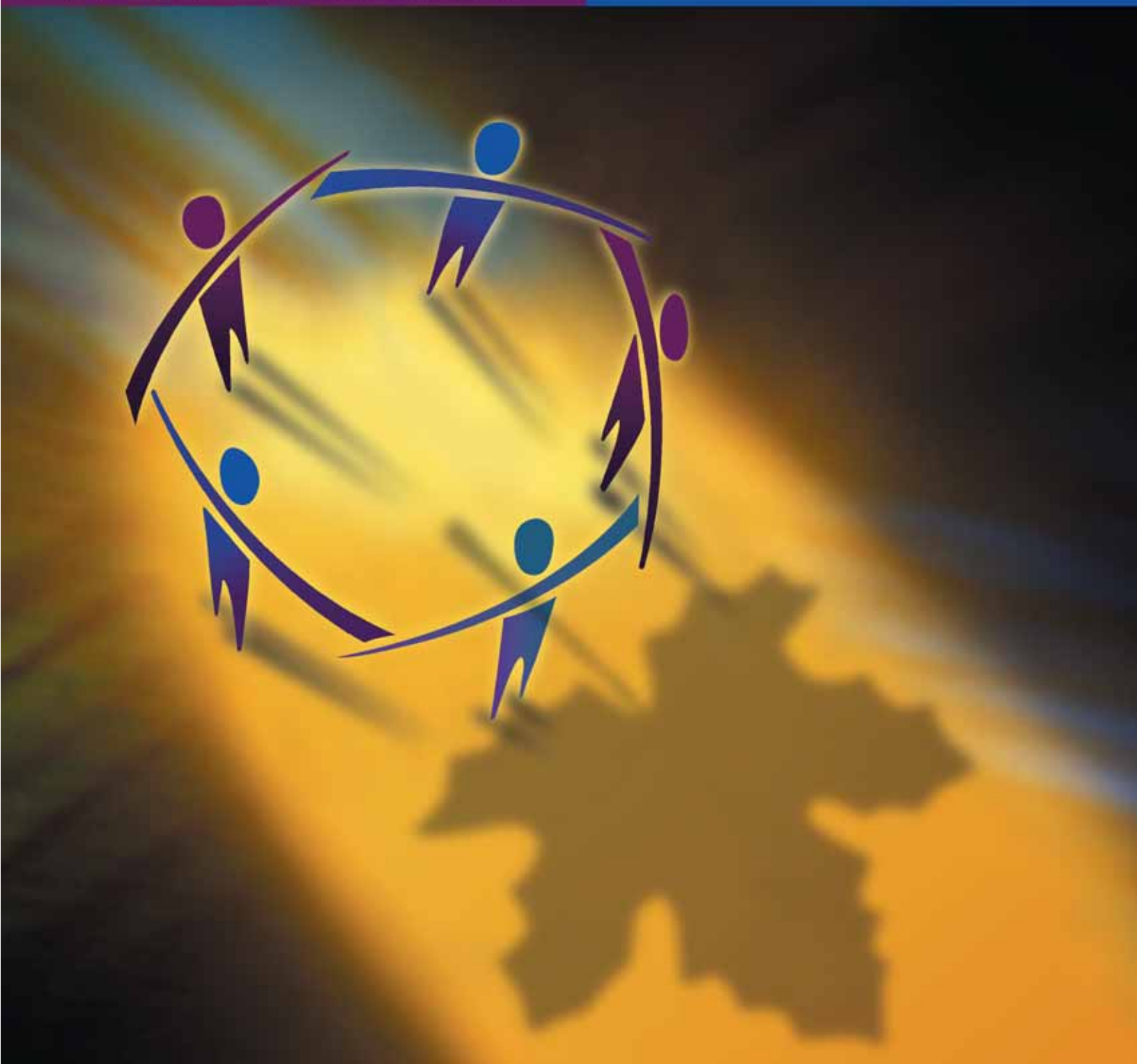
Dialogue Tool Kit

Canadian Biotechnology Advisory Committee



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SECTION 1

Background

SECTION 1

Pages

1

BACKGROUND

A Made-In-Canada Approach to Talking About Biotechnology

Like most industrialized countries around the world, Canada must grapple with new and transformative technologies, including biotechnology, that have introduced important economic and social change.

Advisory Committee Addresses Genetically Modified Foods

In September 1999, the Government of Canada appointed a panel of experts from diverse fields to provide independent advice on issues of biotechnology. The Canadian Biotechnology Advisory Committee (CBAC) quickly established a list of priority topics, and the development and use of genetically modified food (GMF) topped that list. Since that time, CBAC has conducted extensive consultations with Canadians, scientists and stakeholders about GMF and the opportunities and challenges they present. After listening and reflecting on these views, CBAC released an interim report in August 2001 and, following further consultations, a final report in August 2002.

