SUMMARY CONSULTATION REPORT

WRITTEN INPUT ON GENETICALLY MODIFIED FOOD

Prepared by the Canadian Biotechnology Advisory Committee

This report summarizes the input received during CBAC's consultations on GM food. The views reflected in this document should not be considered consensus views of respondents, nor should they be construed to reflect the views of CBAC.

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Introduction

The Canadian Biotechnology Advisory Committee (CBAC) is an independent expert advisory committee created to assist the Government of Canada in forming public policy on a range of biotechnology subjects.[1] It provides advice to the Biotechnology Ministerial Coordinating Committee (BMCC) which includes the federal Ministers of Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, Industry and International Trade.

In 2000, CBAC initiated a project on the Regulation of Genetically Modified (GM) Food. Following a period of information collection and issue analysis, CBAC produced a Consultation Document outlining 10 key issues related to GM food and a series of possible ways forward for resolving them. The main purpose of the Consultation Document was to explain the key issues identified by CBAC and to seek views on these matters. It also provided an opportunity for respondents to describe additional views, general or specific, on any other aspect of GM food regulation of interest or concern to them. Canadians were invited to respond to one, some or all of the questions, and to develop and submit comments either individually, in small groups or on behalf of an organization.

CBAC released the Consultation Document in March 2001. The document was posted on CBAC's web site and mailed to over 150 individuals and organizations on CBAC's mailing list. Various organizations such as producers, environmental and citizen groups, consumers, health professionals and industry kindly assisted CBAC in the electronic circulation of the document, by posting it on their respective web sites or circulating it to their members. Canadians were invited to provide comments electronically, by fax or by mail.

This report presents an analysis of the written comments submitted by Canadians in response to the Consultation Document on the Regulation of Genetically Modified Food, and electronic submissions and letters regarding GM food policy that were received by CBAC during the course of the consultations. The views expressed in this report will be taken into consideration by CBAC, along with other streams of information, in developing its initial report to Government on the regulation of GM food, due in June 2001, as well as its set of formal recommendations that will be delivered in 2002.

[1] Detailed information on CBAC, its work plan and current activities, as well as other information on the GM food project, is available through the Committee's Web site at www.cbac-cccb.ca or toll-free number: 1-866-748-2222; TTY/ATS: 1-866-835-5380.

Design

The Consultation Document consists of four main sections. The "Introduction and Purpose" section explains CBAC and puts the document in context. "Genetically Modified Foods and the Canadian Regulatory System" outlines what GM food is and how it is regulated in Canada. The section entitled "Ethical Context" discusses public interest as CBAC's primary criterion in developing its recommendations and proposed for discussion a series of values and principles that could serve as a basis for better informing the discussion of potential recommendations. The section on "Key Issues Affecting the Regulation of Genetically Modified Foods" forms the core of the Consultation Document and presents CBAC's 10 key issues related to the regulation of GM food.

CBAC has grouped the 10 key issues into three broad themes as shown below. The consultation document describes each issue and presents some of the possible solutions for the issues. Questions are at the end of each issue to elicit from Canadians their views on specific aspects of the subject and to invite them to provide other comments if desired. These questions appear again in Annex 2 of the document as a complete questionnaire.

Themes	**Issues**
Good Governance	Transparency Separation and Independence of Regulatory Functions Ensuring Safety During Research and Development Activities Opportunities for Public Involvement Post-Market Monitoring for Risks and Benefits Capability and Capacity in the Regulatory System
Information and Choice	Information Provision Labelling
Social and Ethical Responsibilities	Environmental Stewardship Broader Social and Ethical Considerations

Annex 2, the questionnaire, consists of three parts. An introductory section asks respondents to indicate if they belong to any of seven interest groups listed, their level of knowledge concerning GM foods and GM food regulation, and their age group. The purpose of this information was to be able to broadly group respondents and better identify any themes or concerns that might exist among particular groups of people. Respondents were not asked to give their names. The next section of the questionnaire repeats the specific questions listed throughout the document. Altogether, 20 specific questions were posed. The last section provides space for additional comments, general or specific. The questions reappear below to facilitate the review of the summary document.

Questionnaire

Questions put forth in CBAC's Consultation Document on the Regulation of Genetically Modified Food.

Please indicate the perspective from which you are responding:

- Consumer(s) of food sold in Canada
- Industry representative(s) involved in biotechnology, food production, distribution or commercialization
- Representative(s) of non-government 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:

- High
- Medium
- Low

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
The page numbers noted beside issue area refer to the relevant page in the Consultation Document 2001, Regulation of Genetically Modified Food.

Transparency

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 this information (e.g. pamphlet, Web site, other)?

2. Do you think there are good reasons for maintaining or revoking the confidentiality of technical health and safety studies and data underlying a decision to approve a GM crop 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

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 (1) for consumer information and education related to foods and (2) for information related to the regulation of foods?

Do you have any other comments on this issue?

Ensuring safety during research and development activities

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

7. What advantages would you see with the publication of a pre-decision summary, and a public comment prior to approval 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

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 food 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

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 it's flexibility 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

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

12. initiative, who do you think should take the lead in initiating it and what criteria would you have to be met for it to be useful to and trusted Canadians?

Do you have any other comments on this issue?

Labelling

13. Given the variety of factors outlined above, do you think the labeling of GM Foods of foods containing ingredients from these sources should be (1) voluntary, (2) mandatory, (3) not pursued at all, and why?

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

15. Are there any 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

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

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 the role?

Do you have any other comments on this issue?

Analysis

Respondents

In total, 36 submissions were received by CBAC. Responses were classified according to the perspective of each respondent, using the seven categories listed in the questionnaire. The number of responses received is as follows:

- Consumers (7)
- Industry representatives (13)
- Representative of a non-governmental not-for-profit organization (5)
- Student (0)
- Academic or research scientist (3)
- Government official (0)
- Other (8)

Among the 12 respondents who indicated their knowledge level, 7 indicated a high level of knowledge and 5 indicated that their knowledge level was medium. No respondent self-identified as having a "low" level of knowledge about the topic.

Among the 5 who identified an age-range, 1 respondent was <25 years, 3 were 26-45, 1 was 46-65 and none were >65.

A number of responses (14) were specifically provided as individual submissions. Some responses (3) were received on behalf of a small group of people (2 to 4 individuals). 19 responses stated the membership of the organization submitting the response (e.g. 45 000 individuals or 180 companies). 17 indicated that their submission reflected the agreed positions of the organization.

Some respondents answered each question in the document while others responded to specific questions or issues of interest or concern to them.

Analysis conducted

CBAC has reviewed the responses received and prepared a summary table of responses to the various questions. For those who did not refer to a specific question in their response, CBAC has either included the information alongside the most appropriate questions (e.g. if it was clearly related to labelling, for example) or captured the information under "other views". Based on this summary of the responses received, CBAC has drawn out the key patterns and messages observed across the responses, e.g. the main types of responses and reasoning, related to a given question and among the "other views".

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

This report is intended to be a reflection of the views of those submitting input to CBAC's consultations on GM food, drawing out key patterns and messages in a qualitative rather than a quantitative manner. The views should not be considered consensus views of respondents, nor should they be construed to reflect the

views of CBAC. Likewise, this report should not be considered to represent the views of the reviewers commissioned to assist CBAC in the preparation of this report, as the reviewers may not necessarily agree with the report or with the views it contains.

Patterns observed

Please refer to page 5 of this report to review the questions referred to in this section.

Question 1 (17 responses)

There was overall strong support for a better description of the regulatory system. Decision trees and hypothetical case studies were suggested as useful methods for helping consumers to understand the food regulatory process in Canada. Suggestions about what information should be provided include steps and timeframe for product approval, lists of products currently under review, criteria for approval, costs involved in product approval and dispute resolution mechanisms.

The favored location of this information was in pamphlets and on web sites. It was noted that compared to pamphlets, web sites are cost effective and easily updated. However, it was also noted that it should not be assumed that everyone has access to the Internet and therefore the information should also be provided in alternate forms that are easily accessible. It was suggested that information should be available everywhere that food is sold and that if there is a relevant web site then it should be noted on food packaging. Other suggestions for where this information should be located included mass media and a toll free number.

There is not strong agreement on who should provide this information, some suggested that government, industry and stakeholders should be responsible for this while others indicated that they did not trust industry information and think that only government should be responsible. Regardless of who provides the information, respondents think that it should be clear, concise, and accessible and not overlap or contradict with other information provided on the same topics.

Another view expressed was that providing a more elaborate explanation of what is being done now will not instill public confidence in the regulatory system and would be a waste of resources.

Question 2 (18 responses)

There is support for maintaining the confidentiality of technical health and safety studies and data and there is also support for making this information accessible. The support for maintaining the confidentiality generally is related to preserving the competitiveness of biotechnology companies in Canada. The rationale is that intellectual property, including the data submitted to have a product assessed for approval, is often the only or the most valuable asset that a biotechnology company has. Releasing this data may put these companies at a competitive disadvantage and could potentially cause large financial losses. Further, it was noted that most of the confidential data is very specific and of no direct use to the consumer.

Those who support revoking the confidentiality generally are concerned about the transparency of the system, adequate information provision to the public, the legitimacy of the regulatory system and maintaining/restoring public confidence in the testing and safety of GM foods. It was noted that independent peer review is an essential element of the scientific process. If the scientific data supporting regulatory decisions is not made public, and as a result not open to review, then the government cannot claim to have a science-based regulatory system. Some expressed concern that, by not releasing the data, it appears that there is something to hide and that the public is not being kept informed. It was noted that although not everyone will be able to interpret the data it should be released because there will be some individuals who will be able to interpret it.

Some respondents expressed the need to balance the rights of the public to timely, adequate information with the desire of the companies to remain competitive. They pointed out that more information than is currently provided could be made available without damaging a company's competitiveness. This would require determining what is *truly* valuable corporate intellectual property and releasing all other data. It was noted that decision summaries, consisting of the results of health and safety studies and rationale for the decision, would be adequate for public information needs. Timely release of these summaries (30 days after the decision was one suggestion) would help build public trust and confidence. A review of current policies on confidential business information might be necessary to ensure an open and transparent regulatory process.

Question 3 (16 responses)

Two categories of ideas were presented - those in favor of releasing detailed locations of field trials and those who oppose the release of this information. Those in favor of publishing the detailed location of field trials expressed concern about contamination of non-GM crops and the need to protect neighboring farms against cross-pollination. It was suggested that the risk of vandalism and crop destruction would be lower if the safety requirements for field trials were "stringent enough" and transparent to the public. Another view in support of releasing the detailed location is to allow other scientists to observe the results.

Suggestions as to what other types of information should be released include; the source of GM material in the crop, the purpose of the test, special precautions and a contact phone number.

Those opposing disclosure of locations expressed concerns about trespassing on the sites of field trials, vandalism and the physical safety of farm workers. There is also the concern that if detailed locations are made public, growers will be less willing to participate in GM crop trials because they may become targets of activists and vandalism. These trials are essential in determining the safety of the products.

Several alternatives to releasing the detailed locations of field trials were suggested:

- Organizers of the GM crop trials should ensure adequate isolation of the trial from other farms.
- The standards of practice and procedures that guide farmers during these trials should be made public as this may reduce concerns about the location.
- Public research facilities, universities, or registrants of field trials could open a field trial to the public to demonstrate GM crops and educate the public.

Some think that the current status quo of publishing the types of technologies that are undergoing trials and the number of trials in a given area was adequate for public information needs.

Other comments on this issue (6 respondents)

Other views expressed in relation to the issue of transparency include:

- As per Royal Society recommendations, increased transparency in the regulatory system and a new philosophy of regulation is required. The respondent notes that regulators base their decisions on data provided by the applicant, who has a vested interest in obtaining approval for the product. There is no provision for independent testing and the applicant can declare that the data and information provided is confidential business information, which means the data cannot be released to the public or to other scientists. As a result, the respondent noted that this data is not subject to any of the normal checks and balances of other scientific research, namely peer review and verification of results in other laboratories.

- ❖ It would be ideal if the government could conduct all safety tests but this is impossible. Therefore it is important to properly control the type and the flow of information that flows between industry and government.
- ❖ Opponents of biotechnology have not had to be transparent about their vested interests; they should be made to do so in order to take part in the debate on biotechnology. Government should create a web site listing those organizations requesting approval for a product and those requesting information.

Other comments:

- ❖ Not enough is known about the long-term effects of GM foods to be able to approve them, test them, or declare them safe.
- ❖ Genetic modification to effect sterilization of seed in subsequent generations should be disallowed as well as the introduction of zoological genes into plant material and vice-versa.

Question 4 (16 responses)

There were two categories of views expressed – those respondents who think that there is not a conflict of interest, and those who think that there is a conflict of interest caused by the current roles and reporting relationships within the federal government. Those that think there is a conflict of interest noted that the government has a dual role of both promoting and regulating products of biotechnology, and that this creates a conflict of interest. It was suggested that a separate ministry to regulate crops and food should be created. This ministry should have adequate resources and be periodically reviewed to ensure that it is able to keep up with new challenges.

Those that think there is not a conflict of interest suggest that it is part of a regulatory agency's mandate to be publicly accountable by providing information about how products are regulated and the steps taken to ensure safety. Some respondents think that the provision of this information has been misinterpreted as promotion of products or technologies. It was also thought that there was not a conflict of interest related to the Canadian Food Inspection Agency (CFIA) because this agency is not involved in the commercial development or marketing of products.

Another view expressed is that there is an *apparent* conflict of interest, which could be minimized by clearly defining the roles and the extent of communications between parties.

Question 5 (16 responses)

Overall respondents suggested that each regulatory agency should provide information related to their mandate and their regulatory activities, while Health Canada should provide consumer information and education related to foods. Alternate suggestions include:

- ❖ CFIA or Health Canada should provide both consumer information and information related to the regulation of foods.
- ❖ A branch of consumer affairs staffed by dieticians and home economists could provide this information.
- ❖ Information and education should be provided by a single entity that is separate from government.
- ❖ Create partnerships with NGO's, the private sector, the Food Biotechnology Communications Network and the Consumers Association of Canada to dissemination the information.

Other comments on this issue (5 responses)

Another view expressed in relation to the issue of separation and independence of regulatory functions is that the current regulatory system is sound and the regulators are fair and rigorous in their food safety assessments. It was noted that the government should better defend its regulatory system.

Other comments:

- The Canadian government has been bowing to the corporate interests of the United States. This is jeopardizing personal health, environmental health and sustainable agriculture in Canada.
- There is a need for specialists and inspectors in food safety and nutrition, especially to inspect fast food restaurants which have lax food quality and cleanliness habits.
- The integrity of the government regulatory agencies is questionable because industry provides funds and resources to AAFC research stations.

