market surveillance to monitor for long-term health and environmental consequences. Part of the rationale appears to be that pre-market safety assessment should provide assurance that GM foods are as safe as their conventional counterparts, and that there is limited knowledge about the long-term effects of any conventional food, let alone GM foods.

Some future novel foods (including GM foods), such as those with significant nutritional changes, could require post-market monitoring to confirm some of the hypotheses formulated in the safety assessment (for example, to ensure that the safe limit of intake of nutrients is not exceeded). Given the increasing complexity of GM plants and foods expected, more elaborate and broadly applied measures and programs for post-market monitoring and review are considered necessary by many.

Some of the Challenges Identified

CFIA has put in place a mandatory stewardship program for varieties of GM corn engineered for resistance to European corn borer (ECB), which have been commercialized and are now widely grown. On the basis of the assessment conducted, a resistance management plan (RMP) was designed to delay development of *Bt*-resistant insects. Authorization of *Bt* corn in Canada requires the implementation of this RMP. It is the responsibility of the developers of *Bt* corn to make certain that corn growers implement the RMP. However, it is unclear whether sufficient auditing or monitoring takes place to evaluate compliance with the RMP or to assess the adequacy of the special conditions.

GM crops tolerant to the herbicides glyphosate and glufosinate ammonium are the most popular GM crops grown in Canada. CFIA recommends that agricultural extension personnel, in both the private and public sectors, promote careful management practices for growers who use these herbicide-tolerant crops in order to minimize the development of multiple resistances. Nevertheless, GM canola plants have been found with resistance to two or three different herbicides. While these plants can be controlled cheaply and effectively with existing techniques, it may be that the appropriate practices are not being followed. There is no formalized post-market monitoring of this environmental concern. The responsibility of the developers of this technology to ensure that stewardship programs are taken seriously is unclear.

Some are concerned that the government does not have ways to easily identify or trace GM foods in the marketplace or to measure food consumption patterns. Because of the wide genetic variability in human populations, the evolution of dietary patterns over time and the difficulty in identifying GM foods consumed, epidemiological studies have difficulty in pinpointing legitimate adverse effects associated with the consumption of GM or other foods.

[15] *Bt* is short for *Bacillus thuringiensis*, a common soil bacterium that produces a protein toxic to certain species of insect larvae. *Bt* crops, such as *Bt* corn, have been genetically engineered to produce this *Bt* protein in certain parts of the plant such as the leaves, which allows the plant to resist damage from these insects.

Moreover, Canada does not have food consumption monitoring programs nor does it have population-based health surveillance programs linked to the long-term impacts of foods.

Canada does not have post-market data on aspects such as sales, use and exports or imports of specific GM or other foods, crops or seeds. This lack makes it difficult to estimate the significance of GM foods in the Canadian diet or economy. Some believe this is important information, while others argue it is not necessary, if GM products are considered comparable with traditional products.

The regulatory system provides for *ad hoc* reviews of new data regarding previously registered products and reconsideration of earlier regulatory decisions. For this purpose, new information can be submitted to CFIA or Health Canada at any time by the developer or other parties. (In some cases, this information is required by law.) The review of new data generally occurs when significant new information has been brought to the attention of the regulators. The system does not require systematic follow-up reviews of all approvals, nor does it provide formal opportunities for regulators to identify, retrieve and review new information on a previously approved product. The system also does not issue invitations to research institutes or academia to submit additional information that might be relevant to the safety of a previously reviewed food or crop. Some believe these elements of a regulatory program would be useful in ensuring that new scientific studies are carefully considered by regulators, and that this would help ensure that products on the market continue to meet current standards, even if their approvals were given several years earlier.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Detection methodologies: The approval of new GM foods, GM crops and other plants with novel traits could require the developer to provide acceptable detection methods for the novel traits or genetic material. This would facilitate post-market detection, monitoring and reporting.

Auditing for conditions applied for environmental safety: For foods and products regulated by the government and approved for sale in Canada but with specific conditions imposed in relation to their safe production (for example, buffer zones around *Bt* corn), operating and publishing audits for compliance with these conditions could be considered.

Environmental and health impacts monitoring: Designing, supporting and conducting additional projects for the detailed, long-term study of health and environmental impacts associated with GM foods/crops could be considered. These could be aimed at increasing the evidence of actual benefits (e.g. decreased pesticide use and groundwater levels of specific chemicals) and adverse effects (e.g. gene transfer and effects in non-target populations), and at determining the conditions or circumstances in which benefits can be increased and risks minimized. Likewise, given that the precise locations of many field trials on GM foods are known to regulatory bodies, a program could be designed for the long-term, follow-up monitoring of field test sites for evidence of impacts, benefits or harms associated with the planting of GM crops.

Food consumption data: Consideration could be given to introducing a program for the monitoring of GM food consumption to provide information on GM food intake by various population groups. As much as possible, it could build on existing efforts for gathering food consumption data more broadly. The program would likely require detailed data on GM and non-GM crop production and imported foods, as well as a mathematical integration model for analysis of the information.

Post-market reports: The private sector could be asked to report annually on one or more of usage, sales, export and/or import data. In conjunction with this, and using the information submitted, Canadian regulatory bodies could publish annual situation reports covering GM and non-GM foods.

Reconsideration of approvals: The government could formalize a process for the periodic reconsideration or reassessment of the safety of GM and other novel foods and crops previously approved for sale in Canada. The intent of this process would be to ensure systematic consideration of any new and relevant information generated following approval of the product. It could be put into operation by using approvals that are time limited and renewed only on reassessment of the product using information from multiple sources, along with confirmation that it still meets the standards and criteria for health and environmental safety.

International Approaches to This Issue

Although some countries have in place systems for food consumption surveillance, a systematic surveillance program for monitoring the long-term population health effects of GM foods does not exist in any country. The regulatory system of countries such as Australia, Japan and the United States is based on the premise that pre-market safety assessment provides assurance that GM foods are just as safe as their conventional counterparts, thus obviating the need for post-approval monitoring. Generally, the responsibility for post-market surveillance is covered by an ongoing duty of care on the part of the developer. This obligation is expressed in Canadian regulations under a "new information" clause, which is similar in intent to that present in the recently approved European Union directive on environmental release of GMOs, which requires developers — or indeed any party — to notify the regulatory body if they become aware of any new information that impacts on human health or environmental safety.

The European Union, in its revised environmental release directive, is now 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.

Issue 6 — Capability and Capacity in the Regulatory System

What This Issue Is About

This issue concerns the extent to which Canada's regulatory system can keep pace with current and future challenges, particularly in terms of trained regulatory and scientific personnel. Science is quickly changing the nature of new foods, and change in turn introduces new scientific challenges for the regulatory system. Government scientists and regulators must have the necessary breadth and depth of expertise to address these events.

Some of the Challenges Identified

As the science involved in the production of GM crops and foods advances, and as the products themselves become more complex, the scientific expertise available to the regulatory system must evolve commensurately. Government experts must have the same level of expertise as their counterparts in the private sector and universities. A critical mass of competent evaluators is required for a credible, effective and efficient regulatory system. The government must also be able to have access to outside expertise when necessary. Outside assistance may be required, for example, when specific expertise is not available in-house, when a product is of significant public interest or when the work load is particularly high. The current level of resources in

Canada's regulatory system may not be sufficient to meet growing needs, and the internal *modus operandi* may not support a **systematic** reliance on outside expertise when and where needed.

To attract and retain highly skilled regulatory and scientific employees, government bodies must provide opportunities for them to continuously upgrade their knowledge and skills. The competition for expertise is particularly strong in those disciplines that have personnel shortages. These shortages are due in part to insufficient investment in the training of graduate students; these experts-in-training are critical for meeting the future needs of regulatory agencies.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Outside expertise: CFIA and Health Canada could increase their use of *ad hoc* expert panel consultations, perhaps putting in place procedures and mechanisms to facilitate the formal, regular, transparent use of such outside expertise. The procedures could outline, for instance, when and under what circumstances outside experts are used, the acceptable range of roles and degrees of information access, how the individual(s) would be selected and the practical aspects of engaging them. Both the in-house training and the contracting of outside experts will require additional funding. Another source of external expertise involves international initiatives (for example, international data sharing and joint reviews) and the further harmonization of international assessment approaches.

Long-term planning: Attention could be focussed on developing a better understanding of the specific types of GM foods likely to enter the regulatory system in coming years. Forecasting studies could also be used to better predict future regulatory needs and how to evolve and prepare for them. As well, regulatory bodies could periodically examine their procedures, capabilities and expertise relative to what they know about the next generation of GM products.

Increased research, knowledge transfer: Government could increase its investment in research that supports regulatory risk assessment and decision making. This would improve the scientific community's knowledge base in disciplines essential to the evaluation of the health and environmental safety of GM crops and foods. Hand in hand with this would be the development of clear mechanisms to transfer new knowledge from the scientific community to regulatory scientists.

International Approaches to This Issue

In Canada, Japan and the United States, government scientists and professionals working within the respective regulatory authorities are responsible for carrying out the risk assessments of GM food crops for livestock feed, food safety and environmental release. This is also true for the safety evaluations of GM foods performed by the Australia New Zealand Food Authority. Alternatively, Argentina, the United Kingdom and Australia (in the case of environmental assessment) have employed, either exclusively or in part, a review system in which scientific advisory committees are responsible for evaluating applications and providing advice to Ministers.