In the last number of years, CBAC stakeholder consultations have produced a uniquely Canadian debate, not only about biotechnology issues per se, but also how to talk about biotechnology. With support from CBAC, stakeholders took it upon themselves to begin fashioning a dialogue framework within which they could conduct discussions about biotechnology products and specifically, about genetically modified food and feed (GMFF) issues. Early on, they agreed on the need to understand and discuss all relevant issues – not only the science, but the potential social, economic, ethical and broader societal impacts that GMFF might produce – to assess whether the technology could deliver positive, negative or neutral outcomes for Canadians. CBAC was keen to encourage the development of such a Dialogue Tool, one with the capacity to bring a wide range of participants to the table for productive and sustained discussions about a complex and sensitive topic.

What is the Dialogue Tool and What Does it Do?

The Dialogue Tool is not intended to produce consensus. However, CBAC and its Exploratory Committee believe it has potential to assist dialogue about not only genetically modified food & feed (GMFF), for which it was originally designed, but other products of biotechnology as well by:

- breaking down a complex issue into its component parts
- characterising the attributes that make a product of biotechnology more or less desirable/ acceptable/ beneficial to Canadian society
- aiding in understanding the science behind an issue
- considering the social and economic benefits and risks
- examining ethical issues
- exploring the linkages with Canadian values
- considering the potential trade offs between and amongst the five consideration themes
- bringing opposing viewpoints to the table by engaging stakeholders who would not normally have the opportunity to examine an issue collectively
- establishing common language
- setting goals for a dialogue
- exploring solutions (i.e. identifying the promising directions or options for policy)
- identifying the conditions required to make a biotechnological innovation more acceptable to certain stakeholder groups
- capturing observations/advice for further dialogue.

The Dialogue Tool is all about creating constructive discussion about biotechnology issues in Canada. It can be used by policy-makers, industry leaders, not-for-profit organizations and academics. It is partly intended to inform policy-making and it is also an educational tool. Individual stakeholders might use the tool to aid in the decision-making process. It also helps identify possible solutions, areas of compromise and Canadian values; it allows different points of view to be heard.

A "Spectrum"

The key output of these discussions was the idea of an "spectrum", developed by stakeholders and some key CBAC members and staff, to focus and aid consultations. The goal of the spectrum was to create a tool for policy dialogue that permits a holistic examination of the subject through the lens of five "consideration themes" – health, environment, socio-economic considerations, ethical considerations and broader societal considerations.

The original design considered four possible outcomes for each consideration theme – acceptable; acceptable with certain conditions; unacceptable at the present time and until more is known or a given standard is met; or not acceptable under any circumstances. A real world parallel to the category "not acceptable under any circumstances" might be an unconditional prohibition (i.e. a ban). "Not acceptable until more is known" might be likened to a moratorium.

Stakeholders Develop the Dialogue Tool

Interest in this approach was so significant that in late 2002, CBAC established an Exploratory Committee (EC) to guide a pilot project to develop and test the spectrum, which was renamed the "Dialogue Tool". The Exploratory Committee was comprised of representatives from the full range of CBAC's stakeholders – industry, the supply chain (farmers, producers, retailers), consumers, faith and public health interests, and environmentalists. In its work, the EC found the tool effective in finding common ground, breaking down barriers to dialogue, and creating common language and purpose between and among stakeholders with shared or conflicting views – particularly when conducted with expert facilitation, good advance planning and strong information sources. Accordingly, the EC reported back to CBAC in the spring of 2003, requesting CBAC's further support for completing the third and final phase of the pilot project. This was to include conducting a Government of Canada orientation session and a "multi-stakeholder meeting", the completion of all materials and the production of a final report to CBAC on the outcome of the pilot project.

How it Works

The Dialogue Tool is in matrix form; its visual components are intended to aid understanding and dialogue. The Tool is designed to plot a real or hypothetical product of biotechnology on this grid so concepts can be grasped, different perspectives

can be aired and the dialogue progress charted. In the first pass, participants create issue profiles under each "consideration area" for the policy issue under consideration. On a second pass, they begin to consider the issue in terms of its "acceptability" or "supportability".

Dialogue participants receive a backgrounder about the biotechnology issue in advance and are asked to agree to certain rules of engagement (i.e. agreement that they are committing to an open dialogue that respects all participants). Each session is facilitated by a trained and expert facilitator to help the participants maintain momentum through the dialogue and to capture their thinking. Sessions typically run between one hour and five hours in length, but could be longer. Consensus is not always the goal and sometimes groups agree to meet again to pursue certain issues or extend their discussion. Understanding another's views and perspective is an important outcome in and of itself.

A dialogue is usually more interesting and productive when it involves participants with different views, but some organizations have used the tool effectively even when their views are closely aligned.

