Stakeholder Sessions

SUMMARY CONSULTATION REPORT

WORKSHOPS ON GENETICALLY MODIFIED FOOD

Vancouver

Saskatoon

Toronto

Halifax

Montreal

Prepared by the Canadian Biotechnology Advisory Committee

April, 2001

Highlights of the Five City Sessions

The views presented in this report are those raised by participants in the sessions. They should not necessarily be considered the views of all participants, and should not be construed as the views of CBAC.

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Introduction

CBAC is an independent expert advisory committee created to provide comprehensive advice to the Government of Canada on policy issues related to the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC members are appointed on the basis of the individual's expertise, not as representatives of stakeholder groups.

CBAC's advice is provided to a senior Cabinet committee, the Biotechnology Ministerial Coordinating Committee (BMCC), which comprises the federal Ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade. CBAC's advice is intended to assist the government with the development of an appropriate policy and regulatory regime.

CBAC is neither pro nor anti-biotech. It is committed to providing sound, comprehensive, evidence-based advice that takes into account the views of Canadians. The mandate is to help the Government of Canada find Canadian solutions to the challenges and opportunities posed by biotechnology. In order to do so, CBAC is following a three-phase approach as outlined below.

Three Phase Approach

At the inaugural meeting in October 1999, CBAC identified the robustness of Canada's system for assessing and regulating biotechnological innovations as an issue requiring study and evaluation. GM food was specifically cited as being of interest and CBAC began the first phase of the project by identifying research topics, locating relevant documentation and generating technical reports on specific questions. The committee reviewed relevant public opinion surveys and expert reports; commissioned documents to stimulate thinking regarding the social, ethical and governance parameters of GM food; held a workshop with regulators to learn more about the Canadian system; and identified key issues and options arising from this sources.

To assist in the work on GM foods, a reference group comprised of individuals with a broad range of stakeholder perspectives (e.g., consumers, environmentalists, farmers and industry) was created to review and advise on the committee's research reports, issues analysis, consultation approach and Consultation Document.

In early March 2001, the second phase of CBAC's project on GM food began with distribution of the Consultation Document on the Regulation of Genetically Modified Food to an extensive national list of interested stakeholders, public interest groups and experts. The Consultation Document was designed to facilitate dialogue among groups and individuals with a particular knowledge of and interest in genetically modified food and how they are regulated in Canada. It invited discussion of ten key issues (e.g. social and ethical considerations, labelling and information provision, and the separation and independence of regulatory functions in government) and poses specific questions that seek the perspectives of respondents. Input was welcomed on this document from stakeholders, experts and interested members of the public before April 20, 2001.

The views presented in this report are those raised by participants in the sessions. They should not necessarily be considered the views of all participants, and should not be construed as the views of CBAC.

CBAC then undertook to collect the views of Canadians through stakeholder roundtables that were held across Canada from April 2 – 10, 2001. Individual CBAC members were present at each roundtable to hear first hand the views of the participants. The roundtables were intended to allow more in-depth discussion of the issues and options associated with the regulation of GM food, and to allow participants to raise other issues participants considered to be critical. The Highlights Document from each roundtable as well as this integrated summary report are available through CBAC's web site.

Initial Report and Phase Three

Following this period of consultation, CBAC members will prepare an initial report to government, taking into consideration the input obtained through responses to the Consultation Document, stakeholder roundtables, commissioned reports and recent opinion surveys. This initial report will clarify issues, options and consequences, and will outline general directions proposed for future policy recommendations related to GM Food. It will be submitted to government and released in the summer of 2001. The third phase of consultations begins with the release of the report, when CBAC will welcome comments for a period of six months. Following this six-month period, and taking into account additional input from Canadians and any other sources of relevant information, CBAC will release its formal recommendations to the Government of Canada. All of CBAC's reports to government are developed and approved by CBAC members, and all reports are made public at the same time as they are submitted to government.

Objectives for Workshops

- To enable stakeholders to explain positions and rationale on key issues, propose and respond to promising policy directions, and describe benefits and consequences of preferred directions.
- To enable stakeholders to identify tradeoffs in policy options and values or principles that could underpin decision making.

Workshop Agenda

8:45 *Welcome and introduction*

9:30 *Breakout groups on key themes/issues*
Groups explore policy/action directions: what is of value/benefit, what are the consequences. Identify tradeoffs and possible values or principles, and note preferred choice(s)

12:00 *Lunch*

12:45 *Breakout groups on social and ethical considerations*
Groups explore 'social and ethical considerations'

2:45 *Break*

3:00 *Reports on highlights of breakout groups*

3:30 *Identify potential values and principles to guide decision making*

4:00 *Closing advice and guidance to CBAC – advice on consultation (flipchart on wall)*

4:30 *Closing*

Participant Selection

In designing the multi-stakeholder workshops, CBAC's goal was to have five full sessions of approximately 35-40 participants in each, representing a range of stakeholder interests, roughly balanced as follows: one-third consumer and civil society; one-third industry (all points of the development, production and retail chain); one-third health professionals, academics/researchers and provincial governments. In addition, where possible, representatives were invited who were knowledgeable about interests and issues in the respective regions where sessions were conducted. In general, participants were drawn from within the membership base of the various organizations invited to participate as well as their official representatives.

Invitations were extended to over 500 individuals While the target attendance for most groups was generally achieved, regrettably the consumer and civil society groups were not well represented.

Prior to the start of the workshops, a group of non-governmental organizations (NGOs) called for a boycott of the session. Their open petition, which they submitted formally to CBAC at its Vancouver workshop, and CBAC's response are presented in Annex D and are available on CBAC's web site at www.cbac-cccb.ca. The boycott severely limited NGO/civil society attendance at the workshops. During the consultations, other participants noted their absence, expressed their strong regrets that the NGO community had chosen not to be present, urged their return to the consultation table and strongly recommended that CBAC pursue their future involvement and input.

Summary of Workshop Design

The workshops began with an overview of the mandate and work to date of CBAC, and the GM Food Committee and their plan and timetable for delivering their recommendations to the federal government. An overview of the day's purpose, outputs and approach followed.

The participants were assigned to break-out groups whose discussions were then conducted in two sets: one set in morning and one in the early afternoon . In morning sessions, participant groups explored two or three of the 10 key issues described in CBAC's consultation document). They discussed: promising policy/action directions (called 'choices' in this approach) for each theme/issue, drawn from the consultation document or by suggestion from the group. They identified what is of value/benefit, and what are the consequences for each choice. They also identified the tradeoffs (acceptable and not acceptable) across the choices as well as values or principles that should guide policy choices for that issue area. They concluded the morning workshop by noting their preferred choice(s) and offering further insights on future policy dialogue for that issue.

In the early afternoon, all break-out groups explored social and ethical considerations including: whether the profile of social/ethical issues presented in the consultation document is complete; whether required regulatory assessments should include social and ethical considerations; possible approaches for finding policy solutions that are balanced; and the appropriate forum/framework for addressing these questions. After this sequence was completed over the morning and afternoon time blocks, the highlights of the discussions were reported in plenary. After the Vancouver workshop, break-out groups in the other cities also discussed a new proposal for a 'GM Foods acceptability/non-acceptability spectrum framework' that resulted from discussions that took place in Vancouver.

Participants then had the opportunity to identify (as individuals) from the various theme workshop reports, those critical values or principles that offer the most potential to act:

- as guides for the governance and organization of the regulatory system; and separately,
- as the basis for making policy choices.

Finally, participants offered closing advice and remarks to CBAC – key messages the participants wanted CBAC to take into consideration as it prepares its report to government. .

This Summary Report

This report summarizes the results of the five workshops held across Canada. . For each issue, the real and perceived challenges and possible ways forward, presented in text boxes, are derived from CBAC's consultation document on the Regulation of Genetically Modified Food.It is intended to represent the main ideas and suggestions of the participants and to reflect shared or majority views and preferences wherever they emerged. It also undertakes to characterize the range of opinions and divergent views heard. Related or similar ideas and suggestions have been grouped, where appropriate, into composite ideas in order to provide coherence. Thus it should be seen as a summary profile of the results, but *not* as a complete and detailed tracking of all the views expressed, nor as a literal transcript.

The views presented are those raised by participants in the sessions. There were occasions when lack of knowledge/background may have led participants to state perceptions of the regulatory system and its operations which may or may not be factually correct. Thus comments in some instances should be viewed as participant perceptions that may require subsequent validation, which we have not undertaken to do in this report.

Theme/Issue Areas

In order to effectively address the various themes and issues and identify and discuss potential ways ahead, stakeholders were divided into four break-out groups. Each group was invited to focus on one theme (i.e., theme A, B, C or D) during the first break-out group session. Theme E was discussed by each group during a second set of break-out groups. Each discussion group was created using a "stakeholder mix" approach, meaning each group ought to have a mix of the perspectives represented (e.g., NGO/Consumer Group, Government, Industry, Academia and Health Industry).

Theme A: Good Governance

- Transparency
- Opportunities for public involvement

Theme B: Information provision

- Information provision to support informed choice
- Labelling

Theme C: Risk and Benefit Considerations

- Environmental stewardship
- Post-market monitoring for risks and benefits

Theme D: Regulatory System

- Separation and independence of regulatory functions
- Capability and capacity in the regulatory system
- Ensuring safety during research and development activities

Theme E: Social and Ethical Considerations

- Broader social and ethical considerations

For background information on these issues, please refer to the consultation document entitled "Regulation of Genetically Modified Food" available on the CBAC web site at www.cbac-cccb.ca.

Theme A - Good Governance

- **Transparency**
- **Opportunities for public involvement**

Real or Perceived Challenges	
Transparency	**Opportunities for Public Involvement**
• Lack of clear information on features of the regulatory system and the approval pathway for new foods, feeds and seeds. • Lack of standardized procedures for dealing with situations e.g. conflicting opinions. • Information on research trials (prior to product approval) not fully disclosed debate whether should be. • List of products currently under review not public and summaries of decisions published long after decision. • Detailed information related to risk assessments, e.g. technical health and safety data, is not disclosed.	• Few or insufficient opportunities for public involvement in the regulatory system. In particular, lack of opportunity for input on regulatory decisions. • Others underline independent approach by regulators with publicly reviewed and internationally accepted assessment methods that should be sufficient for public confidence.

Possible Way Forward #1

Communicate product decisions, and the rationale for such decisions, immediately on approval. OR Communicate proposed product decisions in advance of approval, to seek input from Canadians, for a limited period of time, on the proposed decisions.

Release technical *health and safety data* used as the basis for regulatory decisions (e.g. on request). OR Release the data unless an exemption is requested and granted (this could be operationalized by developing specific criteria for exemptions.) OR Obtain agreement from developer to release portions or a summary of the technical health and safety data.

Consultation Preference [Communicating Product Decisions]

In all the workshops there was agreement that the product review decision should be communicated immediately on approval and that doing so would demonstrate government/ regulatory accountability and transparency. Standardized information sharing strategies should be defined and adopted (e.g. internet, newspaper, TV, radio) and the accessibility of this information should be promoted. Information and education can take place at different levels, and information should be tailored e.g. through general information for non-technical audiences and technical summaries and data for informed communities.

