Regulation of Genetically Modified Food

Consultation Document 2001

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In order for your views to be considered in a timely fashion, please return your completed questionnaire to CBAC by **Thursday April 12, 2001**.

INTRODUCTION AND PURPOSE

The Canadian Biotechnology Advisory Committee (CBAC) is an independent expert advisory committee created to assist the Government of Canada in the formulation of public policy on a broad range of biotechnology subjects. Its advice is provided to the Biotechnology Ministerial Coordinating Committee (BMCC), which comprises the federal Ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and and International Trade. CBAC's members bring expertise in diverse fields such as science, business, nutrition, law, environment, philosophy, ethics and public advocacy, and serve on a part-time, volunteer basis. CBAC's Program Plan 2000 describes in detail the committee's organization, operating procedures and program of activities. 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 viewed and obtained through the CBAC Web site: *www.cbac-cccb.ca*.

CBAC currently is preparing advice for government on *The Regulation of Genetically Modified Foods.*[1] CBAC wishes to solicit the views of Canadians on this topic and take these into consideration in developing its advice. This Consultation Document is an important instrument through which CBAC is seeking this input. This document describes ten key issues and poses specific questions that seek the perspectives of respondents. These questions as well as an area for general comments are compiled in Annex 2.

This consultation document is directed primarily to groups and individuals with a particular knowledge of and interest in genetically modified (GM) foods and how they are regulated in Canada. All Canadians interested in providing views to CBAC are invited to respond. You may respond to one, some, or all of the questions contained in this report, and you may develop and submit comments individually, in small groups, or on behalf of an organization. Comments can be submitted electronically, using an on-line document and questionnaire at *http://www.cbac.gc.ca/GMFood_english.htm*, or in hard copy, by completing and returning the **questionnaire in Annex 2 of this document**. For this latter purpose, the questionnaire can be sent in by facsimile, at (613) 946-2847 or by mail to:

Genetically Modified Foods Consultations
Canadian Biotechnology Advisory Committee
7th Floor, Room 744B
235 Queen Street
Ottawa ON K1A 0H5

In order for your views to be considered in a timely fashion, please return your completed questionnaire to CBAC by **Friday April 20, 2001.**

To assist in the dissemination of this Consultation Document, CBAC is seeking the assistance of a network of organizations representing producers, environmental interests, consumers, health professionals, industry and various citizen groups. CBAC is also collecting the views of Canadians through multistakeholder workshops and other feedback received by mail and through its toll-free number and Web site. Following this period of consultations, CBAC will prepare a summary report of input that will be available on the CBAC Web site. CBAC will take this input into consideration, as well as that obtained through expert reports, commissioned studies and recent public opinion polls, and produce an initial report to government that will clarify issues, options and consequences, and contain proposed advice for public policy related to GM foods. CBAC's report to government is expected to be released in the summer of 2001, and will be publicly available through CBAC's toll-free number and Web site.

[1] Details on the stages of CBAC's work on genetically modified foods are provided in Annex 1.

This initial report will help prepare and set the stage for further discussion with Canadians. Following its release, CBAC will welcome comments for a period of 6 months. As well, CBAC is planning a Citizen Engagement Initiative addressing GM foods and other topics in the fall of 2001. On the basis of these, CBAC will review its initial advice and release formal recommendations. Information on all CBAC activities will continue to be available on the CBAC Web site and can also be obtained through the CBAC toll-free number.

For readers interested in other topics of biotechnology, please note that CBAC is also, at this time, initiating consultations on Intellectual Property and Patenting of Higher Life Forms. Please contact CBAC or consult the CBAC Web site for details and documentation.

On February 5, 2001, the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology[2] *released a report entitled Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. Their report addresses scientific aspects of food biotechnology as well as some of the other issues covered in this Consultation Document. You may wish to consult this related report for additional views and background information on this subject. CBAC will be considering the report of the Royal Society in preparing its advice to government. If you are interested in providing CBAC with comments on the Royal Society report, a forum for this purpose has been created on the CBAC Web site: http://www.cbac.gc.ca/english/forum/Question.aro?VID=116.*

GENETICALLY MODIFIED FOODS AND THE CANADIAN REGULATORY SYSTEM

The term "genetically modified foods" (GM foods) refers to foods that have been produced using recent advances in gene technology, such as gene cloning, gene splicing and plant transformation.[3]

Over the past 10,000 years, advances in agriculture, for example, improved yield and quality of foods arose from selective plant and animal breeding. Except for the past 100 years, most of it was conducted through trial and error. In the case of plants, selection was based on healthy appearance, vigorous growth, higher yields and desirable appearance, taste and smell of the edible portions.

Since the beginning of the 1900s, breeders have been seeking to expand the genetic variability of plants by artificially inducing mutations. Mutation breeding (or accelerated mutagenesis) uses chemicals or radiation to create random changes in the genetic structure of plants. Some of these mutations result in the expression of desirable traits, which are selected by plant breeders for commercial production. Commercialization of plants produced by accelerated mutagenesis has been growing since the 1950s. The Food and Agriculture Organization of the United Nations estimates that by 1994, about 1800 cultivars worldwide had been produced, either directly or indirectly from this technique.

In the past three decades, modern biotechnology has allowed the production of plants, animals and microorganisms with traits that may not have been introduced through either traditional breeding or accelerated mutagenesis. Using recombinant-DNA technology, genes conferring novel or altered traits can be isolated, cloned and incorporated into plants. This "genetic engineering" is more precise than randomly creating mutations, because the basis for the change is understood at both the DNA and the protein level.

Although traditional plant selection and breeding may have included an evaluation of safety, it was not

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

[3] GM foods are also referred to sometimes as "genetically engineered foods" (GE foods). For purposes of this document, the term GM foods is used throughout.

formally recognized as such. In any event, there was little documentation of the processes for establishing the safety of new foods. Since the 1980s, the diversity of new traits that can be introduced into food using biotechnology, as well as the use of chemical inputs such as pesticides and fertilizers in food production, have challenged this traditional approach to food safety.

The need for an increased focus on regulatory issues affecting biotechnology was highlighted in a 1990 review of Canada's National Biotechnology Strategy. In response, a federal government-wide approach was developed, which included agreement among federal regulatory departments on a set of principles for regulating biotechnology products. These principles were formulated to ensure that the practical benefits of biotechnology products and processes were balanced with the need to protect the environment, human health and safety. Canada's existing regulatory framework is based on the principle that the characteristics and traits of a product determine risk, not the technology used in its production. Thus, under this program, all agricultural commodities and food products, whether they are produced using conventional breeding, accelerated mutagenesis or recombinant-DNA technology, are governed under the same rules.

Because Canada's approach to food regulation is broader than just genetically modified foods, the guidelines and regulations address issues regarding plants with novel traits (PNTs) and novel foods distinctively. Although this document deals with GM foods, readers should remember that these foods in the Canadian context are considered novel foods, which can include foods produced by means other than genetic manipulation or genetic engineering, and some of the issues discussed in this document can be viewed from the broader perspective.

Currently in Canada, the regulation of GM foods is coordinated between the Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada.[4] Health Canada is solely responsible for assessing the human health safety of foods, including GM foods, and approving their use in commerce in Canada. The CFIA is responsible for regulating the importation, environmental release, variety registration and use in livestock feeds of GM plants and seeds. 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 including organisms and microorganisms that may have been produced through biotechnology to determine if they are toxic as defined under CEPA. The Department of Fisheries and Oceans (DFO) is currently developing draft regulations on Transgenic Aquatic Organisms. Until these are in force, applications for the commercial development of transgenic fish would be assessed from an environmental perspective under the CEPA.