The dialogue process has the capacity to highlight and/or capture:

- **Emergent issues:** New or dominant issues arise from the dialogue as participants seek clarity and a better understanding. As the dialogue progresses, participants become sensitive to those issues that are the most critical or will have the greatest impact.
- **Qualities/attributes/characteristics that affect the degree of supportability:** The dialogue helps identify the factors that contribute to making a product of biotechnology more or less supportable/desirable/acceptable/beneficial, and the intensity of the views held on it.
- **Risks, benefits and trade offs:** Discussion of the qualities/attributes and the overall impression of a product allows participants to weigh both risks and benefits, and to look for trade offs or for areas of agreement.
- **Possible solutions:** Dialogue groups strive to identify possible solutions or ways to mitigate the most serious concerns.
- **Resulting observations, considerations or advice for moving forward:** Summarize the issues, overall impressions, relative acceptability/supportability of the case elements, including options for moving forward or bringing adjustments or solutions to bear, or suggestions for further study and dialogue.

Step-by-step with the Dialogue Tool

- Participants are guided through a dialogue process using the dialogue tool to see how a complex case can be deconstructed into more understandable components.
- The test policy issue is examined from the perspectives of health, environment, socio-economic, ethical and other broader considerations (e.g. international). Participants consider the risks, impacts, benefits, implications and possible trade offs under each consideration theme.
- Participants then assess the relative degree of "acceptability" or "supportability" for each consideration.
- The group then explores those possible conditions or mitigations that could affect the receptivity of the case in question. Participants conclude by making suggestions for further work that could improve understanding and subsequent societal dialogue on the case.

The Dialogue Tool is used to look at issues associated with products of biotechnology though the lens of five "considerations" or "themes" – health, environment, social considerations, ethical considerations and broader considerations such as international implications.

Dialogue Tool Chronology

- In early 2001, as part of its *Regulation of Genetically Modified Food* project, CBAC prepared a consultation document to solicit input from Canadians on ten key issues.
- CBAC held a series of multi-stakeholder workshops in five cities across Canada on GM foods and feed in April 2001. Several environmental non-governmental organizations (ENGOs) decided to boycott these consultations.
- The *Acceptability Spectrum* as a preliminary concept, was first considered at the initial consultation session in Vancouver, in April 2001, and reviewed and enlarged at each subsequent consultation event.
- The GM Foods Reference Group was established by CBAC to serve as an informal advisory board and sounding board for the GM Food Project. It was comprised of 12 members from diverse backgrounds who served between December 2000 and April 2001. The Reference group was asked to review and comment on the GM Food Project's research profile, consultation approach, results and communications. The Reference Group also liked the idea of the spectrum and suggested it be pursued further.
- In August 2001, CBAC issued an Interim Report on *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*.
- At the final meeting of the CBAC GM Foods Reference Group in 2001, a number of individuals representing a range of stakeholder interests felt that a further attempt should be made to engage the ENGOs that had boycotted the initial round of consultations. At the time, the objective of keeping all stakeholders engaged was not directly linked to the development of the Dialogue Tool.
- CBAC established an Exploratory Committee (EC) to take the *Acceptability Spectrum* – now known as the Dialogue Tool – to its next stage, and mandated it to design a Dialogue Tool and process. The Committee consisted of 13 individuals from non-governmental organizations (including ENGOs, public health, faith/religion and consumer groups), GM biotechnology developers, supply chain organizations (farm producers, food processors and retailers), and the CBAC co-chairs, all guided by an expert facilitator.
- CBAC proposed a three-step process for the Committee. The first phase entailed designing and implementing the overall process, including taking decisions on whether and how to proceed at each step. The second phase entailed focussing on the topics and dialogue deemed most relevant to each individual stakeholder group (single stakeholder meetings). The third phase expanded the process to take into account the collective view of all stakeholder groups.
- In the Spring of 2002, as part of the second phase, six stakeholder sessions were conducted among the following constituencies:
    - faith/religion groups
    - supply chain group (farmers, producers and retailers), with some health representatives
    - consumers and health groups
    - biotech developers group
    - consumers group (Québec)
    - civil society/NGOs/ENGOs/academe group.
- In its first report to CBAC in June 2002, the Exploratory Committee noted that the "*Acceptability Spectrum* is an innovative tool with the potential to make a significant contribution in advancing the dialogue on genetically modified food and feed, biotechnology in general and other policy issues in Canada." The Committee proposed that the pilot be continued to a full multi-stakeholder consultation (Phase 3).
- In March 2003, Exploratory Committee members agreed to change the name of the tool/project to the Dialogue Tool.

- The Exploratory Committee reported to CBAC in May 2003, and provided a further refined Dialogue Tool. It recommended a Government of Canada orientation session, followed by a full testing of the tool with multiple stakeholders (which had not yet occurred as planned). The Exploratory Committee endorsed the tool as a means to encourage a full airing of issues, helpful input and interventions, and constructive dialogue.