In addition, the health and safety data used as the basis for the regulatory decision should be accessible and available using easy to understand language for the public with more detailed scientific information available for expert review. Where the product information is considered confidential or proprietary, the regulator should pursue allowable exemptions with the developer, while keeping the public interest paramount. . It was seen to be important to distinguish between the confidentiality of data when submitted for review and how it may be different after approval, i.e. the status of confidentiality may change at different stages.

Tradeoffs

Release of production decisions immediately on approval was desirable as long as:

- strategies were developed to share information dissemination costs;
- the detailed information was communicated and accessible on a timely basis (e.g. within 48 hours);
- the information is easily accessible, concise and targeted to the language of distinct publics
- the accessibility is promoted
- technical details are available with possible conditions, i.e. confidentiality agreements, an exemption process, an editing process, etc.

Other Options [Communicating Product Decisions]

In addition to releasing the product decision on approval, several groups did not feel that it was enough to post the decisions once made, but felt that the public should also have access to information on decisions that are under consideration, what procedures will happen with the particular product and where it is now in the process. This was seen as an effective way to demonstrate transparency, but the need to protect proprietary information is also clearly important. Therefore, the suggestion was that the information disclosed would be of a general nature and not include specifics such as the name of the proponent, the location of field trials, the gene construct, etcThe groups recognized that as we get farther down the road with GM foods, products themselves will become more specialized so it may become difficult to reveal only

general information. For this reason, it would be advisable to allow for an exemption to the process under specific circumstances.

As for public involvement some groups felt there was a need to develop a process for public input, say 60 days prior to the final decision. This would demonstrate transparency and help to shift public perception that government is pro industry.

Two possibilities were put forward for the release of product information for products submitted for regulatory review. The first is to release all information as it becomes available. The second possibility involves two stages: releasing information on the application for approval along with the reasons for product development at the time of submission, and releasing the remainder of the information at the time the decision is made.

One group put forward the idea that a new regulatory process should be developed in order to improve governance in general. Below are listed some of the activities that could be included in the new process:

1. Immediately following the submission of a GMO application, Government, the proponent and a third party (to be determined), will work together throughout the product approval process, and will scope and resolve the issues associated with obtaining approval.
2. Immediately on submission of an application, the public is notified through the media.
3. Health Canada, CFIA and the proponent will conduct the current regulatory assessments. In addition, both the proponent and the third party will conduct separate benefit assessments.
4. Both the regulatory body and the third party assessor provide for public input.
5. Implement a public input step within the process for all assessments. In addition, develop a feedback mechanism to respond to concerns raised from public input.
6. Both the government and the industry would share the cost (a.k.a., intervenor funding) associated with third party analysis.
7. Develop timelines for each step of the process.
8. Develop and include a dispute resolution step to ensure differences are addressed appropriately.
9. As soon as a product is approved, release a summary health and safety document including the proponent's name. In the case of a rejected product, publish the decision without the name of the proponent.

Possible implications of the group's proposed new process

- Potentially time consuming.
- Enables a better understanding of the regulatory process.
- Provides for informed choice on the part of the public.

- Demonstrates democracy.
- Could be a disincentive/hindrance for small companies.
- A major risk associated with releasing product information too early in the regulatory process is that it may change; this may affect the accuracy of the product information that is in the public domain.

Possible Way Forward #2

Adopt a policy of non-disclosure of detailed information on authorized field trails. OR Release detailed information. OR the status quo – release general information but not the location of trails. AND develop criteria for departure from the default policy.

Consultation Preference [Field Trial Disclosure]

Those groups that reviewed this question opted for the status quo, i.e. release general information but not the location of field trials. The approach was seen to be adequate in terms of public protection since the regulator had knowledge and could apply necessary monitoring and controls, and yet would not subject the developer to the risk of vandalism.

Possible Way Forward #3

Improve communication about the Regulatory System. Develop high quality materials that describe regulatory bodies, respective laws, steps and criteria in product approval path.

Consultation Preference [Improved Communication]

All workshops agreed on the need for an enhanced communication plan that would strengthen openness and transparency, help educate and inform the public, build confidence and trust in the regulatory system, and underscore the current competency and rigour of the Canadian regulatory approach. The communication should also consider GM foods within the broader food system.

One group expanded on these urgings to outline a number of communication ideas as follows.

We have to recognize that there is a wide variety of publics needing different levels and types of information. Communication is required about the regulatory process in general – what the process is for, how it works, what are the benefits, how it is safety maintained, etc. Many different channels are required; we can't just assume that because it's on the web, it is accessible or that the process is transparent. The strategy requires a much more pro-active educational blitz approach, engaging the public at the local level – for example through women's groups, church groups, and working with professionals such as dieticians to take the information out to their constituencies. Government tends to think in terms of national campaigns, but that is not sufficient for the level of learning required. A second important role that government could play

would be as a source of credible information that public leaders could go to that could in turn be disseminated at the local level

Critical to include in the communication plan is the appointment of a "figurehead", or champion among the government stakeholders whose key responsibility is communication to the public about what the government is doing. While it is clear the regulatory arm of government cannot take an advocacy role for any specific aspect of biotech, it is legitimate that it take an advocacy role vis a vis its own processes. Defending (with passion and eloquence) the regulatory system and the decisions it has made is not the same thing as defending products, and a more active role on this front would counteract some of the misinformation circulated by other pressure groups. This role could be played by someone likethe head of the CFIA. Such a champion would be informed by many different sources, but would lead the government "voice" to the public, ensuring a coordinated message from the many different departments and agencies with responsibility in this area.

A final consideration with regard to a government communication plan is to look carefully at the success of lobbyists on this front . They work at the grass roots, local level, they build a strong foundation of understanding and they have excellent spokespeople capable of galvanizing public support. Messages need to be well founded on facts, but they need to be delivered taking into account human feelings and perceptions, because this is how attitudes are formed. The basic rule is "never leave the podium empty". Government could be well served using a similar strategy, with its own messages about how the regulatory system works to ensure safety.

Values for Theme A

At this point in the session, the group working on Theme A would identify the top five values that they felt were the most important to guide future policy choices for this theme. The results of this selection are outlined in Annex B (parts A and B).

Theme B – Provision of Information

- **Information provision to support informed choice**
- **Labelling**

Real or Perceived Challenges	
Information Provision to Support Informed Choices	**Labelling**
• Information on biotechnology and GM foods is often complex and geared to a well-informed audience. • Information about the regulation of these foods is not user-friendly or readily accessible. • Information on biotechnology and food often appears designed to sway the reader to provide support for or against the technology and the products. • A reliable, comprehensive and credible source of information on food biotechnology in Canada is not available.	• GM products are not labelled systematically (either voluntarily or under a mandatory scheme), limiting consumer choice regarding whether or not to consume GM food. • The segregation and verification system associated with labelling would require an infrastructure and resources that could increase food costs, and could limit the ability of some countries to participate in international trade. • Lack of standards and lack of harmonization in international labelling standards causes diversity and ambiguity in labelling practices. • Mandatory labelling may result in fewer products on the market (i.e. less choice) and may preclude possible benefits of some GM products. • There may be trade law implications associated with mandatory labelling.

Possible Way Forward #1

Improve the quality and accessibility of information. And tailor the information to a wide audience with different levels of interest and technical knowledge.

Introduce a proactive and two-way communication strategy that could be used to increase public awareness and provide opportunities for citizen engagement.

Establish a centralized body for consumer information on food production (including traditional foods), GM and other foods, applicable laws and regulations, research initiatives, social and ethical issues, etc.

Consultation Preference [Provision of Information]

The provision of helpful, accessible, credible information on biotechnology and GM Foods was seen as critical to public understanding, to an informed debate, and to a supportable policy direction.

The overall picture emerging from across the workshops was a combination of recognizing, coordinating and drawing upon the variety of excellent and diverse current sources of information, combined with the establishment of a centralized and consolidated information resource, most likely at arms-length from government (although some groups saw existing federal agencies as performing that potential central function).

Related key points were:

- There is a pressing need to have access to a linked/consolidated information base on GM foods available to interested parties, one that includes information from all sources – government, industry, research etc.
- There is also a pressing need for expanded opportunities for members of the public to engage in conversations around GM foods as a way of becoming better informed, and able to make better food choices and provide better direction to government. A public that is not well informed can not contribute meaningfully to the development of policy on GM foods. A key reason why this hasn't happened is that it appears that neither government nor industry has dedicated resources to play this information provision role. Informing the consumer has been an afterthought, and there is now a need to play catch-up. The key source of information for consumers has been the media and this is not enough
- An approach to accessing "a comprehensive and authoritative source of information" is to recognize that there are many diverse and excellent sources out there (as examples, the Council for Biotechnology Information, the University of Nebraska world wide

information source for biotech products, CFIA data base on information on Canadian products, etc.).

- A central or linked, authoritative, credible information resource should include information not just about products, but about the regulatory process as a whole. It was also suggested that this source of information should be harmonized with the U.S. system (where many Canadians now get information).
- One model to look to which was considered to be working very well is Health Canada's Pest Management Regulatory Agency with its on-line access to information about specific products. A potential starting point for information on GM foods could be Health Canada's Canadian Health Network. There are, however cost implications, as the timeliness and accessibility of the information would be critical and there are questions as to whether the government was willing to invest in such an endeavour at this time. Given the substantial downsizing in key government organizations, it would be critical to ensure that there was enough high quality staff and direction to be able to be credible in the provision of public information. It is important to ensure that we don't create a bureaucratic "island". Another potential problem with this approach is that where there is a disconnect in terms of trust between the public and government, there might not be a high level of confidence in information coming from government.
- The Food Biotechnology Communications Network could also be a key player as a point of access for information on GM foods.
- As well as playing a key role in orienting people with questions related to biotech to an appropriate source of information, Health Canada could play a role in getting information out to the public at a number of levels – to public health professionals who will forward it to their contacts with the public, as well as responding to basic questions from members of the general public.
- A requirement was expressed for much better risk and benefit communication for the public by both government and industry. Information in circulation should not just focus on the risks or potential dangers of GM foods, but also on the potential benefits to society that might accrue. As well, it was suggested that information in circulation should not just focus on GM foods, but on the overall system we have in Canada for ensuring food safety.
- We need multiple points of access to good information; including each government department describing clearly its own operations, the roles played by food companies etc. We also need to recognize that there is an important translation task to move knowledge from the scientists to the consumer, and probably along a several point scale. The same issue will be described differently to health professionals, educated consumers, etc.
- The lack of clarity around what consumers really want to know with respect to GM foods is a major challenge and the analysis of this question should inform any information strategy.

Possible Way Forward #2

Domestically: Support effort to develop a meaningful voluntary approach for *labelling* foods in relation to GM content. OR Design and adopt a mandatory labelling scheme.

Internationally*:* Promote and contribute to the development of a *harmonized international labelling* scheme.

Consultation Preference [Labelling]

Most workshops began this theme by raising fundamental questions about the labelling challenge, including the concern that labelling was being offered as a solution, but the problem it is answering is not clear. While some participants felt that considerable consumer research had been done, a number of participants insisted that more research is required in terms of what consumers need with regard to labelling and information, and what costs they are willing to pay for more information. While there was a sense that labelling is inevitable given the strong consumer demand to do so, and the likely unwillingness on the part of public figures to resist this demand, there remain many concerns. Firstly, it is unfair that GM foods should be singled out for any kind of standard labelling practice just because they are coming on stream at this time. Many "grandfathered" foods that are in the system now may contain more dangers to the consumer (e.g. related to pesticide use), so providing real consumer choice would require the development of a labelling system that covers all food.

