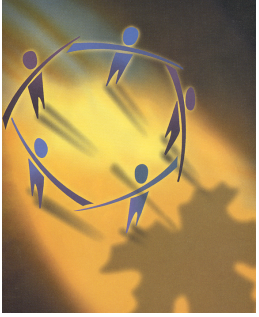

Toronto Session

HIGHLIGHTS DOCUMENT

WORKSHOP ON GENETICALLY MODIFIED FOOD

Prepared by the Canadian Biotechnology Advisory Committee

April 6, 2001

Highlights of the Toronto Session

The views presented in this report are those raised by participants in the session. They should not be considered consensus views of all participants, and should not be construed to reflect the views of CBAC.

Consultation Participants

Stakeholders

Stephen Allen – Presbyterian Church in Canada
Mary Raymond – Consumer's Association of Canada
Carol Culhane – OHEA
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 Growers
Anna Ilnyckyj – Food Industry Competitiveness Branch
Keith Mussar - Food & consumer Product Manufacturer (AM Only)

Technical Resources

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Stakeholder Workshop Objectives

The current series of stakeholder workshops on Genetically Modified (GM) food has two main objectives:

- 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 trade-offs in policy options and values or principles that could underpin decision making.

Themes/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. For each of these themes and issues, the text below summarizes the preferences and other views expressed by participants in the session. The information should not be considered to represent consensus positions of the participants.

Theme A - Good Governance

Transparency and opportunities for public involvement

The 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 should 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 new process

- Requires a definition of the third party, its roles and responsibilities.
- Achieves transparency and adequate opportunities for public involvement and feedback.
- Increases public confidence and trust in the overall regulatory system.
- Increases cost (i.e., time consuming).
- For this process to succeed, government must make it a priority.

The underlying values which could assist in developing policy in this area are as follows:

- Accountability – refers to an open system that clearly lays out the regulatory process including objectives, criteria, steps, independent review, communications and post-approval monitoring.
- Inclusion – all impacted and concerned parties are involved in the approval process.

Theme B - Information Provision

Information provision and labelling

In addition to the issues presented by CBAC in its consultation document, additional issues raised by participants included the concern that labelling was being offered as a solution, but the problem it is answering is not clear. More research is required as to what consumers need in terms of labelling and information, and what costs they are willing to pay for more information. Another concern is the "deafening" silence of government officials in explaining how the system works.

One way forward suggested was doing much better risk and benefit communication for the public by both government and industry. If we don't have a well informed public, policy will be shaped by a misinformed public. Information in circulation should not just focus on GM foods, but on the system we have in Canada for ensuring food safety. One problem of this approach is that there is a current disconnect in terms of trust between the public and government, so there might not be a high level of confidence in information coming from government. Given the substantial downsizing in key government organizations, it is critical to ensure that there is enough high quality staff and direction to be able to be credible in the provision of public information.

A second way forward in terms of information has to do with a need for reliable access to information about GM foods. Some countries, such as Britain, have appointed a specific organization to be in charge. The suggestion from this workshop group is that we need multiple points of access to good information; including each government department describing clearly its own operations, the Food Biotechnology Communications Network could be a key player, food companies have a role, etc. We 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.

With respect to labelling, the group felt that the Canadian General Standards Board should be left alone to do its work, and encouraged to "take it slow and get it right". Some countries have had to retract their labelling standards, as they couldn't function in reality (i.e., they were not practical). The general consensus is that labelling practices should be voluntary. That said, 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. There is no consensus yet on what should be labelled (GE and GM foods? GE foods only? Positive labelling? Negative labelling?). The group 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. It was agreed that the consequences of mandatory labelling could indeed be to undermine the sector.

Canada should continue to participate in the development of international standards and guidelines, and should push the CODEX process to work towards a product within a shorter time frame than 7-8 years.

The underlying values which could assist in developing policy in this area are as follows:

- Consumer choice in food – giving consumers the opportunity to make real choices based on good information.
- Trust – by regulating the system and processes that bring food to the consumer.
- Transparency – ensuring nobody is hiding anything.
- Democracy – refers to the decisions made for the benefit of the majority while respecting the perspectives of the minority. Being respectful of diversity.
- Science base – ensure decisions are based on science and not subjective opinions.

Theme C - Risk and Benefits Considerations

This section encompasses two subject areas and their real/perceived challenges:

- Environmental Stewardship
- Post-market monitoring

In this theme area, the way forward involved a series of proposed activities to address the challenges. The following discussion outlines the "story line" that was followed in the group's discussion, that is to say, the group discussed the risks and relative benefits of each activity.

Environmental stewardship

This was not seen to be 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, i.e., 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. This knowledge needs to be better integrated. In order to strengthen the knowledge base, there may be a requirement to review the environmental legislation.

With respect to the life cycle approach, would this 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.

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.