Other resources

- http://www.cbac-cccb.ca/
- Developing a Dialogue Tool on Genetically Modified Foods and Feeds in Canada (Pilot Project) Report of the Exploratory Committee to CBAC (May 2003) (NB: This report includes the Brief Overview of the Dialogue Tool).

Getting Ready for a Dialogue Session

The Dialogue Tool is definitely a "Made-In-Canada" solution to bringing people together to talk about the challenges and issues involved with biotechnology in Canada.

Dialogue Tool

Participants invited to work with the Dialogue Tool should remember that it is a work in progress. Although it is still under development, in its current form, the Dialogue Tool is the result of the focused efforts of experts and stakeholders who have tested it in working sessions and who are committed to a frank and open discussion of these issues in Canada. These stakeholders found that the Dialogue Tool was effective in opening up a constructive discussion about topical, and sometimes controversial, biotechnology issues, even where there were strong opposing views.

Members of the Exploratory Committee who developed the Dialogue Tool note that successful dialogues sessions require the following:

- Good quality background information about the policy issue or case study to be discussed;
- Background orientation material about the Dialogue Tool and how it works.
- Common agreement among participants about how they will function in the dialogue;
- Expert facilitation that ensures that all points of view are heard and that the Dialogue Tool is used effectively; and
- Concluding statements that highlight where the dialogue ended, next steps that might be pursued and key points arising from the dialogue.

The materials that follow will help you prepare for a session using the Dialogue Tool. The products used by way of example, in the Dialogue Tool documentation, are genetically modified food and feed (GMFF). Remember however, that the Dialogue Tool is intended for, and can be adapted to other products or processes of biotechnology. You should read them in advance of your dialogue session. In addition, further material on the Dialogue Tool can be found at www.cbac-cccb.ca .

Where the Dialogue Tool Focuses Discussion

Using the Tool, the dialogue process helps participants unpack a complex case into more defined issues using focusing questions within five areas: health; environment; socio-economic; ethical; and broader societal considerations. The issue profiles can then be more clearly understood, considered and weighed to determine tradeoffs, conditions, and solutions that could affect the future of the case.

In general terms, the process can enable discussion of a policy case in a variety of dialogue models that combine the following:

1. **The issues arising** [seeking clarity, better understanding and a sense of which issues are the most critical/have the most impact]
2. **The qualities/attributes/characteristics of the case that affect the degree of supportability** i.e. that make it more or less supportable/desirable/ acceptable/beneficial [here we seek an identification of the best and worst qualities and the level of intensity of each]
3. **The risks, benefits and trade-offs arising from these qualities/attributes and the overall impression when these are combined and weighed** [here we seek an examination of the risks and benefits weighed together and any trade-offs, and the resulting overall impression using the spectrum structure/colouring/or terminology. i.e. differentiating the degree of acceptability/supportability/desirability]
4. **The expectations for addressing the issues/outcomes arising from the dialogue** [here we seek an indication of areas where possible solutions, or ways to address the most serious concerns, or the conditions that might be needed to mitigate the concerns]
5. **The resulting observations, considerations, or advice for moving forward** [here we seek to summarize the issues, overall impressions, relative acceptability/ supportability of the case elements or overall, options for moving forward or bringing adjustments or solutions to bear, or suggestions for further study and dialogue].

Steps in the Dialogue Process

A trained facilitator will walk participants through the dialogue process. As you get ready to participate, it sometimes helps to consider how the dialogue process is designed. Using the coloured version of the Dialogue Tool, a small group of dialogue participants will consider a sample, or real, policy issue associated with a product or products of biotechnology. Facilitation staff will keep track of your comments and the “profiles” you build as you progress through the discussion. In the end, you may not have reached consensus, but you will have plumbed the depths of the issue and considered many of the ways – positive, negative or neutral — it could possibly affect Canadians.

Here's how you'll step through your dialogue process:

1. Identify the qualities or attributes of the biotechnology product. Determine if these are unique to the product or also relate to other products of biotechnology, and list them in relation to the five areas of consideration (i.e. health considerations, etc). NB: This step can be done in advance.
2. In each area of consideration, characterize the attributes which make the product more desirable/acceptable/beneficial to Canadian society (i.e. what are the characteristics that would favour its use).
3. In each area of consideration, characterize the attributes which make it less desirable/acceptable/beneficial to Canadian society (i.e. what are the characteristics that would mitigate/argue against its use).
4. Define the issues that arise in each area of consideration when considering the subject qualities in that area.
5. Engage in a dialogue on the issues, seeking clarity, better understanding and a sense of which issues are the most critical/have the most impact, and the expectations there are/may be for addressing these issues.
6. Identify the risks and benefits of the product in each area of consideration (environmental, socio-economic, etc), drawing upon the review of more favourable and less favourable qualities.
7. Weigh the risks and benefits together and consider the potential trade-offs in and across the areas of consideration.
8. Using the spectrum breakout, identify which area of the spectrum best fits the subject, after discussing and weighing all the factors above – do this for each consideration area, and then overall.
9. Choose the 'preferred language' (see language list in tool) that best describes the position of the product in each consideration area and then the overall position of the product (note: if 'conditions' are called for, then suggest the type of conditions or further information that could be called for).
10. Identify possible solutions (i.e. promising directions (for policy or activity) that could be explored).
11. Provide any observations/advice on further dialogue that should be explored about this product.
12. Debrief the experience drawing out impressions, lessons and potential applications elsewhere.