There are problems of enforceability with respect to labelling standards. They require testing methodologies that are not necessarily in place. In the absence of adequate testing methodologies, labelling could result in conveying false or misleading information to consumers. We really don't know enough about what the Canadian consumer is asking for. We need to do a lot more qualitative and quantitative research, including looking at the cost-benefit trade-offs from the perspective of consumers. Another issue is the question of the role or purpose of food labelling. Would the labelling of GM foods be for reasons of health and safety or to enhance consumer choice?

On balance most groups favored voluntary labelling, as opposed to mandatory labelling or no labelling. Some groups felt the Canadian General Standards Board (CGSB) (who are reviewing this issue), should be supported to do its work, and encouraged to "take it slow and get it right". Another strong preference was to participate actively in the development of international standards (including the CODEX work), and use this as a standard in Canada. Canada could then add more detailed or rigorous standards.

Nevertheless, the labelling direction was seen as complex with all options providing both benefits and serious concerns. The difficulties were illustrated in the following points:

- While the suggestion is for voluntary, vs. mandatory labelling, there is an assumption that a voluntary standard will be universally adopted by industry, giving it an effect that may be considered to be the equivalent of mandatory labelling.

- However, the key dilemma with labelling is that if we label negatively ("GM-free food") this acts as a warning to consumers and increases the stigma that GM foods have. If we label positively ("this is a GM food") the likely response of consumers, at least short term, will be to avoid purchasing those foods. This would create economic stress on the part of the producers, and therefore would not likely be an approach that the industry would agree to. One suggestion made is to focus on the safety process rather than the production process, by labelling "this product has passed the strict safety standards of the Canadian regulatory process".
- An advantage of a voluntary process is that it would give Canada some breathing space to wait and see how the mandatory processes undertaken by other countries work out.
- There is a big concern that labelling not be assumed to be the answer to the need for information on the part of consumers. If there is increased consumer confidence in the system, labelling becomes less critical.
- Some groups felt that there was definitely some support in society for mandatory labelling, but that it came mostly from a position that wants to see the complete elimination of biotechnology. They felt that the consequences of mandatory labelling could indeed be to undermine the sector.
- Another option suggested is that labelling of GM foods could be based on the current system – labelling with regard to the risk of the product for consumers. Or, it could take a relatively new direction and label for the process that went into the production of the food (similar to organic food labelling). Those putting forward these options expressed a preference for the latter model on the grounds that it enabled consumers to make food choices based on ethical considerations of GM food processes. The recognized consequence of this choice was that it could entail increased costs to consumers.
- A challenge identified concerning labelling and information is that we haven't traditionally labelled for food "processes", but usually to describe product attributes (e.g., allergenicity) - particularly the risks.
- If the labelling system were voluntary, it would probably develop like organic foods – companies would elect product differentiation to sell into niche markets ("Guaranteed GM-free"). The problem here is that it would still not be promoting consumer choice, since the majority of foods would go unlabelled. The key value around labelling has to be to protect and enable consumer choice.

Values for Theme B

At this point in the session, the group working on Theme B would identify the top five values that they felt were the most important to guide future policy choices for this theme. The results of this selection are outlined in Annex B (parts A and B).

Theme C – Risk and Benefit Considerations

- **Environmental stewardship**
- **Post market monitoring for risks and benefits**

Real or Perceived Challenges	
Environmental Stewardship	**Post-market monitoring for risks and benefits**
• Reduced capacity in ecosystem science in Canada in past decade. • Weaker links between technical experts in ecosystem science and regulatory officials. • The more complex future generation GM foods may require additional expertise. • Are current internationally accepted principles for the assessment of GM foods sufficient? Is a stronger scientific basis needed to better address ecological impacts of proposed products?	• Absence of official mechanisms for monitoring the long-term impacts of GM foods and crops. • Lack of methods for identification or traceability of GM foods in the marketplace, and lack of post market data such as sales and exports or imports of specific GM foods, crops or seeds. • Difficulty measuring food consumption patterns or estimating the significance of GM foods in the Canadian diets. • While *ad hoc* reviews of new data about previously registered products is provided for under the current regulations, no systematic follow-up reviews of approvals is required.

Possible Way Forward #1 – Environmental Stewardship

Strengthen the knowledge base through significant *investment in research* (e.g. ecosystem science), facilitating creation of expertise in ecosystem dynamics and ecosystem-level impacts of technological initiatives, and by engaging in international collaborative projects. Consider emphasis on relevant Canadian sectors such as agriculture, forestry and coastal aquaculture.

Consider whether/how *a Life Cycle Approach* can be applied to the assessment and/or management of GM products.

Maintain and strengthen current approach based on *internationally applied principles*.

Strengthen environmental assessments of GM crops to examine more carefully possible horizontal gene transfer, effects on biogeochemical cycles mediated by soil micro-organisms, micro-organisms, persistence of GM organisms, pest resistance and alteration of natural ecosystems.

Consultation Preference [Environmental Stewardship]

Investment in research

In general, all groups agreed that there is a need to deepen and broaden the knowledge base with respect to ecosystem science. However, this is not a GM-specific issue. For example, traditional farming/agrarian practices have been challenged, as have many practices that have proven to affect the environment. As a result there is an ongoing need to develop new and acceptable alternatives in order to respond to a need for better environmental stewardship. The biased nature of knowledge was discussed, that is to say, the source of knowledge brings different perspectives. Nonetheless, there is a need for a relevant knowledge base of intersecting fields of science. There is a requirement to better integrate knowledge across environmental sectors (e.g., forestry, fisheries, and environment) and share the information. This will allow for effective strategic decision making. In order to do so, various layers of government will need to cooperate. This being said, participants were sceptical that this degree of cooperation is attainable in the short term. Any required changes in legislation or policy were perceived not to be "change friendly".

For reasons of public good and commercialisation of products, the knowledge base must be strengthened. The increased level of knowledge will benefit both industry and the public. Because both benefit, both should contribute to the funding of this research. In areas where fiscal restraint is an issue, Canada should build on an already existing international knowledge base, in addition to maintaining and developing knowledge that is unique to Canada.

Currently the vast majority of research being done appears to be funded by industry. In order to create some balance in GM food research, there is a need for additional government-led GM food research, in part because of the responsibility government carries to ensure the safety of food available to Canadians.

Life cycle approach

With regard to a Life Cycle approach, views were mixed and quizzical. Most groups were not completely clear about the applicability of the life cycle approach to GM food. It was perceived as an interesting alternative approach since it appears to consider potential impacts from a broader perspective, and as a result these impacts might be considered more thoroughly.

Participants were unsure if this would imply a different approach to the assessment of GM foods i.e., different from the current product based approach? If so, there will be a need to clearly define what a "Life Cycle Approach" will include. If the process is significantly different, there will be definite capacity issues. In addition, there will be a need to create incentives to encourage stakeholders to participate in the process.

The proposed Life Cycle Approach might be theoretically sound, however potential costs raise issues of feasibility. A significant and practical challenge of this approach would be the definition of meaningful beginning and end points in order to confine a potentially infinite process. The approach could cause or create an insatiable need for assessment information. Requiring basic elements supplemented by additional voluntary components could be commercially viable. However, the feasibility of such an approach may be limited; and informed consumers may question the overall value of the costly investment. The life cycle approach was also perceived as potentially slowing down the assessment process.

Internationally applied principles

Linking to and utilising international approaches was seen as generally important to environmental stewardship. Maintaining and developing the approach with international application will allow us to continue to think globally. This ambitious undertaking will require an initial scoping exercise to determine the scope of the overall challenge. Subsequently, strategic investments would be made based on Canadian vested interests and current areas of expertise and utilising a client-focused approach. Clients should be consulted.

Some participants felt that underlying international principles are fundamentally weak (e.g., elements of the Biosafety Protocol). In addition, there is division amongst the scientific communities on these issues. A broad framework will be feasible, but countries will need to develop their own guidelines specific to their own environments. Canada may have much at stake in this area, given that a significant portion of our GNP is derived from export products. An international approach to the risk *assessment* process is possible, however an international approach to risk *management* touches on issues of each nation's autonomy and sovereignty. As a starting point, an international body could enable collaboration, with individual members providing either process expertise and/or commodity expertise.

GM Crop- Environmental Assessments

With respect to GM environmental crop assessments and scientific research, there was general agreement that these activities were desirable. However, significantly increasing GM environmental crop assessment procedures will risk causing product delays. With respect to scientific research and expertise, our regulators must be on par or better than product developers. In both cases (i.e., GM food assessments and scientific research), there were questions with respect to accountability, funding and resourcing. These assessments need to include more comprehensive indicators (e.g. of potential impacts of GM foods) and attach some clear liability and accountability to the regulatory process.

With the potential threats GM foods pose to the environment, more resources need to be allocated to long-term environmental studies in order to evaluate these potential impacts. Participants were unsure whether the technology currently exists to adequately evaluate/predict the potential environmental impacts of GM foods.

Strengthening of the GM assessment process is needed but must be related to the life-cycle process, product usage and traceability. The approach must be pragmatic, feasible and viewed as part of a preventative process.

Possible Way Forward #2 – Post Market Monitoring

Conduct and make greater use of high-quality, long *term multidisciplinary scientific studies* of potential health and environmental impacts of GM organisms.

Require *detection methods* for the *novel traits* or genetic material in GM products.

Conduct *audit for special conditions* required in relation to environmental safety, for example, buffer zones around *Bt* corn.

Monitor consumption of GM food.

Require and *publish annual data on usage,* sales, exports and/or imports of GM products.

Formalize a process for the *periodic reconsideration or reassessment* of the safety of GM foods and crops previously approved for sale in Canada.

Consultation Preference [Post Market Monitoring]

Detection methods for novel traits

In general, most groups felt there is a requirement for new detection methods for novel traits or genetic material in GM products. It may be important to ensure detection of GM characteristics (in particular) in processed food, in order to allow freedom of informed choice by the consumer,

i.e. better detection methods will allow for the crucially important labelling of GM products, thereby supporting informed choice.

Some detection methods for GM foods/transgenes exist, but we need more and better methods. Traceability and detection are not mutually exclusive methods, but traceability is more consistent with an audit trail methodology in which the process by which a product was produced (or its origin) is known. Both will be needed because of international agreements being developed.

There is a definite requirement for detection methods for purposes of "traceability," trade monitoring and product labelling/identification. It is also a non-tariff trade issue that promotes consumer trust and choice.

Long-term scientific studies are not a preventive measure but do provide valuable credibility. Good evaluations require definition of "end points" and risk thresholds. It is difficult to support a technology when no long-term studies have been carried out.

However, questions were raised about post market monitoring. Proposing additional post-market studies related to monitoring for risks and benefits assumes that the current pre-market assessment process isn't sufficient. As well, in the current system, products are assessed on the basis of novel traits. Proposing post-market studies for GM foods seems to mean that we will start assessing on a GM product basis (on the basis of the manufacturing process). This approach could create trade barriers.