Draft Recommendations Regarding Good Governance

1. Structure, Organization and Operation of the Federal Food Regulatory System

Observations: *The federal food regulatory system relies on a number of regulatory bodies, some being more active on issues pertaining to GM and other novel foods 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. Health Canada and the Canadian Food Inspection Agency (CFIA) function more closely than other parts of the system, but coordination with the*

other parts appears weak. There is no individual leader or spokesperson for food safety matters at the federal level for either GM and other novel foods or for food in general. GM and other novel foods are currently a small part of the overall food safety systems, but this may change in the near future. The degree to which the regulatory function remains independent from the government's promotional activities is not clearly described.

Draft 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 clarify 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.*

Specifically, we recommend the following measures:

1.1 Appointing a chief safety officer for GM and other novel foods. This person will become the focal point and spokesperson on all federal GM and other novel food safety matters — related to human health as well as environmental safety — and will coordinate activities of the individual regulatory bodies. This officer will chair a new assistant deputy minister (ADM) committee on GM and other novel food safety (see below). This person will be appointed *ex officio* member of all rulings committees operated by regulatory bodies within the food regulatory system.

1.2 Establishing a committee at the ADM level to oversee GM and other novel food safety regulation for Canada. Representatives from federal regulatory bodies will be involved in the assessment and approval/registration of products of biotechnology and related inspection and enforcement activities (at a minimum, Health Canada, the Canadian Food Inspection Agency, Environment Canada, and Fisheries and Oceans Canada). The committee's responsibilities will include ensuring effective interdepartmental and interagency coordination and communication, comprehensive regulatory coverage, and planning and analysis activities. Specific functions would address:

- Coordination and communication of product assessments as well as proposed and final regulatory decisions.
- Coordination of communication activities and tools aimed at external audiences.
- Elimination of gaps and counterproductive overlaps in the regulatory system.
- Evaluation of the adequacy of the existing guidelines covering experimentation involving recombinant DNA and other forms of genetic modification. This function should be pursued to determine the ability of existing guidelines to ensure health and environmental safety during research and development activities, the extent to which they are applied by researchers in public and private organizations, and whether further action, including greater regulatory scrutiny or a single national standard for research and development is needed to protect health and the environment.
- Management of the government's scientific and technical expertise. The aim would be to ensure that it is maintained and built up where necessary, and is adapted in anticipation of future regulatory needs, following periodic evaluation of new research findings and market trends.
- Preparation and publication of standard operating procedures to clearly describe the delegation of decision-making authority, the strategies in place to insulate officials from inappropriate influence, the procedures and rationale for engaging non-governmental experts and expert panels in regulatory

processes, the policies regarding the preparation of decision documents for public review prior to final decision making, and the details regarding rulings committees and other elements of internal reviews.

- Examination of opportunities for ongoing improvement of risk assessment and risk management activities, and of inspection and enforcement capacity in relation to more complex, newer generation products. This function should be conducted with a view to ensuring routine monitoring for compliance with conditions of approval associated with the production of plants with novel traits or novel foods.

1.3 Ensuring effective independence of regulatory functions from the industry and trade promotion functions of the federal government. CBAC recommends that the federal government carefully scrutinize its internal operations and relationships with stakeholders, and modify them where needed. All communications and communication materials should be assessed, and specific attention should be paid to the involvement of regulators in the negotiation of international policy and trade rules. These measures should be undertaken to ensure the highest degree of integrity and independence in the conduct of regulatory functions, to avoid exacerbating the perception of mandate conflict, and to ensure an appropriate role for regulatory officers in international activities. For those regulatory bodies that do not already have in place a standing committee through which all proposed decisions on GM foods and other novel foods must be vetted, CBAC considers it essential to establish one.

1.4 Having the Auditor General of Canada monitor and publicly report on regulatory bodies involved in assessments and decision making related to foods sold in Canada, with emphasis on the independence of regulatory functions, and the effectiveness of standard operating procedures.

2. Evaluation of Long-term Health and Environmental Impacts

Observations: *The federal government conducts research related to GM foods. Work is also under way internationally. However, a number of additional tools and programs are needed to effectively assess and anticipate long-term health and environmental impacts associated with GM and other novel food.*

Draft 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.*

This activity involves the following measures:

2.1 Requiring the inclusion of effective detection methodologies for transgenes as part of the application process for requesting approval of novel products.

2.2 Developing food consumption data in order to improve the risk assessment process. Providing a greater understanding of potential exposure to certain foods would assist in the identification of populations that may be at higher than normal risk and in monitoring for long-term effects of certain food consumption patterns.

2.3 Ensuring that new scientific or technical information is taken into account within a reasonable time frame. This objective could be achieved by including in product approvals a preset deadline before which a reassessment of any new information related to the product or otherwise relevant to its risk assessment is conducted.

2.4 Introducing a broad-based program of long-term research into GM organisms that are part of the human food chain. This task would improve our scientific knowledge of health and environmental harms as well as benefits of the products in question. Leadership should be shown in studying crops for which Canada is a global leader (e.g. canola, identity preserved soy, durum wheat, flax and malt barley). International collaboration and information sharing as well as programs for developing similar information on other novel foods are also recommended.

3. Transparency

Observations: *While there is a desire within the federal government to be more transparent in its regulatory functions, constraints (and possibly legal impediments) remain. There is insufficient emphasis on transparency. The communication of information related to the regulation of GM and other novel foods has not been highly effective.*

Draft 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.*

We recommend the following measures:

3.1 Continuing to involve the Canadian public in the development of laws, regulations, policies and programs related to the Canadian food regulatory system.

3.2 Improving information and communications about the federal food regulatory system. Decision trees could clearly describe the regulatory authorities, responsibility centres and relevant laws, activities, stages of risk assessments and decision processes, progression through the regulatory system, relevant time lines, mechanisms to resolve differences of opinion, and opportunities for public input at various stages.

3.3 Maintaining a readily accessible public record of the GM and other novel food products currently under review as well as the status of the assessment.

3.4 Communicating GM and other novel food risk assessments and proposed regulatory decisions systematically through published documents. This would include a 45-day comment period for public input on the proposal. This should be followed by a final decision document, amended as appropriate, based on the input received. These documents should cover, at a minimum, the following topics:

- identification of product
- description of development and production of the GM foods, plant, or ingredient
- methods of analysis/detection
- nutritional data
- description of information related to health hazards – end points evaluated, summary of test data and results, key conclusions regarding data package
- dietary exposure – explanation of assessment of potential exposure
- conclusions regarding impacts for human health
- description of information related to environmental traits and possible hazards – end points evaluated, summary of test data and results, key conclusions regarding data package
- fate and behaviour in the environment – explanation of assessment of potential environmental fate and behaviour (e.g. persistence, distribute, gene flow)
- conclusions regarding impacts on the environment
- impacts on sustainability.

3.5 Making publicly available the detailed scientific and technical data reviewed by the government in conducting human health and environmental safety assessments of GM foods and other novel foods. For this purpose, a review should be conducted to ensure an accurate interpretation of existing provisions in the *Access to Information Act*. As well, consideration should be given to any necessary amendments to applicable laws and regulations. The disclosure requirements should not, however, include details such as how to construct and manufacture the product, as this could significantly jeopardize a company's competitiveness. Furthermore:

- The information should be available for products sold in Canada and for products being proposed for market approval.
- Existing provisions in the *Access to Information Act* should not be viewed as requiring the government to keep confidential any technical or scientific data that have not been kept strictly confidential by the owner of the data (e.g. if the data have been made public or are available to the public as a result of the product being approved in another country).
- Consideration should be given to any necessary amendments to applicable laws and regulations in order to allow the release of the data.

3.6 Re-examining pollen drift and reassessing the buffer zones currently applied to field studies of GM crops and other plants with novel traits. Information on pollen drift should be required in all submissions for approval of plants with novel traits. Growers within five kilometres of a field study involving GM crops should have access to more detailed information, on request, in order to protect 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 because of the risk of damage through vandalism. Further study is needed to better understand the characteristics and risks associated with GM products.

3.7 Publishing, on an annual basis, information on government inspection programs, findings related to compliance with measures concerning GM products, the frequency of non-compliance and measures applied to rectify non-compliance.

3.8 Publishing, on an annual basis, information on the government's research program and research results related to health and environmental safety aspects of GM foods, plants and feed, and other novel products.

Theme 2: Information and Choice

Respect for diversity and autonomy means accepting people's different ways of life and cultural beliefs, and also allowing them to make informed choices based on their personal values and interests. In the context of GM foods, this means providing people with comprehensive, accessible information and with practical tools to enable choice. The issues and recommendations presented in this theme are intended to enhance the quality of information provided to enable people to make informed choices.

Issue 7 — Information Provision to Support Informed Choice

What This Issue Is About

To make informed choices about the food they eat, Canadians need access to accurate, balanced, easy-to-access information about the production, regulation, nutritional value, risks and benefits, and other aspects of the foods available in the marketplace. The core of the issue resides in finding the best ways to supply the information and the best sources to do the job.

Some of the Challenges Identified

Despite attempts to provide clear information (for example, through various government Web sites), the material available to Canadians about biotechnology, GM foods and the regulatory system remains difficult to find and understand.

Part of the problem is that the material itself is often complex. The challenge is to present material in a form suitable to different audiences that is accurate as well as easy to understand. Another challenge is to present the material in an unbiased manner, so that it truly supports informed choice and generates trust. The information currently available often appears designed to sway the reader either for or against the technology and/or the products and to promote specific views and behaviours.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Better information about the regulatory system: An initial step may be to improve the description and communication of information about the Canadian food regulatory system for GM and other novel foods, and to ensure that the material provided is complete, understandable and easily retrievable. A variety of media (for example, Internet, booklets, articles) could be used to make the information more widely available. The material could be presented with various levels of complexity to be helpful to different readers.