Question 6 (17 responses)

Some respondents think that the existing approaches to ensuring safety in research and development are adequate and others think that these approaches are not adequate. Those respondents that think the current standards are adequate noted that continued efforts are necessary to ensure that the existing standards and guidelines are being followed. As new technologies are developed, this issue may need to be re-evaluated as it is important that approaches to safety evolve with developments in research. It was noted that a single set of regulations might be difficult to implement and may not offer long term benefits. In part, this is because the level of risk is different depending on the type of crop and gene being experimented with.

The respondents that think that the existing approaches are not adequate suggested that the Precautionary Principle should be adopted and new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe. It was also suggested that GM foods should not be compared to similar conventional foods, rather, they should be rigorously tested in a way similar to that of new drugs.

Two key issues relating to post-market monitoring suggested by a respondent include:

- Safe-to-fail experiments. Relying on post-market monitoring assumes that adverse effects can be detected and controlled. This may not always be the case. The respondent notes that if 'safe-to-fail' release of GM crops is not possible, the Canadian government should consider the ethics of continuing with this technology.
- Liability. Should adverse effects occur, who is liable? The respondent thinks that this issue is particularly important for organic farmers who currently risk losing markets if their crops are combined at any stage with GM varieties.

Another view expressed is that if regulators suspect, upon reviewing a submission, that Good Laboratory Practices have not been followed, they should be able to order further investigation and possibly deny approval.

Other comments on this issue (1 response)

Another view expressed is that the regulatory agencies should provide guidance to product developers on what would be appropriate and inappropriate potential products.

Question 7 (18 responses)

Most respondents agreed that a pre-decision summary document - one that presents a summary of the risk assessment and the proposed regulatory decision - would be useful. It was noted that GM crops involve complex and uncertain technologies and therefor better decisions will arise from processes that include a diverse range of knowledge and experience. Some respondents think that pre-decisions summaries and public comment periods would be beneficial in that they would allow the public to be involved in decisions about GM food and to provide input about the acceptability of new products. It was also suggested that this process would increase the transparency of the system and provide an opportunity for the public to learn about the regulatory system and about GM foods. It was noted that if pre-decision summaries are to be provided, they should be for all foods, not just GM foods.

Some respondents noted that this exercise would only be effective if it offered real involvement for the public and if there is a mechanism whereby concerns raised during the public comment period could be addressed. However, there is concern about the ability of the general public to interpret the data provided and the potential for misinterpretation. Some respondents suggested that the final decisions should remain with the regulatory agencies and that the regulatory approval system should remain science-based. Questions arise regarding how the public input will fit into the regulatory system, such as; how will the input be assessed? Would the public expect veto power?

The information that respondents suggested should be included in the summary is:

- The allergenicity, nutrition and chemical tests conducted and the results;
- The length of time that the tests were conducted for;
- Whether the tests looked at cumulative effects;
- The corporations involved;
- The effects of the genetic modification;
- Detailed reasoning behind regulatory decisions;

Respondents that did not think a pre-decision summary would be useful instead, thought that the public should be involved in setting policy to guide regulatory agencies and that individual product decisions and accountability should rest with the regulatory agencies. It was suggested that if the complete regulatory process is transparent and open to public scrutiny then the public would be more likely to trust regulators to make good safety decisions on their behalf.

Other comments on this issue (4 responses)

Other views expressed in relation to the issue of opportunities for public involvement include:

- There should be an easy way for the public to provide input into the regulatory process and there should be a mechanism to ensure that issues raised by the public are addressed.
- All risks and benefits associated with the genetic modification should be available for review by the public.
- Publishing a pre-decision summary and offering a public comment period could lengthen the time it takes to get a product approved and politicize the regulatory process.
- The issue is primarily one of risk. The public should be reassured that there have been no adverse health or environmental effects as a result of agricultural biotechnology. Agencies should also continue to be vigilant with new products and they should involve the public.

Question 8 (13 responses)

Respondents agreed that post market monitoring is useful and necessary for a variety of reasons including:

- To demonstrate that GM foods are safe;
- To build public support for the regulatory system;
- To track the long-term effects of GM crops.

Responses varied in regards to the suggested ways forward. There are six proposed methods for post market monitoring listed in the Consultation Document:

- Detection methodologies;
- Auditing for conditions applied for environmental safety;
- Environmental health impacts monitoring;
- Food consumption data;
- Post market reports;
- Reconsideration of approvals.

It was noted that while they all have advantages, there is not one method that will solve all the long-term health and environmental concerns that exist. Environmental and health impacts monitoring was noted as useful but it should not be limited to just GM foods. Monitoring GM food consumption would require segregation and labelling of foods making the information costly and difficult to obtain. Some questioned whether the benefits would be worth the cost. Detection methodologies, especially internationally accepted methodologies, were noted as useful because reliable detection of GM food will be required to enforce labelling standards and international trade regulations. In contrast detection methodologies were also noted as not necessary because in many cases the traits are detectable.

Other respondents suggested that the post market monitoring process could involve extending the current post harvest monitoring system established by the CFIA for confined field trials (Dir 2000-07) to the approval process under "unconfined release" (Dir 94-03). The post market monitoring system used by the chemical industry was also noted as a good model. It was suggested that industry should further enhance stewardship programs that provide monitoring and that they should bear some of the costs associated with ongoing monitoring. Another suggestion is that the current techniques of 'adaptive management' should be explored in relation to how they can be applied to the assessment and monitoring of GM crops.

Some respondents think that the current approach of developing post market monitoring systems on a case-by-case basis is better than developing a formal program because it allows for flexibility and responsiveness to changing circumstances. An example provided is the multi-stakeholder oversight group for Bt corn. It was also suggested that the need for post-market monitoring could effectively be circumvented by placing an emphasis on health and environmental assessments prior to approval of a product.

Question 9 (16 responses)

There were two categories of responses – those respondents that support automatic reassessments of GM crops and foods and those that do not support this. Respondents that support an automatic reassessment expressed concern about potential long-term adverse effects of GM crops. It was suggested that ongoing studies for GM crops should be mandated. Some respondents are concerned that GM foods already on the market have not gone through a stringent enough approval process and therefore should be reassessed as soon as possible. It was suggested that those conducting the reassessment should have the power to remove the food from the market if necessary.

Concern was expressed about the potential burden of cost that might be placed on Industry as a result of reassessments. It was suggested that if reassessments are undertaken they should not require expensive and

long-term testing from Industry, as is required in the initial application. Some respondents supported the establishment of triggers for reassessment, although only one trigger; new information about a product was specifically noted in the responses.

Respondents not in support of automatic reassessment think that the current system, which provides for ad hoc reviews, as new information becomes available, is adequate. Some respondents feel that automatic reassessments may suggest that the regulatory system is inadequate. It was noted that resources should not be diverted from the safety assessment of new GM foods to reassess foods that have already been deemed safe. Furthermore, it was also noted that the guidelines for reassessment of GM crops should not be any different than those for conventional crops.

Another view expressed is that a five-year review period would be useful, if there is also a mechanism in place for the government to deem that a crop is no longer novel.

Other comments on this issue (4 responses)

Other views expressed in relation to the issue of post-market monitoring for risks and benefits include:

- Opponents of biotechnology have raised issues such as monitoring, not because they are concerned about safety but because they want to stop the commercialization of GM foods.
- If new data were to indicate that there were no concerns with a technology, the government should have a mechanism for removing the regulatory requirements for that class of technology.
- GM foods should not be monitored; they should be removed from the market completely.
- Increase government financial support for research on food-borne pathogens and antimicrobial resistance related to the hog industry.

Question 10 (17 responses)

Respondents agreed that the use of external expertise by regulatory agencies is beneficial. However, many respondents think that the government must first ensure that there is sufficient in-house expertise to assess outside work, to address all types of foods that are put forward for approval and to maintain independent decision making capabilities. It was noted that the roles of both internal and external experts must be transparent and external experts must disclose any ties to the biotechnology or organic industries. The potential roles suggested for external experts include:

- To complement and confirm the initial work of government;
- To assist with a higher workload when necessary;
- To offer specific expertise when required;
- To maintain the integrity of the review process.

Some respondents think that the government should rely less on research done by the biotechnology companies and hire more scientists or fund university research. It was suggested that research that comes from publicly funded labs is the most credible to the public. Some respondents expressed the idea that efforts should be made to reduce the duplication of research studies done on the same products. In this regard it was suggested that the government not repeat peer reviewed studies conducted by industry or academics and that harmonized assessment approaches, data sharing and joint review with other jurisdictions be considered.

Other views expressed are:

- ❖ Regular peer reviews of the risk assessments done by regulatory agencies should be conducted. An arms length panel of experts that publicly reports their decisions should conduct these reviews.
- ❖ The government can create and maintain regulatory flexibility through diversification, i.e. by providing incentives and resources for developing alternatives to biotechnology;
- ❖ Regulatory capability and capacity can be increased by establishing and maintaining advisory boards (on scientific, economic, social and ethical issues), whose membership is diverse, independent and accountable.

Question 11 (17 responses)

Many ideas were presented regarding how the government can ensure adequate capacity to regulate future GM products. It was suggested that the government will need to have a long-term vision, as well as flexibility, to keep in control of the information coming in. Some respondents noted that the government will need to maintain a strong internal capacity to adequately monitor and regulate upcoming products. It was suggested that the government will need to hire more scientists and increase the budget for independent research. Respondents suggested several ways in which government regulatory scientists can prepare for future products including:

- ❖ Attendance at national and international scientific conferences;
- ❖ Monitoring the scientific literature;
- ❖ Consulting with Industry through early notification and pre-submission meetings;
- ❖ Formally establishing closer links to the research community;
- ❖ Secondment of regulatory scientists to private biotechnology industries;
- ❖ Conduct national and international research.

Another view expressed is that there should be international harmonisation of review procedures where feasible. However, it was also noted that Canada should not lower its biotechnology regulatory standard to align with that of other countries and that the risk assessment should continue to be science-based.

Some respondents think that currently the regulatory system cannot address the challenges presented by GMOs and that better identification, testing and segregation systems are needed before new varieties are introduced. It was suggested that the government should not be exploring the issue of developing capability and capacity to regulate new GM foods when there remains the option to ban them.

Other comments on this issue (2 responses)

Other views expressed relating to the issue of capability and capacity in the regulatory system include:

- ❖ The regulatory agencies are fully capable of dealing with future products.
- ❖ Scientists and government researchers should be selected for prudence and commitment to truth and allowed to do their due diligence.

Question 12 (16 responses)

There were two categories of responses to this question – those that think a comprehensive source of information on GM foods would be useful and those that do not think this would be useful. Those that support the initiative see it as a useful reference tool for consumers and as a useful method for educating consumers. Some respondents point out that several sources of information on GM foods already exist. It was suggested that as a first step these sources should be linked together and coordinated to avoid duplication. Respondents suggested that the information should include risks and benefits of using, and of

not using, genetic modifications. Further, some respondents think that this service might also gather public input and not simply be used only to disseminate information.

There were a variety of suggestions with regards to who should take the lead on this initiative. Some respondents think that government should take the lead with representation from consumers, academics, industry and health professionals. Within government, some suggested that Health Canada should take the lead while others think that all relevant departments and agencies should be responsible. Some respondents think that a non-governmental and non-corporate body should lead this initiative.

Those respondents that do not support this initiative think that it is duplicating the other sources that already exist, such as the Food Biotechnology Communications Network. It was suggested that the cost of this initiative would be prohibitive and that the number and scope of issues are too much for one source to handle. Rather, the government should create a centralized source that addresses general questions and can refer consumers to broader information sources if necessary. It was suggested that a single source of information might create mistrust among consumers.

Other comments on this issue (3 responses)

Other views expressed in relation to the issue of information provision include:

- Offering consumers the choice of whether or not to eat GM foods is a weak argument for growing the crops given that the long-term environmental effects are still unknown.
- Caution and protection and preservation of human health should be more important than profit.
- Build on existing infrastructure, do not duplicate efforts.

Question 13 (26 responses)

Respondents indicated support for both voluntary labelling and mandatory labelling of GM foods. Those that support voluntary labelling are concerned about the possible effects that might result from a mandatory labelling scheme including:

- Negative trade implications;
- Increased food costs;
- Reduced consumer choice (as food manufacturers limit product lines to either GM or non-GM);
- Confusion associated with claims such as ‘may contain’;
- Segregation costs.

Some respondents indicated that support should be given to the current initiative being undertaken by the Canadian General Standards Board with regards to developing a voluntary labelling standard.

Those that support mandatory labelling are concerned about consumer choice and food safety. They see mandatory labelling as necessary because:

- Product safety is not the only concern that consumers have with GM foods, mandatory labelling would allow consumers to choose based on other concerns such as social, ethical and environmental concerns;
- The testing that is done on GM foods is not independent enough or stringent enough to assure safety of the products. For that reason GM foods should be labelled so that consumers can choose whether or not to consume them.

Suggestions regarding what information should be provided on labels include:

- Material differences in nutrition;
- Composition of the product;
- Known safety issues such as potential allergens;
- Intended use.

It was also suggested that Canadian labelling regulations should be modeled after those in the European Union.

Some respondents suggest that food labels are limited as to the amount of meaningful information that they can provide. As a result, they will need to be complemented with other information. It was suggested that research be conducted to determine the optimal method for conveying useful information to the consumer regarding GM foods.

Question 14 (16 responses)

All respondents think that Canada should develop its own labelling scheme. Some respondents think that an international labelling standard is going to take a long time to be agreed upon. They suggest that Canada should not delay developing its own standard while waiting for an international consensus. Another view is that Canada should develop its own standard that is unique to Canadian values and needs. It was also noted that Canada's labelling scheme, once developed, could serve as a model for other countries.

Some respondents supported developing a Canadian standard while monitoring the status of international standards and continuing to work with CODEX to develop an international standard. Respondents suggest that Canada should then align its domestic standard with the international standards if it serves our interests.

Question 15 (14 responses)

Initiatives that respondents suggested the government should undertake regarding the labelling of GM foods include:

- A consumer education program. It was suggested that this is an essential component of any labelling program. This could be undertaken in cooperation with producers, manufacturers, consumer groups and academics. A bar code on labels was also suggested as a method for educating consumers regarding the information on the label.
- Commission clear, unbiased research on labelling.
- Develop a program to ensure that labelling claims regarding "GMO free" and "organic" are true.

Some respondents think that the labelling discussion should be left to the Canadian General Standards Board, others feel that any future initiatives should be undertaken in consultation with this board.

Other comments on this issue (3 responses)

Other views expressed in relation to the issue of labelling include:

- Opposition to GMO's is not only based on safety issues but also on social, ethical and political issues. Mandatory labelling is the only way to offer everyone an informed choice.
- Any labelling scheme should be based on a "product" approach rather than a "process" approach.
- Labelling schemes within Canada should be coordinated between federal and provincial governments and the private sector. Internationally, Canada should support the Codex Alimentarius Committee on

Food Labelling in trying to harmonize international standards. The labelling scheme must be meaningful, affordable and enforceable. Labels should be clear and accurate with no complex scientific terminology and they should not use negative claims but should indicate that the product has been improved in a manner relevant to the consumer.