If products are deemed safe and/or approved, the purpose of detection methods seems unclear. However, it is certain that trade partners will require detection methods to meet their approval processes. Of course, the processes must be cost effective and reasonable so as to minimize negative impacts.

Special audits

With regard to special audits, industry is currently responsible for auditing for any special requirements applied by regulators as a condition for approval of a GM product. Although, some felt that industry is not in a position to objectively audit for special requirements. Ontario participants mentioned that in 80% of the cases, farmers are compliant. Nonetheless, concern was expressed regarding the non-compliance of the remaining 20%. In these cases, farmers may not be informed or may have a perception that the audit is not entirely necessary. An internal audit process combined with third party audits can be effective. Nonetheless, reasonable audit levels and "special conditions" require better definition. The use of special audits was recognized as a way to verify the efficiency of "special conditions" being imposed on industry by the regulators, as a condition of approval. Additionally it increases public confidence in the regulatory system.

Consumption patterns/Annual usage data

Groups generally agreed that before monitoring GM consumption patterns, Canada must start investing in the development of baseline data to determine "general consumption" patterns and trends, not just data for GM foods. It was noted that it is challenging to effectively monitor GM food consumption given that there is no traceability/labelling of GM foods. To some this was

seen as a costly exercise with limited relative benefit. While others felt that there may be a need for this information in order to clearly identify and understand the potential ramifications of GM foods. Additionally, this data would also contribute to increased public confidence in the Canadian food system and avoid potential backlashes. A proposal for consumption data for GM food only is also based on an assumption that these foods are inherently different from other foods. In fact, some felt that GM foods (or the process by which they are developed) are fundamentally different and as such were subject to special treatment.

Data regarding sales/usage/export/imports is being developed in certain communities (relationship to traceability was noted). However, there will be a need to provide incentives to share the data. Some issues of parochialism and proprietary information will come to the fore. Many identified the publishing of GM sales and usage data as a lower priority. In order to be practical, data would need to be disaggregated. One of the difficulties with this option involves the competitive nature of the information. Sales and usage data could be considered to be proprietary. Deriving estimates from mathematical modelling was determined to be a relatively "crude" method of estimation.

Some participants also noted that requiring organisations to provide information on sales, usage, import or export of GM food for subsequent publication may not be relevant or practical. This type of data may be useful for market development, but may not necessarily be of general public interest.

Reassessments

On the question of ongoing reassessments of previously approved foods and crops, they were seen by some as required in order to build flexibility and adaptability into the regulatory process. However, the majority of the regulators reassessment processes are ad hoc. However, the Bt Corn reassessment could be a model for other formalized reassessment processes (e.g. soybean). Formalizing the reassessment process will not automatically create the new information needed to re-evaluate the product. How will we ensure that new knowledge regarding GM products is amassed and is used properly? As with other issues, there are also capacity issues that must be addressed.

Values for Theme C

At this point in the session, the group working on Theme C would identify the top five values that they felt were the most important to guide future policy choices for this theme. The results of this selection are outlined in Annex B (parts A and B).

Theme D – Regulatory System

- **Separation and independence of regulatory functions**
- **Capability and capacity in the regulatory system**
- **Ensuring safety during research and development activities**

<table>
<tr><th colspan="2">Real or Perceived Challenges</th></tr>
<tr><td>Separation and independence of regulatory functions
Possibility that separation of regulatory activities for health and environmental protection from government activities related to the promotion of GM foods may not be sufficient.
Poor communication of roles and responsibilities, and of approaches for handling possible conflicts of interest.
Information criticized for failing to be neutral, and for appearing to some to promote GM foods.</td><td>Capability and capacity in the regulatory system
Insufficient resources for research related to regulatory activities (e.g. Research on improving the risk assessment process) and to attract, maintain and further develop technical expertise within regulatory bodies.
Less than optimal capacity (critical mass of people needed to do assessments of high numbers of submissions quickly and thoroughly).
Insufficient PhDs and training of PhDs for future regulatory needs.
Internal operations may not support systematic reliance on outside expertise.</td></tr>
<tr><td colspan="2">Ensuring safety during research and development activities
Early stages of research and development are not regulated by the federal government’s food regulatory system; the existing guidelines and standards are generally not legally binding, and my not capture all research programs.
Early stages of research may not be conducted using measures to minimize possible adverse effects. Where measures are applied, it is unclear which methodologies and safeguards are being followed by various researchers.
The degree to which researchers comply with the guidelines is not clear, and the means of enforcing compliance may not be sufficient if they are not legally binding.</td></tr>
</table>

Possible Way Forward #1 – Separation/independence of regulator

Alternate reporting relationships for regulators (e.g., have the CFIA report to the Minister of Health, to a separate Minister or to Parliament directly).

Greater transparency in the regulatory system regarding functions and operations (e.g. clarification of roles, responsibilities and approaches for maintaining independence of regulatory functions).

Increase formality (i.e. standardize) *in internal procedures* (e.g., delegation of authority; role of senior managers).

Consultation Preference [Separation/Independence of Regulator]

All groups considered that the current separation of the promoter and regulator functions in the regulatory system is adequate as there are strict controls on the role and independence of the regulatory function. However, the public may not always be completely at ease with the separation. This relative uneasiness may become especially true as future regulatory activities regarding GM food increase in number and complexity. The main challenge therefore is communication to the Canadian public in order to maintain public trust, addressing the adequacy of the regulatory process, the specifics of the safety regime and the separation of regulatory functions from promotion. Additionally, an opportunity for public input into the regulatory framework is required (2 way communication).

The possibility of creating a separate ministerial reporting structure would wrongly imply a problem and would be counterproductive. We should consider the role of a third party advisor like CBAC to monitor and advise on the independence of the regulatory functions.

To ensure confidence and trust, the government also needs to demonstrate that its regulatory process is rigorous enough not to accept a demonstrable number of GM food submissions on health and safety grounds, i.e. those that fail to meet health and safety standards. The government also needs to demonstrate that there is sufficient publicly funded research to ensure objectivity and independent analysis of risks. Some felt that we should also emphasize public research geared towards alternatives e.g., organic farming.

Related concerns raised included:

- As regulatory/academic research increasingly receives a significant part of their funding from industry, it may compromise the scope and focus of "public interest" research and contribute to the sense of lack of independence.

- Whether and how the regulatory system should incorporate social, environmental and economic impact considerations, including global interdependencies, has not yet been determined.
- Whether there is adequate corporate reporting on social and environmental impacts remains unclear.
- Any public advertising/statements should separate the promotional and regulatory sponsor/agency roles.

Possible Way Forward #2 – Capacity in the Regulatory System

Increase investment in research that supports regulatory decision making and risk assessment.

Facilitate and *increase the use of outside expertise* such as individual technical experts and *ad hoc* expert panels. Create a transparent system for the use of outside expertise that outlines the specific situations and acceptable roles and purposes for using such expertise, selection mechanisms and logistics).

Draw on international expertise through regulatory activities such as joint reviews.

Forecast future regulatory needs

Consultation Preference [Capability and Capacity in the Regulatory System (specifically scientific)]

All groups expected that the regulatory system more than likely will need additional resources given current and increased demands projected, as well as the expanding regulatory scope expected to cover the entire food chain including R&D through production, to the product at the consumer level. The regulatory function will need enhanced scientific expertise as well as broader multidisciplinary expertise.

We should draw on expertise outside the regulatory system both inside and outside the country to augment the capacity, e.g. draw upon certified laboratories and outside peer reviews. Regulators should draw on outside expertise to better deal with exceptional cases, rather than on a routine basis, and to ensure the regulatory regime is kept current and is peer assessed for accuracy and balance.

Canada should also pursue a shared regulatory agenda with other countries to allow each country to focus on areas of regulatory competency using common standards (without it reducing or effecting Canadian standards), thereby improving our combined capacity. As well, there is a requirement on a global level to develop a shared strategy to ensure that the approaches and standards that ensure food safety, production and sustainability are consistent internationally – this would help reduce the burden of regulatory requirements across products and countries.

We should not lose sight of the fact that Canada is currently a world leader in terms of food safety, and we should be proud of it, and be careful to not reduce our own standards as a result of international developments and relationships.

Related concerns raised included:

- We are unsure if universities will educate/graduate a balance of both applied and theoretical research experts, given industry pressure for applied vocations. With fewer graduates in areas of pure research, the regulatory system will have fewer candidates to draw upon in filling future human resources needs.

- A rigorous comparison of the U.S. and Canadian systems should be undertaken before pursuing either harmonization of the current regulatory system or the development of a joint regulatory system.

- The current range of regulations should be reviewed to determine whether they are still relevant and critical to safety and health, in order to provide a more effective regulatory system and reduce the burden of excessive regulations – all this in order to provide a more effective regulatory approval process.

Possible Way Forward #3 – Safety During Research

Strengthen existing (voluntary) guidelines related to ensuring safety during research and development. OR Develop a single, performance based, *minimum standard* for recombinant-DNA experimentation, aimed at minimizing human health and environmental concerns.

Apply the *standard as a guidelines*, or *entrench the standard* in regulations. If entrenched in regulations, it could be an absolute requirement or, exemptions could be permitted (e.g. if equivalent measures are in place).

Consultation Preference [Ensuring safety during research and development activities]

In general, all groups supported the need to develop guidelines and standards covering research and development activities (prior to the regulatory review of products) and to find a way to incorporate them in the regulatory system, although not necessarily within the regulations themselves (except in the case of special risks), and to develop a program for monitoring performance against these standards/guidelines..

Views were mixed on whether current regulations and voluntary guidelines covering research and development are adequate. Three ways forward were suggested representing different levels of comfort with the current approach.

1. Consolidate the existing regulations and guidelines to bring clarity and focus and to identify if there are any gaps. In addition, existing guidelines (both voluntary and mandatory) should be rolled out and used as educational documents for scientists and researchers.

2. Strengthen existing guidelines by developing and promulgating Standard Operating Procedures (SOP) for all aspects of research related to GM organisms.

3. Refocus existing and new guidelines We should establish the principle that regulatory oversight should match the organism's level of risk. Thus, the R&D guidelines on products at risk could be refocused to match the level of risk. This raises the question of equivalent regulatory oversight of non-genetic research practices in plants.

All groups felt that we should collect and summarize the descriptions of all current mandatory and voluntary processes in order to publicly exhibit accountability within the industry, and ensure that accountability to these processes is transparent and demonstrated.

A number of questions were raised that should guide further approaches to this issue, namely:

- The degree to which the guidelines are being followed should be examined more closely. As well, we have taken a reactionary approach to communicating the actual rigour and effectiveness of the R&D practices and guidelines, and as a result left the system open to potential concern and fear.

- What remains unclear are the levels or stages of research that are regulated. Do current regulations adequately cover industry research, knowing the incredible speed at which new developments are being made? Regulations should not be the only way common standards are being identified and followed in R&D (and in biotech processes in general), which suggests the need for a balance between regulations, guidelines, and best practices.

Values for Theme D

At this point in the session, the group working on Theme D would identify the top five values that they felt were the most important to guide future policy choices for this theme. The results of this selection are outlined in Annex B (parts A and B).