Create a centralized information body: A centralized body for consumer information on food biotechnology could provide information on food production, GM foods and other novel food biotechnology, relevant laws and regulations, scientific knowledge, perspectives on ethical and social issues, ongoing research and activities, and how to contribute to government-related activities. To convey balanced information, it may be useful to discuss traditional foods and plant-breeding practices, and to provide a meaningful description of the benefits, risks and uncertainties associated with different types of foods.

Increase public awareness and engagement: In addition to the above options, a proactive communications program may be useful for increasing public awareness. Opportunities for Canadians to comment on various aspects of GM foods could be provided through public dialogue sessions.

Issue 8 — Labelling

What This Issue Is About

The issue surrounding the labelling of GM foods concerns whether Canada's current system is sufficient, whether it should be supplemented with a meaningful voluntary labelling standard, or whether a systematic but mandatory approach should be adopted.

The current regulatory system in Canada requires the mandatory labelling of all foods, including GM products, for health and safety. For instance, any significant nutritional or compositional changes or the presence of allergens must be labelled. It is necessary that claims made on food labels can be verified. All statements included on product labels must be understandable and truthful; they must not be misleading. Currently, it is optional whether or not to label a food item as being a product of biotechnology.

To ensure that labelling is meaningful and not misleading, the Canadian Council of Grocery Distributors (CCGD) and the Canadian General Standards Board (CGSB) are currently developing a Canadian standard for the voluntary labelling of GM foods. The CCGD 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 CGSB is a standards development organization in the federal Department of Public Works and Government Services. These bodies are working with consumer groups, food companies, producers, interest groups and government to develop the standard for labelling.

Some Canadians would prefer a systematic mandatory approach for the labelling of GM foods. This preference is triggered by a range of reasons, including concerns for health and environmental safety, lack of information of government processes addressing safety concerns, and social or ethical matters. Mandatory labelling is seen by some as the only way to ensure that those who do not want to consume GM foods can identify and select among products on the basis of their GM content. (Note: Bill C-287 was introduced into the House of Commons of Canada as a private member's bill on April 26, 2001. The Bill proposes a mandatory scheme for the labelling of genetically modified food, through amendments to the Canadian *Food and Drugs Act*.)

Many countries including Canada are working together on an international approach. For example, Canada is actively involved with the CODEX Committee on Food Labelling, an international committee with government representatives from several countries, to arrive at a common international position on labelling. When finalized, the standards will be voluntary, as are all CODEX standards. CODEX standards are increasingly relevant in international trade.

It appears that the core issue of labelling is related to values and choice. The questions at hand are whether values and choice are sufficient reasons to invoke labelling to identify which products are or are not produced using techniques of genetic modification. Should such labelling be mandatory? Or does voluntary labelling, as in the case of organic products, provide reasonable or sufficient choice?

Some of the Challenges Identified

Although certain mandatory requirements do exist regarding the labelling of all foods including GM foods, it is of concern to some that the labelling does not take into account social and ethical concerns or production methods. These issues could influence people's choices. Under the current

system, one cannot easily choose whether or not to consume GM foods, due to the absence of a labelling standard for GM products. This could be seen as restricting personal autonomy. It has been suggested that organic produce, which is purported not to contain GM foods, may be an option for those preferring not to consume GM foods. However, the lack of effective detection methods for GM products or ingredients puts in question whether these claims are verifiable. Moreover, the availability of organically based processed foods is limited.

If GM products were labelled systematically, people would have the choice to consume GM foods, regardless of whether their choice is based on health and safety reasons, or personal beliefs and preferences. Some argue that a formal labelling scheme could also reduce differences in labelling practices. Standardization could help make labels more clear, meaningful and accurate.

Labelling would require a system for segregating GM crops from conventional crops at the wholesale level and for verifying claims, possibly on an international scale. Some are reluctant to develop a system to segregate crops in bulk because they fear that bringing attention to the fact that much of the produce is genetically modified would hurt their market. Also, it is possible that these requirements could increase food costs, impede beneficial research and development, and harm the ability of less developed countries to export products. Some believe, however, that these requirements will be needed with or without labelling due to demands by trading partners. One preference that was observed was for resources to go toward more testing and assessing of foods for safety rather than on labelling initiatives.

Labelling could be complicated. It is estimated by producers and the food industry that up to 75 percent of all processed foods include corn, soya or canola products as ingredients. Since Canadian wholesalers do not generally separate conventional crops from GM crops, these products are mixed. Food processors have no way to know how much GM material they are using. Tests do exist to identify some GM crops and ingredients, but these have limitations in terms of what they can test for, commercial availability and cost effectiveness.

The effective implementation of labelling provisions, whether mandatory or voluntary, is severely limited by the lack of objective, internationally accepted, standards for verifying the presence or absence of a GM food in a food product. This problem is further compounded in some voluntary schemes that propose labelling of highly refined food products that do not contain DNA or protein, such as oil from canola, corn or soybean, or sugar from sugar beet, when they are derived from GM food crops. Without adequate means of verification, the requirements imposed by any labelling protocol are difficult to enforce. The lack of standardization and verification methods has been one of the chief criticisms levelled at mandatory labelling of GM foods, which is viewed by some as arbitrary and trade protectionist.

With regard to the option of voluntary labelling, one challenge identified is that companies may not label GM foods if it is not required of them. This would render the voluntary labelling standard virtually meaningless if it is not adopted by industry.

Some think that a mandatory system is the only way to ensure informed choice and freedom of choice. However, others are concerned that a mandatory system could result in foods not being introduced to the market for fear of consumer rejection. Conversely, they could be removed from the market due to low sales, which could withhold from the public products with potential consumer, environmental and economic benefits. A mandatory labelling system might also be considered to be contrary to international trade obligations. This could draw retaliation from trading partners and harm the international competitiveness of Canadian GM food products.

Some of the Options Considered

The following options were among those considered by CBAC for domestic action in relation to labelling:

- Supporting efforts to develop a meaningful voluntary standard for labelling foods (e.g. the current CGSB/CCGD initiative).
- Developing a mandatory labelling scheme.
- The need for a reliable verification system (e.g. including detection methods and a monitoring program) to support labelling, whether it is voluntary or mandatory.
- Adding to labels an information source Canadians can contact for more information about GM foods, and promoting the use and understanding of the labelling system.

Regarding the international aspects of food labelling, CBAC has considered, in particular, Canada's role in promoting and contributing to the development of a harmonized international labelling scheme for GM foods.

CBAC recognized early on that, while labelling provides an important means of informing Canadians about food, it does not provide all of the information necessary to make a completely informed choice. Any labelling scheme would work best in tandem with adequate provision of information through other means.

International Approaches to This Issue

Provisions for the mandatory, or voluntary, labelling of GM foods has been perceived as the key means of providing consumers with the information they need to make choices in the marketplace. 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 (e.g. whole foods versus processed foods versus 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.

In January 2001, the U.S. FDA announced its draft guidance to industry on *Voluntary Labelling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*. The purpose of this guidance is to advise food manufacturers on the acceptability of various types of label claims and to reinforce the fact that labelling must be truthful and not misleading. Of particular importance, 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 bioengineering" there should be no connotation of superiority.

Draft Recommendations Regarding Information and Choice

4. Information and Informed Choice

Observations: *Canadians want easy access to reliable and complete information regarding food including GM and other novel foods. The current information sources are criticized for being unreliable, incomplete, overly technical or otherwise ill-suited to the needs of the general public. Canadians also want to be able to choose whether or not to buy GM foods. Consumer choice can be influenced by health and environmental concerns as well as by principles, beliefs and values. Labelling is currently required for such health concerns as the presence of an allergen or a significant*

nutritional change. Current laws allow voluntary labelling if it is not misleading. However, the absence of a systematic and reliable standard for labelling food regarding whether or not it is derived from genetic modification prevents labelling claims such as "GM free" from being verified. Other countries are putting forth various forms of voluntary or mandatory labelling policies.

Draft 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.*

We recommend the following measures:

4.1 Establishing a centralized food information service as the primary avenue through which the government provides food-related information, including on GM and other novel foods, to Canadians. The service should reflect effective cooperation among all parts of government with roles related to food regulation, food research, food policy and consumer affairs. The information disseminated for the most part should originate in the federal government, and should always be unbiased. The organization and operation of the service should be based on a comprehensive strategy. Funding for related government communication and information activities should be consistent with the strategy.

4.2 Developing, as part of this strategy, reliable information for use by health care professionals and other intermediates (such as doctors, nurses, nutritionists, dieticians, teachers, community workers, consumer associations, the general public and the media).

4.3 Developing a labelling system for foods with GM content. Work should continue on an international labelling scheme to:

- Develop a set of clear labelling criteria regarding the GM content in food. Further effort could be placed on the ongoing labelling initiative of the Canadian General Standards Board and Canadian Council of Grocery Distributors.
- Ensure that any label statements regarding genetic modification are verifiable, and that programs and techniques are in place to ensure their validity.
- Implement the labelling standard voluntarily, at least initially, in order to test its adequacy and effectiveness, and widely promote its use so that people have real opportunities to make informed choices.
- Continue to work with other countries in international fora to develop a harmonized international approach for labelling regarding genetic modifications.
- Depending on the success of this approach — and especially if it fails to provide Canadians with sufficient choice regarding the food they consume — further consideration should be given to a mandatory labelling scheme.