- The "plants with novel traits" (PNT) definition should not be used in labelling. A crop cannot be tested to determine if it has been derived from mutagenesis. Under a PNT labelling definition this would require segregation of nearly all food ingredients from field to consumer. This cost would be prohibitive and virtually impossible using current technologies. More sophisticated, faster evaluation and detection techniques must be developed.

Question 16 (17 responses)

There was strong support for improving the scientific knowledge base. Some respondents think that studies should be conducted to further understand the environment and the environmental sustainability of agri-food biotechnology products. Other respondents suggest that currently the stewardship programs and knowledge base is adequate but further knowledge will be necessary to regulate future GM products. It was also suggested that further studies are required to be able to make unequivocal statements about the safety of biotechnology products. Some respondents think that collaboration with international environmental assessment projects would be useful in identifying potential environmental concerns.

There were several suggestions as to who should fund this research including:

- The research should be collaborative between government, industry and university scientists;
- The government should fund most of the research but industry should contribute to a fund, which is then distributed for relevant research;
- Research should be undertaken by private research institutions with funding from government and industry.

It was suggested that environmental stewardship will require clearly and openly defining the parameters of harm including indirect and long-term effects, examining the baseline for acceptable risk and recognizing uncertainty.

Other views expressed are that further research is not necessary and that with current products the issues of environmental safety have been fully explored.

Question 17 (14 responses)

Responses fell into three categories – those in favor of a life-cycle approach, those who do not think this is needed and those that support long-term testing and improvements to the science.

Some respondents in support of a life-cycle approach suggest that it is useful for all products, not just those that are GM. It was suggested that the environmental benefits as well as the risks of GM crops must be compared to conventional crops when determining environmental impact.

Other respondents think that the knowledge base and expertise may not exist to handle a life-cycle approach, they question when a product will be assessed enough to make a judgement. Some respondents think that a life-cycle approach is not necessary unless the weight of scientific evidence supports further in-depth monitoring. Others think that this approach should be applied on a case-by-case basis.

Other views expressed are that ongoing improvements to the science base is essential and that long-term testing for ecological effects of biotechnology products is necessary, particularly with respect to effects from “horizontal gene transfer.”

Other comments on this issue (3 responses)

Other views expressed in relation to the issue of environmental stewardship include:

- Lessons should be learned from the experiences with CFC's and DDT, which probably underwent the standard scientific assessment at the time but were later proven dangerous to the environment. GM foods should be banned because the long-term health and environmental effects are uncertain.
- The current knowledge base and testing procedures for environmental effects are inadequate, plants producing nutraceuticals, vaccines, enzymes and chemicals, as well as transgenic trees, pose additional environmental hazards. As per the Royal Society's Expert panel report, more research is needed to build better evaluation capability and to understand food safety and environmental impacts. Funds should be made available to scientists from all sectors to research these topics (RS 6.9). All research should be peer reviewed. Reviewers and researchers must remain independent of biotechnology corporations.
- Long-term multidisciplinary studies of potential environmental impacts should be conducted.

Question 18 (14 responses)

Social and ethical issues that respondents indicated were missing from those discussed in the Consultation Document include:

- The religious aspect of GM foods;
- The role of industry. Industrial development contributes to economic growth and job creation, which leads to social benefits;
- Whether an opportunity to take advantage of the possible benefits of GM food should be denied because of concerns about potential negative impacts, assuming all reasonable measures are taken to protect against such negative impacts;
- Exploitation of genetic resources for commercial gain;
- GM crops were commercially approved without public consent;
- The patenting of higher life forms;
- Xenotransplantation and animal welfare.

Some respondents think that ethical and social issues should be addressed at a higher and broader level than the food regulatory system, they suggest that the regulatory system must remain science-based. A model provided for handling social and ethical issues is that developed by Genome Canada entitled "Genome Ethical, Economic, Legal, Social Issues" (GELS).

It was noted that it is impossible to fully separate scientific and social/ethical issues. Maintaining a 'science-based' system reflects an ethical position (e.g. a decision to exclude other factors), and value judgements are incorporated into every stage of the current decision making framework (e.g. the decision to use primarily proponent-generated data). It should be recognized that the current regulatory system is value laden.

Other views expressed by respondents are that the developed world is taking advantage of developing nations by forcing subsistence farmers to buy new seed every year and by potentially putting them at risk given that the long-term impacts of GM crops and foods are unknown.

Question 19 (13 responses)

There is strong support for addressing social and ethical issues. Some suggestions for approaches to addressing the issues include:

- Allowing the United Nations to oversee the issues;
- Appointing an ethical committee of people from different backgrounds to oversee the issues;
- Through the political system, establish norms and tolerances which could then be turned into legislation or principle for the regulatory system to follow;
- Holding multi-stakeholder consultations with industry, academia, government and the public sector;
- CBAC could establish an ethics working group to address these issues and provide advise to government;
- As a condition for awarding federal research money to projects above a certain threshold level, social and ethical issues should have to be incorporated. The results should then be posted in an accessible and user-friendly manner.

Other views expressed are that comfort with ethical issues changes over time. An example is organ transplants. Large infrastructure should not be put into place to handle these issues. It was also suggested that the regulatory system remain science-based.

Question 20 (13 responses)

There is strong support for not having regulators handle social and ethical issues on a product-by-product basis. Rather, some respondents suggest that these issues can be best handled at the broad government policy level. It was noted that this would allow for objectivity and predictability. It was suggested that broader social and ethical issues should form the basis for deciding on acceptable uses of GM technology and should not enter into individual product decisions. Another suggestion is to appoint an arms length expert group to draft guidelines regarding social and ethical issues. These guidelines should then be followed by industry.

Other comments on this issue (1 response)

Another view expressed in relation to the issue of broader social and ethical considerations is that it is not clear how the "activities that may be helpful to identify possible solutions" on page 21 of the Consultation Document, really address the social and ethical considerations noted earlier in the chapter. The activities may be useful for other reasons but they are not a direct path to obtaining answers to the social and ethical issues.

Other key points and issues raised

Other key points raised in the submissions fell into three categories: comments on, or related to the issues discussed in the Consultation Document and the regulation of GM foods in general; comments regarding the Consultation Document and comments regarding CBAC and CBAC's consultation process.

Comments regarding the regulation of GM food

Comments in this section generally fell into two categories: issues around trust and confidence and concerns regarding genetic diversity and the safety of GMOs.

Trust and Confidence

There are concerns regarding the research that has been done by the developers and proponents of products of biotechnology. Some think that this research is not trustworthy while others think that the developers and proponents are in a conflict of interest position by testing their own products. It was noted that

Canadians increasingly mistrust corporations and government. Some respondents are concerned that the regulatory system does not serve the public interest because government is beholden to industry.

Other respondents are concerned that if the government does not take decisive action to prove to the consumer that GM foods are safe and build public confidence then the technology may be lost or set back several years. It was noted that in the past Canada's regulatory system has been considered to place unnecessary impediments in the way of commercial development of novel food products. Now, this regulatory system could play a major role in demonstrating the safety of Canadian products of biotechnology. Respondents suggest that it is important to defend our regulatory system and not let it be weakened by economic cutbacks.

Concerns were expressed about an imbalance in government expenditures related to biotechnology. Some respondents note that there is a lack of research on food safety and environmental risks while the government is giving millions of dollars to BIOTECanada. They suggest that at least some of that money should go toward exploring alternatives to biotechnology.

Genetic Diversity and the Safety of GMOs

Some respondents are concerned about a further loss of genetic diversity that is resulting from the use of biotechnology. They note that the advent of agriculture led to the progressive abandon of many varieties of plants and that genetic modification and plant patenting legislation contributing to further loss of varieties. It was noted that the safety of our food crop depends on genetic diversity.

Respondents suggest that strong measures need to be taken by the government to protect biodiversity, promote sustainable agriculture, and protect the environment and human health. In this regard some respondents suggest that the government increase the enforcement of environmental legislation and that regulatory agencies need to increase the rigors of their testing.

Some respondents want a moratorium on GM foods while more research and testing is conducted, including further testing of products currently on the market. Other respondents think that we will never know enough about the long-term effects of GM organisms on human health and the environment and therefore they want a complete ban on GM products.

Comments regarding the CBAC GM food Consultation Document

Some respondents think that there are examples of biased wording in the Consultation Document. Examples provided include:

- Page 2 states that Agenetic engineering is more precise than randomly creating mutations because the basis for the change is understood at both the DNA and protein level.@ It was noted that this is misleading because at present it is impossible to control the site of integration or the number of copies of the construct that become incorporated. Each transformation event is unique so that GM Adaughter@ plants will all be distinct from one another. Respondents note that the RS panel addressed this issue on pages 18-19 and 183-185.
- Page 19 states that GE organisms can be produced using Agenetic material-sometimes from closely related species or from species that are distantly related or even essentially unrelated.@ Respondents think that this reveals a bias toward minimizing the revolutionary nature of genetic engineering. They note that with these techniques DNA from several totally unrelated organisms can be combined and introduced into a plant. It was also noted that this section leaves the impression that conventional breeding is solely based on mutagensis. Respondents point out that this is incorrect. Mutation breeding is a supplement to conventional hybridization methods. Respondents also point out that

mutagensis breeding was not recognized until 1927 and as such cannot have been used since the beginning of the 1900's.

- It was noted that the section on the regulatory process implies that the efficacy of the approvals system is accepted by CBAC. For example the phrase on page 3 that states A These principles were formulated to **ensure** (emphasis added) that the practical benefits of biotechnology products were balanced with the need to protect the environment, human health and safety." Respondents note that the RS panel commented on a number of weaknesses in the current system and it is clear that the risks of harm to people, livestock and the environment are not given adequate weight in regulatory decisions.
- Some respondents think that the Consultation Document misses the most relevant ethical question of all, namely, was it ethical to introduce GE plants without prior public discussion of their acceptability or any indication to the public as to which specific items are products of the technology? They think that Substantial Equivalence is vague and it is an assumption, not an experimentally verifiable fact (RS panel report page 177 and following).
- It was noted that the Consultation Document refers to the concern that people may be denied beneficial products because of consumer rejection. Respondents point out the right of consumers to choose not to buy something if they know what is in it is a free market principle usually championed by corporations.
- Some respondents think that the Consultation Document reads as if all of the information needed to reach scientifically valid conclusions regarding the risks and benefits of GE crops and foods is attainable. Respondents think that given the complexities of cellular processes, the ecosystem and our ignorance of both areas, no such firm conclusions are possible. As a result some respondents think that a precautionary approach should always be used.

It was noted that biotechnology might not provide the best solutions to the problems confronting agriculture and the food industry. Some think that the consultation document portrays biotechnology as essentially beneficial, and implies that the continued development and commercialisation of GM crops and food is inevitable. It was pointed out that the Consultation Document does not explore the idea that there might be safer, less uncertain and more effective alternatives to the technology, or that government funds should be reallocated to support alternative agricultural practises. Some respondents supported the RS expert panel comments, on page 29, when they noted that there is a need for a much broader research agenda which would look at systems and methods of agriculture so that society will be able to make informed choices between alternate approaches to food production.

Some respondents think that there are issues missing from the Consultation Document. Primarily concerns centred around the fact that the document did not identify options such as a moratorium on current and future GM foods. Some respondents think that this is necessary until adequate further testing is done on GM food and crops, and public consultations undertaken. Other respondents think that there should be a complete ban on GM food and crops. Respondents also noted that the document did not address the question of who would be liable if negative health and environmental effects do result from the use of GMOs.

With regards to the specific issue of 'Ensuring safety during research and development activities' it was noted that the Consultation Document covers "laboratory safety" issues and then "post-market monitoring" issues, but does not address field testing of GM crops at a magnitude that is sufficient to detect both potential harms and benefits. It was noted that this long-term field testing was one of the greatest challenges facing GM crops and foods and should have been addressed in the Consultation Document. It was also noted that before considering the details of pre- and post-market testing, the Canadian government and public would benefit by examining broader questions about long-term policy goals (environmental, health, agricultural and economic) as well as developing alternatives to GM crops (particularly in light of growing market uncertainties).

Comments regarding CBAC and CBAC's consultation process

Some respondents think that the committee's mandate is to foster the growth of the biotechnology industry because the committee is housed within Industry Canada and includes, they think, many members who have ties to the biotechnology industry. It was expressed that the membership of the committee excluded many of the prominent, knowledgeable, experienced and trusted members of civil society who were nominated.

Some respondents think that the timelines for the stakeholder consultations and the deadlines set for reporting to the Biotechnology Ministerial Coordinating Committee (BACC) are unreasonable and limit NGO's participation.

It was noted that CBAC is charged with starting a "national conversation" with Canadians on genetic engineering. Some think that rather than conversation, the issue demands consultation that is focussed on basic questions of environmental risk, ethics and the social need for, or desirability of genetic engineering. Some respondents noted that CBAC used its web site as its primary outreach tool and that, as such, it was not adequate. Some feel that CBAC's outreach strategy is poorly defined and does not meet the requirements of public consultation. It was suggested that CBAC adopt a more open, inclusive and transparent public process including open and extensive public consultations to obtain a more accurate and representative analysis of public opinion and concerns. Town-hall style meetings were suggested as one way of achieving this goal.

Other views expressed are that the research papers commissioned by CBAC are an inadequate and inappropriate treatment of the issue. It was noted that they are missing a critical sociological perspective on biotechnology and the current controversy.

There is concern that there is a lack of political will to deal with the fundamental questions surrounding genetic engineering and that these questions should be dealt with in the House of Commons. It was expressed that there is a lack of trust on the part of Non Governmental Organization's and Civil Society Organization's regarding the government's approach to GM foods. In this climate, it was suggested, CBAC needs to be more visible and active to successfully obtain public or stakeholder participation.

Some think that CBAC should adopt a broader mandate that addresses larger questions about the role of biotechnology, and alternatives to biotechnology, in Canadian environmental, health, economic and social policies. It was suggested that CBAC should adopt a more open, inclusive and transparent public process that includes more open and extensive public consultations.

With regards to addressing social and ethical issues some respondents think that CBAC has portrayed these issues too narrowly and as separate from the science involved in regulatory issues. It was noted that science, and our current science-based regulatory system, is tightly bound to social and ethical issues (e.g., the acceptability of close government-industry ties; the primacy of scientific and economic factors over other types of knowledge and reasoning and the importance of international trade and harmonisation of regulatory standards). It was suggested that CBAC ask a broader range of questions and adopt a wider analytical framework for addressing these questions. Specifically it was suggested that CBAC work to understand the social nature of the biotechnology debate, including the scientific basis for decision-making. This analysis should examine issues such as:

- The role of science in the current institutionally mandated 'science-based' regulatory process. What data are used in the decision-making process? What experiments are done? Is the science adequate to

draw conclusions about the safety of GM crops and food? Who conducts the tests and who decides if they are adequate?