Theme E: Social and Ethical Considerations

Real or Perceived Challenges
• **Ethical Acceptability:** Some consider the production methods used in the genetic engineering of food to be intrinsically wrong. Some question the need for the products. For others the current and future benefits of the technology are considerable and justify the pursuit of the technology. • **Traditional Knowledge and Resources:** Individuals and societies that contributed knowledge and genetic resources to benefit the generation of new GM foods may not share in the financial gains because corporations hold the patents. Those improved seeds and varieties may be sold back to the source societies and farmers at substantial profit. Some consider the benefits to growers and consumers in these societies to be of significant value and therefore are less concerned. • **Power Imbalance and Vulnerability:** Currently, the greatest benefit of GM foods is often seen as one of productivity and financial gain, shared among a few (e.g. manufacturers and producers) while, in the event of unforeseen impacts on health or the environment, the burden would be felt by a larger population. Others view the benefits as being shared more broadly stating that there are beneficial effects related to job creation, the economy, reduced pesticide use etc. The acquisition of an increasing share of the GM food market by several large life science companies is of concern to some because it is seen as a source of diminished self sufficiency in food production and a threat to sovereignty. Others see this as a necessity of developing GM foods. GM foods are considered by some to be a means of alleviating poverty and starvation around the world. • **Environmental Ethics and Economics:** Environmental ethics and environmental conservation require that companies and society not undermine the long-term health of the environment and its natural diversity of plant and animal species. Some consider that, for this ethic to be respected, further consideration of the meaning and application of environmental ethics in context with GM foods is required. • **Framework for Addressing Broader Social and Ethical Issues:** Food regulatory systems, in Canada or abroad, generally do not consider the above issues in regulatory decisions on individual products. Some think these considerations should be addressed by the regulatory system; others do not think this is appropriate forum and prefer that these issues be addressed from a higher and broader policy perspective.

In this part of the workshop, all groups worked through the same theme and set of questions. Their responses are characterized and summarized in the following.

Should the current regulatory assessments that are based on scientific evaluation and risk assessment, add broader social and ethical considerations?

Generally, all groups agreed that social and ethical considerations should be considered within the food policy environment but insisted that they should not be a part of the current scientifically based, regulatory review process at this time, i.e. social and ethical considerations should not be added to the regulatory process. They are hard to define and there are a number of different and legitimate perspectives that are difficult to reconcile, and it is important that health and safety risk assessments are not corrupted. Social and ethical considerations should be worked out in the policy/political arena and should provide broad guidelines to a regulatory framework.

What are the challenges we face in attempting to incorporate social and ethical considerations into the policy environment?

- Participants noting the need to distinguish between social and ethical dimensions, felt that socio-economic considerations would be more definable and approachable than ethical concerns which would likely be highly subjective, and derived from substantially different moral and analytical reference points. In that respect the ethical debate lags behind the development of new science. One idea proposed was to eliminate the word "ethical" because it does not discriminate between individual and societal ethics; and substitute "values and principles". Another major challenge is that we are short on trained ethicists with a background in biotechnology, and on biotechnology scientists with some training in ethics.
- There is a lack of public involvement in this debate and the public has a very limited understanding of the GM issues. As a result, we may need to address the educational challenges before engaging the social/ethical questions. This would mean educating the public on the product/process distinction.
- Responding to the right of consumers/users to know and to have access to the information they need.
- The public is reacting intuitively and is concerned. Given that other technologies historically have sometimes failed to contain negative impacts on health, safety and the environment, these experiences have carried over to concerns for transgenic technology.
- There is an unclear consumer demand in terms of: variety, quality, safety and enhanced nutrition of food.
- Dealing domestically with public perceptions in other countries.

- How do you differentiate between GM foods and other research and products that derive from scientific processes and may result in mutated or altered products?
- What is the standard for acceptability of a food product (e.g., as safe as an organically grown product?).
- To develop a social and ethical framework requires that we define and understand the aspects that should be incorporated within the term "social". A starting point could be to look at food from two perspectives and to outline the social considerations for each as follows:
  - Food as societal necessity ("grow to live"):
    - The meaning of food in our society
    - The effect on the quality of life for both consumer and animal
    - The effects on agriculture.
    - The source, integrity and knowledge of the food source and production path.
    - Sustainability of communities.
    - Freedom of choice for consumers.
    - Values and objectives for food as a necessity and life sustaining element.
  - Food as a produced commodity ("live to grow"):
    - The effects on agribusiness.
    - Environmental impacts.
    - Sustainability of industry.
    - Freedom of choice for producers and farmers.
    - Transfer of technology e.g., IP rights.
    - Opportunities for employment and education in the food sector.
    - Values/objectives for food as a commodity.
    - Impact on trading practices of other nations (the dependencies created both with external sources and within own communities).
    - Value/economic benefits of food in our economy.
- Social/ethical considerations should not be product based.
- We have the tendency to focus more on the risks in GM foods (e.g. Royal Society report) than the benefits. This could result in keeping beneficial products off the market.
- The key question is the safety of food. This question needs to be addressed first and foremost by the regulatory process.
- The level of scientific literacy is highly variable, especially with respect to developing nations. There is a need for education and informed debate.
- Currently the stakeholder groups are separated and distant ideologically, and are pursuing their own views rather than seeking common ground.
- Increasingly, industry is taking the lead in research, with the resulting questions – who is setting the research agenda, and for what purposes.

What are the potential ways ahead that we might pursue to address this question?

- We need an educational approach to inform the public before attempting to widen the discussion on social and ethical issues. Special attention should be put on creating a reliable source of unbiased and sound information (similar to the Food Biotech Communication Network) in order to help address the current lack of education.
- Adding broader social and ethical considerations would allow this technology to be used to its greatest benefit and the public would be more comfortable being in on consultations.
- There is a "scale of concerns" that we can identify. Of low concern seem to be plant to plant initiatives. Of greater concern are transgenic initiatives from animal to plant, and of greatest concern is anything involving human genes. The suggestion is that as our knowledge increases with respect to plant to plant applications, our comfort level may grow in other areas.
- Explore the applicability of a model similar to the Canadian environmental assessment process which includes social and economic impacts as well as elements of public participation.
- Need to address the broader questions of social change affecting society and biotechnology and not just focus on GM foods (e.g., multinational influences, impacts and adoption of technology, and using this to determine Canadian direction on major sectors like biotechnology).
- Consider the attributes of "good and ethical producers" and use these to educate and shape policy.
- A totally separate entity could be created at arms length from current science-based regulatory bodies. This entity would be multi-stakeholder, well funded, autonomous and accountable.
- The framework could include two levels of social impact assessment. The first would be a voluntary assessment, conducted by industry. The second assessment would take place immediately following the safety assessment.
- The social and ethical framework should include clear definitions and criteria to distinguish consumers, producers, other stakeholders, regional differences, etc.
- Before granting a product final approval, provide the public an opportunity to take an in depth look and comment on the results in a public response period.
- Add a risk-benefit approach to current scientific evaluations and risk assessment process. As well, address social and ethical concerns using cost benefit analysis.

- The current framework needs to include the impact that would result from not approving a product, delaying its approval or fast tracking its approval. It would be useful to have a framework or checklist against which to measure/consider product, so that its social acceptability can be ascertained before research and financial resources are invested.
- A distinction should be made between freedom of choice and long term societal impacts.

What is the appropriate forum or process for addressing these broader social and ethical dimensions?

- Hold broad consultations with the public and stakeholders to develop inputs into the framework (multiple sectors, multiple age groups). An appropriate forum for dealing with socio-economic issues could be the combination of public discussion (perhaps led by CBAC), and involving the seven relevant departments. The regulator (e.g., CFIA) can ask for guidance from such a forum around newly breaking issues.
- Social-ethical considerations should be debated in the political arena, by elected officials, informed by public debate. This model worked well in the area of reproductive technology and stem cell research. Parliament should provide collective direction, and should determine ethical guidelines for regulators to work with. Although it takes a while to get the results into legislation, the ongoing dialogue can be taken into consideration by regulators.
- Like the subject of abortion, this discussion is going to be multi-dimensional, engaging the media, Parliament, public consultation, and the courts. A concern with respect to public consultation is whether the public is informed enough to contribute substantively to the discussion at this time. If we ground our approach to public consultation in a process of public education, we could look forward to more informed public engagement. A suggestion with respect to public education is that we begin this in the schools with ethical considerations as part of the science curriculum.
- CBAC needs to focus on the tangible issues of health and safety and be the guardian of the public good.
- Undertake a process to encourage and include the voices of the uncomfortable and those who are on the margins of affluent society and from other countries, to inform the dialogue on social and ethical issues.
- Develop and apply a mechanism (e.g., national group of Canadians with a range of age profiles) to design a social and ethical framework based on the public dialogue.
- In terms of an appropriate forum for handling social and ethical issues, there should be more science expertise in policy positions in government, balancing the current preponderance towards economic (and other types of) expertise. The Health Minister Alan Roch's Advisory Board may also be a viable example of a forum in which social and ethical aspects of biotechnology can be worked out.

- Suggestions for next steps in public consultations include focusing on the opinion leaders – Dieticians of Canada, Consumer Association, College of Physicians and Surgeons, MLA's.
- Possibility of drawing inspiration from the European model - an ethics committee (bio-vigilance committee) made up of resource people qualified to make an ethical analysis.
    - A committee could also be mandated to deal with socio-economic matters in general (for instance, ethics, socio-economics); in effect a watchdog role.
    - The committee must be separate from the science-oriented evaluation process.
    - This filter must not become a barrier.
    - The parties involved and the stakeholders must be represented. A much larger representation is called for to air the very different points of view that exist.
    - Would this committee have a consulting or a decision-making role?
- Encourage industry to develop key ethics policies as it has done regarding the environment and ensure proper monitoring of these mechanisms by the government.

New Proposal: GMF Acceptability/Non-Acceptability Spectrum

Early in the consultation series, during informal discussions at the end of the Vancouver session, a new idea arose, suggesting a GM Foods acceptability framework. The framework as proposed, might offer the basis for constructive discussion among the strongly diverse views including those who felt the regulatory environment was too burdensome vs. those who felt unanswered questions and vulnerabilities warranted a moratorium on any further GM Foods development and exploration.

Under this framework, GM products would be analysed and placed on a spectrum ranging from acceptable to unacceptable (i.e. banned). GM products would be characterised either as: acceptable; acceptable with conditions; unacceptable at the present time (i.e. moratorium - unacceptable until more is known or a given standard is met); or, not acceptable under any circumstances. Products or groups/classes of products could be analysed against criteria and placed in an appropriate location on the spectrum. Consideration could be given to health and environmental safety, social issues, ethical issues and broader societal implications focused on international issues. Products could move from one category to another when more is known/validated or threshold standards are met. The approach would be developed outside of the existing regulatory process – which is science and risk based. The various possible mechanisms for implementing this framework would need to be explored, including the relationship of this activity with the regulatory system and with the broader regulatory governance structure.

Acceptable	**Acceptable with conditions**	**Not acceptable now (until more is known or certain standards are met)**	**Not acceptable under any circumstances**

Groups in subsequent sessions discussed this emergent proposal and their responses follow.