Before reaching the market, each genetically modified food and crop is evaluated by a process that compares the characteristics of the new product with those of a conventional counterpart that has a history of safe consumption or use in agriculture. This assessment is based on an internationally applied principle and considers the following factors:

- The method of development of the food crop including (in the case of GM products) the molecular biological data that characterizes the genetic change.
- The composition of the novel food compared with non-modified counterpart foods.
- The nutritional information for the novel food compared with non-modified counterparts.
- The potential for new toxins.
- The potential for causing allergic reaction.
- Environmental impacts

Additional research or testing can be required if regulators are not satisfied at any stage in the process. Only if all criteria are met will a novel food be allowed access to the Canadian market. Since 1994, this approach has resulted in approval of 43 plants with novel traits for environmental release and 48 novel foods for commercialization. Without exception, all

[4] For further information, please visit the following Web sites: Health Canada *(http://www.hc-sc.gc.ca/english/food.htm#novel)*; Canadian Food Inspection Agency *(http://www.cfia-acia.agr.ca/english/toc/bioteche.shtml)*; Environment Canada *(http://www.ec.gc.ca)*.

of the GM foods approved to date in Canada have been the result of incorporating (or selecting for) one or two single-gene traits into plants. Most of these traits have been targeted toward reducing agricultural inputs by endowing plants with resistance to insects and/or viruses or with tolerance to broad-spectrum herbicides. These products were designed to be comparable in composition and nutritional quality with their traditional counterparts.

Worldwide, the estimated area under cultivation with GM crops for 2000 was 44.2 million hectares (109.2 million acres),[5] an increase of 11 percent over the 1999 area for GM crops and more than four times the area planted to GM crops in 1997. To put this into context, this area is equivalent to an area almost twice the size of the United Kingdom. Four countries, the United States, Argentina, Canada and China, accounted for 99 percent of the global GM crop area, with respective percentages of 68 percent, 23 percent, 7 percent and 1 percent of total arable land planted to GM crops. Nearly all of this area was devoted to growing just four different GM crops, namely, soybean (58 percent), corn (23 percent), cotton (12 percent) and canola (7 percent).

Potential Benefits:

- *Reduced use of chemical inputs.*
- *Increased food production to help meet global needs.*
- *Improved nutritional value.*

Potential Concerns:

- *Adverse long-term impacts on health and the environment.*
- *Limitations in the ability to properly assess future products.*

As with any new enabling technology, the genetic modification of organisms may bring both potential benefits and raise concerns. The next generation of GM foods will be much more complex and will blur the boundary between foods and therapeutics. The product mix will include nutraceuticals, edible vaccines and biopharmaceuticals produced in plants and animals. A recent example of such a "second generation" product is "Golden rice," which was genetically engineered to enhance its content of iron and carotene, a precursor of vitamin A.

While adverse health effects associated with the production or consumption of the current generation of GM foods have not been established, there remain concerns about possible adverse environmental impacts. Concerns have also been raised about second generation products that may emerge in the near future. Even though Canada's regulatory system has a number of strengths, many believe that there are opportunities for improving efficiency, effectiveness and public understanding of the system. These and other issues will be explored in more detail throughout the remainder of this document.

[5] James, C. (2000). Global status of commercialized transgenic crops: 2000. *ISAAA Briefs* 21: Preview. ISAAA: Ithaca, NY.

ETHICAL CONTEXT

Ethical judgments are not "stand-alone" judgments. Rather, they are "all things considered" judgments. They are integrative judgments that take into account economic, political, legal, scientific and other factors. In this respect, ethics is not one factor among many, but rather a judgment that takes into account all relevant factors.[6]

CBAC views the public interest as the primary criterion for the development of sound government policies and programs. It 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 balancing of the diversity of interests and priorities of the people of Canada.

CBAC has identified the following as the ethical context for its consultation and discussion with Canadians. CBAC welcomes your input and contribution on the applicability of these in the context of the GM foods.

CBAC's task in developing recommendations on biotechnology is to integrate these various factors and develop a set of recommendations that best serve the greater good and overall public interest. As the ethical context is further developed and refined, it will serve as an analytical basis with which to study the issues and better inform the discussion of potential recommendations.

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.

[6] cf. Annex 1 reference to Dr. Michael McDonald.

KEY ISSUES AFFECTING THE REGULATION OF GENETICALLY MODIFIED FOODS

CBAC has identified 10 key issues related to the regulation of GM foods. These have been grouped under three broad themes.

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 to support informed choice*
	• *Labelling*
• *Social and ethical considerations*	• *Environmental stewardship*
	• *Broader social and ethical considerations*

These issues form the basis of this consultation document. In the pages that follow, each issue is described, and some possible ways forward are outlined. CBAC has approached and described these issues primarily from the perspective of GM plants and crops at this time. In many cases, however, these issues pertain to GM foods more broadly or may involve not only GM foods but other products and technologies as well. This is particularly true for issues discussed under social or ethical considerations. The possible ways forward described for each issue may also be more broadly applicable, and your responses to the questions posed and your additional feedback in the questionnaire can likewise be focussed on a particular type of GM product, or may be of a more general nature, or both.

A number of reports relevant to these issues have been commissioned by CBAC. These are listed in Annex 1. You may wish to consult these sources for additional information and perspectives. The documents are available on-line at *www.cbac-cccb.ca* or by contacting CBAC directly.

THEME 1: GOOD GOVERNANCE

Transparency

Transparency is essential to foster a sense of trust in public institutions and, as such, is a key element of good governance. Within the context of GM foods, the debate on transparency has been about being accountable for the decisions taken, and the availability of information on risk assessments and decision-making processes for granting or withholding approval: how assessments are performed, the information on which they are based, the conclusions and decisions that are drawn, and disclosure of the list of products under review for approval.

Real or Perceived Challenges

Both CFIA and Health Canada have been criticized for not effectively communicating their roles in regulating GM foods. There seems to be a lack of clear information available to Canadians on features of the regulatory system such as the activities of different government bodies or agencies involved in regulating foods, how decisions are made that allow a new product onto the Canadian market, and what information is considered by government during this process. CBAC has not located what it considers to be a clear description for the pathway followed by applications for the approval of new foods as they progress through the system.

There appears to be a lack of standardized procedures for dealing with some situations or issues, such as the resolution of differences of opinion that may arise internally between officials or between officials and companies requesting approval. This may lead to difficulties in communicating effectively with the public, may raise questions about the fairness of the system, and may potentially undermine public confidence.

With respect to research tests conducted in the field prior to a product's approval, information on the trials is not fully disclosed. For example, neither the full data package on the product nor the detailed location of such tests are typically communicated. There is an ongoing debate over whether or not such trial information should be released.

The list of products currently undergoing review is not publicly available. Once a decision to approve a product for environmental release or use in food is reached, it is made public through the publication of decision summaries. These documents provide a brief description of the product characteristics, the safety issues that were addressed by the developer and a rationale for the regulatory decision. These summaries of decisions are frequently published long after the actual decision has been made.

The government does not disclose detailed information related to its assessments — in particular, the technical health and safety information and the data that are evaluated by government risk assessors are not normally made available because current regulations provide for commercial data to be considered confidential. As well, there may be inconsistencies in the interpretation or application of the legal limitations.

Some Possible Ways Forward

Improving Communication about the Regulatory System: The government could develop materials including diagrams or decision trees that would clearly describe the regulatory bodies and respective laws, and the steps and criteria involved in the progression of a product approval application through the regulatory system. Accessible, easily understood information of this sort could help build a better understanding of Canada's regulatory system for biotechnology products, including GM foods.

Developing Formal Processes: Regulatory bodies could also develop more formal processes for various aspects of their operation such as dealing with differences of opinion that occur internally, as well as between regulatory officers and a new food's proponents. This would allow for improved transparency of the regulatory system's operation.