SECTION 2

Preparation and Facilitator Orientation Guide

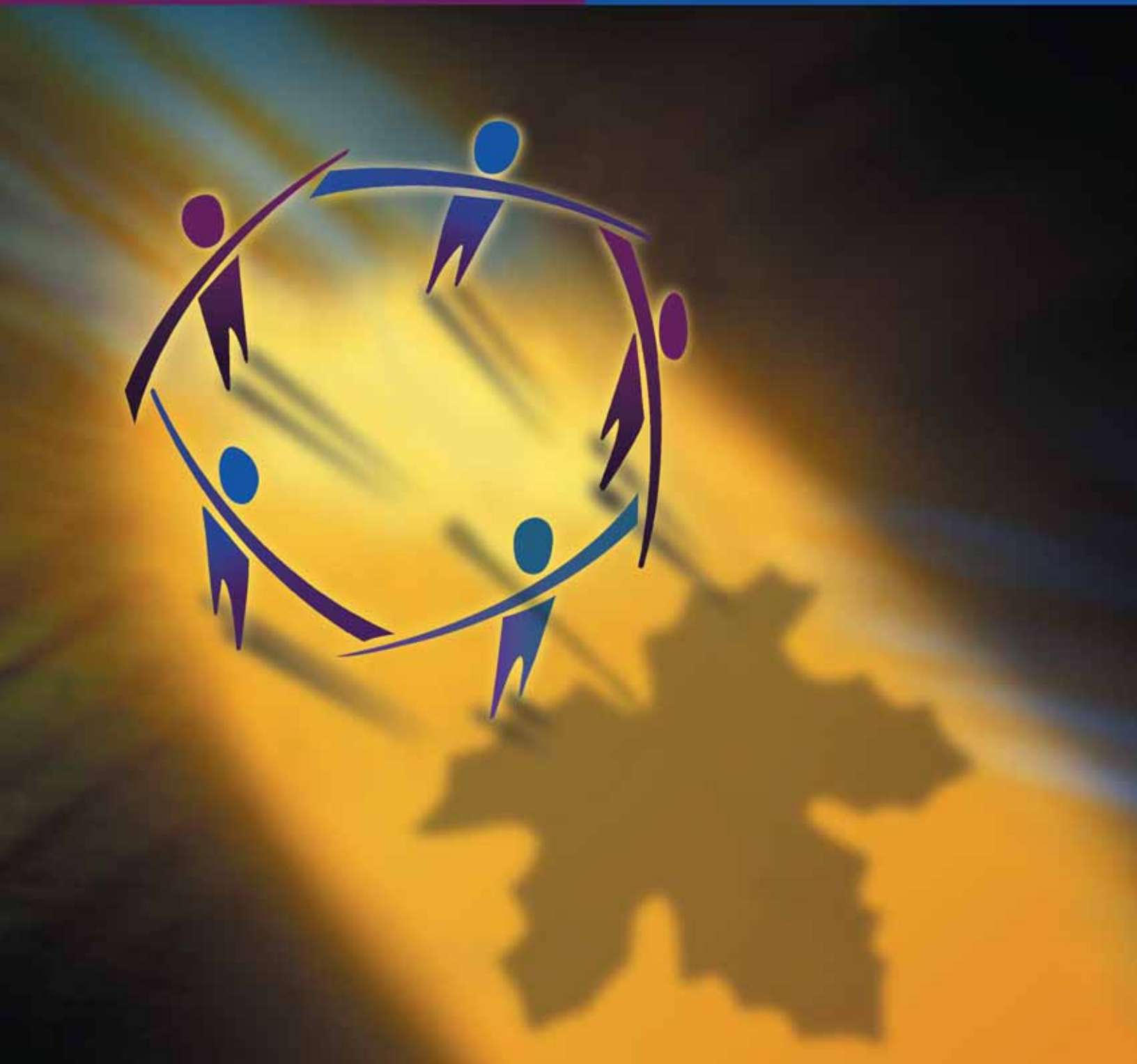
SECTION 2

Pages

Dialogue Tool

Orientation Guide

Canadian Biotechnology Advisory Committee



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PREFACE

This Dialogue Tool Orientation Guide serves as an introduction to a unique Dialogue Tool and process that has evolved over the past two years, as the Canadian Biotechnology Advisory Committee (CBAC) has explored the many issues associated with products of biotechnology.