- A detailed analysis of social and institutional commitments that affect regulatory decisions for example, corporate relations, trade agreements and international pressures.
- The depth and consequences of government-industry ties in promoting and regulating biotechnology.
- The proportion of public funds allocated to support biotechnology as compared to funds for research on risks and benefits, and alternative technologies.
- Issues of consumer choice such as labelling, food security, and control of seed stock.
- Adequacy and methods of public consultation and participation in past, current and future regulatory processes.

It was noted these issues contain scientific, social, ethical, economic and political components and are vital to understanding how people *experience* their lives, and therefore how they perceive, accept or reject biotechnology.

Annex 2

Acronyms

AAFC	Agriculture and Agri-Food Canada
BMCC	Biotechnology Ministerial Coordinating Committee
Bt	Bacillus thuringiensis
CBAC	Canadian Biotechnology Advisory Committee
CFC	Chlorofluorocarbon
CFIA	Canadian Food Inspection Agency
CSO	Civil Society Organization
DDT	Dichlorodiphenyltrichloroethane
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organism
NGO	Non-Governmental Organization
PNT	Plants with Novel Traits
RS	Royal Society

Annex 1

Table of Responses

The first two columns in the following Table of Responses refer firstly to the issue number and secondly to the question number as they appear in the Consultation Document 2001. The third column is the category number. Specifically this refers to the perspective of the individual or group who is responding as they indicated in the questionnaire. A key is provided below that indicates the perspective referred to by each category number. The next three columns refer to the knowledge level, number of people represented by the response and the age range of the respondent if respondents provided these categories of information. The final column is a summary of the response provided to the question. The questions that are referred to in this table appear on page 5 of this document for easy reference.

Category Key:
1: consumer(s) of food sold in Canada
2: industry representative(s) involved in biotechnology, food production, distribution or commercialization
3: representative(s) of non-governmental not-for-profit organization
4: student(s)
5: academic(s) or research scientist(s)
6: government official
7: other

ISSUE	QUES #	CAT.NO	KNOWLEDGE	NO. REP.	AGE RANGE	HIGHLIGHTS OF RESPONSE
1	1	1.1		Multiple		Diagrams, decision trees and hypothetical cases would be useful in helping consumers understand the regulatory process. Documents should highlight the complexity of the process and the difficulties that can be encountered. The information should be easily accessible by everyone in formats such as, the internet, pamphlets and through a 1-800 number.
1	1	1.2	Medium	1	26-45	A description would be useful but not sufficient. Information should be available everywhere food is sold. If there is a relevant web site address it should be noted on food packaging.
1	1	1.5	Medium	1	26-45	Make information about the regulatory system available in pamphlet form and on a web site.
1	1	2.1		Multiple		Information provision is the responsibility of government and all stakeholders. Information between industry and government should be coordinated to avoid contradiction and overlap. Government information should be available on one comprehensive, user-friendly web site.
1	1	2.2	High	under 5	46-65	A pamphlet describing the regulatory process would be useful.
1	1	2.3		Multiple		A comprehensive description of the regulatory approval path that includes case studies, cost estimates and timeframes, would be useful. Government should provide information on safety assessments; other stakeholders should provide information on science, health impacts etc.

1	1	2.4	High	21, 000 members		Concise and understandable information for the public should be available on web sites, in pamphlets (which are distributed in healthcare stores, food retailers, food/healthcare exhibitions etc.) and promoted in the media. Detailed information on data requirements, decision points, appeals etc. should be provided to applicants, via the regulatory agencies' web sites, to ensure equity and predictability.
1	1	2.5	High	45, 000 members		Substantial information regarding the food regulatory system is already available on Health Canada and CFIA web sites. Pamphlets and web sites are useful tools for providing information to the public, although web sites are more cost effective and easily updated. A list of products currently under review should be made available.
1	1	2.6		37 organizations		A detailed description would be useful. Also provide: a list of products currently under review, environmental studies available to read, a 45-day comment period before registration. No molecular characterization or gene sequences should be made public.
1	1	2.7	High	16 +		Information on safety decisions and government requirements should be made available to consumers.
1	1	2.8	High	20,000 members		As per 2.5
1	1	2.9		180 companies		Information detailing processes, timeframes, criteria and dispute resolution should be available on web sites or additionally through mass media. Balance domestic requirements against other countries to ensure that disadvantages for technology development are not created in Canada.
1	1	2.12		Multiple		Information detailing the regulatory process including steps, length of time and cost should be made available through pamphlets, web sites and/or a toll free number.
1	1	2.13	High	16+		A standardized description of the regulatory process for use by all regulatory departments would be useful. Information should use case studies, time frames and flow charts and it should be clear, coordinated and accessible.
1	1	3.1	Medium	16+		Regulatory agencies should increase the transparency of scientific data and scientific rationales behind decisions. CBAC site could serve as the central distributor or link to information.
1	1	3.2	High	16+		A description would be useful. Ministries involved in the regulation of biotechnology should make consistent, comprehensive and cooperative information available through their regular means of communication. Information should be shared with communications organizations outside of the government to help to disseminate consistent information to the public.
1	1	5.1		4 people		Simply explaining in a more elaborate way what is being done now will not help to instill public confidence and will be a waste of resources.
1	2	1.1		Multiple		Data and information that is truly a commercial threat should not be made public, most of the confidential data is very specific and of no direct use to the consumer. All other data should be public as this allows consumers to better understand the process.
1	2	1.2	Medium	1	26-45	All health and safety data should be released to allow consumers to be as informed as possible.
1	2	1.5	Medium	1	26-45	All health and safety data should be available to the public. This reassures the public of their safety.

1	2	1.6	Medium	1	26-45	All health and safety data should be available to the public because there are many individuals and groups who are able to interpret it. Withholding information creates suspicion in the public about the validity of the data and analysis.
1	2	1.7	Medium	1	under 25	All data used to evaluate a product should be available for public review.
1	2	2.1		Multiple		A careful distinction should be made regarding what is truly valuable corporate intellectual property and what could be released without being commercially damaging. Truly valuable corporate intellectual property should not be released as it is central to the successful management of biotechnology companies.
1	2	2.2	High	under 5	46-65	All health and safety data should be available to the public. Clear information should not be obscured due to profit motives.
1	2	2.3		Multiple		Intellectual property, including the data submitted to support product approval, is the most valuable asset to a biotechnology company and should not be made public. Currently the substance of the safety assessment is adequately covered in the regulator's summary decision document, which is public.
1	2	2.4	High	21,000 members		A summary decision document including a synopsis of all relevant information pertaining to the decision should be published a maximum of 30 days after the decision is made. Pre-notification of products currently under review should consist only of a list, not the scientific data that the regulators are evaluating. Few people have the ability to fully understand the scientific data, releasing it could cause misinterpretation and emotional based responses. The public should entrust decisions to the regulatory agency reviewers. The publication of appropriate information in a timely fashion will help build public trust and confidence.
1	2	2.5	High	45,000 members		Summaries of health and safety studies should be made available. This would satisfy the public's information needs without sacrificing business competitiveness, which may occur if detailed data were released.
1	2	2.6		37 organizations		Summaries of environmental assessment data should be available with the full studies available in a library to read only.
1	2	2.7	High	16+		Most safety data should be publicly available upon request by anyone.
1	2	2.8	High	20,000 members		As per 2.5
1	2	2.9		180 companies		Process transparency is necessary to ensure continued consumer confidence in the safety of food. Timely provision of information to consumers about health and safety studies is necessary to maintain an informed public. Summaries of assessment data and product decisions may be adequate. Information regarding the health and safety of novel foods are available to the public and open to comment through the *Canada Gazette*.
1	2	2.12		Multiple		Intellectual Property is the most valuable asset to a biotechnology company. If the competitiveness of a company will be compromised by releasing the full studies then only summaries of the health and safety assessment data should be released.
1	2	2.13	High	16+		Technical health and safety data should be confidential information. Conditions for the release of this information must take into account how the release of the information will affect a company's competitive position.

1	2	3.1	Medium	16+		Technical health and safety studies should be carried out by promoters and manufacturers of food biotechnology products. The data and results should be released to the public. This would restore public confidence that the products have been adequately tested and are safe.
1	2	3.2	High	16+		Information relating to a company's competitive advantage must be kept confidential. All other information should be available.
1	2	5.3		2		Releasing technical data is *crucial* for the legitimacy of the regulatory process. Independent peer review is a hallmark of the scientific process. The Canadian government cannot claim to have 'science-based' regulations, if the data is confidential. Proprietary information can be separated from safety data to ensure protection of commercial interests when necessary. However, a review of current policies on confidential business information and access-to-information might also be necessary to ensure an open and transparent regulatory process.
1	3	1.1		Multiple		The number of trials per general area should be disclosed rather than the exact location of field trials. Disclosing the location of field trials may jeopardize the trial itself and if the exact location is published problems with the results of field trials will be overshadowed with doubt that the trial was tampered with.
1	3	1.2	Medium	1	26-45	Detailed locations of field trials should be disclosed to the people in the area and the farmers. Those fields should be sealed to prevent the spread of the trial seeds.
1	3	1.6	Medium	1	26-45	Detailed locations should be disclosed so that neighbors can take precautions.
1	3	1.7	Medium	1	under 25	Detailed locations should be disclosed. If the safety requirements for field trials are stringent enough and transparent to the public than there will be less of a threat of crop destruction.
1	3	2.1		Multiple		Respondent avoids disclosing detailed field trial locations, as there is concern that this may lead to destruction of property and physical conflict. It may also put field workers at risk. However, all registered field trials must be listed with the CFIA and therefor are available to the public.
1	3	2.2	High	under 5	46-65	Detailed locations should be disclosed, along with the trial objectives and details of the genetic modification and purpose so that other specialists and scientists may observe the results.
1	3	2.3		Multiple		Detailed locations should not be disclosed in order to protect the physical safety of workers and to protect the crops from vandalism. The CFIA has detailed guidelines for field testing of GM crops and also publishes a summary of field trials. This is adequate to ensure public safety and accountability under Canadian legal requirements.
1	3	2.4	High	21,000 members		Detailed locations should not be disclosed as this invites vandalism and trespassing. Publication of the technologies undergoing field trial and the number of trials is adequate for transparency purposes. An alternative is to invite the registrants to conduct public open-houses/field tours at their field site. This could be used as an educational tool.
1	3	2.5	High	45,000 members		The current approach of providing summaries of trials by crop and region is adequate for public information needs. Release of detailed trial locations may result in the reduced willingness of growers to participate in GM crop trials because they may become targets of activists/vandalism as has occurred in other jurisdictions. These trials are necessary to determine the safety of the products.

1	3	2.6		37 organizations		Detailed location to the farm level, not plot level, should be provided. Criteria for disclosure should include the crop, the gene and where it came from, the purpose of test, special precautions, and a contact phone number. There should be strong punitive measures against vandalism put into place.
1	3	2.7	High	16+		Detailed location should not be disclosed, as it will increase the risk of crop destruction. Organizers of these trials should ensure adequate isolation to prevent cross contamination.
1	3	2.8	High	20,000 members		As per 2.5.
1	3	2.9		180 companies		Disclosure of the detailed location increases the risk of vandalism. Making transparent the standards of practice and procedures farmers who perform such trials are guided by may reduce concerns about the location.
1	3	2.12		Multiple		Detailed locations should not be disclosed. This increases the risk of vandalism.
1	3	2.13	High	16+		Detailed locations should not be disclosed because of the threat of vandalism. Growers should be protected from these threats. CFIA publishes a summary of field trials in Canada, this information ensures accountability.
1	3	3.2	High	16+		Detailed locations should not be disclosed to protect the investment developers have in the trial. Public research facilities and/or private companies should have one field trial open to the public to demonstrate GMO crops.
1	3+	1.1		Multiple		Ideally the government should conduct all safety tests. This may be impossible so it is important to properly control the type and the flow of information that flows between industry and government.
1	3+	1.2	Medium	1	26-45	Not enough is known about the long-term effects of genetically modified foods to be able to approve them, test them or declare them safe.
1	3+	2.2	High	1-May	46-65	Genetic modification to effect sterilization of seed in subsequent generations should be disallowed as well as the introduction of zoological genes into plant material and vice versa.
1	3+	2.7	High	16+		Opponents of biotechnology have not had to be transparent about their vested interests; they should be made to do so in order to take part in the debate on biotechnology. Government should create a web site listing those organizations requesting approval for a product and those requesting information.
1	3+	5.1		4		As per RS panel recommendations, there is a need for greater transparency on the part of regulatory agencies and a change in the philosophy of regulation. The data on which regulators make their decisions is provided by applicants, who have a financial interest in obtaining approval for the product, it may be deemed confidential by the applicant, which prevents scrutiny by outside experts and independent replication of test results. As a result, scientific data on which the regulators make their decisions bypasses all the typical safeguards put on other scientific research. Detailed scientific results on which regulatory decisions were made must be readily available to interested parties-preferably in the form of actual peer reviewed articles. All other relevant information should be on the agencies web site.

2	4	1.1		Multiple		There is an apparent conflict of interest caused by current roles within government. This could be minimized by clearly defining roles and the extent of communications between parties. Assessment and approval bodies should be independent of economic promotion bodies.
2	4	1.2	Medium	1	26-45	The fact that the Canadian government has not banned genetically modified foods, while European governments have suggests that the government is in a compromised position.
2	4	1.5	Medium	1	26-45	There is a conflict of interest between the roles of promotion and regulation of GMOs within government. This is discussed in the RS panel report.
2	4	2.1		Multiple		Government agencies must be publicly accountable by providing information about what they do. A careful distinction is required between providing information and being perceived as promoting the industry through this information. The latter creates the potential for a conflict of interest
2	4	2.2	High	under 5	46-65	Conflict of interest exists when large corporations influence politicians; this results in reduced funding of research. Government research and regulatory scientists must be immune from the suggestions of politicians.
2	4	2.3		Multiple		There is no conflict of interest caused by current roles and reporting relationships. The CFIA produces material that promotes what they do as regulators but that does not promote products. The CFIA does not deal with the commercial development of products or market development.
2	4	2.4	High	21,000 members		There is no conflict of interest caused by current roles and reporting relationships. All relevant organizations maintain separate roles and reporting relationships. There is a clear set of checks and balances built into the roles and reporting relationships pertaining to biotechnology regulation. Having the CFIA report to the Minister of Health, as suggested in the Consultation Document, would reduce accountability and increase the potential for conflict of interest.
2	4	2.5	High	45,000 members		There is no conflict of interest caused by current roles and reporting relationships. Canada's food regulators have provided information about how new foods are regulated; this has been interpreted as promotional by some. Regulatory agencies need to do more in terms of providing information about how new foods are regulated.
2	4	2.6		37 organizations		There is no conflict of interest; regulators are competent and honest in their evaluations.
2	4	2.7	High	16+		There is no conflict of interest. Doubts as to a conflict of interest are due to opponents of biotechnology who have a vested interest in creating uncertainty.
2	4	2.8	High	20,000 members		As per 2.5.
2	4	2.9		180 companies		There is no conflict of interest. CFIA is not involved with the technical or market development of products. It is part of the CFIA mandate to provide information about how foods are regulated, this is essential to the process of transparency and is not promoting products of biotechnology.
2	4	2.12		Multiple		There is no conflict of interest. Materials produced by the CFIA are to provide the public with information about the regulatory process. These materials are consistent with transparency.
2	4	2.13		16+		There is no conflict of interest. The CFIA is not involved with the commercial or market development of products.
2	4	3.1	Medium	16+		As noted by the RS panel, there is an apparent conflict of interest because of the government's dual objective of promoting the biotechnology industry and of protecting the public.