In general terms, participants found the acceptability spectrum idea interesting, with several attractive qualities and with enough initial merit, to warrant pursuing further. There were considerable challenges seen in progressing the idea especially: the imagined complexity of the criteria and the difficulty of practically applying them; the difficulty of mandating a workable and acceptable group to create the framework; and the scope and influence that the resulting use of the framework would have in our society.

Participant comments are characterized in the following.

Likes (the attributes or benefits that were attractive or useful)

- Helpful and worth pursuing, and a useful construct to consider
- Good tool for discussion, and provides a useful vocabulary and starting point
- Provides a vocabulary/basis to talk about GM foods "acceptability".
- Could be helpful if it was advisory (but should not be used as a gate in the regulatory chain).
- Could bring divergent views to the table to pursue these questions.
- It provides more options and alternatives. It serves as an educational mechanism for the proponents. It would allow and encourage public debates regarding social acceptability of GM food products.
- The process will help deal with communication issues and open up the unfocused dialogue that is raging within the current context.

Dislikes/concerns (the aspects that were less attractive or raised issues/concerns)

- Will be very difficult to create.
- Hard to find an objective group with the time to give input and develop this.
- The category "acceptable with conditions" will potentially raise questions with the public who will be concerned that the product is not completely safe, given the presence of the word "conditions". Also raises questions about who monitors the conditions, who is liable, etc.
- Should this not also apply to the acceptability of non-GM foods/products, and where does this lead to?
- It may only address a small set of the social and ethical questions.
- Some are still concerned about the need to look at alternative forms of food development.
- The process should not be technology-centred.

Suggestions for ways forward:

- A GM foods acceptability/non-acceptability spectrum could be applied in the context of overall goals for a healthy food system, an assessment of alternatives, the precautionary principle, and third party assessment.
- There is potential of a GM food acceptability/moratorium spectrum to help identify the width, breadth and depth of public acceptance of GM foods. The suggestion was made to start with a spectrum on all of biotechnology, and develop a specific one for GM foods, to give people an understanding of the larger issues in which GM foods 'fit'. The suggestion was made to refer to "Biotechnology Acceptability Spectrum" and "GMF Acceptability Spectrum" respectively.

- There is still a need to articulate why GM foods should or should not be pursued in our society i.e., the rationale and benefits need to be articulated as well as risks and benefits.
- The spectrum should incorporate both risks and benefits, and acceptability risk consideration should be balanced with relative benefit. For example, a product that uses transformative technology to cure cancer should be more socially/ethically acceptable.
- Three categories of criteria may be required: science, non-science (social and ethical), broad social/ethical or societal.
- More precise technology should make it easier to define criteria (biotechnology/bio-informatics).
- In considering an acceptability/moratorium spectrum the following should be taken into account:
  - The value given to the use of a product
  - The weight given to each category within the spectrum
  - Applying the framework requires a body of persons with expertise in each of the dimensions (ethical, social, health, safety, environmental and corporate).
  - It also requires ethical guidelines set by parliament
  - Two options: the spectrum is guided by a government decision-making body and implemented before proponents invest too much; or, an advisory body guides the application of the policy which is implemented by government departments.

Acceptability Spectrum

Categories / Criteria	Acceptable	Acceptable with conditions	Not acceptable now (until more is known or certain standards are met)	Not acceptable under any circumstances
Scientifically based criteria (health and safety)				
Social/economic				
Ethical				
Other societal (focus on international)				

Priority Values Exercise

In each city session, workshop groups defined the desired values that could underpin policy development for each of the four themes A, B, C, D.

The values for themes A and D were combined with the seven values listed in the 'Ethical Context' section of the CBAC Consultation Document and participants individually selected the top five from the combined list that were the most compelling as guides for the *governance and organization of the regulatory system*. Similarly, the values for themes B and C were combined with the seven values listed in the 'Ethical Context' section of the CBAC Consultation Document and participants individually selected the top five from that combined list that were the most compelling as the *basis for making policy choices* around GM foods.

The following table displays the values arranged from top to bottom in order of their frequency of being chosen as one of the most compelling guiding values. . See Annex B for definitions of these values as they were defined by participants.

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

The results reveal the following:

1. Certain values dominated the ratings and suggest a strong desire to see these values underpin both the regulatory system and policy choices. There were:

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

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

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

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

   - **Safety and caution** – that we should exercise caution in developing policy and regulating GM Foods, and be diligent in our concern for safety, both related to human health as well as the environment. [For this value, several similar value rankings were combined, e.g., safety of food, long term safety, etc.]

2. **The values selected for the 'Regulatory System'** could be grouped into themed clusters as below.. These clusters reveal a set of key desired and principled qualities that should underpin the regulatory system, as follows:

a) a highly principled set of qualities around accountability and transparency;

- Accountability/leadership
- Transparency
- Integrity/honesty
- Ethical
- Separation of promoter and regulator

b) a knowledge based cluster that emphasizes the science base and quality of the information;

- Science based
- Education/knowledge
- Product based
- Quality and authenticity of information
- Verifiable

c) a set that focuses on the sense of justice, and balance of risk and benefit, with the goal of broadly accessible benefits;

- Justice
- Risk benefit
- Beneficience
- Social optimisation

d) a cautionary set emphasizing sustainability and health and safety;

- Caution
- Future sustainability
- Health/safety
- Prudence

e) a set that underscores the need for innovative but workable solutions that are compatible internationally;

- Respect for diversity
- Workable
- Balanced regulation
- International compatibility

f) a set that underlines the need for public participation and informed choice.

- Autonomy
- Participative process

3. **The values selected to guide 'Policy Choices'** could also be grouped into themed clusters as below. These clusters also reveal a set of key desired and principled qualities that should be used to guide policy choices, as follows:

a) a highly principled set of qualities around accountability and transparency;

- Accountability/leadership
- Transparency
- Integrity
- Trust

b) a set that is closely aligned to the first set underlining the need for confidence in a system that acts responsibly;

- Stability/confidence
- Democracy
- Credibility and responsibility

c) an informed choice set that emphasizes the need for good public knowledge, grounded in science and that enables consumer choice;

- Informed/public choice/public knowledge
- Science based
- Autonomy
- Participative
- Consumer choice in food

d) a set that focuses on the sense of justice, balance and objectivity;

- Justice
- Equitability
- Objectivity
- Balance

e) a cautionary set focused on the safety of both food and the environment;

- Safety of food
- Caution
- Food environment safety
- Prudence
- Long term safety

f) a set that incorporates sustainability and respect for diversity along with the goal of broadly accessible benefits;

- Sustainability
- Social benefits
- Beneficience
- Respect for diversity
- Nature ethics

g) a set that raises the need to support a successful market within a fair playing field.

- Fairness/level playing field
- Market success

Advice to CBAC

At the end of each session, table groups were asked to offer closing general advice to CBAC (as it prepares its report) incorporating what to keep in mind, or address as a priority, or to consider carefully. Their advice has been collected into the following common messages.

1. CBAC currently has a very low profile. The organization needs to become more visible in the eyes of Canadians. In so doing, it should address any misperceptions among some groups such as whether they have a bias in favour of GM Foods.

2. CBAC should ensure unbiased information related to both GM Foods and the regulatory process is available to the public. This information should be used as part of an educational campaign with balanced assessments of risks and benefits.

3. Increase the participation of civil society (NGO community in particular) to ensure their point of view is incorporated. In all the sessions, participants noted that the NGO community absence/modest representation was regrettable and reduced the likelihood of NGO views and suggestions being considered. Participants deplored the fact that a sizeable NGO group had chosen to boycott and felt CBAC needed to pursue their return to the consultation table. The international NGO input should be sought as well.

4. Review the Canadian food regulatory system with fairness, for both the risks and benefits of GM Foods, with a sense of confidence in the rigour and integrity of the existing system, and with a focus on health and safety concerns.

5. Develop a vision around the Canadian food supply/food system with an emphasis on health and the economic aspects of food. Place discussion of GM Foods within this larger vision of the Canadian food system.

6. Leverage our international image where Canada is recognized as having an appropriate and effective system to deal with novel foods.

7. Pursue a broadened public consultation process. CBAC needs to actively seek and engage the Canadian public with a variety of opportunities and channels for Canadians to express their views, e.g., public fora, hearings, written/oral submissions, electronic media (cable TV, radio, etc.), internet, etc. The process should be transparent and needs to be preceeded and accompanied by an educational dimension so that any substantive engagement is informed by knowledge of the facts and the current regulatory system in place along with a balanced treatment of both the risks and benefits. Therefore, a public engagement goal is not likely to be accomplished over the short term, in a single event/interaction but should be designed around a longer term or sustained dialogue with Canadians.

8. Address social and ethical issues at a higher level within the food system.

9. Ensure the regulatory approach does not unduly prevent or impede global trade of our products.

10. Consider the appropriate further roles for the Canadian government in this area, e.g. the degree of government short and long term scientific studies/research needed; which issues require engagement by elected officials; whether to consult and develop a proactive strategy for food and agriculture to address the economic viability, environmental sustainability and public health and safety of the food system.

Emerging High Level Themes of the Consultation

When all the experiences and outputs of the five consultation sessions are reviewed and considered 'from a higher level', there are several crosscutting themes that emerge and that thread through the workshops. These high level themes were identified in discussion with those who conducted and facilitated the sessions and reflect the significant impressions that arose.

1. The need for a vision for the Canadian food system.

The need for a strategic outlook and Canadian vision around food as a commodity that addresses: how we see the business and economics of food; the roles of key contributors to the sector including farmers; the model of promotional strategies to support the sector; the regulatory model and principles to guarantee the health and safety of consumers and others; and strategic goals for the food commodity. This should embrace a proactive agenda for food and agriculture that addresses the economic viability, environmental sustainability, and public health and safety of the food system.

2. A broader and inclusive view of all food vs a more restricted view of GM Foods and novel foods.

The need to define the scope of the regulatory purview and the larger debate around GM Foods, i.e. should the scope include all novel traits and foods, and other mutative processes? should other food related practices that impact health and safety (e.g. pesticide use) be grandfathered or reopened and included? should the standards applied to other processes like organic development apply equally, or more or less to transgenic organisms? Whatever the defined scope, it must be supported by a reasonable and fair rationale that is applied consistently.

3. Why debate GM Foods? – Why Now?

The need to provide a foundation rationale that explains and clarifies: the reasons for the development of biotechnology in general and GM foods in particular; why these developments are emerging so strongly now; and why it is critical to engage the key questions and considerations that arise from society's potential involvement and use of GM foods; and why it is important to assess both the risks and benefits that arise in this area.

4. Leadership

The need for strong demonstrated leadership on the Biotechnology and GMF file that will coordinate the various policy dimensions and guide the debate toward a resolution that results in a coherent policy direction and a set of objectives for Canada. The need for Canada to take a leadership position internationally in areas that significantly affect

Canada and/or where Canada has a depth of experience, innovative thinking, and consensus building skills.

5. Consumer trust

Consumer trust and confidence in the regulatory system and in the health and safety of our food is paramount and stands as the highest goal. The process of building and sustaining trust needs to start with sustained public education and a regulatory process built on accountability and transparency.

6. Pride and confidence in Canada's system

As we engage this review and develop a federal policy and a Canadian strategy, we should start with a strong sense of pride and confidence in the current regulatory system for food which is viewed as among the very best in the world.