Communicating Product Decisions and Supporting Safety Data: Both CFIA and Health Canada could improve the timeliness of their published decision summaries by releasing them upon approval of a product or in advance, in draft form (see "Opportunities for Public Involvement"). It is not unusual for these documents to be published a year or more after the actual regulatory decision has been made, and there is no clear reason for this delay. Government could also consider adopting a system of pre-notification of which products are currently undergoing review.

With respect to broader disclosure of information related to product safety studies (and any requests for data that underlie the decision document), there are a number of options: government could release this information because it believes it to be of significant 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 or human health safety testing, the results of which could be disclosed. To manage fairly the situations in which a company feels that this degree of transparency would significantly compromise its business competitiveness, a set of criteria could be developed and applied as the basis for requesting exemption from the release of the data.

Regulated Field Tests: There are two basic options with regard to publishing the detailed location of field trials on GM foods. One is to adopt and apply a policy of non-disclosure for the location of field trials. The other is to give full disclosure, with the release of detailed information by the regulators. The latter may be more compatible with providing full transparency to Canadians. However, the former is more respectful of the grower, who risks possible acts of vandalism, but who is proceeding in compliance with Canada's laws; that is, the grower would have requested and obtained permission to conduct the trial, consistent with government criteria. A third option is to continue with the status quo, whereby general information on field trials is obtained through regulatory agencies. This does not include detailed locations of field trial sites, but describes, for instance, the number of trials taking place and the region in which these are occurring.

Along with the chosen approach to information on the detailed location of field trials, it may be useful to develop 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, and the criteria would assist in their being considered carefully, consistently and on transparent grounds.

Questions:

1. *Would a description of the regulatory system, as proposed, provide the kind of information someone would need to learn more about the regulatory system and how decisions on GM foods are made? Do you think you would use this information? If so, how? Where would you like to be able to locate the information (e.g. pamphlet, Web site, other)?*
2. *Do you think there are good reasons for maintaining or for revoking the confidentiality of technical health and safety studies and data underlying a decision to approve a GM food or crop? Please explain. Do you think some particular health and safety data should be released and why?*
3. *Do you think the detailed location of field trials should be disclosed? Why? If a set of criteria for disclosure were established, what kinds of things would you recommend including?*

Do you have any other comments on this issue?

Separation and Independence of Regulatory Functions

The federal government has a number of different responsibilities related to biotechnology and food, such as developing policy and making laws (domestically and internationally); communicating policy decisions and risk; facilitating the responsible use of biotechnology, industry and trade; regulating (evaluating nutritional value and health and environmental risks for this purpose); undertaking scientific research in support of regulation and risk analysis; and undertaking development of new agricultural crops and practices to support food production in Canada. A critical consideration is how government can fulfil these different obligations and ensure that regulatory functions such as technical reviews and regulatory decisions are sufficiently independent of influence of pressures for market development.

Real or Perceived Challenges

While Health Canada, Environment Canada, Fisheries and Oceans Canada, and the CFIA all have a role in the regulatory regime, the discussion in this section is focussed on the CFIA.

The CFIA reports directly to the Minister of Agriculture and Agri-Food Canada and this Minister has substantial authority in CFIA legislation such as the *Feeds Act* and *Seeds Act*. The Department of Agriculture and Agri-Food Canada has a clear mandate to promote agricultural biotechnology and international trade in agricultural commodities. Some observers have suggested that, given the CFIA's

reporting relationship to the Minister of Agriculture and Agri-Food, the separation of regulatory activities for health and environmental protection from other government activities and from political processes may not be sufficient. Others refer to the autonomy of CFIA from the department per se, and argue that the separation and independence of regulatory functions is sufficient, since the department has no authority over the regulatory decisions of CFIA.

Communication and information play important roles in demonstrating the extent and nature of the separation. It is important to deliver clear and accurate messages about roles and responsibilities, and about an organization's approach to handling situations that may appear to create a conflict of interest. Government may not always be effective in clearly communicating these features of its regulatory operations. Furthermore, the food regulators have been criticized for producing information that appeared to some observers to promote GM foods. Although these materials may have been intended to help inform Canadians, the result may instead undermine government's credibility as a neutral evaluator and regulator of the foods and other products of technology.

Some Possible Ways Forward

Given the differences of views in relation to the reporting relationship of the CFIA to the Minister of Agriculture and Agri-Food, some suggest that it could be useful to consider alternate reporting relationships, such as having CFIA report to the Minister of Health, to a separate Minister or to Parliament directly.

As discussed above in relation to the issues of transparency, government regulatory bodies could also give priority to standardizing further their internal procedures. This may answer questions about how government works, and may ensure greater transparency and better communication of information on government's regulatory system.

Government regulatory bodies, very generally, could undertake to communicate more effectively how they achieve effective separation of their regulatory functions from other government activities and responsibilities, and maintain the integrity of their assessments and decisions.

Recognizing that there is a need for 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 and systematic education program that provides information on a range of foods or technologies. As well, whether this kind of information function should be the responsibility of regulatory bodies or non-regulatory parts of government could be given additional consideration.

Questions:

4. *Do you think there is or is not any conflict of interest caused by the current roles and reporting relationships within the federal government, in areas related to GM foods? If so, what are they and what solutions do you suggest?*
5. *What agency or agencies in government should be responsible (i) for consumer information and education related to foods and (ii) for information related to the regulation of foods?*

Do you have any other comments on this issue?

Ensuring Safety During Research and Development Activities

A novel food undergoes many processes before it passes through Canada's food regulatory system and, if allowed, makes its way onto the Canadian market. Plants with novel traits, including those developed using genetic engineering, are produced in laboratories and are studied in growth chambers or greenhouses under conditions of environmental isolation. The genetic manipulation procedures used in the production of GM crops (e.g. gene isolation, cloning, sequencing and transformation) are the same as those used in work with other genetically modified organisms such as bacteria and viruses.

In Canada, codes of practice have been established by research institutions. Canadian Institutes for Health Research (CIHR) have established "Laboratory Biosafety Guidelines" and "Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells." These guidelines apply to work involving genetically modified organisms. There are also internationally recognized standards for "Good Laboratory Practice" that are commonly applied. Adherence to these

guidelines is required by federal funding agencies such as CIHR, Natural Sciences and Engineering Research Council and National Research Council as a criterion for eligibility under their programs. University or institutional biosafety committees are responsible for monitoring compliance. In some cases — although not all — the Good Laboratory Practices carry the force of law.

Real or Perceived Challenges

The early stages of research and development ultimately leading to the production of GM foods do not fall within the regulatory mandate of Health Canada or CFIA. The existing guidelines and standards are generally not legally binding in all cases, and may not capture all research programs.

Some observers are concerned because early stages of research and development conducted in Canada may not always conform with 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 are being followed by various researchers. A third concern is that the degree to which researchers comply with the guidelines is not clear, and the means of enforcing compliance may not always be sufficient if they are not legally binding.

Canada's voluntary CIHR guidelines are similar in intent and implementation to guidelines published by the U.S. National Institutes of Health. However, some countries, such as Argentina, Australia and the United Kingdom, have entrenched their laboratory biosafety guidelines in regulation. In these countries there is a mechanism for some level of mandatory government review of all experimentation involving genetic manipulation and genetically modified organisms.

Some Possible Ways Forward

It may be possible to develop a single, performance-based, minimum standard for recombinant-DNA experimentation, aimed at minimizing human health and environmental concerns. The standard could remain voluntary, or Canada could create specific legislation and regulation to control recombinant-DNA experimentation. Such regulations could be absolute or could permit exemptions on a case-by-case basis for specific facilities or low-risk activities, or for those that apply other approaches as effective as those of the standard.