Theme 3: Social and Ethical Considerations

The public interest in CBAC's view is the primary criterion for the development of sound government policies and programs. As presented earlier, it comprises the health of Canadian citizens, the quality of life of Canadians, the health of the environment, the prosperity of the Canadian economy as well as a sustainable, peaceful global community. Social and ethical issues related to the public interest permeate several aspects of the regulation of GM and other novel foods as well as the numerous issues and recommendations presented in this report. Policies to promote and protect human health and the environment by their very nature are reflections of a certain ethical position and social value. The purpose of this theme is to go one step further to address some of the broader social and ethical dimensions of food biotechnology.

Issue 9 — Environmental Stewardship

What This Issue Is About

Environmental stewardship is a key issue in the consideration of social and ethical responsibilities. It goes beyond traditional environmental protection to embrace the larger question of sustainability and the integration of important societal goals such as population health, social well being, environmental conservation and economic prosperity. It involves leadership with respect to the products and technologies generated, and it calls for consideration of possible long-term cumulative impacts of all sorts — on health, the environment and the economy. Expertise in disciplines such as ecosystem science is essential, as are international cooperation on global environmental issues and close links between scientific and regulatory communities. Environmental stewardship can apply to virtually any type of activity or product, including biotechnology.

A significant feature of environmental stewardship is a life cycle approach to assessing products, processes, technologies and services. This approach recognizes that all stages of a product's existence (for example, manufacturing, transportation, distribution, use/reuse, waste management) have impacts in several areas — for instance, quality of life, the environment, the economy and other domains — that are important in considering the product's risks and benefits. Also inherent in this approach is an assessment of the need for the product, its added value, alternatives and broader matters of sustainability.

As described above in the section on *GM Foods and the Canadian Regulatory System*, Canada's regulatory system does examine GM crops for at least some environmental impacts. However, no system exists for the broader stewardship aspect.

Some of the Challenges Identified

The knowledge base: The knowledge basis that supports environmental stewardship draws to a large degree from ecosystem science. It requires a thorough understanding of the structure and dynamics of ecosystems, and how natural and human activities can affect them. Concerns have been raised that Canada's capacity in ecosystem science has diminished over the past decade, due largely to cutbacks in funding opportunities for research and education in ecology-related disciplines. Some think this may have curtailed opportunities for links between regulatory and scientific experts in this field, and reduced the expertise available for sophisticated assessments of GM and other novel crops. Some believe that with the more complex "second generation" GM crops and foods expected in coming years, more research in ecosystem science will be needed.

Product assessments: With respect to government assessments of GM and other novel crops, some observers believe that applying internationally accepted principles and working with international counterparts may help bring more countries to an agreed-upon standard for assessments. As additional nations develop expertise in these approaches, they will be in a better position to consider, on an ongoing basis, what needs to be refined and improved. At present, in the context of approving GM and other novel foods in Canada and elsewhere, some believe that the common principles and approaches to assessments are insufficient, and call for a stronger approach. They also suggest that a more solid scientific basis would allow assessments to be conducted that better address the ecological impacts of proposed products.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Strengthening the knowledge base: A significant investment in research, and an enhanced knowledge base related to ecosystem dynamics and the ways technology can affect an ecosystem, are key to environmental stewardship. Given Canada's important export market and international role in areas such as agriculture, forestry and coastal aquaculture, these disciplines in particular could become the focus of ecological research initiatives. Attention could be given to including international collaborative projects and to the sharing of new information among countries.

Leadership through the life cycle approach: Some think that it may be worthwhile to consider how the life cycle approach might be applied to GM and other novel products. Others believe this is not necessary for the effective regulatory assessment and management of GM and other novel crops and food, and that environmental stewardship in agriculture should be examined in the broader framework of farming rather than simply as an issue of GM crops.

Product assessments: The science of assessing environmental effects depends upon open access to information and rigorous review. Environmental assessment of GM crops is challenging, since there is a potential for impacts to extend well beyond the time and place of their introduction; both natural and agricultural systems are of concern. Some believe that current systems for assessing GM organisms, relying on internationally accepted principles, are thorough and sufficient. Others believe that existing assessment procedures need to be strengthened to more carefully examine possible horizontal gene transfer, effects on biogeochemical cycles mediated by soil microorganisms, persistence of GM organisms, pest resistence and alteration of natural ecosystems. Furthermore, it is felt by some that greater focus is needed on high-quality, long-term, multidisciplinary scientific studies of potential environmental impacts of GM organisms, and that, when introductions spread across a whole region, impacts on whole landscapes may need to be addressed.

Issue 10 — Broader Social and Ethical Considerations

What This Issue Is About

In international discussions about GM foods, several broader ethical and social issues have arisen. These are associated directly or indirectly with the origin and production of GM foods and with their introduction into various societies. The issues, related largely to justice, beneficence (that is, doing or producing good) and respect for cultural diversity and traditional knowledge, are the subject of significant international debate and, in some cases, can influence people's attitudes toward GM foods.

It is important to note that these broader social and ethical considerations are generally not limited to GM foods, and therefore, their consideration and management might better be undertaken in a context broader than GM foods or even

biotechnology. Regulatory mechanisms or institutions currently in place may suffice for handling some of these questions. Others, however, may require new venues and approaches for national and international dialogue, negotiation and action.

Some of the Categories of Concerns

Ethical acceptability: Biotechnology allows scientists to produce organisms with various combinations of genetic material — from closely and distantly related species, and even from species that are not related at all. Some believe that such genetic modifications are intrinsically wrong. For others, it is a problem only when the combinations are from distantly related species. Still others question that these products are necessary. Nonetheless, some believe that the technology generates considerable benefits and that these benefits justify its pursuit. Given this diversity of views, it has been recommended by some that, due to ethical beliefs, certain processes or applications of GM food technology should not be pursued under any circumstances.

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, corporations can produce new genetic combinations well suited to a given purpose or environment. However, when these corporations hold the patents on these items, the individuals and societies that contributed to them may not share in the financial gains. As well, corporations sometimes sell these products — for example, improved seed and plant varieties — back to the source societies and farmers at substantial profit. While such matters are of concern to some, they are less compelling to others who believe that the growers and consumers in these societies derive substantial value from them. 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 (for example, manufacturers and producers), while any unforeseen negative impacts on health or the environment would likely befall a larger population. In response to this, some advocate focussing more effort on achieving a better balance, with greater benefits for consumers and traditional societies. Others believe that the benefits are more broadly shared, and that the positive effects in terms of job creation, the economy, reduction in pesticide use, etc., as well as possible unforeseen and unintended benefits, would be experienced by large segments of the population.

At present, several large life science companies hold an increasing share of the GM food market. This domination of the market causes discomfort and fear in some people who see it as a source of diminished self-sufficiency in food production and a threat to the sovereignty of some nations. Due to the length of time and the expenses involved in getting a product through the regulatory system, others regard this development as a necessity.

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. Many argue that this happens not just with GM foods or even biotechnology, but with any sophisticated technology.

Food biotechnology can also be seen as a way to alleviate poverty and starvation, and as part of the solution to vulnerable societies. They consider it a way to foster food security, feed another three billion people by 2050 and address the problems of a shrinking agricultural base and increasingly scarce water supplies without degrading the environment. Some advocates of the technology perceive a need for transferring biotechnology to developing countries and bringing cutting-edge research to poor farmers. They support a cooperative approach that focusses on meeting the specific needs of lesser developed nations.

Environmental ethics and economics: Environmental ethics dictate that it is ethically 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. Some believe that to adhere to this ethic, greater attention must be given to environmental economics. Environmental economics can generally be described as the range of possible economic approaches that would directly or indirectly contribute to environmental conservation. These approaches include, for instance, financial incentives such as subsidies or disincentives such as taxes that encourage people to make environmentally sound decisions. In the context of GM and other novel foods, some suggest that further consideration of the meaning and application of environmental economics may be warranted.

Mechanisms for addressing broader social and ethical issues: How and where should the broader social and ethical issues of GM foods be considered and resolved? Domestic regulatory systems for food safety address the issue of potential health and environmental risks, relying essentially on scientific factors and evaluations. Ethics are incorporated in the sense that health and environmental safety are considered priorities, and policies aimed at protecting the most sensitive segments of society, such as children and the elderly, are adopted. But food regulatory systems, both in Canada and abroad, generally do not consider the kinds of issues outlined above in their decisions on individual products.

Some believe that for more attention to be paid to these broader ethical and social dimensions, such matters should be addressed as part of the individual product evaluations. It is feared by others that a broader debate at the product level could be a strategic act to delay product approvals. Concern also exists that this would reduce the predictability of the regulatory process and the basis on which any related decisions are made. There is a concern that modifications to the basic purpose of assessments, by including the social and ethical considerations more specifically, could put a country's policies at odds with its international obligations and with international harmonization efforts in product safety assessments and decision making. The alternative proposal from proponents of the science-based regulatory system, therefore, is that these issues should be addressed from a higher and broader policy perspective. This could involve Parliament, or it could be addressed through an expert committee assigned to advise government on such matters, by addressing classes of products and activities rather than individual product decisions.

Some of the Options Considered

CBAC initially considered the following options in regard to this issue.

Identifying an appropriate forum for addressing broader social and ethical dimensions of GM foods: Recognizing that the current paradigm for regulatory decisions is based on scientific evaluations and risk assessments, further work may be required to identify the best approach for better defining and actively addressing the broader ethical and social issues as well as the trade-offs between and among them. A key question is whether or not the

regulatory system should or could be modified to add broader social and ethical considerations to case-by-case, product-level regulatory decisions. Whether the issues call for action by a different level or body of government, by the judicial system or Parliament, or by industry or societies more generally, could be the subject of review.