The policy case study used as an example, genetically modified food and feed (GMFF), is an issue on the agendas of governments and populations around the world. New biotechnology products and processes may offer solutions to a wide range of food production issues, but they also raise ethical and other challenges that concern the citizens of the world. In Canada, the federal government established CBAC to provide comprehensive advice on current policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC is also tasked with providing Canadians with easy-to-understand information on biotechnology issues, and providing opportunities for Canadians to voice their views on the matters on which CBAC is offering advice to the Government.

To fulfill part of its mandate, CBAC embarked on an ambitious schedule of expert and public consultations on GM foods three years ago. While the consultations delivered good information, solid scientific background and generalized public input, CBAC and its members recognized that some of the key stakeholder groups were looking for new, less traditional ways to be consulted and to talk about biotechnology (genetically modified foods, in particular). While the debate in Canada about GM foods was not, and is not, as polarized as that found in other parts of the world, there was a danger that strong views at both ends of the spectrum would paralyze or even shut off discussion about these topics. For instance, some environmental non-government organizations are opposed to biotechnology but recognize the need for dialogue to come to agreement upon where that opposition begins and ends. And so began a very Canadian dialogue about how to talk about the complex issue of biotechnology and how to keep the dialogue alive.

The result was the creation of a pilot project focused on developing more appropriate consultation methods and, eventually, the development of a Dialogue Tool. The tool is a simple, printed matrix that helps a group of people “unpack” one or more of the complex issues associated with products of biotechnology, such as GMFF. In the course of one to two days, participants can walk through a series of process steps and arrive at the heart of some of the most complex scientific and ethical issues likely to be considered by citizens and their governments. The tool lets them view an issue from different angles. It enables examination of a wide range of broad issues as well as specifics and narrower questions. It affords expert and non-expert inputs. It looks for alternatives. It encourages respectful dialogue and education. But most importantly, it allows the group to determine what they like, what they do not like, what they are concerned about and where they finally “sit” vis-à-vis the GM issue at hand. A real or hypothetical policy case provides the substance of the dialogue. The tool and process do not necessarily produce full consensus, but common ground is often found among participants with widely divergent interests and opinions.

The Dialogue Tool is a unique, “Made-in-Canada” public discourse device. It borrows from other public consultation methodologies and extends beyond traditional public opinion polls or focus groups. The Dialogue Tool is used to look at issues through the lens of five “considerations” or “themes” – health, environment, socio-economic considerations, ethical considerations and broader considerations such as international implications. Best of all, it was designed and tested by many of the stakeholders who had asked for new and different ways to be engaged by government on issues of biotechnology.

The Dialogue Tool is all about creating constructive discussion about biotechnology issues in Canada. Policy makers, industry leaders, not-for-profit organizations and academics can all use the tool. It can be used to inform policy making, while also serving as an educational tool. And it can be used by individual stakeholder groups or by a group of stakeholders to aid in decision-making processes. By helping to identify central issues, underlying value questions, possible solutions, areas of compromise and Canadian values, it encourages different points of view to be heard.

A committee of individuals drawn from the food producing sector, the biotech industry, growers, public interest groups (including consumer and public health groups), faith organizations and environmental groups have devoted considerable time over the past few years refining the tool and the process that it supports.

Armed with scientific knowledge and input from experts and the public, governments have and will make decisions about the future of biotechnology products and procedures in Canada. (The Government of Canada will certainly continue to protect the public with regulations based on reliable science about the health and environmental impacts of new products entering the marketplace and new biotechnology procedures.) Linked together, or independent of each other, these decisions contribute to and shape Canadian policy on biotechnology. The Dialogue Tool has the potential to inform and illuminate these decisions. It can support the public policy process and engage people from all walks of life along the way. And so far, in trials with groups both internal and external to government, it has shown a capacity for keeping dialogue participants working together and committed to a constructive dialogue.

The Dialogue Tool and the process that goes with it have been tested on single interest groups, government officials and a variety of stakeholder organizations. As such, they are still "works in progress" and are constantly being adjusted as we learn more about how to use the tool and how to make it more effective.

2

AN ORIENTATION GUIDE TO THE DIALOGUE TOOL AND PROCESS

Why an Orientation Guide?

This orientation guide is intended to help you understand how the tool evolved, where it is useful, how to think about what true "dialogue" means and how to encourage public debate about controversial issues like GM foods.

It will provide you with some of the background you might need as a dialogue organizer, participant, or facilitator, and will help you manage an effective dialogue about biotechnolgy issues. In time, with input from stakeholders, CBAC plans to further develop this orientation guide and produce a step-by-step User Guide. The orientation guide provides useful background and orientation materials, sample policy cases, simple explanations of the dialogue process, testimonials from participants and copies of the Dialogue Tool itself.