Some also believe that further regulation of this technology will make it more difficult for small companies or university researchers to engage in the development of new products. Some refer to the lack of evidence of health or environmental harm related to the current research and development activities, and propose no additional regulatory requirements for this work.

Questions:

6. *Do you think the existing approaches to ensuring safety in research and development are satisfactory or not? Please explain your answer.*

Do you have any other comments on this issue?

Opportunities for Public Involvement

Unlike comparable systems in countries like Australia and the United States, Canada's regulatory regime generally makes no provision for public input or comment throughout the risk assessment of a product leading to a regulatory decision. Discussions take place between government risk assessors and the proponent seeking approval of the novel food or crop. But there are no formal opportunities for external scientific bodies, experts or other Canadians to provide comments on an application.

Real or Perceived Challenges

There is a range of views regarding the opportunities for public involvement in the regulatory system and the current lack of an opportunity for public input into individual regulatory decisions on products. The absence of involvement on individual decisions is viewed by some as a weakness of the regulatory system. The concern is that it precludes consideration of all relevant knowledge and views and hinders transparency of decisions and trust in the system. Others think the decisions warrant the public's confidence without additional input, since all reviews are conducted and decisions are made by independent government regulators using assessment methods that have been established with public input and that integrate generally accepted international approaches to risk analysis.

Some Possible Ways Forward

As mentioned above in the issue of transparency, both Health Canada and CFIA publish decision summaries explaining their regulatory decision and the scientific rationale on which it is based. In the interest of adding opportunities for public involvement in government decision making, these decision documents could be made available in advance of the proposed decision, and serve as the basis for requesting comments from Canadians for a given period of time, such as 30 or 60 days. Comments received could be taken into account before a final decision is taken.

In Canada, a model for incorporating public participation in the regulatory decision-making process exists in the registration of a new pesticide active ingredient under the *Pest Control Products Act* and to an application for significant new uses of a previously approved active ingredient. The Pest Management Regulatory Agency (PMRA) publishes Proposed Regulatory Decision Documents that contain summarized product safety data approved by the proponent. Public comment on the proposed decision is accepted for a period of 45 days, after which PMRA publishes a final decision document that also serves to address its consideration of the comments received.

Another possible way forward is to maintain the current status with input on the development of policies and legal requirements but without input on individual decisions.

Questions:

7. *What advantages would you see with the publication of a pre-decision summary, and a period of public comment prior to approval of a GM food or crop? If you think a pre-decision summary would be useful, what information would you like to see in this document? Please explain your answer.*

Do you have any other comments on this issue?

Post-market Monitoring for Risks and Benefits

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. Currently this applies only to *Bt* crops.[7] There are no official mechanisms for monitoring the long-term impacts of GM foods and crops. In Canada, as in most other countries, the responsibility for post-market surveillance is covered by an ongoing duty of care on the part of the developer. The developer is expected to monitor for existing and emerging risks that may be associated with its product and notify the regulatory authorities whenever new information is uncovered.

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 upper safe limit of intake of nutrient is not exceeded). Given the increasing complexity of bio-engineered plants and foods expected to reach the market in coming years, interest in more elaborate and more broadly applied measures and programs for post-market monitoring and review is growing.

Real or Perceived Challenges

CFIA has mandated a 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 that was conducted, a resistance management plan was designed to delay development of *Bt*-resistant insects. Authorization of *Bt* corn in Canada requires the implementation of this resistance management plan. It is the responsibility of the developers of *Bt* corn to make certain corn growers implement the resistance management plan. It is unclear, however, whether sufficient auditing or monitoring take place to evaluate compliance or to assess the adequacy of special conditions required.

GM crops tolerant to the herbicides glyphosate and glufosinate ammonium are the most popular of all the GM crops grown in Canada. CFIA recommends that agricultural extension personnel, in both the private and public sectors, should promote careful management

[7] "*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. These crops can then resist damage from these insect larvae because when the insect eats the plant, the protein induces a toxic effect in the insect's gut and the insect dies.

practices for growers who use these herbicide-tolerant crops so as to minimize the development of multiple resistances. Nevertheless, GM canola plants have been found with resistances to two and three different herbicides. While these plants can be controlled cheaply and effectively with existing techniques, it may be that recommendations for managing some herbicide-tolerant GM crops are not sufficient to ensure that appropriate management practices are followed. Formalized post-market monitoring of this as an environmental concern is lacking, and the responsibility of the developers of this technology in making sure that stewardship programs are taken seriously is unclear.

It is of concern to some that government does not have methods permitting easy identification or traceability of GM foods in the marketplace or any other means of measuring food consumption patterns. Moreover, Canada does not have food consumption monitoring programs, and there are currently no population-based health surveillance programs linked to long-term impacts of foods. In Canada, as in most other countries, the responsibility for post-market surveillance is covered by an ongoing duty of care on the part of the developer. The developer is expected to watch for existing and emerging risks that may be associated with its product, and notify the regulatory authorities whenever new information is uncovered.

There is a lack of post-market data such as sales, use, exports or imports of specific GM foods, crops or seed. As a result, it is difficult to estimate the significance of GM foods in the Canadian diet or the Canadian economy. Some believe this information is important to have; others argue this information is not necessary, given that the GM products are considered safe.

The regulatory system provides for *ad hoc* reviews of new data regarding previously registered products and for 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.) However, the review of new data generally occurs when significant new data have been brought to the attention of the regulators. The process does not require systematic follow-up reviews of all approvals. It does not provide formal opportunities for regulators to identify, retrieve and review new information on a previously approved product. And it does not publish invitations to research institutes or academia to submit additional information that may be relevant to the safety of a previously reviewed food or crop. Some believe these elements of a regulatory program may be useful in ensuring that new scientific studies are carefully considered by regulators and may help ensure that approvals maintained over an extended period of time continue to reflect recent science, even if they were given several years earlier.

Some Possible Ways Forward

Detection Methodologies: The approval of new GM foods, GM crops and other plants with novel traits may require the developer to provide acceptable detection methods for the novel traits or genetic material. Methodologies such as these may be instrumental in allowing effective post-market detection, monitoring and reporting.

Auditing for Conditions Applied for Environmental Safety: For foods and products regulated by government and approved for sale in Canada but with specific conditions imposed in relation to their safe production (e.g. buffer zones around *Bt* corn), operating and publishing audits for compliance with these conditions may be considered.

Environmental and Health Impacts Monitoring: Designing, supporting and conducting additional studies for the detailed, long-term review of health and environmental impacts associated with GM foods/crops could be considered. These studies could be aimed at finding evidence of actual benefits (e.g. decreased pesticide use and groundwater levels of specific chemicals), adverse effects (e.g. gene transfer and effects in non-target populations) and conditions or circumstances in which benefits can be greatest and risks minimized. Similarly, given that the precise location of many field trials on GM foods is known to regulatory bodies, long-term, follow-up monitoring of field test sites could be undertaken to gather evidence of impacts, benefits or harm associated with the planting of GM crops.

Food Consumption Data: Consideration could be given to introducing a program for the monitoring of GM foods consumption to provide information on GM foods

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, and a mathematical integration model for analysis of the information.

Post-market Reports: The private sector could be asked to report annually on its usage, sales, exports and/or imports. A legal basis for these requests/submissions may be considered if needed. 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: It may be advisable for government to formalize a process for the periodic reconsideration or reassessment of the safety of GM 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. This could be put into operation by using approvals that are time-limited, or renewed only upon reassessment of the product using information from multiple sources and upon reaffirmation that it still meets the standards and criteria for health and environmental safety.