Further defining the issues: Further work could be undertaken to better define the broader social and ethical issues relating to GM foods. This endeavour could be undertaken jointly with experts and organizations in Canada and abroad that are already involved in these issues, including international organizations and foreign governments. A better understanding of the perspectives of the general public might also be pursued in further defining these issues.

Assessing the issues against fundamental principles: Once the issues are better defined, each issue could be assessed against an overall framework of principles and values. With reference to the issues presented above under the heading *The Ethical Context*, this assessment could assist in testing and refining a core set of principles and developing values as a basis for public policy making. With respect to advancing the ethical and social issues *per se*, the set of principles and values could serve as a lens for further analysing and understanding each issue, and through which existing policies could be reviewed and reconsidered.

Finding solutions that reflect core principles and values for public policy making: These solutions might include:

- Researching long-term ecological impacts, including a focus on issues of particular importance for developing countries and making available to them the knowledge and technology resulting from this work.
- Analysing Canada's international development policies and programs to identify how they might better contribute to global food security; emphasizing activities and research designed to address the specific concerns and needs of vulnerable societies; and respecting the diversity of cultures and unique methods of food production.
- Reconsidering domestic laws and international agreements from the perspective of broader social and ethical concerns, and considering what changes might be needed to better address ethical and social issues (for example, the nature of ownership/partnerships, biodiversity controls with encouragement for countries to adopt them, economic drivers to support an environmental ethics, etc.).
- Undertaking these activities with international collaboration so that all countries facing these issues agree on the ways to address them and ensure coherence between national and international policy.

A further option was identified during the course of the consultations and is presented below. This option addresses social and ethical perspectives through a framework that could generate dialogue on specific GM foods as well as on the values and principles that underlie the Canadian public's attitudes toward these foods.

Developing a Framework to Consider the Acceptability/Non-acceptability of GM Foods

Throughout Phase 1 of its work on GM foods and in preparations for Phase 2, CBAC focussed on critical aspects of the regulation of GM foods. In its consideration of the social, ethical and legal factors associated with regulatory programs, CBAC's point of departure — arguably the general assumption among most members — was that GM foods would be part of our collective reality and that a discussion

of how they should be regulated is therefore appropriate. In other words, CBAC proceeded as though it was generally assumed that GM foods do exist and will continue to exist.

During its consultations, CBAC heard differently. CBAC heard that whether GM foods should be part of our collective future also warrants discussion, as does the issue of the line to be drawn between GM foods that Canadians consider acceptable and those they do not. CBAC heard that this concept had been inadequately addressed in its deliberations to date, including in its Consultation Document.

As a result of this feedback, CBAC introduced a new segment in the consultation and received feedback on a framework that might facilitate a discussion of the acceptability or unacceptability of GM foods. The framework is based on the premise that different kinds of GM foods could be classified along an Acceptability Spectrum as being more or less acceptable, according to a variety of criteria. The Acceptability Spectrum, as shown below, 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. GM foods that are considered not acceptable under any circumstances could be recommended for an unconditional prohibition (banned). Those that are unacceptable at the present time could be placed under a moratorium.

It became clear during the discussions that people assign foods to a particular category for a variety of reasons. These reasons include, for instance, matters of health and environmental safety, social implications (such as economic impacts), ethical issues (such as the view of some people that combining animal and plant DNA is unethical), and broader societal implications (such as the concentration of power or other global or international impacts that can result from approving a particular food or class of foods).

These various influences were used to generate a two-dimensional framework building on the initial Acceptability Spectrum, as shown on page 49. Health and environmental safety considerations are separated from the other influences by a bold line because these are the elements on which the current regulatory system primarily bases its decisions on GM foods. A bold line is also drawn between broader social considerations and the influences to its left, to represent the significant international scale of many of the broader societal issues at play.

It should be noted that the Acceptability Spectrum framework introduces features that are unique in discussions of a federal food policy. First, it acknowledges that some people's views regarding the acceptability of products may be based on more than health and environmental safety considerations, and it builds on the notion that certain foods might

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

Using this framework, it could be feasible to assign either groups or classes of foods 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.

be considered unacceptable by the public if they have social or ethical implications — on a domestic or international scale — that outweigh their perceived benefits. Second, it suggests that in some circumstances governments and/or industry should perhaps be considering postponing or preventing the marketing of given foods for reasons other than health and safety risks.

	Health and environmental safety	*Social considerations*	*Ethical considerations*	*Broader societal considerations*
Acceptable				
Acceptable with conditions				
Not acceptable until more is known or certain standards are met				
Not acceptable under any circumstances				

The implications are significant, given the current system of domestic and international trade laws. They raise the critical question of authority. How would decisions that take into account these social and ethical elements be implemented, given current national and international laws? How can they be applied if they are not based on the kind of criteria that fall within the regulatory system's science and risk-based assessments and decisions? Possible mechanisms for implementing this framework would need to be explored, including in particular voluntary and industry-driven approaches. The relationship and complementarity of this activity with the regulatory system and with the broader governance structure would require closer consideration.

Through initial discussions, it appeared that the framework could be useful in engaging Canadians in a dialogue about the values and criteria that determine the acceptability of GM foods in the eyes of the public.

Draft Recommendations Regarding Social and Ethical Considerations

5. Environmental Stewardship

Observations: *Currently, there are no binding international standards for environmental assessments for any application, including GM and other novel foods. Work is under way and progress is being made in identifying "best practices." Nonetheless, CBAC believes there is room for improvement in the current approach to environmental assessments for research into long-term impacts and the degree to which ecosystem effects are being considered.*

Draft 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.*

We recommend the following measures:

5.1 Establishing a well-supported and collaborative national research program to improve knowledge about the long-term effects of GM organisms used in novel foods or used in food production on the natural, agricultural and other ecosystems.

5.2 Exploring over the short term and implementing options for integrating a stronger ecosystem perspective into environmental risk (safety) assessments of GM and other novel foods. A report of options should be developed and released publicly within a year. Key elements would include national and international research collaboration needs and the potential for making better use of ecological expertise.

5.3 Strengthening over the medium term the environmental assessments of novel foods and GM processes used in food production. Independent panels with a strong ecosystem perspective should oversee peer review of experimental design and data, and recommend ecologically meaningful experimental protocols for each new class of GM introductions. This task would require building a strong base of expertise to cover key ecological and environmental concerns, such as environmental persistence of GM organisms, effects on biogeochemical cycles, reproductive biology such as pollen flows, harmful effects of horizontal gene transfer, diminution of biodiversity, insect resistance to GM insecticidal products and cumulative effects.

5.4 Taking a precautionary approach to ensure a conservative safety standard for environmental and health concerns related to GM and other novel foods. Special concern should be taken with regard to potentially catastrophic kinds of risks. This does not imply, however, a zero-risk approach. Under circumstances where it is appropriate to use substantial equivalence as a framework to structure the safety assessment of novel foods, it is necessary to ascertain whether the composition of the plant has been changed in any way. Examples are the introduction of new hazards into food, an increase in the concentrations of inherently toxic constituents, a decrease in the expected nutrient content, or the introduction of unwanted characteristics such as antibiotic properties into natural ecosystems.

5.5 Assessing the implications and suitability of recommendations 5.1 to 5.4 above for broader application throughout the environmental regulatory system.

6. Other Social and Ethical Considerations Related to GM Foods

Observations: *The debate over GM foods is polarized between those supporting the application of biotechnology (e.g. rDNA technology) to foods and those against it. The search for common ground between advocates of different views is hindered by the lack of suitable tools to systematically consider and evaluate on an ongoing basis the social and ethical factors that influence public acceptability of specific food.*

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.

Moving Forward from Here

Refining the Federal Food Regulatory System

This Interim Report focusses primarily on the regulatory context within which Canada assesses GM foods for safety and regulates their introduction into the marketplace. The following issues, among others, are presented:

- transparency, particularly with respect to the regulatory decision-making process
- opportunities for public involvement and input
- the independence of regulatory agencies
- the scientific expertise underpinning the risk assessment process
- the importance of situating GM foods within a broader social and political perspective.

These issues are discussed in this Interim Report in the context of GM foods and other novel foods. CBAC considers these to be central to its mandate of studying and advising on the regulatory system for GM foods. These are not unique to GM foods, however. They may apply as well in other areas of public policy, not the least of which is the regulation of other forms of plants and foods with novel traits. Insofar as this Interim Report seeks to inform and influence the GM foods policy agenda, it is with the realization that government's course of action in this area needs to be consistent within an overall strategy for food safety and security. Therefore, CBAC recommends that the federal government consider the applicability of these recommendations, once finalized, not only in relation to GM foods but also in the larger context of the Canadian food regulatory system.

A National Food Policy

It has been argued that Canada should have a national food policy in order to address issues of health, environmental sustainability and broader issues of food security.[16] Although it is clearly beyond the scope of this project and CBAC's mandate to articulate such a policy, our draft responses to key issues on the regulation of GM foods may provide some guiding principles that such a strategy could embody. These principles include legitimate confidence in the safety and quality of foods available to Canadians, a highly transparent and accountable governance system, easy access to understandable, accurate information about food and nutrition, the freedom to choose acceptable foods, and preservation of a viable and sustainable food production system.

Next Steps

CBAC's next steps in relation to GM foods and the Canadian regulatory system begin with a comment period on the content of this Interim Report. (Comments should be submitted by January 31, 2002.) During this period, CBAC is inviting the views of experts, stakeholder groups and members of the public. In particular, CBAC is seeking views on the draft recommendations including suggestions for improvements or alternatives to these. CBAC also hopes to receive input on the usefulness of the Acceptability Spectrum in facilitating dialogue on GM foods and, in particular, the social, ethical and broader societal issues associated with producing, trading and consuming these foods. Phase 3 will conclude with the preparation of formal recommendations and their submission to the Government of Canada.