2	4	5.1		4		The departments involved are in conflicting roles as promoters and regulators of biotechnology. A ministry should be created whose job it is to regulate crops and food. Sufficient resources are required and staff members must be treated as professionals. There should be a provision for periodic reviews of the agency to ensure the quality of its work and that it is able to keep up with new regulatory challenges.
2	5	1.1		Multiple		One single, separate entity from within the government should be responsible for providing consumer information on foods and technology. It is important to balance the information because even science can be subjective.
2	5	1.2	Medium	1	26-45	Health Canada should provide consumer information and education related to foods. Agriculture Canada should provide information about the regulation of foods.
2	5	1.6	Medium	1	26-45	Health Canada should provide consumer information and education related to foods and information about the regulation of foods.
2	5	2.1		Multiple		Each regulatory agency should be responsible for providing its own public information. Coordination of information release should take place at a high governmental level such as the BMCC. There should be regular reviews of the regulatory approval process itself to ensure it is sufficient given the changing science and situations.
2	5	2.2	High	under 5	46-65	Consumer information and education related to foods should be the responsibility of consumer affairs and staffed by home economists and dieticians. Information on the regulation of foods should be the responsibility of Agriculture and Agri-food Canada and the CFIA.
2	5	2.3		Multiple		Each regulatory agency should be responsible for providing its own public information related to their regulatory mandate. Health Canada should be responsible for consumer information and education. The government should ensure that the public understands that regulatory activities are coordinated among several federal departments and that each follows a consistent approach.
2	5	2.4	High	21,000 members		Each regulatory agency should be responsible for proactively providing its own public information on all aspects of their role in the food system including their regulatory mandate. Government agencies need to substantially improve their communication to the public.
2	5	2.5	High	45,000 members		Health Canada should provide consumer information and education related to foods. The CFIA and Health Canada should be responsible for providing their own public information related to their regulatory mandate. Non-government groups should also provide such information.
2	5	2.6		37 organizations		Health Canada should provide consumer information and education related to foods. Each regulatory agency should be responsible for providing their own public information related to their regulatory mandate and assessments. The Food Biotechnology Communication network and the Consumers Association of Canada could also disseminate the information.
2	5	2.7	High	16+		CFIA should provide consumer information and education related to foods and information about the regulation of foods because they do the safety assessments.
2	5	2.8	High	20,000 members		As per 2.5.
2	5	2.9		180 companies		Health Canada is mandated with the role of providing consumer information and education. Each regulatory agency is mandated with providing information related to its regulation of foods. More public information regarding regulatory responsibilities is needed.

						public information regarding regulatory responsibilities is needed.
2	5	2.12		Multiple		CFIA should take the lead in providing consumer information and education related to foods as well as in providing information about the regulation of foods. Other regulatory agencies should play a supportive role based on expertise.
2	5	2.13	High	16+		Each regulatory agency is responsible for providing its own public information related to their regulatory mandate. The federal government is responsible for informing the public of what the mandates and responsibilities of each agency are.
2	5	3.1	Medium	16+		Health Canada should provide consumer information and education related to foods and information about the regulation of foods.
2	5	3.2	High	16+		Health Canada should be responsible for providing information about the regulation of foods. Any ministry or agency that is associated with food should be able to provide information to the public. Partnerships with NGO's and the private sector can benefit information provision.
2	5+	1.2	Medium	1	26-45	Personal health, environmental health and sustainable agriculture are in jeopardy because of political indecisiveness. The Canadian government should not bow to corporate interests.
2	5+	2.2	High	1-May	46-45	There is a need for specialists and inspectors in food safety and nutrition especially to inspect fast food restaurants which have lax food quality and cleanliness habits.
2	5+	2.6		37 organizations		The government does not stand up for what is already a good food regulatory system.
2	5+	2.7	High	16+		Personal experience has demonstrated that the CFIA and Health Canada do not give preferential treatment and that their assessments are rigorous and focused on ensuring the safety of products.
2	5+	7.5				The integrity of government regulatory agencies is questionable because industry provides funds and resources to AAFC research stations.
3	6	1.1		Multiple		Standardized safety measures are important because the quality of safety measures varies from one laboratory to another but implementing them might be difficult and may not offer any real long-term benefit.
3	6	1.2	Medium	1	26-45	The existing approaches are not satisfactory
3	6	1.6	Medium	1	26-45	The existing approaches are not satisfactory
3	6	1.7	Medium	1	under 25	GM food should not be compared to a similar product that has been deemed safe, it should undergo rigorous evaluation similar to that of new drugs.
3	6	2.1		Multiple		The existing approaches are satisfactory. Safety issues are covered by existing federal and provincial regulations, by internal procedure manuals and work place safety committees.
3	6	2.2	High	under 5	46-65	Not sure but safety should be a priority to maintain the integrity of genetics and biotechnology.
3	6	2.3		Multiple		The existing approaches are satisfactory.

3	6	2.4	High	21,000 members		The existing approaches appear satisfactory. The onus to adhere to good laboratory practices should be on the researcher. If government regulators suspect, on reviewing a submission, that these practices have not been followed they should be able to order further investigation and possibly deny approval.
3	6	2.5	High	45,000 members		The existing approaches are satisfactory. The suggestion that new legislation be created to control recombinant-DNA experimentation wrongly implies that new food products developed through these technologies pose unique risks.
3	6	2.6		37 organizations		Existing standards are good. A single set of regulations is problematic because the level of risk is very different depending on the type of crop and gene that is being experimented with.
3	6	2.7	High	16+		The existing approaches are fully satisfactory.
3	6	2.8	High	20,000 members		As per 2.5.
3	6	2.9		180 companies		Continued efforts are required to ensure that the existing standards and guidelines are followed. Current third party accreditation processes may serve as models for consideration.
3	6	2.12		Multiple		The existing approaches are adequate. It may be appropriate to revisit this in the future.
3	6	2.13	High	16+		The existing approaches are adequate, they can be considered a "gold standard" for ensuring safety during research and development.
3	6	3.1	Medium	16+		As noted by the RS panel, GM crops and foods should be more rigorously tested. The Precautionary Principle should be adopted - new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe.
3	6	3.2	High	16+		The approaches to safety need to evolve as research and development become more advanced.
3	6	5.3		2		Before considering the details of pre- and post-market testing, the Canadian government and public would benefit by examining broader questions about long-term policy goals (environmental, health, agricultural and economics) as well as developing alternatives to GM crops (particularly in light of growing market uncertainties).
3	6+	2.7	High	16+		The regulatory agencies should provide guidance to developers on appropriate and inappropriate potential products.
4	7	1.1		Multiple		A pre-decision summary would be useful if it were more detailed than the current summaries are. It should include a list of tests and a summary of results. Especially important to the public are allergenicity tests and nutrition and chemical tests. The advantage of such an approach is that it is democratic and it empowers the public.
4	7	1.2	Medium	1	26-45	A pre-decision summary would allow the public to be involved in the decisions. It has to be real involvement and not just an exercise. A pre-decision summary should note the corporations involved, the length of time tests were carried out and whether the tests looked at cumulative effects.
4	7	1.6	Medium	1	26-45	The advantage of a pre-decision summary would be the opportunity for everyone to respond and potentially influence the process. The summary should include as much information as possible including the detailed reasoning behind decisions.
4	7	1.7	Medium	1	under 25	There should be enough information available to evaluate the quality of the scientific data collected.

						collected.
4	7	2.1		Multiple		The advantage of a pre-decision summary is transparency. The final decision must be science based and rest with the regulatory agencies. The period between application and decision must not be unduly extended. How will public input fit into the regulatory system i.e.: what steps taken would constitute adequate public notice? how would the input, which may lack scientific rigor and objectivity, be assessed?, would the public expect veto power?, would formal hearings be part of the process? etc.
4	7	2.2	High	under 5	46-65	The public has the right to determine the safety and acceptability of new products. The advantage of pre-decision summaries and public comment periods are public input into the acceptability of new products. The pre-decision summary should include objectives and effects of modification.
4	7	2.3		Multiple		Pre-notification rules for GM foods should not be any different than those for other products. The public should be involved at the policy setting stage while regulatory agencies and government should be responsible for the regulatory decisions. The current system provides ample opportunity for public involvement in the setting of policy as it applies to GM crops and food.
4	7	2.4	High	21,000 members		There are few advantages to a pre-decision summary/public comment period. If the full regulatory process is transparent and open to public scrutiny, the public is likely to trust the trained regulators to make good decisions on their behalf. Non-scientists should be excluded from the process because they do not have the technical expertise to contribute constructively to product evaluations. There would be benefit to a mechanism whereby the regulators could solicit input on new technologies from external public sector scientists.
4	7	2.5	High	45,000 members		The advantages would be increased transparency and public involvement, however much of the general public may not be able to interpret the data provided. Summaries may be misinterpreted as complete rationales for decision-making. If pre-decision summaries are offered they should be for all foods, not just GM foods. There has to be a mechanism whereby the concerns raised during the public comment period can be addressed, this may require additional resources.
4	7	2.6		37 organizations		The advantage is the perception that the public is able to state their concerns. The summary should be the same as the existing decision document. The final decision document should address science-based concerns raised during the comment period.
4	7	2.7	High	16+		The advantage is the opportunity for the public to comment. All the data should be available on the regulatory agencies' web sites. The summary should include information on the crop, gene, intended effect and safety assessments conducted.
4	7	2.8	High	20,000 members		As per 2.5.
4	7	2.9		180 companies		There currently is pre-notification in the Canada Gazette with a comment period. Additional public input would increase transparency. Models should be carefully designed to ensure they will be used by the public and add value to the process. The summary should contain data summaries and decision summaries.
4	7	2.12		Multiple		The advantage would be that those who were interested could review the data.
4	7	2.13	High	16+		The public should be involved in setting the policy. Responsibility and accountability for individual product decisions should reside within the government and the regulatory agencies.

4	7	3.1	Medium	16+		A pre-decision summary would be useful only if the current reliance on substantial equivalence were replaced and new GM products were given rigorous safety assessments.
4	7	3.2	High	16+		The advantages would be the opportunity for public involvement and the opportunity for the public to learn more about new technologies and how the regulatory system works but decision documents must be posted more quickly.
4	7	5.3		2		Public review of pre-decision documents would be an improvement over the current system. When dealing with complex and uncertain technologies such as GM crops, better decisions will likely arise from processes that include a diverse range of knowledge and experience. However, public involvement in the decision-making process must go far beyond reviewing pre-decision documents. Many organisations and individual citizens have clearly expressed the desire to participation in larger questions about *whether* GM crops are an appropriate technology, and how alternatives can be developed.
4	7+	1.7	Medium	1	under 25	There should be an easy way to provide feedback and the process should ensure that issues raised by the public are addressed.
4	7+	2.2	High	under 5	46-65	All risks and benefits associated with the modification should be published and available for review.
4	7+	2.7	High	16+		The real question is one of risk. The public should be made aware that there have been no adverse health or environmental effects as a result of biotechnological crop production. Agencies should continue to be vigilant with new products and involve the public.
4	7+	2.12		Multiple		Concerns about a pre-decision document/public comment period are that it could significantly lengthen the time it takes to get product approval and it could politicize the process.
5	8	1.1		Multiple		Post-market monitoring can be a useful tool to track long-term effects. All of the proposed methods have advantages and disadvantages; there is not one method that will solve the long-term health and environmental concerns that exist. It may be impractical to track consumption data of GM foods. Detection methodologies are not necessary because, in many cases the traits are detectable. The most important factor to monitor is if GM foods are harmful in the long-term. Completing long-term nutritional studies before approval can minimize post- market complexity.
5	8	1.7	Medium	1	under 25	Determine who will be held liable should negative effects be discovered.
5	8	2.1		Multiple		Post market monitoring is essential to demonstrate that GM foods are safe, and to build public support for the regulatory system. A monitoring process should be administered by a joint industry/government system with clearly demarcated lines of responsibility. Information should be disseminated throughout the life cycle of the product. Industry should further enhance stewardship programs that provide monitoring. Consideration should be given to extending the current post-harvest monitoring system already established by the CFIA for Confined Field Trials (Dir 2000-07) to the approval process under "Unconfined Release" (Dir 94-03).
5	8	2.3		Multiple		Post market monitoring evaluation could parallel post harvest land use as outlined in Guidelines for Confined Field Trials (Dir2000-07). Industry has an ongoing duty to monitor its products and report new information to government. Industry is willing to cooperate with regulatory agencies on issues related to post market monitoring.