Questions:

8. *Which of the ways forward identified above, if any, are needed? Are there others that you would recommend?*
9. *Should Canada re-assess GM crops and foods already on the market for several years? If so, should there be triggers for a re-assessment and what should these be, or should it be automatic at a given time after approval?*

Do you have any other comments on this issue?

Capability and Capacity in the Regulatory System

Rapidly advancing science is changing the nature of new foods and the scientific challenges facing regulators. The issue of capability and capacity within government pertains to the breadth and depth of scientific and regulatory expertise within regulatory agencies. At the heart of the product evaluation process in Canada is scientific peer-review, which has served as the basic mechanism for evaluating the authenticity and significance of innovation in every area of scientific endeavour. Risk assessors for GM crops and foods must have expertise equivalent to that of the academic or industrial scientists who developed these products. A critical mass of competent evaluators is required for a credible, effective and efficient regulatory system.

Government has acknowledged this to some extent by making additional investments. In the Budget 2000, the federal government allocated $90 million specifically to enhance government's capacity for dealing with products of biotechnology. Included in this amount was the funding for several activities within Health Canada to boost scientific capacity, invest in the regulatory system and increase public involvement in and awareness of the regulatory system, particularly as it relates to the issue of biotechnology. A factsheet on this topic is available at: *http://www.hc-sc.gc.ca/english/archives/releases/2001/2001_13ebk2.htm.*

Real or Perceived Challenges

As the science involved in the production of GM crops and foods evolves and as the complexity of the products under assessment increases, it is argued that the scientific expertise available to the regulatory system must remain current. Government has a responsibility to ensure that the level of scientific expertise is contemporary and appropriate. In conjunction with this, the regulatory system could provide for effective access to outside expertise (individuals or panels, Canadian or international) when, for example, specific expertise is not available in-house, a product is the subject of significant public interest, or the workload of the regulatory body is particularly high. The current level of resources may not be sufficient to meet growing needs, and the internal *modus operandi* may not support systematic reliance on outside expertise where and when needed.

To compete effectively for a highly skilled work force, government bodies must provide continuing enhancement of the expertise of their employees. Contributing to the competition for expertise is an apparent lack of experts in some relevant disciplines even today, in part because of insufficient investment in the training of graduate students. These experts-in-training will be needed in order to fulfil future needs of the Canadian regulatory agencies.

Some Possible Ways Forward

CFIA and Health Canada have occasionally used *ad hoc* expert panel consultations to supplement their in-house knowledge. Consideration could be given to the increased use of this outside expertise. As well, procedures and mechanisms could be put in place that facilitate formal, regular and transparent use of such outside expertise or individual outside experts. The procedures could outline, for instance, the specific situations and acceptable purposes for using outside experts, the acceptable range of roles and degrees of information access, clear criteria and mechanisms for selecting the individual(s), and logistics associated with their engagement. Additional funding may be needed for both the maintenance of expertise within the regulatory system and the use of outside expertise.

Another source of outside expertise involves international activities and networks. Drawing expertise through international regulatory activities, for example, through data-sharing programs and joint reviews, and the further harmonization of assessment approaches could also be helpful in this regard.

In order to better prepare for the future, and ensure the availability of expertise required of the regulatory system for the assessment of these products, attention could be placed on developing a better understanding of specific types of GM foods that can reasonably be anticipated to enter the regulatory system in the coming years.

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

With respect to long-term planning for future regulatory needs, forecasting studies can be used to better predict future regulatory needs and how to evolve/prepare for them, based on current and anticipated developments in GM foods technology. Related to this, regulatory bodies could conduct periodic studies of internal capacity and capabilities relative to the knowledge about next-generation GM products.

Questions:

10. *What do you think are the desirable balance and appropriate roles of internal technical experts and outside expertise? How might the government ensure that it maintains flexibility to address all types of crops and foods that are put forth for approval?*
11. *How might the government improve its capability and capacity to identify and plan for the arrival of new GM crops and foods that will come forth for approval in the future?*

Do you have any other comments on this issue?

THEME 2: INFORMATION AND CHOICE

Information Provision to Support Informed Choice

Information provision promotes autonomy and being able to make an informed choice means Canadians have a proper understanding on which to base decisions as to the kinds of foods they wish to consume. Informed choice is contingent on providing Canadians with information on the production, regulation, nutritional value, risks and benefits of various foods available on the Canadian market. Providing this information responds to the desire of Canadians to be able to draw upon reliable sources of information and expertise for a better understanding of foods sold in Canada.

Real or Perceived Challenges

Information about biotechnology and GM foods is often complex and is often geared to a well-informed audience. Likewise, information about the regulation of these foods in Canada is neither user-friendly nor readily accessible, and is often dense and difficult to understand. The problem exists despite attempts at providing clear information, such as that developed and made available through government Web sites.

Information about biotechnology and food, including information provided about the regulatory system, often appears designed to sway the reader — to provide support for or against the technology and the products — and therefore can be said to be biased. Even when it is balanced, the information may appear to promote specific views and behaviours. For this reason, it is unlikely to generate trust and truly support informed choice.

There does not appear to be a comprehensive, authoritative and credible source of information on food biotechnology in Canada that one can consult for complete and balanced information.

Some Possible Ways Forward

An initial step may be to improve the description and communication of information about the Canadian food regulatory system, and ensure that information provided is complete, understandable and easily retrievable. This would benefit from the use of a variety of media in order to ensure accessibility to all Canadians who wish to be informed. The information should be presented with various levels of complexity to be helpful to different readers.

A centralized body for consumer information on food biotechnology may also be desirable. It could provide information on food production, GM foods and food biotechnology, laws and regulations, scientific knowledge, perspectives on ethical and social issues, ongoing research and activities related to these facets of food biotechnology. It could also provide opportunities for accessing detailed information on providing input into government activities on foods and GM foods. To convey balanced information, it may be useful if traditional foods and traditional plant breeding practices were also discussed and if a meaningful description of the benefits, risks and uncertainties associated with different types of foods were provided.

In addition to the above sources, which individuals could access, a proactive communications program may be useful for increasing public awareness, and it has been recommended that there be opportunities for citizen engagement through public dialogue sessions.

Questions

12. *How useful do you think it would be to create a comprehensive and authoritative source of information on GM foods (or foods more broadly) for Canadian consumers, and why? If you support this initiative, who do you think should take the lead in initiating it, and what criteria would have to be met for it to be useful to and trusted by Canadians?*

Do you have any other comments on this issue?

Labelling

In Canadian law, requirements that currently exist for the mandatory labelling of GM foods address aspects of food safety. Nutritional changes, compositional changes and the presence of allergens must be labelled, and these features of foods must be verifiable. Applicable laws include the *Food and Drugs Act* administered by Health Canada and the *Seeds Act* and *Feeds Act*, administered by the CFIA.

There is a desire among some Canadians for the systematic labelling of GM foods. This is triggered by a diversity of concerns, including health and environmental safety and social or ethical concerns. The

Canadian General Standards Board (CGSB) and the Canadian Council of Grocery Distributors (CCGD) have been mandated to develop a national system for standardized, voluntary labelling of foods as to their GM content. One of the significant questions for Canada is whether voluntary labelling can be sufficient, or whether a mandatory mechanism is required and feasible. Other countries have activities related to GM food labelling — involving voluntary and mandatory schemes — and many countries including Canada are working together on an international response to this issue.

Real or Perceived Challenges

Although mandatory requirements do exist for the labelling of GM foods, it is of concern to some that these do not take into account social or ethical concerns or production methods, as these characteristics of a food may impact people's values and influence their choices. If GM products were labelled systematically, people would have the choice to consume GM foods, organic foods or others, whether their choice is based on health and safety reasons or on personal beliefs or preferences. Some argue that a formal labelling scheme could also minimize diversity in labelling practices, which is more likely to ensure that labels are clear, meaningful and accurate.