[16] MacRae, R. (1999). Policy failure in the Canadian food system. *In:* For hunger-proof cities: sustainable urban food systems. M. Koc, R. MacRae, L.J.A. Mougeot & J. Welsh (eds), p. 182-194. International Development Research Centre, Publications Dept., Ottawa.

Annex A — Members of the Canadian Biotechnology Advisory Committee

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Chair, Canadian Biotechnology Advisory Committee
Director, Centre for the Advancement of Medicine, University of Manitoba, Winnipeg, Manitoba

Dr. Mary Alton Mackey
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Mrs. Denny Warner
Manager, Vanderhoof Chamber of Commerce, Vanderhoof, British Columbia

Annex B — CBAC Publications, Commissioned Reports and Companion Documents

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 Dr. Michael McDonald, Director, Centre for Applied Ethics, University of British Columbia.

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

Food and Agricultural Biotechnology: Incorporating Ethical Considerations, by Dr. 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 Professor 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 Professor 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 Dr. 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 Dr. Marc Saner, Managing Director, Ethics and Policy Issues Centre (EPIC), Department of Philosophy, Carleton University.

Secondary Analysis of Public Opinion Research Regarding Genetically Modified Food and Related Biotechnology Issues, 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 Dr. Susan Sherwin, Munro Chair in Philosophy, Department of Philosophy, Dalhousie University.

CBAC Publications on GM Foods

Regulation of Genetically Modified Food: Consultation Document 2001, February 2001.

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

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

Companion Documents

In addition to the Report of the Royal Society Panel on the Future of Food Biotechnology (see Annex D), the following international expert reports on the science informed the decisions of CBAC:

FAO/WHO. 1996. *Biotechnology and Food Safety*. Report of the Joint FAO/WHO Expert Consultation. (30 September – 4 October 1996).

FAO/WHO. 2000. *Safety Aspects of Genetically Modified Foods of Plant Origin. Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology* (29 May – 2 June 2000).

FAO/WHO. 2001. *Evaluation of Allergenicity of Genetically Modified Foods. Report of the Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology* (22–25 January 2001).

IFT. 2000a. IFT expert report on biotechnology and foods: Introduction. *Food Technology* 54: 124–36.

IFT. 2000b. Expert report on biotechnology and foods: Human food safety evaluation of r-DNA biotechnology-derived foods. *Food Technology* 54 (9): 53–61.

IFT. 2000c. Expert report on biotechnology and foods: Labelling of r-DNA biotechnology-derived foods. *Food Technology* 54 (9): 62–74.

IFT. 2000d. Expert report on biotechnology and foods: Benefits and concerns associated with recombinant DNA biotechnology-derived foods. *Food Technology* 54 (10): 61–80.

United States. National Research Council. 2000. *Genetically Modified Pest Protected Plants: Science and Regulation.* Washington, DC: National Academy Press.

United States and European Union. 2000. *U.S.-E.U. Biotechnology Consultative Forum. Final Report.* U.S. Department of State.

Organisation for Economic Co-operation and Development. 2000. *GM Food Safety: Facts, Uncertainties, and Assessment.* The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods.

Organisation for Economic Co-operation and Development. 2000. *Report of the Task Force for the Safety of Novel Foods and Feeds*. 86/ADDI. Paris: OECD, 17 May.

Annex C — Feedback on an Appropriate Ethical Context

During the multi-stakeholder consultations conducted by CBAC during the winter of 2001, participants considered the seven values presented under the heading *The Ethical Context* and in the earlier Consultation Document. They discussed values and principles that could be used to guide the government in organizing the regulatory system and in making policy choices involving GM foods. The values and principles from the workshops in all five locations are listed in the following table, ranked according to the number of times the idea was raised. To view an explanation or definition of these terms as provided by participants, please refer to the document *Summary Consultation Report — Workshops on Genetically Modified Food* on CBAC's Web site.

Organization of the Regulatory System	**Policy Choices**
Accountability/leadership	Accountability/leadership
Science-based	Informed choice/informed public/knowledge
Transparency	Transparency
Education/knowledge	Safety of food
Prudence/caution	Justice
Justice	Integrity
Product-based	Caution
Respect for diversity	Sustainability
Risk-benefit	Food environment safety
Integrity/honesty	Science-based
Autonomy	Prudence/caution
Beneficence	Long-term safety
Future sustainability	Equitability
Participative process	Autonomy
Quality and authenticity of information	Trust
Social optimization	Social benefits
Health safety	Participative
Workable	Objectivity
Balanced regulation	Fairness/level playing field
International compatibility	Diversity
Verifiable	Consumer choice in food
Ethical	Beneficence
Separation of promoter and regulator	Stability/confidence
	Democracy
	Market success
	Credibility and responsibility
	Respect for diversity
	Nature ethics
	Balance

Certain ideas appear to emerge from the values and principles listed and dominating, to some degree, in the ratings shown above. The following common threads appeared.

Accountability/leadership: The idea that stakeholders would be held accountable and answerable and that relevant authorities take responsibility for ensuring that the regulatory system works.

Transparency: The idea that the regulatory process, the information used to make decisions and the resulting decisions are as open and accessible as possible.

Science-based [for the regulatory system]: The idea that the regulatory process should be anchored in sound scientific principles and identified risk, using accepted and rigorous scientific assessment methodologies.

Informed choice/informed public/knowledge [for guiding policy choices]: The idea that policy choices would be informed, and would be fact- and knowledge-based; furthermore, that the policies would support and enable an informed public to make real choices based on good information.

Safety and caution: The idea that we should exercise caution in developing policy and regulating GM Foods, and be diligent in our concern for safety, both related to human health as well as the environment. (For this value, several similar value rankings were combined, including safety of food, long-term safety, etc.)

The commonality of these ideas may suggest a certain desire to see these values as part of the underpinning of both the organization of the regulatory system and the basis for policy choices. Upon further analysis, it is suggested that **the values selected for the regulatory system** could be grouped into thematic clusters as shown below. These clusters reveal a set of key desired and principled qualities that should underpin the regulatory system.

A highly principled set of qualities around accountability and transparency:
- accountability/leadership
- transparency
- integrity/honesty
- ethical
- separation of promoter and regulator

A knowledge-based cluster that emphasizes the science base and quality of the information:
- science-based
- education/knowledge
- product-based
- quality and authenticity of information
- verifiable

A set that focusses on the sense of justice, and balance of risk and benefit, with the goal of broadly accessible benefits:
- justice
- risk-benefit
- beneficence
- social optimization

A cautionary set emphasizing sustainability and health and safety:
- caution
- future sustainability
- health/safety
- prudence

A set that underscores the need for innovative but workable solutions that are compatible internationally:
- respect for diversity
- workable
- balanced regulation
- international compatibility

A set that underlines the need for public participation and informed choice:
- autonomy
- participative process

The **values selected to guide policy choices** could also be grouped into clusters as shown below.

A highly principled set of qualities around accountability and transparency:
- accountability/leadership
- transparency
- integrity
- trust

A set that is closely aligned to the first set underlining the need for confidence in a system that acts responsibly:
- stability/confidence
- democracy
- credibility and responsibility

An informed choice set that emphasizes the need for good public knowledge, grounded in science and that enables consumer choice:
- informed choice/informed public/knowledge
- science-based
- autonomy
- consumer choice in food

A set that focusses on the sense of justice, balance and objectivity:
- justice
- equitability
- objectivity
- balance

A cautionary set focussed on the safety of both food and the environment:
- safety of food
- caution
- food environment safety
- prudence
- long-term safety

A set that incorporates sustainability and respect for diversity along with the goal of broadly accessible benefits:
- sustainability
- social benefits
- beneficence
- respect for diversity
- nature ethics

A set that raises the need to support a successful market within a fair playing field:
- fairness/level playing field
- market success

Annex D — Royal Society Panel Recommendations

The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology[17] on February 5, 2001, released a report titled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada.* This document addresses scientific aspects of food biotechnology (e.g. assessments conducted by regulatory bodies with a view to protecting health and the environment) as well as some of the issues addressed by CBAC in relation to the organization and operation of the regulatory system and related social, ethical and legal issues. The report is a valuable reference for additional views and background information on the subject of GM foods.

Early on in its GM foods project, CBAC committed to considering the report of the Royal Society Panel when preparing its advice to government. In order to do so, CBAC created a forum on its Web site so that anyone interested in providing CBAC with comments on the Royal Society report could do so. CBAC has considered the Royal Society Panel's recommendations and a matrix illustrating the points of intersection with the key issues CBAC has been focusing on is presented below.

Many of the recommendations of the Royal Society of Canada Panel on the Future of Food Biotechnology address key issues on which CBAC has been focussing.

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
Transparency	4.9 The Panel recommends that all assessments of GM foods, which compare the test material with an appropriate control, should meet the standards necessary for publication in a peer-reviewed journal, and all information relative to the assessment should be available for public scrutiny. The data should include the full nutrient composition (Health Canada, 1994), an analysis of any anti-nutrient and, where applicable, a protein evaluation such as that approved by the United Nations Food and Agriculture Organization (FAO). 6.1 The Panel recommends that all ecological information on the fate and effects of transgenic biotechnology products on ecosystems required under existing regulations should be generated and made available for peer review. 6.8 The Panel recommends that research data from experiments conducted by industry on the potential environmental impacts of GM plants used in Canadian Environmental Protection Agency assessments should be made available for public scrutiny. 7.2 The Panel recommends that the design and execution of all testing regimes of new transgenic organisms should be conducted in open consultation with the expert scientific community.