5	8	2.4	High	21,000 members		The current approach of developing post-market monitoring programs specific to the particular technology on a case by case basis is better than formalizing a program. It allows for flexibility and responsiveness to changing circumstances. An example is the multi-stakeholder oversight group, which developed a monitoring program for Bt corn. This group is composed of members from all pertinent stakeholders.
5	8	2.5	High	45,000 members		Grower audits and education programs should continue. Environmental and Health Impacts monitoring would be useful but should not be limited to GM crops. Comparative assessments of GM and non-GM crops might yield more meaningful information. Monitoring GM food consumption would require strict segregation and labelling of GM foods. The benefits of such information are difficult to see given the costs.
5	8	2.6		37 organizations		Detection methodologies are needed. Large dietary studies create problems because often GM foods are identical to conventionally grown products.
5	8	2.7	High	16+		Detection methodologies are not necessary as long as there are no identified safety risks.
5	8	2.8	High	20,000 members		As per 2.5.
5	8	2.9		180 companies		Analytical methodologies, especially internationally accepted methodologies, would be beneficial because reliable detection of GM foods is essential for enforcing labelling standards and international trade regulations. Post market monitoring would be useful. Food consumption data may be perceived as useful but it is costly and difficult to obtain. Demonstration of consumer benefits of GM crops may increase the acceptance of the technology.
5	8	2.13	High	16+		Post market monitoring would be worthwhile; the chemical industry would be a good model. Industry does bear some responsibility for developing detection methodologies and for ongoing monitoring but the burden of cost placed on the producer will be increased.
5	8	3.1	Medium	16+		A process for the reassessment of GM crops already approved in Canada, GM food consumption data and long-term health impact studies and post market monitoring of GM foods, are all needed.
5	8	5.3		2		The methods identified in the consultation document are useful. CBAC should also investigate how the current techniques of 'adaptive management' can be applied to assessment and monitoring of GM crops. Two key issues related to post-market monitoring are: ❖ Safe-to-fail experiments. Relying on post-market monitoring assumes that adverse effects can be detected and controlled. This may not always be the case. If 'safe-to-fail' release of GM crops is not possible, the Canadian government should consider the ethics of continuing with this technology. ❖ Liability. Should adverse effects occur, who is liable? This is particularly important for organic farmers who currently risk losing markets if their crops are combined at any stage with GM varieties.
5	9	1.1		Multiple		GM foods should be automatically reassessed for a certain period of time and then triggers should be established to continue the reassessment as needed.

5	9	1.2	Medium	1	26-45	All GM products on the market should be reassessed as soon as possible because none have gone through a stringent approval process.
5	9	1.6	Medium	1	26-45	Ongoing studies should be mandated for GM crops including studies that look at the effect the crops are having on the ecosystem.
5	9	2.1		Multiple		Regular reassessments would be good as long as they are not positioned as re-applications with expensive and long-term testing to be met by industry each time. To carry force, those conducting the reassessment have to have the power to deny re-licensing approval. A re-assessment process with these attributes is a better way to go than the "independent arm's length" panel for reassessment that was suggested by the RS panel.
5	9	2.2	High	under 5	46-65	GM crops should be regularly reassessed for several years; there should be triggers and the power to remove a food from the market.
5	9	2.3		Multiple		Canada should not reassess approved GM foods and crops. Programs for post market monitoring, like that developed for Bt corn, are good. Resources should not be diverted from assessment of new foods to reassess foods that are already deemed safe.
5	9	2.4	High	21,000 members		The present system allowing for ad hoc reviews as new information becomes available is adequate. Market tracking mechanisms should be considered in the broader context of societal consumption and health patterns, not just in the context of GM foods. Epidemiological studies are not sufficient to determine adverse health effects in a population. Long-term impact studies should only be undertaken where there is reasonable potential for concern to exist.
5	9	2.5	High	45,000 members		It would not be useful to conduct regular post market assessments in the absence of new scientific developments or information that cause concern regarding a product.
5	9	2.6		37 organizations		A five-year review process would be worthwhile if there is a process where a crop can be deemed to be no longer "novel".
5	9	2.7	High	16+		Reassessments should only occur if a problem has arisen.
5	9	2.8	High	20,000 members		As per 2.5.
5	9	2.9		180 companies		GM food or crops should not be automatically reassessed. The regulatory system provides for ad hoc reviews of new data and submission of new data is open to the public.
5	9	2.12		Multiple		GM foods should not be automatically reassessed just because they are GM. They should only be reassessed if new information is discovered as with conventional foods.
5	9	2.13	High	16+		Automatic reassessments of GM food might suggest that the regulatory system is inadequate. Resources should not be taken away from the assessment of new foods to reassess foods that have already been deemed safe.
5	9	3.1	Medium	16+		Post market studies of long-term adverse effects should be conducted on GM foods that have been on the market for several years.
5	9	3.2	High	16+		Post market monitoring should be triggered by any new health and safety information brought forward either domestically or internationally. It should also be automatic.
5	9+	1.2	Medium	1	26-45	All GM foods should be taken off the market.

5	9+	2.4	High	21,000 members		If new data were to indicate that there were no concerns with a technology would the government remove the regulatory requirements for that class of technology?
5	9+	2.7	High	16+		Issues such as monitoring have been raised by opponents of biotechnology specifically to stop commercialization of GM foods, not for safety reasons.
5	9+	2.10		Multiple		Recommends increased government financial support for research on food-borne pathogens and antimicrobial resistance related to the hog industry.
6	10	1.1		Multiple		Collaboration with a pool of external technical experts is necessary.
6	10	1.2	Medium	1	26-45	The government must be able to conduct stringent and independent safety tests.
6	10	1.6	Medium	1	26-45	The government should hire more scientists who should be actively involved in conducting research and in assessing the research that is submitted. If the government does not want to hire directly then they should fund more research chairs in universities. Overall the government needs to rely less on research done by those who develop and market the products.
6	10	2.1		Multiple		Currently regulatory bodies are at risk of not being able to keep up with the rapidly expanding biotechnology industry. More internal hiring is required as well as contracting research out to university and provincial labs. Research that comes from publicly funded labs is the most credible to the public.
6	10	2.2	High	under 5	46-65	The government needs to hire more internal expertise and not rely on outside expertise, which may be funded by industry.
6	10	2.3		Multiple		The government needs to maintain the expertise to evaluate and judge the scientific material it receives. This does not all have to be done in-house. Much of the science that underlies product development is published in the scientific literature, and thus is subject to peer review.
6	10	2.4	High	21,000 members		The government needs to maintain a reasonable number of highly trained and well-paid risk assessors. These assessors should be able to solicit input from external experts, as required for specific expertise, to assist with a higher workload and to maintain the integrity of the review procedure. They should also have the opportunity for additional training as newer technologies are developed.
6	10	2.5	High	45,000 members		A formal mechanism of consulting with external experts will be useful but regulatory bodies must maintain sufficient levels of expertise to allow for independent decision making. The approval process must also remain timely. Harmonization of assessment approaches, data sharing and joint reviews with other jurisdictions may also be beneficial. Harmonization efforts should not compromise current regulatory standards, which should remain science-based.
6	10	2.6		37 organizations		The regular analysis of data should be the role of regulators. If regulators require external expertise to judge something that they are unsure of then this should be possible. Outside expertise could be drawn from other countries as well.
6	10	2.7	High	16+		When the necessary expertise is not available in house then the government should use external expertise. External expertise must be required to disclose ties with biotechnology or organic industry.
6	10	2.8	High	20,000 members		As per 2.5.

6	10	2.9		180 companies		The use of external expertise would complement internal expertise. The roles of both internal and external experts must be transparent. Procedures and process should be harmonized as much as possible to facilitate data sharing and minimize duplication. There should be timeframe accountability.
6	10	2.12		Multiple		All research does not have to be done in-house. However, the government must be able to maintain adequate in-house capacity to assess outside work, to be able to address all types of foods that are put forward for approval and to determine what would need to be done internally to ensure a full assessment of a product. Canada should work with other governments to ensure that work is not being duplicated.
6	10	2.13	High	16+		Internal expertise must be maintained but it is not necessary to duplicate peer reviewed scientific work that has been done by external academics or industry.
6	10	3.1	Medium	16+		As per RS panel recommendation 9.3, a system of regular peer review of the risk assessments upon which the approvals of GM foods are based upon should be conducted. As per RS panel recommendation 7.3, an arms length panel of experts should monitor the outcomes of all tests on new transgenic organisms and report their decisions in a public forum.
6	10	3.2	High	16+		Internal expertise must be increased and maintained first. External expertise should be used to complement and confirm the initial work of government staff.
6	10	5.3		2		The government can create and maintain regulatory flexibility through diversification, i.e. by providing incentives and resources for developing alternatives to biotechnology. The current dilemma (high investment; high market uncertainty; high uncertainty regarding risks and benefits) is largely the result of unwavering commitment by the Canadian government to agricultural biotechnology over the past twenty years. Regulatory capability and capacity can also be increased by establishing and maintaining advisory boards (on scientific, economic, social and ethical issues) whose membership is diverse, independent and accountable.
6	11	1.1		Multiple		The government has to have a long-term vision and remain flexible to keep in control of the information coming in. The government must develop some way of knowing what products are pending. Pre-submission meetings should be considered so that the group submitting knows what the process is and the government can focus on the evaluation.
6	11	1.2	Medium	1	26-45	This question assumes that GM foods will come forth for approval in the future. It does not reflect an objective process. It is not necessary to develop regulations when banning GM foods is an option.
6	11	1.6	Medium	1	26-45	Increase the budget for independent research, either within government or in universities.
6	11	2.1		Multiple		Regulators need to stay close to the discovery process. Attending national and international conferences can be valuable to regulators. This will require resources.
6	11	2.2	High	under 5	46-65	The government should hire more people to research and regulate upcoming products.

6	11	2.3		Multiple		Regulatory agencies will need to maintain their internal capacity and keep in step with Canada's trading partners. Monitoring scientific literature, attendance at scientific conferences, building in-house scientific activities and surveying companies active in biotechnology research and development will help determine the types of products in the pipeline. Risk assessment should continue to be science-based.
6	11	2.4	High	21,000 members		Government can be made aware of upcoming technologies through contacts and contracts with university and public sector researchers. International harmonization in the review of GM technologies should be incorporated where feasible although Canada must not lower its biotechnology regulatory standard to align with that of other countries.
6	11	2.5	High	45,000 members		The formal establishment of closer links with the research community and international regulatory bodies as well as ongoing training of regulatory personnel would provide sufficient capacity to identify and regulate upcoming products.
6	11	2.6		37 organizations		The government should not do internal research but should contract research from outside of the government, domestically and internationally.
6	11	2.7	High	16+		Developers of new technologies and products will notify regulators of what is coming because they realize new technologies and products will require a longer time to approve.
6	11	2.8	High	20,000 members		As per 2.5.
6	11	2.9		180 companies		Government regulatory scientists should attend international and regional scientific conferences and keep current with the published literature. Enhancing communication networks and secondments with private organizations developing GM products will help regulators anticipate the new products coming.
6	11	2.11		Multiple		The current regulatory system is not adequate to address the challenges presented by GMOs. Better identification, testing and segregation systems are needed before new varieties are introduced.
6	11	2.12		Multiple		Government scientists and regulators should consult with industry and attend relevant scientific conference and review the scientific journals to keep informed of new products and technologies that are coming.
6	11	2.13	High	16+		The government can keep informed of new GM crops and food through monitoring the scientific literature, participating in industry and scientific conferences and by ensuring regulatory bodies are adequately resourced.
6	11	3.1	Medium	16+		The government should reinvest in independent research and evaluation, use ad hoc expert panels and international research and regulatory activities.
6	11	3.2	High	16+		The government should provide more funding for public research, work closely with universities to develop academic programs in regulatory affairs and aggressively recruit Ph.D. graduates. The government must also remain aware of applications in other countries.
6	11+	2.2	High	under 5	46-65	Scientists and government researchers should be selected for prudence and commitment to truth and allowed to do their due diligence.
6	11+	2.7	High	16+		The agencies are fully capable and able to deal with future products.

7	12	1.1		Multiple		This initiative would be useful as a consumer reference and a consumer education tool. It is important that it be a government initiative with equal representation from government, consumers, academics and industry. To be trusted the body must be impartial and able to honestly answer questions including acknowledging areas where data is limited.
7	12	1.2	Medium	1	26-45	To be considered trustworthy, the source of information should be non-corporate and non-governmental.
7	12	1.6	Medium	1	26-45	This initiative would be very useful. Government should initiate and maintain it.
7	12	2.1		Multiple		Several sources of information currently exist. The value in this initiative would be in linking all the existing sources together where information gaps could be identified and filled, and duplication, overlap and contradictory information could be avoided.
7	12	2.2	High	under 5	46-65	This initiative would be useful to protect consumers from corporate powers who often choose profiting over ethics and the effect on the individual. The government should take the lead. Scientists and specialists should be separated from government interference and be free of any financial or investment interests in industry.
7	12	2.3		Multiple		There are a number of information sources already available to the public. As a first step, these activities should be coordinated to avoid duplication.
7	12	2.4	High	21,000 members		The cost of such an initiative would be prohibitive and the number and scope of issues would be too much for one source to handle. There is a need for a centralized source of information to address general queries and refer consumers to more specific sources if needed. The government should utilize existing information resource centers. Public endorsement by government departments and by consumer groups would help instill consumer trust.
7	12	2.5	High	45,000 members		There are a number of information sources already available to the public. A single source of information might generate mistrust among consumers.
7	12	2.6		37 organizations		This initiative would be duplicating what the Food Biotechnology Communications Network is already doing. They currently provide accurate and balanced information. Information provided to the public should be vetted by outside experts.
7	12	2.7	High	16+		This initiative would not be useful. Consumers want to know that the regulatory agencies are doing their job of ensuring a safe food supply. The government should support and defend its safety decisions.
7	12	2.8	High	20,000 members		As per 2.5.
7	12	2.9		180 companies		This initiative would be very useful, it would educate consumers and clarify the complex issues around food biotechnology. It should involve government, industry, health professionals and consumer groups. There are currently many sources available that could be combined.
7	12	2.12		Multiple		Government should take the lead on this initiative, in cooperation with industry and consumer groups. The information should include the risks and benefits of using genetic modifications as well as the risks and benefits of not using them. The information should be distributed on the internet.

7	12	2.13	High	16+		This initiative would be useful. It should be coordinated between all relevant agencies and departments.
7	12	3.1	Medium	16+		This initiative would be useful and could also gather public input. Health Canada should take the lead.
7	12	3.2	High	16+		The Food Biotechnology Communications Network already does this. Government should work to improve this service.
7	12+	1.2	Medium	1	26-45	Offering informed choice is a weak argument for allowing genetic modification of crops. We have no way of knowing the long-term effects and whether or not consumers choose to eat the foods; they are still being grown in the environment.
7	12+	2.2	High	under 5	46-65	Prudence and protection and preservation of the individual and family take precedence over profit motives.
7	12+	3.2	High	16+		Build on current infrastructure-don't duplicate what has already been done.
8	13	1.1		Multiple		Mandatory labelling is the ideal approach because it forces the market to answer to consumer demand. However if a mandatory labelling standard is not implemented, a good voluntary standard that satisfies all parties and will be broadly used would still be beneficial.
8	13	1.2	Medium	1	26-45	GM foods should be banned. If not, labelling is absolutely mandatory.
8	13	1.3				Specific regulations on food labelling are needed. They should be specific and not use the words "may contain."
8	13	1.4				Start mandatory labelling immediately until proper independent testing of GM foods had been done.
8	13	1.5	Medium	1	26-45	Labelling should be mandatory. Not all consumer concerns can be addressed through the regulatory assessments such as ethical, social and environmental concerns, labelling would allow for consumer choice.
8	13	1.6	Medium	1	26-45	Labelling should be mandatory to allow consumers to choose.
8	13	1.7	Medium	1	under 25	Labelling should be mandatory to allow consumers to choose.
8	13	2.1		Multiple		Labelling should be voluntary, support the Canadian General Standards Board Initiative.
8	13	2.2	High	under 5	46-65	Labelling should be mandatory.
8	13	2.3		Multiple		Labelling beyond the current requirements should be voluntary. Consumers should have access to meaningful information about all food products regardless of how they were developed. Food labels are limited in the amount of meaningful information they can provide and need to be complimented with other information.
8	13	2.4	High	21,000 members		CBAC should endorse the current process underway by the Canadian General Standards Board to develop a voluntary standard. Mandatory labelling will not enhance consumer choice and it may lead to misleading label claims, market opportunism and/or increased costs to the consumer. Labelling alone will not provide consumers with useful information.