Labelling would require a segregation system and a means of verifying claims (possibly on an international scale). Some are concerned that these requirements could increase food costs, impede beneficial research and development and have significant implications for the ability of lesser developed countries to engage in trade with export markets. Some believe, however, that these requirements will be needed with or without labelling, because of (current or future) demands by trading partners. Others would prefer to see resources allocated to more effort on the testing and assessment of foods for safety rather than on labelling initiatives.

Because of the lack of harmonization in international labelling schemes and thresholds for the labelling of GM content, it is possible that the schemes and threshold may be construed as arbitrary and contrary to trade laws.

Some think that a mandatory system, as opposed to a voluntary one, is the only approach that can ensure freedom of choice and is essential for informed choice. Others are concerned, however, that a mandatory labelling system may result in foods not being introduced to the market for fear of consumer rejection, or in being removed from the market due to low sales, and that consumers may be denied products with potential consumer, environmental and economic benefits. A mandatory labelling system could also be considered to be contrary to international trade obligations, drawing retaliations from trading partners and reflecting negatively on Canadian food products in the international marketplace.

Some Possible Ways Forward

Domestic: It may be desirable to support efforts to develop a meaningful voluntary standard for the labelling of foods in relation to their content in GM material. In particular, this would involve pursuing and completing the existing initiative to develop a voluntary standard through CGSB and CCGD. To provide reasonable choice to consumers, as well as confidence in their choices through a voluntary system, it may be useful for labels to refer to a source for further information on GM foods, and measures could be undertaken to facilitate and promote broad use and understanding of this system. An alternative approach would be to begin considering and designing elements of a mandatory labelling scheme for GM materials in foods sold in Canada.

International: A second element of a path forward could be to promote and contribute actively to the development of a harmonized international labelling scheme in relation to GM foods.

It is important to note that labelling alone cannot ensure informed choice, since it does not provide extensive background information for the consumer to develop a good understanding of the food. It does, however, constitute an important element of such a choice. The provision of information discussed earlier in this document would be a critical foundation for any labelling scheme for GM products.

Questions:

13. *Given the variety of factors outlined above, do you think the labelling of GM foods or foods containing ingredients from these sources should be (i) voluntary, (ii) mandatory or (iii) not pursued at all, and why?*
14. *Should Canada continue developing its own labelling scheme? Should Canada focus on an international standard? Or can these two routes be addressed simultaneously?*
15. *Are there any other initiatives you would like to see Canada undertake regarding the labelling of GM foods? What are these? Why?*

Do you have any other comments on this issue?

THEME 3: SOCIAL AND ETHICAL CONSIDERATIONS

These issues are included in this Consultation Document in order to introduce the concepts and initiate more in-depth consideration. These may be among the topics discussed in CBAC's future Citizen Engagement Initiative, but CBAC invites any preliminary comments on these at this time.

Environmental Stewardship

Broadly defined, environmental stewardship builds on traditional environmental protection measures such as assessments for environmental impacts, and prevention and enforcement activities. Stewardship involves the larger question of sustainability and the effective integration of key societal goals such as population health and social well-being, environmental conservation and economic prosperity. It involves leadership with respect to the products and technologies one generates, 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, and international cooperation and close links between scientific and regulatory communities must be maintained. In this sense, environmental stewardship can apply to virtually any type of activity or product.

Real or Perceived Challenges

The Knowledge Base: The knowledge base that supports environmental stewardship draws to a large degree from ecosystem science — a thorough understanding of the structure and dynamics of ecosystems and of the implications for different ecosystems of various natural and human activities. Concerns have been raised that capacity in ecosystem science has been reduced in Canada over the past decade, largely due to cutbacks in funding opportunities, including those for research and education in agroecology-related disciplines. Some think that this may have decreased the opportunity for close links between Canadian experts in this field and regulatory experts in government, and may have reduced the expertise available for sophisticated assessments of GM crops. With regard to the more complex "second generation" GM foods and crops expected in the coming years, a resurgence of

research in ecosystem science may be needed to provide a stronger scientific foundation for the effective assessment of these products.

Product Assessments: With respect to government assessments of GM crops (see Theme 2 above), some observers think that applying internationally accepted principles and working with international counterparts may assist in bringing many more countries up to an agreed standard for assessments. As more countries develop expertise with these approaches, they would be in a better position to consider on an ongoing basis what needs to be refined and improved. At the present time, in the context of approving GM foods in Canada and elsewhere, some believe the common principles and approaches to assessment are not sufficient, and call for a stronger approach. They also suggest a stronger scientific basis would allow assessments to be conducted that better address ecological impacts of proposed products, with greater insight into the linkages between managed ecosystems, particularly agricultural ecosystems, and natural systems.

Some Possible Ways Forward

Strengthening the Knowledge Base: A significant investment in research and an enhanced knowledge base related to ecosystem dynamics and ecosystem-level impacts of technological initiatives is important for ensuring the best possible 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 generated in Canada and elsewhere throughout the international community.

Leadership through the Life Cycle Approach: A significant feature of environmental stewardship is a life cycle approach to products, processes, technologies and services. This approach recognizes that all life cycle stages (e.g. manufacturing, transportation, distribution, use/reuse, waste management) have impacts (e.g. environmental and economic implications) that are important when considering the harms and benefits of products. In its broadest sense, the consideration of risks and benefits includes the need for the product, added value, alternatives, and broader matters of sustainability. Some think that it may be worthwhile to consider how the life cycle approach might be refined to apply to GM products.

Others consider this to go beyond what is necessary for effective regulatory assessment and management of GM foods and crops, and believe environmental stewardship in agriculture should be examined in a framework much broader than the production of GM crops — rather it is inherent in farming itself.

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 resistance 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.

Questions:

16. *Do you think the effective regulation of GM foods requires improvements in the scientific knowledge underpinning environmental stewardship and, if so, who do you think should be financing this research?*
17. *In determining the environmental impact of a GM crop, is it sufficient to examine its impact within the context of its use in agriculture? Do you think a life cycle approach is useful? If so, how would it be applied?*

Do you have any other comments on this issue?

Broader Social and Ethical Considerations

In the global discussion of GM foods, a number of broader ethical and social issues have arisen. They are associated directly or indirectly with the origin and

production of GM foods and with their introduction into different societies. These issues, related largely to justice, beneficence and the respect for diversity and traditional knowledge, are the subject of debate internationally and, in some cases, affect people's attitudes toward GM foods.

It is important to note that these issues are generally not limited to GM foods, however, and their effective consideration and management may best be undertaken in a broader context than GM foods or even biotechnology. Regulatory mechanisms or institutions currently in place may suffice for handling some of these questions, but others may require new venues and approaches for national and international dialogue, negotiation and collaborative action.

Categories of Concerns

Ethical Acceptability: Biotechnology allows scientists to produce organisms with various combinations of genetic material — sometimes from closely related species or from species that are distantly related or even essentially unrelated. To some, these genetic modifications leading to GM foods and crops are considered intrinsically wrong. For others, this is of concern only when the combinations are from more distantly related species. In addition, some question the very need for the products. For still others, the current and future benefits of the technology are considerable and justify the pursuit of this technology. Given this diversity of views, some recommend giving consideration to whether, ethically, some processes or applications of GM food technology should not be pursued under any circumstances.

Traditional Knowledge and Resources: Societies around the world may be rich in resources and knowledge that would be beneficial to the generation of new GM foods. By using this knowledge and these resources, corporations could produce new genetic combinations well suited to a given purpose or environment. While the patents are held by these corporations, individuals and societies that contributed knowledge and genetic resources may not share in the financial gains. A related practice is the sale of these improved seeds and varieties back to the source societies and farmers at substantial profit. Others are less or not concerned, because they consider the benefits to growers and consumers in these societies to be of significant value. Discussions about these issues are becoming more common in international fora, and some companies have implemented benefit sharing on a limited basis.