[17] For more information, please visit the Royal Society Web site: **http://www.rsc.ca/foodbiotechnology/indexEN.html**

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	9.2 The Panel recommends that the Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and the scientific rationales upon which their regulatory decisions are based.
Separation and Independence of Regulatory Functions	9.1 The Panel recommends that Canadian regulatory agencies and officials exercise great care to maintain an objective and neutral stance with respect to the public debate about the risks and benefits of biotechnology in their public statements and interpretations of the regulatory process.
Post-market Monitoring for Risks and Benefits	4.6 The Panel recommends development of mechanisms for after-market surveillance of GM foods incorporating any novel protein. 5.3 The Panel recommends that the tracking of transgenic animals be done in a manner similar to that already in place for pedigree animals, and that their registration be compulsory. 5.7 The Panel recommends that a national research program be established to monitor the long-term effects of GM organisms on the environment, human health, and animal health and welfare. 5.11 The Panel recommends that Environment Canada and the Canadian Food Inspection Agency establish an assessment process and monitoring system to ensure safe introductions of GM organisms into Canada, according to the intent of the *Canadian Environmental Protection Act*. 6.2 The Panel recommends the carrying out of exhaustive, long-term testing for ecological effects of biotechnology products that pose environmental risks, especially with respect to persistence of the organism or a product of the organism, persistent effects on biogeochemical cycles, or harmful effects resulting from horizontal gene transfer and selection. 6.9 The Panel recommends that a federally funded multidisciplinary research initiative be undertaken on the environmental impacts of GM plants. Funds should be made available to scientists from all sectors (industry, government and university) with grant proposals subject to rigorous peer review. 6.12 The Panel recommends that standard guidelines should be drawn up for the long-term monitoring of development of insect resistance when GM organisms containing “insecticidal” products are used, with particular attention to pest species known to migrate over significant distances.
Capability and Capacity in the Regulatory System	5.5 The Panel recommends that federal and provincial governments ensure adequate public investment in university-based genomic research and education so that Canada has the capacity for independent evaluation and development of transgenic technologies.

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	5.10 The Panel recommends that university laboratories be involved in the validation of the safety and efficacy of GM plants and animals. 6.4 The Panel recommends that a detailed analysis be undertaken of the expertise needed in Canada to evaluate environmental effects of new biotechnology products and, if the appropriate expertise is found to be lacking, resources be allocated to improving this situation. 6.11 The Panel recommends that an independent committee should evaluate both the experimental protocols and the data sets obtained before approvals of new plants with novel traits are granted. 7.3 The Panel recommends that analysis of the outcomes of all tests on new transgenic organisms should be monitored by an appropriately configured panel of "arms-length" experts from all sectors, who report their decisions and rationale in a public forum. 9.3 The Panel recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non-governmental) and independent panel of experts. The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review.
Information Provision	4.11 The Panel recommends that the Canadian Nutrient File should be updated to include the composition of genetically engineered foods and be readily available to the public. 5.9 The Panel recommends that a data bank listing nutrient profiles of all GM plants that potentially can be used as animal feeds be established and maintained by the federal government.
Environmental Stewardship	6.7 The Panel recommends that environmental assessments of GM plants should not be restricted to their impacts on agroecosystems but should include an explicit consideration of their potential impacts on natural and disturbed ecosystems in the areas in which they are to be grown. 6.10 The Panel recommends that companies applying for permission to release a GM organism into the environment should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact. 6.15 The Panel recommends the establishment of comprehensive research programs devoted to the study of interactions between wild and cultured fish. Reliable assessment of the potential environmental risks posed by transgenic fish can be undertaken only after extensive research in this area.

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	7.1 The Panel recommends that approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for causing harm to the environment or to human health. Such testing should replace the current regulatory reliance on "substantial equivalence" as a decision threshold. 7.4 The Panel recommends that Canada develop and maintain comprehensive public baseline data resources that address the biology of both its major agroecosystems and adjacent biosystems. 7.5 The Panel recommends that Canada develop state-of-the-art genomics resources for each of its major crops, farm animals and aquacultured fish, and use these to implement effective methodologies for supporting regulatory decision making. 8.1 The Panel recommends the precautionary regulatory assumption that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe. The Panel rejects the use of "substantial equivalence" as a decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities because such a regulatory procedure is not a precautionary assignment of the burden of proof. 8.5 The Panel recommends a precautionary use of "conservative" safety standards with respect to certain kinds of risks (e.g. potentially catastrophic). When "substantial equivalence" is invoked as an unambiguous safety standard (and not as a decision threshold for risk assessment), it stipulates a reasonably conservative standard of safety consistent with a precautionary approach to the regulation of risks associated with GM foods.
Risk Assessment Approaches[18]	4.1 The Panel recommends that federal regulatory officials in Canada establish clear criteria regarding when and what types of toxicological studies are required to support the safety of novel constituents derived from transgenic plants. 4.2 The Panel recommends that regulatory authorities establish a scientific rationale that will allow the safety evaluation of whole foods derived from transgenic plants. In view of the international interest in this area, the Panel further recommends that Canadian regulatory officials collaborate with colleagues internationally to establish such a rationale and/or to sponsor the research necessary to support its development. 4.3 The Panel recommends that, in view of the availability of suitable alternative markers, antibiotic resistance markers should not be used in transgenic plants intended for human consumption.

[18] Risk assessment approaches are not a CBAC issue *per se*, but are listed here for completeness in reflecting the recommendations of the Royal Society Panel.

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	4.4 The Panel recommends that the Canadian government support research initiatives to increase the reliability, accuracy and sensitivity of current methodology to assess allergenicity of a food protein, as well as efforts to develop new technologies to assist in these assessments. 4.5 The Panel recommends the strengthening and development of infrastructures to facilitate evaluation of the allergenicity of GM proteins. This could include development of a central bank of serum from properly screened individuals allergic to proteins which might be used for genetic engineering, a pool of standardized food allergens and the novel GM food proteins or the GM food extracts, maintenance and updating of allergen sequence databases, and a registry of food-allergic volunteers. 4.7 The Panel recommends that the appropriate government regulatory agencies have in place a specific, scientifically sound and comprehensive approach for ensuring that adequate allergenicity assessment will be performed on GM foods. 4.8 The Panel recommends that approvals should not be given for GM products with human food counterparts that carry restrictions on their use for non-food purposes (e.g. crops approved for animal feed but not for human food). Unless there are reliable ways to guarantee the segregation and recall if necessary of these products, they should be approved only if acceptable for human consumption. 4.10 The Panel recommends that protocols should be developed for the testing of future genetically engineered foods in experimental diets. 5.1 The Panel recommends that the Canadian Food Inspection Agency (CFIA) develop detailed guidelines describing the approval process for transgenic animals intended for (a) food production or (b) other non-food uses, including appropriate scientific criteria for assessment of behavioural or physiological changes in animals resulting from genetic modification. 5.2 The Panel recommends that the approval process for transgenic animals include a rigorous assessment of potential impacts on three main areas: • the impact of the genetic modifications on animal health and welfare • an environmental assessment that incorporates impacts on genetic diversity and sustainability • the human health implications of producing disease-resistant animals or those with altered metabolism (e.g. immune function).

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	5.4 The Panel recommends that transgenic animals and products from those animals that have been produced for non-food purposes (e.g. the production of pharmaceuticals) not be allowed to enter the food chain unless it has been demonstrated scientifically that they are safe for human consumption. 5.8 The Panel recommends that changes in susceptibility of genetically engineered plants to toxin-producing microbes, and the potential transfer of these to the animal and the food supply, be evaluated as part of the approval process. 6.3 The Panel recommends that, in evaluating environmental risks, scientific emphasis should be placed on the potential effects of selection operating on an introduced organism or on genes transferred to natural recipients from that organism. 6.5 The Panel recommends that the history of domestication, and particularly the time period and intensity of artificial selection, of GM plants should be taken into account when assessing potential environmental impacts. Species with a short history of domestication should receive particularly close scrutiny because they are more likely to pose environmental risks. 6.6 The Panel recommends that environmental assessments of GM plants should pay particular attention to reproductive biology, including consideration of mating systems, pollen flow distances, fecundity, seed dispersal and dormancy mechanisms. Information on these life history traits should be obtained from specific experiments on the particular GM cultivar to be assessed, not solely from literature reports for the species in general. 6.16 The Panel recommends that potential risks to the environment posed by transgenic fish be assessed not just case-by-case, but also on a population-by-population basis. 6.17 The Panel recommends that identification of pleiotropic, or secondary, effects on the phenotype resulting from the insertion of single gene constructs into GM organisms be a research priority. 8.2 The Panel recommends that the primary burden of proof be upon those who would deploy food biotechnology products to carry out the full range of tests necessary to demonstrate reliably that they do not pose unacceptable risks.