With respect to GM food assessments and scientific research, there was general agreement that these activities were desirable. Significant GM food 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.

Post-market monitoring of risks and benefits

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.

Industry is currently responsible for auditing for any special requirements applied by regulators as a condition for approval of a GM product. In 80% of the cases, farmers are compliant. Concern was expressed regarding the non-compliance of the remaining 20%. These farmers may not be informed or may have a perception that the audit is not entirely necessary.

Canada requires baseline data regarding general food consumption, not just data for GM foods. All categories of food should be part of this programs, including GM foods. To some this is seen as a costly exercise with limited relative benefit. 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.

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.

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 capacity issues that must be addressed.

The underlying values which could assist in developing policy in this area are as follows:

Group C felt that some of these items were "values", while others were "principles. A compromise position was reached. This list is to be considered "things that are valued", be they values or principles.

- Accountability – responsiveness, substantiation, transparency, answerability (ensuring enforcement/compliance).
- Knowledge – commitment to seek truth and disseminate/use knowledge appropriately.
- Respect for diversity – related to life forms. Recognize the relative benefit or harm of other life forms (e.g., pathogens).
- Justice – fair distribution of benefits and burdens, recognizing that there are significant social/ethical issues related to the definition of the word "fair".
- 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".

Theme D - Regulatory System

Separation and independence of regulatory functions

The current separation of the promoter and regulator functions in the regulatory system is considered adequate as there are strict controls on the role and independence of the regulatory function. The main challenge remains 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).

Related concerns:

- 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
- There is, and will continue to be, a need to provide consumers with a choice between GMO and non-GMO foods.
- 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.

Capability and capacity in the regulatory system

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 the R&D through producer 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. 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.

It should be noted that the public in general no longer understands the food system. This represents a significant education challenge - one that actually goes beyond GM foods.

Ensuring safety during research and development activities

Current regulations and voluntary guidelines covering R&D (before regulatory assessment) are seen as adequate. What would be helpful is the consolidation of these regulations and guidelines to bring clarity and focus and to identify if there are any gaps. However, 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 associated with 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.

The underlying values which could assist in developing policy in this area are as follows:

- Open and transparent communications – develop the appropriate vocabulary, use correct and fair facts, and make information open and transparent.
- 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.
- Science based safety reviews – science should remain the basis for health and safety regulatory reviews.
- 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.

Theme E - Social and Ethical Considerations

During the afternoon break-out sessions participants began by discussing broader social and ethical questions as they related to GM foods. Following this, the groups were asked to react, discuss and provide feedback on a GMF acceptability/non-acceptability spectrum framework that has been introduced and that has evolved over the course of these stakeholder workshops on GM food. 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 (that could be developed) and placed in an appropriate location on the spectrum. Products could move on the spectrum as 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 and complementarity of this activity with the regulatory system and with the broader governance structure.

Group A

Challenges

- We require a different framework that addresses Social and Ethical considerations, since the current scientifically based regulatory system must remain in its current form.
- The absence of identified common Canadian societal values.
- A distinction should be made between freedom of choice and long term societal impacts.
- Debating GM foods in isolation from the rest of the Canadian food system.

Potential Ways Ahead

- 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.
- Define what are Canadian societal values to provide the foundation for the development of a framework to assess social and ethical elements.

Group B

Challenges

- Responding to the right of consumers/users to know and to have access to the information they need.
- Canada's right to determine its own path with respect to GM foods.

Potential Ways Ahead

- Social 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-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. Although it takes a while to get the results into legislation, the ongoing dialogue is taken into consideration by regulators.
- The appropriate forum for dealing with socio-economic issues is the combination of public discussion (perhaps led by CBAC), and involving the seven departments involved. The regulator (e.g., CFIA) can ask for guidance from such a forum around newly breaking issues.
- The group appreciated the 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. "Moratorium" is too negatively value-laden.
- As a follow-up to the papers prepared by CBAC regarding social and ethical issues, it was suggested that CBAC develop some simple guidelines for ethics that can be used by scientists, professionals, policy makers that help those not specifically trained in ethics or philosophy to understand how to consider ethical issues.

Group C

Overview discussion – Broad social/ethical considerations

- Nomenclature/labels are misleading. Examples of "loaded" terms include: vulnerable, GM itself, profitability, big (interpreted as bad and corrupt).
- Power shifts are occurring. The balance of power between governments and corporations may be shifting in the favour of corporations. This questions the credibility of our institutions.
- There are material/knowledge gaps between "rich and poor" (individuals, groups and countries)
- Profitability is good, but not at any cost.
- The cost of jeopardizing credibility must be balanced. Society could inadvertently be destabilized by acting rashly.

- The current scientific assessment process does not consider societal/ethical values
- The ethical debate lags behind the development of new science.
- The level of scientific literacy is highly variable, especially with respect to developing nations. There is a need for education and informed debate.