It has been designed to help you start thinking about the Dialogue Tool, in its current format, and how useful it would be in helping to manage public consultations or expert discussions about GMFF or other biotechnology issues. The guide provides a sense of the high-level thinking and philosophy applied by CBAC's Exploratory Committee (EC)[1] as they developed and tested the tool. While the EC and CBAC still consider the tool and process to be "works in progress" they are enjoying more and more positive feedback from those who have used both in test situations. The feedback comes with valuable input about how the tool could be improved or used differently.

Thinking About the Dialogue Process

As you use the orientation guide, or eventually try out the Dialogue Tool, keep in mind that the goal is not necessarily to achieve consensus but to inspire and encourage dialogue, to bring different viewpoints to the table and to share expertise and perspective. In some cases, people using the tool have changed their minds or admitted that they learned something new. And sometimes consensus has been achieved. Most people said the dialogue was worth it for what they learned, how they were able to listen to others, and how free they were to put their own views forward. Participants have also commented that they are able to break down complicated, often highly scientific, information so they can become more comfortable about their level of understanding and appreciation of the many impacts of new technologies.

In an important sense, this is intended first as a 'Dialogue Tool' not a formal 'consultation tool', i.e. it is designed to provide outcomes and benefits for all participants, whether as new learning or insights, appreciation of other significant views and rationale, increased confidence that constructive and respectful dialogue is possible, and the potential for convergence on promising ways ahead or even solutions. This does not preclude the use of the Tool/Process in formal consultations to provide response and advice to a consultation sponsor on policy questions/choices, but the first priority is to the round table exchange among participants.

1 See Appendix 9 for a list of Exploratory Committee members.

This guide will aid understanding of the concepts and philosophy behind the Dialogue Tool so it can be used to its best effect. The Dialogue Tool itself is fairly straightforward, but there are twists in the road that may need further clarification. The guide offers some helpful prompts and ways to follow the logical flow of the dialogue process. It can also help you decide when and how to the use the tool, where to start and where to end. Further, the guide is packed with tips and reference materials that participants, organizers and facilitators can use or adapt for their own purposes.

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THE DIALOGUE TOOL MODEL AND APPROACH

What is the Dialogue Tool?

The Dialogue Tool is a printed matrix or grid, with strong visual components that aid understanding and dialogue (see Appendices 6 and 7). The tool includes a "spectrum" that is designed to help people figure out the degree to which they find a biotechnology product, acceptable, or not in the Canadian context. The tool uses comparative terminology (e.g. "acceptable/supportable/beneficial/desirable" through "unacceptable"), as well as colour to differentiate those degrees of support. In some ways, the Dialogue Tool provides a "temperature reading" of the views about a specific biotechnology product. It also allows stakeholders with different points of view to build bridges between their respective positions.

The dialogue approach involves a 6-step process, guided by an expert facilitator, where participants explore all dimensions of a biotechnology product case study, including its features, risks and benefits, issues and implications, and then propose summary observations and suggestions on the future for the case example. In this approach, participants discuss ideas in small groups, exchange views in plenary session with the whole group, note their opinions in individual survey instruments, and record their individual views in a private workbook as appropriate.

Definition of GM/GMFF

For the purposes of this dialogue approach, the focus is on a case study of genetically modified crops and livestock for food, and feed (either as individual products or classes of products). This has been shortened to 'Genetically Modified Food, and Feed', and in this document will be represented by the acronym GMFF. As it is commonly understood, the term "genetically modified" refers to food or feed that has been produced using recent advances in gene technology, such as cloning, gene splicing and the introduction of single genes into plants (or animals) through a process called transformation. These and other techniques are often collectively referred to as recombinant DNA (rDNA) technology and they define a set of tools for "genetically engineering" organisms (e. g. plants, animals and bacteria). The dialogue approach will generally focus on cases that are the result of such genetic engineering as defined here.

Five Ways to Look at a GMFF Policy Case Study

More importantly, the tool and the dialogue process help people break down or "unpack" what would appear to be a highly complex and often confusing subject matter. Specifically, participants using the tool are challenged to look at a real or hypothetical policy case study through the lens of five different themes – health, environment, socio-economic considerations, ethical considerations and broader societal considerations.

With the help of a facilitator, participants take a first pass down the matrix and create "profiles" for the sample policy case under each of the five consideration areas.

While the focus of the case study is on food products modified using rDNA techniques, the developers of this Tool are aware that many other new and traditional techniques are being used to modify food and feed products. It should be understood that similar issues exist for all techniques used in the modification of food and this tool can be used to help the open discussion of these issues, regardless of the modification technique under discussion.