CBAC ISSUES	RECOMMENDATIONS OF THE ROYAL SOCIETY OF CANADA PANEL ON THE FUTURE OF FOOD BIOTECHNOLOGY
	8.3 The Panel recommends that, where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harm to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product. 8.4 As a precautionary measure, the Panel recommends that the prospect of serious risks to human health, of extensive, irremediable disruptions to the natural ecosystems, or of serious diminution of biodiversity, demand that the best scientific methods be employed to reduce the uncertainties with respect to these risks. Approval of products with these potentially serious risks should await the reduction of scientific uncertainty to minimum levels.
Other	5.6 The Panel recommends that the use of biotechnology to select superior animals be balanced with appropriate programs to maintain genetic diversity, which could be threatened as a result of intensive selection pressure. 6.13 The Panel recommends that a moratorium be placed on the rearing of GM fish in aquatic netpens. 6.14 The Panel recommends that approval for commercial production of transgenic fish be conditional on the rearing of fish in land-based facilities only. 9.4 The Panel recommends that the Canadian Biotechnology Advisory Committee (CBAC) undertake a review of the problems related to the increasing domination of the public research agenda by private, commercial interests, and make recommendations for public policies that promote and protect fully independent research on the health and environmental risks of agricultural biotechnology.

Annex E — The Future of Food Biotechnology

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 44 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.

This annex looks at a few examples of how biotechnology may affect food production over the coming years.

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 species or recovered as spontaneous or induced mutations have been incorporated into cultivated varieties of many major crop species. This process is now being supplemented by 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 resistance to diseases caused by these agents is now well established, and commercial varieties of potato, squash and papaya have been developed this way. This remains an important approach that may be further exploited in order to fight significant crop diseases, particularly in the developing world. For example, the yield of cassava, a staple food for more than 500 million people in sub-Saharan Africa, can be reduced by up to 80 percent due to infection from the African cassava mosaic virus.

Plants can defend themselves from disease in several ways. Some of these 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 the death of cells near the entry point of the pathogen. This "walls off" the disease agent and prevents its spread. As our understanding of natural host defence mechanisms improves, the potential exists to enhance these processes or to transfer resistance from one species to another using the techniques of genetic engineering.

Ways that fungal resistance in plants has been increased by transferring or modifying plant defence capabilities are shown in the following examples:

- Tomatoes have been altered by the introduction of an enzyme, stilbene synthase,[19] from grapevine to be resistant to *Phytophthera infestans* which was largely responsible for the Irish potato famine in 1845–46.

[19] J. E. Thomzik et al, "Synthesis of a grapevine phytoalexin in transgenic tomatoes (*Lycopersicon esculentum* Mill.) conditions resistance against *Phytophthera infestans*," *Physiology and Molecular Plant Pathology* 51 (1997): 265–78.

- Cucumbers have improved resistance to grey mould (*Botrytis cinerea*) due to a chitinase gene from rice.[20]

Other examples include the expression of antibacterial peptides and proteins, resistance against fungal toxins introduced into cereals, and protection against soil nematodes that attack the roots of plants and spread disease. The recent cloning of a "master switch" gene, which is responsible for regulating the production of many disease-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

Humanity needs to be able to produce increasing amounts of food to serve the nutritional requirements of an ever increasing population. Arable land available for food production is very limited, however, often because of conditions of high salt, lack of water, frigidity or chemical contamination. It is postulated that food production needs could be alleviated somewhat by plant varieties that are resistant to these common environmental stresses.

High salinity affects about 20 percent of agricultural land overall and about 40 percent of irrigated land. The adaptability of some plants to high salt or drought conditions is the result of many gene products acting together. This makes it difficult to introduce salt and drought tolerance by either traditional breeding or modern molecular biology. Nevertheless, some progress is being made by engineering plants to have higher levels of compounds such as glycine betaine,[21] which protects plant cells against the effects of salt. Other approaches that focus on increasing the rate at which the sodium ions of salt can be "pumped out" of plant cells have increased the salt tolerance of tomatoes.[22]

Soil with high levels of acidity results 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. The yield of maize, for example, is reduced by up to 80 percent when grown on acidic soils. Plants that are naturally tolerant to high aluminum concentrations secrete malic or citric acid, which helps prevent the roots from absorbing the aluminum. The introduction of a bacterial gene into papaya has made the plant more tolerant of aluminum,[23] but it is not yet clear what effect the extra citrate production may have on plant physiology.

Yield Improvement

Some of the existing commercialized GM crop varieties, particularly those with resistance to disease or to insects, have raised actual crop yields, but 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. These are all being addressed through biotechnology approaches.

Genetic manipulation of the metabolic pathway used to convert sucrose into starch (e.g. to bypass intermediate steps in the process) has resulted in potatoes with significant increases in starch content.[24] These potatoes have a lower moisture content, higher energy yield per unit weight, improved texture and less fat absorption on frying.

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

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

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

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

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

All plants require a source of "fixed" nitrogen in order to grow. For leguminous crops such as soybean, alfalfa and pea, this is provided through a special "symbiotic" relationship with nitrogen-fixing *Rhizobium* bacteria, which live in close association ("nodules") with the plant's root system. For other crops such as cereals, fertilizers supply this nitrogen requirement. Two approaches to increasing the availability of nitrogen are currently being pursued. These include the genetic modification of *Rhizobium* to enhance the tendency of the bacteria to form root nodules,[25] and the introduction of nitrogen-fixing traits 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 hemoglobin gene from bacteria into tobacco plants allowed the plants to germinate three to four days earlier and to develop faster, accumulating 80–100 percent more fresh weight after 35 days.[26] Exactly how this happens is not clear, however, and it remains to be seen if it can be repeated in other crops or how it would translate into increased yields under actual field conditions. This may be a function introduced into GM plants of a next generation.

Nutraceuticals

In addition to providing essential vitamins and minerals, plants synthesize tens of thousands of secondary metabolites, some of which may affect human health. This trait is another reason why plant-rich diets are considered healthy.

Nutraceuticals are foods or parts of foods that have medicinal value. For example, a compound found in broccoli,[27] Sulforaphane, has been shown to offer some protection against breast cancer in mice.

Improving the nutritional quality of foods and plants may have significant health impacts. One approach for achieving this goal is through genetic modification of well-targeted food crops. The most publicized case is that of "golden rice," which is genetically engineered to help alleviate vitamin A deficiency. Rice, a staple food for nearly half the world's population, does not contain ß-carotene, the precursor of vitamin A. Two genes from a daffodil and one from a bacteria have been introduced into rice to increase its ß-carotene content.[28] The potential benefits can be seen using the example of South East Asia, where rice is a staple food. Vitamin A deficiency affects about five million children each year, causing an eye disease that in many cases leaves them blind. Increased vitamin A can also help prevent diarrhea and measles, which cause up to two million infant deaths per year. The potential for this modified rice to alleviate vitamin A deficiency has not been confirmed and will require further study.

Similarly, tomatoes have been modified to contain up to four times the normal level of lycopene, a carotenoid pigment,[29] which is a potent antioxidant that may reduce the risk of coronary heart disease and certain types of cancer.

Vitamin E is the most important fat-soluble antioxidant in our diet. It has been associated with several cardiovascular benefits. Natural sources of vitamin E are oilseeds, such as canola and soybean, which contain a mixture of different kinds of molecules called "tocopherols." The most beneficial

[25] J. M. Barea et al, "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 (1996): 361–69.

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

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

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

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

of these is alpha-tocopherol, but it is present in most products in relatively small amounts. By introducing a gene into seeds of a relative of canola, called *Arabidopsis thaliana*, this proportion has been increased to more than 95 percent.[30]

Iron deficiency is one of the world's most common dietary deficiencies, affecting an estimated one to two billion people. The most common symptom of iron deficiency is anaemia, 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 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.[31] It has been estimated that a meal-size portion of this transgenic rice would provide 30–50 percent of a person's 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 in 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*, which encodes a phytase, a compound that breaks down phytate.[32] 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 phosphorus,[33] 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 antigens (agents that stimulate a protective immune response) 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.

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

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

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

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

There is no effective vaccine for severe diarrhea, which causes nearly 2.5 million infant mortalities per year. Enterotoxigenic *E. coli* (ETEC) and *Vibrio cholerae* (cholera) are the primary agents responsible for causing diarrhea. 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.[34] 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.[35] Other examples include the development of "edible" vaccines against hepatitis B virus,[36] Norwalk virus[37] (responsible for viral gastroenteritis, which makes up about 25 percent of the cases of "travellers' diarrhea") and rabies virus.[38]

The expression of specific proteins in plants may also be used to help prevent deleterious immune responses such as those that occur in autoimmune 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 an antibody that suppressed the autoimmune response that would normally have destroyed the insulin-producing cells in the pancreas.[39]

Plants as Factories

Increasingly, food crops are being engineered for non-food purposes; that is, in the production of industrial proteins, pharmaceuticals and other products. Some examples include the production of an antimicrobial protein (lysozyme) in tobacco plants, the expression of growth factors and interleukins, the introduction of special proteins (hydroxyproline-rich) 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 some therapeutic antibodies in plants is also possible through genetic engineering. One example of these so-called plantibodies designed for use in human therapy is to combat the dental bacterium *Streptococcus mutans*, which is involved in forming plaque and hence dental caries.[40] Another example is the expression in soybean of a complete "humanized" antibody against genital herpes virus.[41]

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

[35] T. S. Mor and C. J. Arntzen, "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, Germany: Kluwer, 1999), pp. 17–20.

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

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

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

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

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

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

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 developing frog embryos laid the groundwork for modern animal cloning, which was most publicly exemplified by the cloning of "Dolly" the sheep in 1997. Microinjection techniques to introduce isolated genes into 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; for example, serving as models to study human disease, development, aging and gene function. The ability to express pharmaceutical proteins in the milk of transgenic animals can produce important therapeutic agents that cannot otherwise be isolated in sufficient quantities from natural sources, or produced in active form in other systems, such as GM microorganisms 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, which 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 (transplants between species) 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 is likely to be submitted for regulatory approval in Canada is Atlantic salmon that has 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 that of normal Atlantic salmon, but they achieve that size in a shorter period of time.