8	13	2.5	High	45,000 members		Labelling beyond the current requirements should be voluntary and based on clear and meaningful standards. Mandatory labelling will increase food costs, reduce consumer choice, as food manufacturers limit product lines to GM or non-GM, and cause negative trade implications.
8	13	2.6		37 organizations		Labelling should be voluntary using the same model as organic.
8	13	2.7	High	16+		Labelling is not necessary because the foods have been proven safe. Negative labels should be allowed as long as they are accurate and do not imply that the food is unsafe.
8	13	2.8	High	20,000 members		As per 2.5.
8	13	2.9		180 companies		Supports the Canadian General Standards Board in developing a voluntary labelling scheme. Food labels should be limited to communicating material difference in nutrition, composition and known safety issues. Consumer research is required to determine the optimal method for conveying useful information to the consumer regarding GM food.
8	13	2.12		Multiple		Labelling should be voluntary, support the Canadian General Standards Board Initiative. Mandatory labelling would impose significant segregation costs onto producers. Labels should convey essential information such as composition, nutrition, intended use and potential allergens.
8	13	2.13	High	16+		Consumers require valid and meaningful information about the food that they eat. Industry should work with government to develop a national standard for labelling.
8	13	3.1	Medium	16+		Labelling should be mandatory.
8	13	3.2	High	16+		Labelling should be voluntary to balance choice with cost at a point of greatest accuracy.
8	13	5.1		4		Mandatory labelling should be required unless the public can be assured through stringent testing requirements and public disclosure of the results, that meaningful steps have been taken to test GM products.
8	13	7.2				Labelling should be mandatory.
8	13	73				Labelling should be mandatory; GMO free labels should be permitted.
8	13	7.4				Labelling should be mandatory to allow consumers to choose.
8	13	7.5				Labelling of all modifications to any plant material, animal or food products should be mandatory.
8	13	7.8		30 people		A Canadian labelling scheme should be modeled after the European Union. Labels should be understandable to the general public.
8	14	1.1		Multiple		Canada should develop its own standards and harmonize them as much as possible with international standards. Nationally, Canada should understand the needs of consumers so their interests can be better represented internationally.
8	14	1.2	Medium	1	26-45	Canada should develop its own mandatory labelling standards. This can be pursued simultaneously with the development of international standards but do not wait on other countries.
8	14	1.6	Medium	1	26-45	Canada should develop its own standards while an international consensus is worked toward.

8	14	1.7	Medium	1	under 25	Canada should develop its own standard. Labelling will be delayed if we wait for an international consensus.
8	14	2.1		Multiple		Canada is a leader in food biotechnology and often serves as a model for other countries. Canada should continue to develop its own standards that address the concerns and issues of Canadians.
8	14	2.2	High	under 5	46-65	Canada should develop its own labelling standards and only adopt international standards if it serves our interests.
8	14	2.3		Multiple		Canada should continue to develop a domestic voluntary standard while continuing to work with CODEX to develop an international standard.
8	14	2.4	High	21,000 members		Canada should continue to develop its own voluntary labelling standards based on Canadian definitions of novel traits/novel foods. Canada should not alter its domestic regulatory process in a way that undermines its scientific integrity, to align with international standards.
8	14	2.5	High	45,000 members		Canada should continue to develop a domestic voluntary standard while continuing to work with CODEX to develop an international standard.
8	14	2.6		37 organizations		Canada should develop its own labelling requirements.
8	14	2.7	High	16+		The grain industry should be allowed to develop identity preserved systems to meet the requirements of manufacturers who do not want GMO's. If linked to a negative labelling system it should not imply reduced safety in GMO's.
8	14	2.8		20,000 members		As per 2.5.
8	14	2.9		180 companies		Canada should continue to develop a domestic voluntary standard while continuing to seek harmonization of domestic standards with international standards.
8	14	2.12		Multiple		Canada should continue to develop its own labelling standard while monitoring the status of international standards. If it is in our best interests to harmonize with international standards than we should do so.
8	14	2.13	High	16+		Canada should develop its own labelling standard that is unique to Canadian's needs.
8	14	3.2	High	16+		International and national labelling schemes can be developed simultaneously.
8	15	1.1		Multiple		A nation-wide educational program is crucial regardless of the outcome on labelling.
8	15	1.2	Medium	1	26-45	Any labelling should be comprehensible.
8	15	1.6	Medium	1	26-45	Imported foods should adhere to our labelling standard if there is no standard in the country of origin. If there is a standard in the country of origin then we should accept their labels while working toward an international standard.
8	15	2.1		Multiple		Currently there are challenges regarding the amount and detail to include on the label. Putting a bar code on the label to provide additional information to consumers could alleviate some of these problems.
8	15	2.2	High	under 5	46-65	Labelling should include details that indicate the source of new material, the objective of including the material and the effects.
8	15	2.3		Multiple		The government should support a consumer education program to accompany labelling. This should be in cooperation with producers, food manufacturers, consumer groups and other

						should be in cooperation with producers, food manufacturers, consumer groups and other stakeholders.
8	15	2.4	High	21,000 members		CBAC should leave the labelling discussion to the Canadian General Standards Board.
8	15	2.5	High	45,000 members		Future initiatives regarding labelling should be done in consultation with the Canadian General Standards Board.
8	15	2.6		37 organizations		Clear unbiased research on food labelling is required. Labelling must be considered in the context of other food labelling requirements, and in terms of public health goals.
8	15	2.7	High	16+		The government should ensure that labelling claims regarding "GMO-free" and "organic" are accurate.
8	15	2.8	High	20,000 members		As per 2.5.
8	15	2.9		180 companies		The government should support a consumer education program to accompany labelling. This should be in cooperation with producers, manufacturers, consumer groups and academics.
8	15	2.13	High	16+		Consumer education will be a critical component of any labelling scheme.
8	15	3.2	High	16+		Canada's leadership role in Codex is positive.
8	15+	1.5	Medium	1	26-45	Some people are opposed to GMOs because of social, ethical and political issues, not safety issues. Mandatory labelling is the only way these people can make an informed choice.
8	15+	2.10		Multiple		Labelling schemes within Canada should be coordinated between federal and provincial governments and the private sector. Internationally, Canada should support the Codex Alimentarius Committee on Food Labelling in trying to harmonize international standards. Labels should be clear, accurate with no complex scientific terminology. Labels should not use negative claims but should indicate that the product has been improved in a manner relevant to the consumer. For labelling purposes the definition of genetically modified should be limited to rDNA technology.
8	15+	2.11		Multiple		Canada's labelling scheme must be consistent with international standards and meaningful, affordable and enforceable. The "plants with novel traits" (PNT) definition should not be used in labelling. A crop cannot be tested to determine if it has been derived from mutagensis. Under a PNT labelling definition this would require segregation of nearly all food ingredients from field to consumer. This cost would be prohibitive and virtually impossible using current technologies. More sophisticated, faster evaluation and detection techniques must be developed. Canada's labelling scheme should be harmonized with international schemes.
9	16	1.1		Multiple		Studies should be conducted to help us better understand nature and the environment. The government should fund this research. Industries that stand to gain from the genetic modification of crops, food etc should also contribute money to a general fund that is then distributed for this type of research.
9	16	1.2	Medium	1	26-45	GM foods cannot effectively be regulated; there will never be enough knowledge to do this. Government research is inadequate because it is under-funded and corporate research is biased.

9	16	1.6	Medium	1	under 25	Improvements in scientific knowledge are needed.
9	16	2.1		Multiple		More scientific knowledge is required to be able to make unequivocal statements about the safety of biotech products. The current regulatory system cannot assume the added responsibility entailed in this. There are many environmentally sensitive products in the pipeline and the Canadian regulatory system must be prepared to handle them. More research is required regarding the environmental sustainability of agri-food biotechnology products. Research should be conducted by government but also by university and provincial labs or agencies like the Network of Centers of Excellence. Respondent argues that industry must contribute significantly to the improvements in the scientific knowledge underpinning environmental stewardship, but this contribution must be credible to the public.
9	16	2.2	High	under 5	46-65	Environmental stewardship should only be addressed if other crops or animal products are affected.
9	16	2.3		Multiple		Environmental stewardship should be assessed in the context of agricultural production, comparing risks and benefits of GM crops to conventional or alternative crops. Ongoing improvements in scientific knowledge are required- this could be achieved by developing in-house scientific expertise or enlisting outside expertise through international scientific fora. This research should be a collaboration between government, industry and university scientists.
9	16	2.4	High	21,000 members		The current environmental stewardship program is considered comprehensive. Collaboration with international environmental assessment projects could be useful to both identify potential environmental concerns and to expedite regulatory approvals. Funding for environmental research should be undertaken by public research institutions with funding from industry and government. This will ensure that the results are in the public interest, more trusted and accessible.
9	16	2.5	High	45,000 members		Continued acquisition of knowledge is beneficial, however current stewardship programs are not inadequate.
9	16	2.6		37 organizations		Regulations should look at the effect of GMO crops on the existing use patterns of pesticides, fertilizers, fossil fuels etc. There could be a positive environmental impact from GMO crops-both negatives and positives should be assessed.
9	16	2.7	High	16+		Further knowledge is not needed, with today's products the issues of environmental safety have been fully explored.
9	16	2.8	High	20,000 members		As per 2.5
9	16	2.9		180 companies		Maintenance of the scientific knowledge base is essential. International networks should be developed and international and domestic processes should be harmonized.
9	16	2.12		Multiple		Improvements in scientific knowledge are beneficial and research should be a collaboration between government, industry and university scientists.
9	16	2.13	High	16+		Ongoing research is a critical component of adequate regulatory decision making.
9	16	3.1	Medium	16+		As per RS panel recommendation 6.4, an analysis should be undertaken of the expertise required in Canada to evaluate new GM products. If expertise is found to be lacking, resources should be allocated to improve the situation.

9	16	3.2	High	16+		Improvements in scientific knowledge are always beneficial. Joint financing programs should be available.
9	16	5.3		2		The effective regulation of GM crops requires improvements in the current knowledge base. This should be *funded* by proponents and government but safety assessments should not be *conducted* by industry, as is currently the case. Environmental stewardship will also require: ❖ Clearly and openly defining the parameters of 'harm'. Definitions must include indirect and long-term effects. ❖ Examining the baseline for acceptable risk. The current standard of 'conventional' (i.e. intensive, chemical-based) agriculture may not be sufficient for achieving environmental stewardship. Other countries have set higher environmental goals. Canada should be a leader in this respect. ❖ Recognising uncertainty. While additional information is necessary, it should also be recognised that we cannot know or predict all possible effects of releasing GM crops. This should be made explicit to the public and precautionary measures should be adopted (e.g. developing alternatives; granting conditional approvals; imposing a moratorium until further research and more thorough public consultations have been conducted).
9	17	1.1		Multiple		The use of a life cycle approach would be wise, as our knowledge is currently limited. Once enough knowledge is gained, then it is possible to monitor only the critical points for a particular product.
9	17	1.6	Medium	1	26-45	A life cycle approach should be used.
9	17	2.1		Multiple		There is merit to using a life cycle approach, base data already exists to do this. A review of the life cycle environmental impacts could be incorporated in the re assessment, re certification process. Government could act as a custodian of the product life cycle process information.
9	17	2.2	High	under 5	46-65	A life cycle approach, in the agriculture approach, would be useful.
9	17	2.3		Multiple		The knowledge base and expertise may not exist to deal with a life cycle approach. When will a product have been assessed enough to make a judgement? Why is there a need to treat GM crops differently from other crops?
9	17	2.4	High	21,000 members		New production technologies need to be evaluated and approved in the context of the agricultural production systems they are enhancing or replacing. Unless the weight of scientific evidence suggests that further in-depth assessment is warranted than a life cycle approach is not necessary. GM traits should not need any further assessment than any other new technology introduced to agriculture.
9	17	2.5	High	45,000 members		In determining the environmental impact of a GM crop the environmental benefits as well as risks must be compared with other conventional and organic crops. Environmental stewardship extends beyond the production of GM crops. In assessing the risks of adopting a technology it is also important to consider the risks of not adopting it.
9	17	2.6		37		A life cycle approach should be used with all food claims like organic, not just GM.

				organizations		
9	17	2.7	High	16+		Until problems arise from the current approach there is no need to increase environmental testing.
9	17	2.8	High	20,000 members		As per 2.5.
9	17	2.9		180 companies		A life cycle approach has merit and may have broader implications than just GM crops. Implementing the approach may be difficult as currently products are pooled for distribution.
9	17	3.1	Medium	16+		As per RS panel recommendation 6.2, exhaustive long-term testing will be required for ecological effects of biotechnology products that pose environmental risks, especially with respect to harmful effects from "horizontal gene transfer." Tests should not be limited to agroecosystems but should consider impacts on the natural and disturbed ecosystems.
9	17	3.2	High	16+		A life cycle approach may be useful if products are evaluated on a case by case basis.
9	17+	1.2	Medium	1	26-45	We should learn from the experiences with CFCs and DDT, which probably went through a scientific environmental impact assessment, and just not allow GM crops.
9	17+	1.7				Long-term multidisciplinary studies of potential environmental impacts should be conducted.
9	17+	5.1		4		The current knowledge base and testing procedures for environmental effects are inadequate, plants producing nutraceuticals, vaccines, enzymes and chemicals, as well as transgenic trees, pose additional environmental hazards. As per RS panel comments, research on a variety of topics is needed to build better evaluation capability, to understand food safety and environmental impacts. As per RS panel recommendation 6.9 funds should be made available to scientists from all sectors to research the environmental impacts of GM plants, these studies should be subject to peer review. It is essential that scientists and reviewers remain independent of biotechnology corporations.
10	18	1.1		Multiple		The religious aspect has not been covered.
10	18	1.6	Medium	1	26-45	The developed world in taking advantage of developing nations. Subsistence farmers should not have to buy new seed each year and given the unknown long term effects of GM foods we are using the developing world as test cases and potentially putting them at risk.
10	18	2.1		Multiple		Social and ethical issues must be discussed to a greater extent than they are now but not within the regulatory system. These issues should be covered at a higher and broader level than the individual product assessment. A useful model is that developed by Genome Canada entitled Genome Ethical, Economic, Legal, Social issues (GELS).
10	18	2.2	High	under 5	46-65	The producers of a new product should have to identify the ultimate goal of the product. If it includes greed for profit at any cost, the exclusion of other products, or control over normal life cycles and other products then the project should be terminated.
10	18	2.3		Multiple		The role of industry in addressing social and ethical issues is not touched on. Industrial development contributes to economic growth and job creation, which leads to social benefits; this should be reflected in the discussion. The regulatory process must remain science-based, the debate about social and ethical issues should take place at the sector or product categories level rather than with respect to an individual product evaluation.