7. Public education before and as part of public engagement

The need for enhanced public education to develop a more informed population in the area of GM foods. This would enable Canadians to understand GM Foods and the key considerations in preparation for engaging in an informed debate on the direction Canada should take, and to enable personal choices about GM Food products.

8. Reliable scientific information

The need for reliable scientific information to provide a factual evidence basis and vocabulary for examining the critical policy questions affecting GM foods and to ensure that scientific based risk assessments within the regulatory process are carried out by reliable, effective, consistent, and verifiable means.

9. Core values for the regulatory system and policy process

The core values that must underpin our regulatory approach are: accountability; transparency; science based; and informed public/consumer choice. They speak for themselves.

10. The topic of GMO/GM Foods is politicized

The topic is politicized and emotional with strongly held views on all sides of the debate. It will be difficult to engage the different interests and the public in a balanced and reasoned pursuit of a Canadian solution, but try we must. The initial challenge is to create the ideas, the mechanisms and the vocabulary for an inclusive and informed public dialogue, that involves mainstream as well as divergent outlooks. The goal must be to find a path and approach that gives clarity and resolution to the future choices to be made.

ANNEX A – Consultation Participants

Stakeholders

Vancouver

- Bill Anderson – Aventis CropSciences Canada
- Katherine Barrett – Faculty of Law and Environmental Studies - University of Victoria
- Dan Wiebe - Rossdown Farms Ltd.
- Sara Carten – Community Fraser Health
- James Hill – BC Research Inc.
- Brian Holl – Lamorna Enterprises Ltd.
- George Hamilton – BC Agricultural Council
- Jerri Lynn Wilkins – BC-info, Science and Technology Agency
- Alex Campbell, Jr. – Thrifty Foods
- John J. Kennelly – University of Alberta
- Pamela Winquist – Dietician
- Keith Mussar – Food and Consumer Products
- Farid Makki – Yves Veggie Cuisine
- Robert Hancock – University of British Columbia
- Susan Crawford – Department of Gerontology – Simon Fraser University
- Cayla Runka – Simon Fraser Health Region
- Reanne Levson – Community Fraser Health
- John Vanderstoep – University of British Columbia
- Janice Macdonald – Dieticians of Canada
- Evelyn Fox – Consumer's Association of Canada
- Paul Stinson – B.C Biotechnology Alliance

Other Vancouver

- Herb Barbolet – Farm Folk/City Folk – Delivered petition

Saskatoon

- Robert Morgan – POS Pilot Plant Corp
- Roy Button – Saskatchewan Canola Development Commission
- Grant Isaac – Biotechnology Management – University of Saskatchewan
- Myka Sinchuk – Biotech Alberta
- Ed Palmer – Agricore
- Graham Scoles – Head, Department of Plant Sciences – University of Saskatchewan
- Michael Mehta –Department of Sociology – University of Saskatchewan
- Bryan Harvey – Coordinator of Agricultural Research – University of Saskatchewan
- Walter Yarish – Chairman, Agricultural Biotech Steering Committee – Alberta Agriculture, Food and Rural Development
- Margaret Crowle – Consumer Association of Canada
- Peter McCann – Ag-West Biotech Inc.
- Lisa Jategaonkar – NRC-BPI
- Wilf Keller – NRC-BPI
- Jonathan Greuel – Saskatchewan Wheat Pool
- Alan McHughen – Crop Development Centre – University of Saskatchewan
- Doug Billet – Saskatchewan Agriculture and Food
- Steve Meister – Aventis CropScience
- Laurie Curry – Food and Consumer Products manufacturers of Canada
- Deborah Straw – Dow AgroScience

The views presented in this report are those raised by participants in the sessions. They should not necessarily be considered the views of all participants, and should not be construed as the views of CBAC.

Stakeholders

Toronto

- Stephen Allen – The Presbyterian Church in Canada
- Mary Raymond – Consumer's Association of Canada
- Carol Culhane – International Food Focus Ltd.
- Joy Kennedy – Taskforce on the Churches and Corporate Responsibilities
- Norris Hoag – Ontario Ministry of Agriculture, Food and Rural Affairs
- Alexandra Lamont – Canadian Wheat Board
- Dale Adolphe – Canola Council of Canada
- Randy Preater – Canadian Seed Growers Association
- Lorne Hepworth – Crop Protection Institute
- Brenda Cassidy – AgCare
- Suk Hing Yiu – Toronto Biotechnology Initiative
- Heather Darch – Aventis Canada
- Quentin Martin – AgCare
- Christine Lowry – Kellogg Canada Inc.
- Ken Hough – Ontario Corn Producers Association
- Eileen Inrig – BIOTECH Canada
- David Castle – University of Guelph
- Geoff Wilson – Loblaw Companies
- Phyllis Tanaka – Canadian Food Information Council
- Diane Weatherall – Food and Biotechnology Communication Network
- Ziaad Mia – Donahue Ernst & Young
- Chris Winter – Conservation Council of Ontario
- Doryne Peace – Biotechnology Food Labelling
- Don McCabe – Ontario Corn Producers Association
- Anna Ilnyckyj – Food Industry Competitiveness Branch
- Keith Mussar - Food & Consumer Product Manufacturers (AM only)

Halifax

- Theresa Glanville – Mount Saint Vincent University
- Bruce Gray – NS Agricultural College
- Margaret Miller – Bio-East
- Shirlyn Coleman – NB department of Forestry
- Laurie Curry – Food and Consumer Products Manufacturers (a.m. only)
- Danny Hendricken – National Farmers Union
- Todd Dupuis – Atlantic Salmon Federation
- Etienne Dako – University of Moncton
- Garth Fletcher – Ocean Sciences Centre, Memorial University
- Eugene Tan – Cooper McDonald
- David Sangster – NS Department of Agriculture
- Jeanne Cruikshank – Canadian Council of Grocery Distributors
- Geordie Ouchterlony – NS Organic Growers Association
- Della Erith – NS Fruit Growers Association
- Marian MacKinnon – Professor, School of Nursing, UPEI
- Judith Fraser Arsenault – Mount Saint Vincent University

Montreal

- Michel Provencher –Direction du patrimoine écologique
- Jurgen Quandt – Aventis Cropscience Canada
- Denis Couture – UPA
- Joseph Caron – Action Réseau Consommateur
- Daniel Chez – Ministère de l'Agriculture, des Pêcheries et de l'Alimentation
- Jeff Wilson – AgCare
- Chris Guillon – Warnex Pharma
- Claude Lapointe – Novartis Canada
- Serge Paquette – Natrel Inc.
- Jean Lefebvre – AMPAQ
- Michel Caron – Centre de Valorisation des Plantes
- Irene Strychar – Faculty of Médecine, University of Montréal
- Shane Morris – University of Guelph

Technical Resources

- Chris Reynolds – Canadian Food Inspection Agency
- William Yan – Health Canada
- Louise Laferriere – Canadian Food Inspection Agency (CFIA)
- Mireille Prud'homme – Health Canada
- Karen McIntyre – Health Canada
- Stephen Yarrow – Canadian Food Inspection Agency (CFIA)

Canadian Biotechnology Advisory Committee

- Suzanne Hendricks
- Dr. Mary Alton Mackey
- Dr. Peter Phillips
- Art Hanson
- Mary Alton Mackey
- Anne Mitchell
- Arnold Naimark
- Françoise Baylis

Canadian Biotechnology Secretariat

- Roy Atkinson
- Kelly Brannen
- Suzanne Fortin

Media Relations

- Carl Martin

Facilitation Team

- Lyle Makosky
- Jean Ogilvie
- Elaine Gaudet
- Jeff Moffett
- Sebastien Malherbe
- Yvon Gauvreau

ANNEX B – Values Exercises

A. List underlying values for the four theme areas as identified in workshops

	Theme A	Theme B	Theme C	Theme D
Vancouver	o Transparency o Integrity o Accountability o Education	o Food and environmental safety o Market success o Precautionary principle o Informed public o Looking ahead	o Transparency o Leadership o Prevention o Credibility and responsibility o Knowledge	o Accountability o Separation of promoter and regulator o Transparency o Quality and authenticity of information
Saskatoon	o Social optimization	o Integrity o Credibility o Public participation o Transparency o Safety of food supply o Fairness	o Equitability o Accountability o Knowledge o Stability/confidence o Social benefits	o Science based o Transparency o Product based o Verifiable o Workable
Toronto	o Accountability o Inclusion	o Consumer choice o Trust o Transparency o Democracy o Science base	o Accountability o Knowledge o Respect o Justice o Integrity	o Transparency o Participative process o Science based reviews o Sustainability and future benefits o Balanced regulation
Halifax	o Autonomy o Knowledge o Accountability o Respect for diversity o Beneficence	o Informed choice o Long-term o Trust in government o Safe cheap food o Fairness/level playing field	o Sustainability o Objectivity o Diversity o Nature ethics o Safety o Balance	o Science based o Transparent o Focus on health, safety, and environmental sustainability o International o Ethical

	Theme A	Theme B	Theme C	Theme D
Montreal	o Risk benefit o Facts o Honesty o Business survival o Caution o Accountability/Leadership o Holistic o Knowledge	o Risk benefit o Facts o Honesty o Business survival o Caution o Accountability/Leadership o Holistic o Knowledge	o Transparency o Accountability o Prudence o Participative process	Not discussed

B. Overall underlying values for the four theme areas

	Theme A	Theme B	Theme C	Theme D
Overall	o Accountability/leadership (4) o Autonomy o Beneficence o Business survival o Caution o Education/knowledge (3) o Facts o Holistic o Integrity/honesty o Inclusion o Respect for diversity o Risk benefit o Social optimization o Transparency	o Accountability/leadership o Business survival o Caution o Consumer choice o Credibility o Democracy o Facts o Fairness/level playing field (2) o Food and environmental safety o Holistic o Integrity/honesty (2) o Informed choice/public (2) o Knowledge o Market success o Precautionary principle o Looking ahead o Long-term o Public participation o Risk benefit o Safe cheap food (2) o Science base o Transparency (2) o Trust (2)	o Accountability/leadership (4) o Balance o Credibility and responsibility o Diversity o Equitability o Integrity/honesty o Justice o Knowledge (3) o Nature ethics o Objectivity o Participative process o Prevention o Prudence o Respect o Safety o Social benefits o Stability/confidence o Sustainability o Transparency (2)	o Accountability/leadership o Balance o Ethical o Participative process o Quality and authenticity of information o Safety o Science based (3) o Separation of promoter and regulator o Sustainability (2) o Transparency (4) o Product based o Verifiable o Workable