Power Imbalance and Vulnerability: As with the introduction of many new technologies, the development of GM foods has raised the issue of a possible imbalance between those who will benefit most and those who will bear the greatest risk of harm from the technology. Currently, the greatest benefit is often seen as one of productivity and financial gain, shared among a few (e.g. manufacturers and producers) while, in the event of unforeseen impacts on health or the environment, the burden would be felt by a larger population. In response to this, some are advocating a better balance, with greater benefits to consumers and traditional societies, or other approaches entirely. Others view the benefits as being shared more broadly, stating that there are beneficial effects related to job creation, the economy, reduced pesticide use, etc., and argue that the possible unforeseen and intended benefits of GM foods would be beneficial to large segments of the population.

Several large life science companies are acquiring an increasing share of the GM food market. Such concentration is a source of fear and discomfort for some. It is seen as a source of diminished self-sufficiency in food production and a threat to some countries' sovereignty. Others view this as almost a necessity created by the costs and time involved with the regulatory requirements for approvals of GM crops and foods that, they say, can only be met by larger companies.

Others consider food biotechnology as a means of alleviating poverty and starvation around the world and as part of the solution to vulnerability. They see a need for increasing cohesion between industrialized and poor nations, for bringing cutting-edge research to poor farmers, and for transferring biotechnology to developing countries. They consider this as a way to foster food security, to feed another three billion people by 2050, and to deal with a smaller agricultural base and increasingly scarce water supplies, while preventing environmental degradation. They support a cooperative approach that would focus on

meeting the specific needs of lesser developed countries without significant delay.

Environmental Ethics and Economics: Environmental conservation forms the basis for an environmental ethic according to which it is ethically wrong for individuals, companies or societies to behave and develop in a manner that undermines the long-term health of the environment and its natural diversity of plant and animal species. In order for such an ethic to be respected, some believe that greater attention should be given to environmental economics. Environmental economics can be generally described as the range of possible economic approaches that would directly or indirectly contribute to the implementation of the environmental ethic — environmental conservation. For instance, there may be financial incentives or disincentives, such as market drivers, taxation policies and subsidy systems, that encourage people to make decisions in line with environmental considerations. In the context of GM foods, some suggest that further consideration of the meaning and application of environmental ethics and economics may be warranted.

Framework for Addressing Broader Social and Ethical Issues: How and where should the consideration and resolution of these broader social and ethical issues be undertaken? Domestic regulatory systems for GM foods, as for other foods and inputs in food production, address the issue of potential health and environmental risks, and rely essentially on scientific factors and evaluations in drawing regulatory decisions. Ethical issues are considered in the sense that health and environmental safety are priorities in food regulatory systems, and policies are adopted to ensure that the most sensitive sub-populations such as children and the elderly are protected. But the food regulatory systems, in Canada or abroad, generally do not consider the kinds of issues outlined above in their decisions on individual products.

Some consider that, in order to give serious attention to these broader ethical and social dimensions, these should be addressed as part of the individual product evaluations. Some fear, however, that a broader debate at the product level could be a strategic act to delay product approvals. And there is also a fear that this will reduce the predictability of the regulatory process and the basis on which any related decisions would be made. There is a concern that modifications to the basic purpose of assessments, by including social and ethical considerations more specifically, could put a country's policies at odds with international obligations, which would be contrary to the desire of some for international harmonization in matters of product assessment and decision making. The alternative proposal from proponents of the science-based regulatory system, therefore, is that these issues be addressed from a higher and broader policy perspective and not on a case-by-case basis. This could involve Parliament. Formation of an expert committee reporting to government to study and advise on these matters in a manner that addresses classes of products and activities rather than individual product decisions may also be a possible format.

Some Possible Ways Forward

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 is needed to identify the best approach for better defining and actively addressing the broader ethical and social issues, and the trade-offs among and between them. A key question is whether or not the regulatory system could and should be modified in order to add broader social and ethical considerations, or some of them, 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 largely could be the subject of review.

Further Defining the Issues: Further work could be pursued to better define the broader social and ethical issues, such as those described above. This could be undertaken in cooperation with other experts and organizations domestically and abroad already considering these issues, including international organizations and foreign governments. A better understanding of the perspectives of the general public might also be pursued in defining these issues — including the Canadian public and individuals from developing countries, through informed public dialogue on these matters.

Assessing the Issues Against Fundamental Principles: Once these issues are better defined, the next step could

involve applying an ethical context of principles and values that serve as a lens through which the issues can be better understood and existing policies contributing to the concerns can be reviewed and reconsidered.

Finding Solutions that Reflect Core Principles and Values for Public Policy Making: Following the above work to define and analyze the ethical and so cial issues further, the identification of solutions could then proceed. The activities that may be helpful to identify possible solutions could involve:

- Conducting research on long-term ecological impacts, with a focus on questions 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 could better support global food security; placing emphasis on activities and research designed to address specific concerns and needs of vulnerable societies; and respecting the diversity of cultures and unique methods of food production.
- Reconsidering domestic legislative framework and international agreements from the perspective of broader social and ethical concerns; and considering what changes may be needed to better address these issues (e.g. changes to the nature of ownership/partnerships, approaches for restricting GM foods that are generally undesirable from an ethical or moral perspective, enforcing biodiversity controls and improving their adoption by countries, economic drivers to support environmental ethics, etc.).
- Undertaking these activities with international collaboration to encourage an appropriate level of harmonization between countries facing these issues and to ensure coherence between national and international policy.

Questions:

18. *Does the above discussion touch on the most important social and ethical issues related to GM foods? Are there others? (Please name and/or describe.)*
19. *Do you think that efforts should be placed on addressing issues such as these? If so, what approaches would you recommend? By or with whom should the work be undertaken?*
20. *If you think there is a need for government involvement in addressing these issues, at what level of governance do you think these should be addressed — by regulators, through case-by-case decisions on each product, or with broader government policy applicable to categories of products or activities? Which body or bodies should play a lead role?*

Do you have any other comments on this issue?

Annex 1 — Overview of CBAC's Special Project on the Regulation of Genetically Modified Foods

At its inaugural meeting in October 1999, CBAC identified the robustness of Canada's systems for assessing and regulating the application of biotechnological innovations as an issue requiring study and evaluation. It specifically cited GM foods as being of special interest. This launched the start of its special project on GM foods. The committee then identified three areas of study:

- The science base underpinning the regulatory processes.
- The governance and organization of regulatory systems.
- The social, ethical and legal dimensions of GM foods.

CBAC refined its plans in December 1999 to focus on the latter two aspects when, after discussions with the government, the Royal Society's Expert Scientific Panel on the Future of Food Biotechnology was created to advise on the scientific capacity of the regulatory system regarding GM foods. CBAC's deliberations will be informed by the outcome of the work of the Royal Society, as it will be by the work of the CGSB and the CCGD that, together, are directing the development of a voluntary Canadian standard for the labelling of foods with respect to the content or origin in genetically modified materials.

CBAC Objectives Regarding the Regulation of GM Foods

- *Identify the issues that require examination in the public debate on GM foods in the broader context of agriculture and food production in general.*
- *Examine issues related to the governance and organization of the food regulatory system for GM foods not examined by the Expert Scientific Panel on the Future of Food Biotechnology.*
- *Examine other issues related to GM foods including social, ethical, legal, economic and environmental issues.*
- *Make recommendations concerning policy options for Canada.*
- *Maintain liaison with the Expert Scientific Panel and to relate its findings to the outcome of the work of CBAC on governance and organization and on social, ethical, legal, economic and environmental issues.*
- *Raise public awareness and engage Canadians in an unbiased manner.*

Information Collection: CBAC began its work on GM foods by identifying specific research topics, locating relevant documentation and generating technical reports on specific questions. The committee reviewed relevant public opinion surveys, commissioned documents to stimulate thinking regarding the social, ethical and moral parameters of GM foods, and held a workshop with Canadian regulators to learn more about the Canadian regulatory system. The reports generated by CBAC on or related to the topic of GM foods are listed below.