10	18	2.4	High	21,000 members		An additional social/ethical issue is whether the opportunity to advance environmental stewardship, and/or food safety, and/or health should be denied because there are concerns about potential negative impacts, if all reasonable measures and safeguards are taken to protect against such negatives.
10	18	2.5	High	45,000 members		Some of the concerns discussed in the section relate specifically to GM foods, others reflect broader concerns such as growing corporate concentration. The food regulatory system should not be expected to address these broad concerns. Broad guidelines based on issues specific to the technology, developed at the policy level, could be used to chart the course for further developments. All social and ethical considerations should be placed within a broad context and should address both benefits and risks. Concerns in these areas are related more to potential uses of the technology than current applications.
10	18	2.6		37 organizations		The ethical dilemma of not proceeding with the introduction of GM products has not been discussed. Can Canada have its current standard of living without continued technological advances and risks?
10	18	2.7	High	16+		The principle opponents of biotechnology have been individuals or groups whose philosophical viewpoint has been best captured by the organics movement. There is currently no real and genuine opposition on religious, ethical or social reasons.
10	18	2.8	High	20,000 members		As per 2.5.
10	18	2.9		180 companies		The discussion touched on many of the important ethical and social issues. The current science-based process provides predictability, objectivity and transparency.
10	18	2.10				There are special ethical considerations related to xenotransplantation and animal welfare.
10	18	2.11				Supports a process that operates parallel to the scientific regulatory process in order to take into account a wider range of interests than purely scientific considerations (e.g. market impact). Another ethical issue is the unfairness of imposing increased cost of segregation on farmers.
10	18	2.12		Multiple		The discussion touched on many of the important ethical and social issues. The regulatory system should remain science-based and transparent. This will allow enough certainty to promote research and development by biotechnology companies to ensure that health and environment is protected.
10	18	2.13	High	16+		The discussion of social and ethical issues was comprehensive.
10	18	3.1	Medium	16+		An ethical issue not covered is that the current phase of genetic engineering sees everything as resources for exploitation.
10	18	3.4				There is a need for public consultation on the ethics and social need for, and desirability of genetic engineering,
10	18	5.1				Respondent believes that the Consultation Document misses the most important ethical issue; namely, that the introduction of GE crops and foods was without genuine public disclosure and informed discussion.

10	18	5.3				It is not possible to fully separate scientific and social/ethical issues. Maintaining a 'science-based' system reflects an ethical position (e.g. a decision to exclude other factors), and value judgements are incorporated into every stage of the current decision-making framework (e.g. the decision to use primarily proponent-generated data). It should be recognised that the current regulatory system is value-laden. Broader ethical issues outlined in consultation document must also be given greater consideration. In particular, the Canadian government should reaffirm its commitment to environmental values/stewardship and examine the role of biotechnology *and other alternatives* in fulfilling this commitment.
10	18	7.2				It is ethically wrong to patent life forms.
10	19	1.1		Multiple		Efforts should be made to understand the concerns and respond to them. An ethical committee made up of experts with different backgrounds could oversee these issues. The committee must be aware of where the public stands on ethical issues.
10	19	1.6	Medium	1	26-45	The United Nations could oversee ethical and social issues.
10	19	2.1		Multiple		As a condition of awarding federal research money to projects above a certain threshold level, social and ethical issues should have to be incorporated. This should then be published in a publicly accessible and user friendly manner. Producer and crop groups must also ensure that the new GM foods meet the needs of customers in both domestic and international markets.
10	19	2.3		Multiple		Efforts should be placed on addressing social and ethical issues; Industry is willing to be involved. Ethics should be politically neutral with the conclusions being the basis of political debate.
10	19	2.4	High	21,000 members		Social and ethical issues should be addressed, but not in the science-based regulatory system. These issues should be debated in the public forum, possibly through the political system to establish norms and tolerances, which then could be turned into legislation or principles for the regulatory system to follow.
10	19	2.5	High	45,000 members		Social and ethical issues need to be addressed. These considerations do not have a single answer but vary greatly depending on the needs, perspectives and values of different groups. The regulatory system should remain science-based.
10	19	2.6		37 organizations		Comfort with ethical issues change over time, for example organ transplants were once a big ethical issue. Lots of infrastructure should not be put into place. For highly controversial issues panels may be useful. Ethical considerations should not need to be discussed for most everyday GM crops (e.g. another variety of *Bt* corn)
10	19	2.7	High	16+		Efforts should not be put into place to address these issues.
10	19	2.8	High	20,000 members		As per 2.5.
10	19	2.9		180 companies		Efforts should be put into addressing these issues. Consider multi stakeholder consultations with industry, academia, government, and the public sector.
10	19	2.12		Multiple		Efforts should be put into addressing these issues. Government should take the lead but gather input from all stakeholders.

10	19	2.13	High	16+		Efforts should be put into addressing these issues. There should be a broad public discussion about ethical and social issues.
10	19	3.1	Medium	16+		CBAC could establish an ethics working group to address social and ethical issues and to provide advice to government.
10	20	1.1		Multiple		An arms length expert group should draft guidelines for industry to follow with respect to the ethical concerns of the public.
10	20	1.6	Medium	1	26-45	Case by case decisions can only be made in the context of a broader policy.
10	20	2.1		Multiple		There is no need for government involvement in addressing social, ethical and socio-economic ideas beyond including 'discussions'.
10	20	2.3		Multiple		Social and ethical issues should be addressed at the broad government policy level. The federal government should coordinate the process. The Canadian policy and regulatory system should strive to be reflective of the ethical and social realities of a broad Canadian society, not a small and vocal segment of the population.
10	20	2.4	High	21,000 members		As per answer to question 19.
10	20	2.6		37 organizations		Managing and evaluating ethics should not be a regulatory role.
10	20	2.7	High	16+		There is not a need for government involvement in addressing social and ethical issues.
10	20	2.8	High	20,000 members		As per 2.5.
10	20	2.9		180 companies		Social and ethical issues should be addressed through a broad approach of government policy applicable on product sectors. This would provide for objectivity and predictability. The federal government should coordinate this process.
10	20	2.12		Multiple		The federal government should take the lead in addressing social and ethical issues. All parties to the discussion need to be aware of what the issues are.
10	20	2.13	High	16+		The federal government should coordinate the discussion of social and ethical issues. These issues must be addressed at the broad policy level through the legislative process and not on a product by-product-basis.
10	20	3.1	Medium	16+		As per answer to question 19.
10	20+	2.4	High	21,000 members		It is not clear how the "activities that may be helpful to identify possible solutions" on page 21 of the discussion document, really address the social and ethical considerations noted earlier in the chapter. These activities may be useful for other reasons but are not a direct path to obtaining answers to the social and ethical issues.

OTHER		1.3				Tests run on transgenic crops are not conclusive because they are run by the same organizations that want to have the product approved. New products may not immediately reveal their toxicity. Test with mice led to third generation animals with deformed vital organs. There is a fear of leaving great grand children a heritage of irreversible genetic mutations. Do not put human genes into livestock, eating the livestock would be cannibalism. Governments must protect human citizens and not only corporate citizens.
		1.4				There is a conflict of interest inherent in corporations testing their own products. There is a lack of research on food safety and environmental risks, meanwhile the government is giving BIOTECH Canada millions of dollars, millions of dollars should be donated to *non-proprietary* agricultural alternatives. Concerned about the majority industry representation on CFIA Ministry Advisory Board. There should be performance trials of animals fed non-GMO vs. GMO grains; studies of chronic exposure of GM food through multiple generations; follow-up on the histological work that demonstrated deformations in rat intestine; safety analyses on field grown and glyophosphate-sprayed soybeans with respect to phytoestrogen problems. Given the high degree of uncertainty in the technology of creating GM foods, the precautionary principle must be followed. Suggests we not continue developing GM food crops. Given the high risk of serious environmental damage, suggests that HC and CFIA must increase the rigours of testing and stop all support for GM crops until more understanding arises.
		1.3				Tests run on transgenic crops are not conclusive because they are run by the same organizations that want to have the product approved. New products may not immediately reveal their toxicity. Test with mice led to third generation animals with deformed vital organs. There is a fear of leaving great grand children a heritage of irreversible genetic mutations. Do not put human genes into livestock, eating the livestock would be cannibalism. Governments must protect human citizens and not only corporate citizens.
		1.5	Medium	1	26-45	The Canadian people increasingly mistrust government and corporations. The Canadian government should listen and respond to people's concerns. The opportunity to provide input is appreciated.
		1.6	Medium	1	26-45	The opportunity to provide feedback is appreciated. Please continue to offer these opportunities.
		1.7	Medium	1	under 25	Who will be held liable if, in the future, it is discovered that there are serious negative health and environmental effects caused by GM crops and foods? It should be determined if there are true benefits that outweigh the risks of GMO's before going further with regulation. The fact that so few corporations control global food supply produces distrust and suspicion in consumers. Transparency across all issues is important. Further discussion with environmental and other groups is needed to address the reason for their boycott of the stakeholder workshops.

		2.1		Multiple		There is a significant loss of public confidence in the safety of the food supply; this is a result of a series of international food crises such as Mad Cow and Foot in Mouth diseases. While consumer 'panic' in North America is not as high as in European countries issues such as the Star Link corn problem threaten to undermine public confidence in the ability to maintain the safety of the food supply. The public controversy around foods from modern biotechnology has now been identified with the broader European food safety crisis. This has resulted in statements from leading international figures that criticize falling quality standards in the food industry. In this environment decisive action must be taken to prove to the satisfaction of consumers that foods of biotechnology are safe to eat. The public's confidence must be restored. If this does not happen there is a real risk that agri-food biotechnology may be lost forever or set back for many years (due to decreased political and financial support). In the past Canada's regulatory system was considered to place unnecessary impediments in the way of commercial development of novel food products. Now, this same regulatory process can play a major role in demonstrating the safety of Canadian products of biotechnology to the world. It is important to defend our system and not let it be weakened by economic cutbacks.
		2.4	High	21,000 members		Support the principle that CFIA regulates GM traits in crops and livestock and Environment Canada regulates traits in organisms not already covered in other legislation. Canada must continue to evaluate products scientifically based on product and not process. Canada's regulatory standards should not be lowered or altered to meet international regulatory or labelling schemes. In future CBAC should concentrate on getting written feedback rather than undertake the cost of holding face-to-face sessions.
		2.5	High	45,000 members		The consultation document presupposes the need to regulate foods based on the process by which they are derived, rather than the product itself. This is contrary to the regulatory approach in Canada and contradicts current research developments. The definition of GM used by CBAC is much narrower than that used by Health Canada. Using a definition that is at variance with regulatory agencies could be misleading and could potentially have negative legal implications. The list of potential benefits is incomplete, increased product quality, increased food safety, reduced food production costs and more efficient use of the existing agricultural land base should be added.
		2.10		Multiple		Canada should maintain a scientifically based regulatory system. All benefits of new technologies must be weighed against potential short and long-term risks. There should be no specific regulations in respect to hogs fed with GM feed, proteins from the feed are destroyed before being absorbed into the animal tissues. To maintain high animal welfare standards impact analysis should be performed for all new types of transgenic hogs. The government should establish a Research Network to address food-borne pathogens and antimicrobial resistance. GM animals result in the genetic erosion of non-GM animals, the government should increase its support of research in animal gene preservation.

		2.11		Multiple		Before new transgenic varieties of wheat or barley are registered for commercial production in Canada the potential market impact and the segregation capability must be considered in addition to health and environmental safety. These products should not be imported into Canada until they are approved for production domestically to maintain the integrity of Canada's quality assurance system.
		3.3		60 organizations		The consultation document fails to identify options such as a moratorium on future releases of genetically engineered products or a review of existing approvals.
		3.4		Multiple		The advent of agriculture has led to the progressive abandon of several varieties (950 vegetables) of plants thereby reducing genetic diversity. Genetic modification and plant patenting legislation has led to a further reduction of the genetic diversity on which the safety of our food crop depends. A moratorium on GM crops is required, including those already produced, analysis of the RS panel recommendations supports this. More in-depth reflection in required so proper choices for a sustainable future can be made.
		3.5		Multiple		GM products already on the market need to be re-evaluated. There is the need for a moratorium on all future GM products until the Canadian public has been fully consulted and the regulatory system has been reassessed, particularly in light of the critique and recommendations of the Royal Society Expert Panel.
		5.1		4		Full implementation of the RS panel's recommendations on pages 191 and 206-7, plus those on testing, would help remedy current problems with the regulation of GM foods. With regards to special GE-plants for the production of Nutraceuticals, Vaccines, Enzymes, and Industrial Chemicals, there is the possibility that the engineered genes will be transferred to non-GM crops through the pollen. With vaccines there is the possibility that different vaccines could be inadvertently administered to large numbers of people. There needs to be discussions and consideration of these issues. CBAC should recommend that a rigorous process to approve the claims that are being made for neutraceuticals be put in place by Health Canada. CBAC will eventually have to look at other GMOs such as GE trees.
		7.1				GMOs have not been adequately studied for effects to human health. Studies done by the companies that request regulatory approval of their product are not trustworthy. We are putting our genetic heritage and that of future generations at risk. There should be a moratorium on all GM foods while further testing, similar to that for pharmaceuticals, is done. It does not matter how long it takes; protecting our planet should be the priority.
		7.2				GM foods should be banned. There should be a careful examination of why there is a big push toward GM foods, many of the claims that the corporations make are not true. Companies should not be allowed to patent seeds. The Precautionary Principle must be applied.
		7.6				All GM products should be banned until we are certain about the risks. Preserve diversity. The government is not listening to the public.

		7.7				Strong measures should be taken by the government to protect the environment and promote environmental sustainability. The government should environmentally assess federal initiatives and regulations. There should be increased public participation in public decisions regarding the environment. The enforcement of environmental legislation should be strengthened. The government should actively participate in formulating international agreements on biodiversity. National standards for regulating the environmental effects of biotechnology should be developed.
		7.8		30		Consultation document offered too late and is too complicated for the public. This is purposely done to keep the public in the dark. GM foods offer no benefits and have not been tested for long-term health and environmental impacts.