Reactions to the GMF Acceptability/Non-acceptability Spectrum Framework

- May be feasible, because not all GM foods are equal. Agreement that some GM foods may be quite acceptable while others could be subject to a moratorium.
- Defining the criteria for the evaluation of acceptability was seen to be challenging. Levels of acceptance within society are highly variable. Some are more accepting than we think, while others feel (although not always able to articulate why) that certain practices are inherently wrong.
- Developing the criteria would perhaps feed the knowledge growth required for stewardship and monitoring and may enable informed choice. However, informed choice implies scientific literacy.
- The development of criteria assumes that there is "objective truth".
- Acceptability should be balanced with relative benefit. For example, a product that uses transformative technology to cure cancer should be more socially/ethically acceptable.
- How will we define the ultimate limits or constraints placed on the use of technology.
- More precise technology should make it easier to define criteria (biotechnology/bioinformatics).

Group D

Challenges

- 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.
- Consumers don't understand the science, thus the difficulty of having an informed dialogue.
- The science in and of itself is neither good or bad (although no science is value neutral), thus the concern should be focussed on the product of the science.
- We may need to address the educational challenges before engaging the social/ethical questions.
- Currently the stakeholder groups are separated and distant ideologically, and are pursuing their own views rather than seeking common ground.

Potential Ways Ahead

- Scientific assessment (for safety and research) should continue to be based on science.

- We need an educational approach to inform the public before attempting to widen the discussion on social and ethical issues.
- 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.
- May require a more open political process (e.g., senate committee hearings).

Reactions to the GMF Acceptability/Non-acceptability Spectrum Framework

Likes (the aspects the group found attractive)

- The overall structure.
- It is beneficial for the concept to be used outside the regulatory process.
- Good framework to help with progress.
- Will lead to significant debate across all dimensions, which is to be encouraged
- Could have merit across other dimensions of biotechnology.
- Allows for proactiveness instead of reactiveness.

Dislikes/Concerns (the aspects the group was concerned about)

- Appears to be reactive to the present.
- Unclear who would be doing the development and application of it.
- Not clear if the spectrum would apply to other countries or products crossing into Canada.
- The potential for politics to dominate the assessment rendering it more subjective.
- The potential complexity of the criteria and the extreme difficulty of gaining reasonably common agreement on these criteria and their use.

Summary of key values

Participants discussed values and principles related to governance and the regulatory system. The following were raised and most widely supported:

Values for shaping the regulatory system

Top five:

- Science based safety reviews
- Accountability
- Open and transparent communication
- Sustainability and future benefits

- Participative process

Other values discussed in groups and supported by some, but not selected as most important include:

- Balanced regulation
- Respect for diversity
- Caution
- Justice
- Beneficence

Values for shaping policy choices

Top five:

- Integrity
- Accountability
- Science base
- Transparency
- Trust
- Justice

Other values discussed in groups and supported by some, but not selected as most important include:

- Consumer choice in food
- Democracy
- Caution
- Knowledge
- Autonomy
- Respect for diversity
- Accountability

Closing ideas and guidance to CBAC

This section outlines the final three or four suggestions made by participants as final thoughts/advice for future consideration by CBAC. These suggestions should not be considered to be consensus views of any of the groups.

General

- Canada is recognized internationally as having an appropriate and effective system to deal with novel foods. There is a need to protect that image, especially on an international level.
- Ensure the regulatory approach does not prevent or impede global trade of our products.
- There is confidence in the Canadian regulatory system, what is being discussed is the capacity of the regulatory system.
- Lack of participation from civil society. As a result, there is a need for a process that really involves a range of perspectives and that results in true dialogue.
- In the final report, acknowledge the work of other organizations, sources (e.g., the Royal Society).
- Identify which cluster of issues requires engagement by our elected officials.
- CBAC needs to consider the longer context of health and nutrition and not just GM foods in isolation.
- Identify and engage "wise" subject matter experts.
- The Canadian government needs to consult and develop a pro-active agenda for food and agriculture to address the economic viability, environmental sustainability and public health and safety of the food system.
- Canada's regulatory framework and support mechanisms for the food system should reflect and be accountable for a national food strategy.
- Canada's approach to food biotechnology should cover a needs assessment including: economic, ethical, environmental, health and social risks, benefits as well as alternatives (e.g., organic agriculture).
- While there are some risks associated with the endorsement of this technology, there are also a number of risks associated with not endorsing it.

Please note that similar reports from each of the five CBAC stakeholder workshops on The Regulation of GM Foods, conducted across Canada from April 2nd to April 10th 2001, will be posted on the CBAC web site. As well, results from all five workshops will be integrated into a single roll-up report that will also be available on the CBAC web site by the end of the month.

Please visit the CBAC web site at www.cbac-cccb.ca or call the CBAC toll-free number at 1-866-748-2222 for additional information or documentation related to this or other CBAC projects.