C. Values ranking exercise by city

	Vancouver	Saskatoon	Toronto	Halifax	Montreal
Regulatory system	o Transparency (16) o Accountability (15) o Quality and authenticity of information (9) o Education (8) o Caution (8) o Justice (7) o Integrity (2) o Separation of promoter and regulator (1)	o Science based (21) o Product based (14) o Transparent (9) o Social optimization (9) o Workable (6) o Accountable (4) o Verifiable (5) o Justice (3) o Knowledge (2) o Autonomy (1) o Respect for diversity (1)	o Science based reviews (14) o Accountability (12) o Transparency (9) o Future sustainability (9) o Participative process (9) o Balanced regulation (5) o Respect for diversity (6) o Caution (5) o Justice (4) o Beneficence (1)	o Transparency (11) o Science based (10) o Accountability (9) o Autonomy (9) o Health safety (7) o Respect for diversity (6) o Beneficence (5) o International compatibility (5) o Knowledge (5) o Ethical (3) o Caution (2) o Justice (1)	o Risk benefit (14) o Honesty (10) o Accountability/leader ship (7) o Knowledge (7) o Prudence/caution (6) o Beneficence (4) o Justice (1) o Respect for diversity (1)
Policy choices	o Food environment safety (12) o Leadership (11) o Justice (10) o Caution (9) o Informed public (9) o Accountability (7) o Environment report o Precaution principle (5) o Looking ahead (4) o Transparency (3) o Market success (3) o Autonomy (3) o Credibility and responsibility (3)	o Safety of food (13) o Informed public (10) o Equitability (10) o Social benefits (8) o Integrity (6) o Knowledge (8) o Stability/confidence (4) o Accountability (4) o Transparency (4) o Knowledge (2) o Justice (1) o Autonomy (1) o Respect for diversity (1) o Caution (1)	o Integrity (14) o Accountability (13) o Science base (11) o Transparency (7) o Trust (6) o Justice (6) o Consumer choice in food (5) o Democracy (4) o Caution (2) o Knowledge (2) o Autonomy (2) o Respect for diversity (1) o Accountability (1)	o Sustainability (12) o Objectivity (7) o Fairness/level playing field (7) o Safety (6) o Informed choice (6) o Long term safety (6) o Diversity (5) o Beneficence (4) o Trust in government (3) o Justice (3) o Autonomy (3) o Caution (3) o Safe cheap food (2) o Nature ethics (2) o Balance (2) o Knowledge (1)	o Transparency (14) o Accountability (8) o Participative process (7) o Knowledge (6) o Prudence/caution (6) o Justice (1) o Autonomy (1) o Beneficence (1)

D. Overall results of values ranking exercise

Regulatory	Policy
• Accountability/leadership (47) • Science based (45) • Transparency (43) • Education/Knowledge (22) • Prudence/caution (21) • Justice (16) • Product based (14) • Respect for diversity (14) • Risk benefit (14) • Integrity/honesty (12) • Autonomy (10) • Beneficence (10) • Future sustainability (9) • Participative process (9) • Quality and authenticity of information (9) • Social optimization (9) • Health safety (7) • Workable (6) • Balanced regulation (5) • International compatibility (5) • Verifiable (5) • Ethical (3) • Separation of promoter and regulator (1)	• Accountability/leadership (44) • Informed choice/public/knowledge (42) • Transparency (28) • Safety of food (21) • Justice (21) • Integrity (20) • Caution (14) • Sustainability (12) • Food environment safety (12) • Science base (11) • Prudence/caution (11) • Long term safety (10) • Equitability (10) • Autonomy (10) • Trust (9) • Social benefits (8) • Participative (7) • Objectivity (7) • Fairness/level playing field (7) • Diversity (5) • Consumer choice in food (5) • Beneficence (5) • Stability/confidence (4) • Democracy (4) • Market success (3) • Credibility and responsibility (3) • Respect for diversity (2) • Nature ethics (2) • Balance (2)

Participant Groups Definition of the Values

Regulatory System List

- Accountability – stakeholders should be held accountable, especially the scientific and regulatory communities.
- Accountability – the parties to GM regulation must be accountable to the processes.
- Accountability – refers to an open system that clearly lays out the regulatory process including objectives, criteria, steps, independent review, communications and post-approval monitoring.
- Accountability – whoever makes the decisions based on factual information needs to be able to justify them.
- Science based – based on sound accepted scientific principles and identified risk, and not incorporating social and ethical considerations.
- Science based safety reviews – science should remain the basis for health and safety regulatory reviews.
- Science based – a world class, highly skilled, science based regulatory regime that is objective, non-biased, independent and uses research as the methodology for product review.
- Transparency – the public has the right to know the process for approvals as well as the information used to make decisions.
- Transparency – regulatory processes and results should be accessible to the public.
- Transparent – the regulatory process and results are open, accessible and understandable.
- Transparent – a regulatory system that is open, accessible and that communicates how the process works as well as the resulting decisions.
- Education – the public has a need to know in order to make informed choices/decisions.
- Knowledge – understanding the information and its implications and ramifications.
- Product based – hazards and risks are associated with things not histories (i.e., final product and not how it was made).
- Respect for diversity – be creative and innovative when it comes to GM foods.
- Integrity – the regulators adopting consultative methodologies to maintain an unbiased position and maintain credibility.
- Autonomy – commitment to pursue informed choice and promote the required conditions to allow Canadians to pursue their fundamental values and interests.
- Beneficence – show the benefits associated with GM foods and not just the risks; show these from a regional, national and international perspective.

- Participative process (full and meaningful) – creating ways in which people and all interested parties can access information and decisions, and can provide input into the process.
- Quality and authenticity of GMO information – information about GM foods should be of high quality and should authenticate/confirm the GM aspects and impacts in a consistent fashion.
- Social optimisation – a new social contract taking into account multiple stakeholders, minimizes social friction and maximizes social cohesiveness, trust, stability, efficiency and accountability.
- Separation of promoter and regulator – demonstrate and communicate evidence that regulatory process and policy is sufficiently independent of the government promotion policy and activities.
- Verifiable – reproducible, consistent, non-arbitrary, with 3rd party oversight that reaches the same conclusions.
- Workable – regulatory process that produces a result and decision without undue time delay and is accessible to smaller companies and institutions.
- Inclusion – all impacted and concerned parties are involved in the approval process.
- Open and transparent communications – develop the appropriate vocabulary, use correct and fair facts, and make information open and transparent.
- Sustainability and future benefits – ensuring we embrace the technology in a way that protects the future legacy of the product, the environment and future users.
- Balanced regulation – providing opportunities for ensuring sustainable Canadian business development.
- Focus on health, safety, and environmental sustainability – a concern/focus on health and safety of food and an emphasis on a safe and sustainable environment.
- International compatibility – collaborate with other countries to advance harmonization and common standards, without compromising acceptable standards for health and safety.
- Ethical – a regulatory policy environment that incorporates ethical considerations/conduct/people, that is based in part on the principle of a moral obligation not to do harm, and to be held accountable for that principle.

Policy Choices List

- Accountability – Definition of objectives and responsibilities
- Accountability – responsiveness, substantiation, transparency, answerability (ensuring enforcement/compliance).
- Accountability/Leadership - responsible authorities are needed to take full responsibility for information disseminated to the public, and product approval decisions.
- Informed public – knowledgeable consumers make better/healthier choices.
- Public participation (Informed public) – ability to make informed choices.
- Informed choice – provide product content to enable the consumer to decide whether or not to acquire it.
- Transparency – share/integrate information.
- Transparency – people understand the system is working in their best interest.
- Transparency – ensuring nobody is hiding anything.
- Transparence - s'assurer que le processus décisionnel est bien compris par le public et que ce processus peut être suivi.
- Safety of food supply – consumer confidence through a strengthened regulatory system.
- Safety – be very careful in regard to potential health implications.
- Justice – fair distribution of benefits and burdens, recognizing that there are significant social/ethical issues related to the definition of the word "fair".
- Integrity – labelling aligned with overall integrity of system.
- Integrity – the need for a code of ethics covering biotech practices (bioethics) harmonized with the regulatory framework. The expectation will then be created that this framework will be adhered to i.e., it will be given "teeth".
- Caution - safety issues, specifically health, must come first. It is important to establish and disseminate safety information, with the best information available today.
- Sustainability – consider long-term social, economic and environmental impacts.
- Food and environmental safety – being rigorous here reduces reliance on labelling.
- Science base – ensure decisions are based on science and not subjective opinions.
- Prudence –intendance « stewardship » en ce qui concerne l'environnement et la santé publique (prudence)
- Long-term safety – both related to human health as well as the environment.
- Equitability – Fair distribution of benefit and burden
- Trust – by regulating the system and processes that bring food to the consumer.
- Trust in government – the government needs resources in order to either live up to and/or redevelop the public's trust.

- Social benefits – Utilizing new technologies to benefit Canadians economically and with respect to health and well being.
- Participation –s'assurer que les choix sociétaux reflètent les valeurs des citoyens par le moyen de participation réelle et débat.
- Objectivity – look at the whole picture; balance the perspectives, both positive and negative.
- Fairness – high quality low cost foods that are safe and accessible.
- Diversity – maintain biodiversity, economic diversity and choice diversity.
- Consumer choice in food – giving consumers the opportunity to make real choices based on good information.
- Stability/Confidence – Balancing social responsiveness with reasonableness and sound thinking.
- Democracy – refers to the decisions made for the benefit of the majority while respecting the perspectives of the minority. Being respectful of diversity.
- Market success – informed acceptance of GM food is important to our success as a trading nation.
- Credibility and responsibility – credible scientific studies allow for responsible decisions to be made.
- Credibility – appropriate people, expertise available to system.
- Respect for diversity – related to life forms. Recognize the relative benefit or harm of other life forms (e.g., pathogens).
- Nature ethics – work with and not against nature.
- Balance – balance competing needs.

ANNEX C – Workshop Evaluations "*On a scale of 1 (poor) to 10 (very good), rate the following"*

Question	Vancouver	Saskatoon	Toronto	Halifax	Montreal	Overall
To what extent did we achieve this objective, **1.a.** To enable stakeholders to explain positions and rationale on key issues, propose and respond to promising policy directions, and describe benefits and consequences of preferred directions.	7.0	7.6	7.2	6.9	8.0	**7.3**
To what extent did we achieve this objective, **1.b.** To enable stakeholders to identify tradeoffs in policy options and values or principles that could underpin decision making.	6.8	7.0	6.5	6.9	7.1	**6.9**
2 Did the opening description of CBAC explain the mandate and program sufficiently?	8.3	7.5	7.8	7.9	8.0	**7.9**
3 Did you have an opportunity to explore the important questions and challenges related to GM Foods?	7.1	8.1	7.0	7.9	6.9	**7.4**
4 Did you have an opportunity to hear and understand other stakeholders' views?	8.0	7.2	7.4	7.7	7.0	**7.5**
5 Did you have an opportunity to express your views on these questions?	8.1	8.5	7.9	8.7	8.6	**8.3**

Question		Vancouver	Saskatoon	Toronto	Halifax	Montreal	Overall
6	By the end of the day, have we outlined and considered a useful range of policy choices for the regulation of GM Foods?	7.0	7.3	6.1	7.6	6.9	**7.0**
7	To what extent could these sessions help inform future thinking on the regulation of GM Foods?	7.3	7.0	6.7	7.4	7.7	**7.2**
8	How effective/helpful was your small group facilitator?	9.0	8.2	8.6	8.8	8.7	**8.7**
9	How was the overall facilitation?	9.0	8.5	8.6	8.9	8.6	**8.7**
10	How informative and useful was the consultation document for this session?	8.4	8.0	7.2	7.8	7.4	**7.8**
11	Were the facilities conducive to a good exchange?	7.8	8.1	8.0	8.5	8.1	**8.1**