Issues Analysis: On the basis of the information collected and with an emphasis on the observations and conclusions contained in the commissioned reports, CBAC identified an initial set of 10 issues, real or perceived challenges underlying the issues and a number of possible policy options intended to address these. This analysis formed the foundation for CBAC's present consultations on GM foods.

Consultations: In order to seek the views of Canadians in developing its recommendations, CBAC has undertaken to consult with Canadians through various mechanisms. The primary vehicle for obtaining the views of Canadians is the present consultations document; other sources include multistakeholder workshops and comments received by mail and through CBAC's toll-free number and Web site. Current public opinion research will also be considered. CBAC will consider the input received and develop its advice and specific recommendations for Canada's policies on GM foods. The report is expected to be completed in spring 2001.

Reference Group: To assist in the above processes, CBAC created a reference group of individuals affiliated with various stakeholder groups to revise and comment on the committee's research reports, key issues, consultation approach, consultation document and communication materials. The group has held two full-day meetings to date. The members of the reference group are not tasked with achieving consensus on their views and preferences, and do not necessarily endorse CBAC's work or its consultation document. They have made a very valuable contribution to CBAC's work through the insights, observations and suggestions they have provided.

CBAC Commissioned Reports on or Related to GM Foods

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

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, Calgary, AB; Dr. Karen Finlay, Associate Professor, Department of Consumer Studies, University of Guelph, Guelph, ON; and Jennifer Arko, Research Assistant, University of Calgary, Calgary, AB.

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, Ottawa, ON.

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

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

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

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, Victoria, BC.

Status Report and Commentary on the International Debate Over the Precautionary Principle, by Dr. Marc Saner, Managing Director, Ethics and Policy Issues Centre (EPIC), Department of Philosophy, Carleton University, Ottawa, ON.

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

Analysis of Relevant Canadian Legislation, by Dr. 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, Vancouver, BC.

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

Disclaimer

CBAC will treat all responses to the questionnaire, by whatever means they are transmitted, as confidential. However, those who choose to transmit their responses electronically should be aware that such transmissions are inherently insecure and CBAC is therefore not in a position to guarantee their confidentiality.

To use the electronic feedback form please click here.

Annex 2 — Questionnaire

Please use this questionnaire to provide your responses to the questions in this consultation document.

To begin — please help our analysis by completing the following table

Please indicate the perspective from which you are responding (please check one of the following)

- ☐ consumer(s) of foods sold in Canada
- ☐ industry representative(s) involved in biotechnology, food production, distribution or commercialization
- ☐ representative(s) of non-governmental not-for-profit organization
- ☐ student(s)
- ☐ academic(s) or research scientist(s)
- ☐ government official
- ☐ other _____

Please indicate your level of knowledge regarding GM foods and their regulation in Canada:

- ☐ low
- ☐ medium
- ☐ high

Are you submitting one questionnaire on behalf of a group or organization? _____

If so, on behalf of how many people are you submitting? _____

If not, please indicate your age:

- ☐ under 25 years
- ☐ 26–45 years
- ☐ 46–65 years
- ☐ over 65 years

Part 1 — Specific Questions

Transparency (see page 7)

1. Would a description of the regulatory system, as proposed, provide the kind of information someone would need to learn more about the regulatory system and how decisions on GM foods are made? Do you think you would use this information. If so, how? Where would you like to be able to locate the information (e.g. pamphlet, Web site, other)?

2. Do you think there are good reasons for maintaining or for revoking the confidentiality of technical health and safety studies and data underlying a decision to approve a GM food or crop? Please explain. Do you think some particular health and safety data should be released and why?

3. Do you think the detailed location of field trials should be disclosed? Why? If a set of criteria for disclosure were established, what kinds of things would you recommend including?

**Do you have any other comments on this issue?*

Separation and independence of regulatory functions (see page 8)

4. Do you think there is or is not any conflict of interest caused by the current roles and reporting relationships within the federal government, in areas related to GM foods? If so, what are they and what solutions do you suggest?

5. What agency or agencies in government should be responsible (i) for consumer information and education related to foods and (ii) for information related to the regulation of foods?

** Do you have any other comments on this issue?*

Ensuring safety during research and development activities *(see page 9)*

6. Do you think the existing approaches to ensuring safety in research and development are satisfactory or not? Please explain your answer.

**Do you have any other comments on this issue?*

Opportunities for public involvement(see page 10)

7. What advantages would you see with the publication of a pre-decision summary, and a period of public comment prior to approval of a GM food or crop? If you think a pre-decision summary would be useful what information would you like to see in this document. Please explain your answer.

**Do you have any other comments on this issue?*

Post-market monitoring for risks and benefits *(see page 11)*

8. Which of the ways forward identified above, if any, are needed? Are there others that you would recommend?

9. Should Canada re-assess GM crops and foods already on the market for several years? If so, should there be triggers for a re-assessment and what should these be, or should it be automatic at a given time after approval?

** Do you have any other comments on this issue?*

Capability and capacity in the regulatory system *(see page 13)*

10. What do you think are the desirable balance and appropriate roles of internal technical experts and outside expertise? How might the government ensure that it maintains flexibility to address all types of crops and foods that are put forth for approval?

11. How might the government improve its capability and capacity to identify and plan for the arrival of new GM crops and foods that will come forth for approval in the future?

** Do you have any other comments on this issue?*

Information provision to support informed choice *(see page 15)*

12. How useful do you think it would be to create a comprehensive and authoritative source of information on GM foods (or foods more broadly) for Canadian consumers, and why? If you support this initiative, who do you think should take the lead in initiating it, and what criteria would have to be met for it to be useful to and trusted by Canadians?

** Do you have any other comments on this issue?*

Labeling *(see page 15)*

13. Given the variety of factors outlined above, do you think the labeling of GM foods or foods containing ingredients from these sources should be (i) voluntary, (ii) mandatory or (iii) not pursued at all, and why?

14. Should Canada continue developing its own labeling scheme? Should Canada focus on an international standard? Or can these two routes be addressed simultaneously?

15. Are there any other initiatives you would like to see Canada undertake regarding the labeling of GM foods? What are these? Why?

** Do you have any other comments on this issue?*

Environmental stewardship *(see page 17)*

16. Do you think the effective regulation of GM foods requires improvements in the scientific knowledge underpinning environmental stewardship and, if so, who do you think should be financing this research?

17. In determining the environmental impact of a GM crop, is it sufficient to examine its impact within the context of its use in agriculture? Do you think a life cycle approach is useful? If so, how would it be applied?

** Do you have any other comments on this issue?*

Broader social and ethical considerations *(see page 18)*

18. Does the above discussion touch on the most important social and ethical issues related to GM foods? Are there others? (Please name and/or describe.)

19. Do you think that efforts should be placed on addressing issues such as these? If so, what approaches would you recommend? By or with whom should the work be undertaken?

20. If you think there is a need for government involvement in addressing these issues, at what level of governance do you think these should be addressed — by regulators, through case-by-case decisions on each product, or with broader government policy applicable to categories of products or activities? Which body or bodies should play a lead role?

**Do you have any other comments on this issue?*

Part 2 — Other Comments

Please use the space provided here for additional comments or feedback