In a second pass, participants identify the issues arising from these profiles. On a third pass, they begin to consider the policy case in terms of its risks and benefits and the apparent "trade offs" that emerge. Eventually, they are asked to comment on the "acceptability" or "supportability" of the policy case based on what they have now learned or explored by moving through the dialogue process. Throughout the dialogue, participants will move between assessing specifics of the case and a range of broader issues derived from the case and arising from the area of GMFFs, and back again.

The Dialogue Tool considers a spectrum of possible outcomes for each consideration theme – acceptable/supportable/beneficial/desirable; acceptable with certain conditions; unacceptable at the present time and until more is known or a given standard is met; or not acceptable under any circumstances. A real world parallel to the category "not acceptable under any circumstances" might be an unconditional prohibition (i.e. a ban). "Not acceptable until more is known" might be likened to a moratorium.

Toward the end of the dialogue, the group explores possible conditions that could affect the receptivity of the case in question. Participants work together to determine if there are **conditions for acceptability** and what those conditions might be, both for each consideration area and for the case overall. They also 'test' the conditions to ensure that it is realistic to expect the case proponent or other key parties involved to achieve the conditions, and then contemplate which conditions are most critical to confirming or improving acceptability.

The last stage looks at 'promising directions' including suggested conditions, new thinking on solutions to mitigate problems that were identified, and guidance on further work that could improve understanding and subsequent societal dialogue on the policy case.

Throughout the process, participants will be informed by background information provided on the case prior to the dialogue session and/or by the contributions of participants who may have factual knowledge and experience related to the case. As well, perceptions may be important to understanding how the case is viewed and influences society, or they may clarify where more facts or research may be needed, or to indicate what we know is all we can know at that point. Hence, facts and perceptions will both have a place in the dialogue, with varied relative importance at different stages of the process.

It is a challenge in any dialogue process, especially involving complex subjects such as GMFFs, to balance discussion between the topic at hand and broader societal issues without shortchanging either. To some participants, it is most desirable to focus discussion on the issue/case at hand. They feel that enlarging the debate beyond case facts (e.g. health/safety issues) only confuses the dialogue. To others, it is difficult, if not impossible, to discuss a policy issue without a larger societal/systemic context.

This question should be clarified by clear agreement beforehand on what the dialogue session is focused on and trying to achieve, i.e. if the objective is feedback on the **case** then a predominant focus on the case is desirable; however if the goal is to understand the concerns for how a case is dealt with in the developmental and regulatory **system** then a focus on the system is warranted; and if the intent is to explore and appreciate the larger **societal context** and the impact of GMFF's then a larger view focus is desirable. The predominant focus selected will also affect the focus, tangibility and influence of improvements and recommendations that a dialogue group might suggest.

The following are the main steps in the dialogue process and the key questions that need to be explored at each stage. A facilitator will guide the discussion throughout, either in small break-out groups or in a full plenary session.

Table 1 (next page) outlines the basic steps in the dialogue process, which an experienced facilitator will lead you through. At each step, there are specific tasks you will be expected to undertake which will lead you to the final outcome at the end of the session. Prior to the session, the facilitator will review the optional added and/or optional methods to determine the best method to employ to successfully work through each step with

Dialogue Tool – Five Considerations

Human Health - Includes toxicity, allergenicity, nutritional value and potential long term impacts on health (e.g. effect on obesity levels, dietary habits, etc.). These considerations may apply to the population as a whole, or to specific sub-groups.

Environment - Includes effects on biodiversity, pollution and sustainability, including effects on targeted and non-targeted species, changes in biological/ecological fitness such as outcrossing [i.e. pollens crossing from one crop to another], or invasiveness.

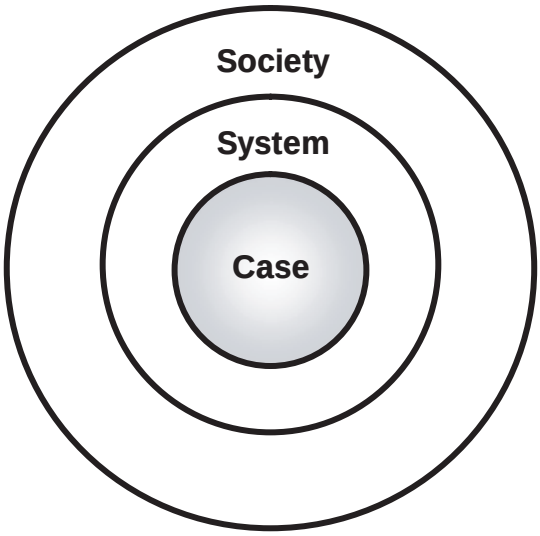
Socio-economic - Economic effects include trade, costs/benefits, productivity, education, economic growth and economies of scale. Social effects include distribution of income, effect on small and large farms, regional effects and consumer choice.

Ethical[2] - Includes ethical or moral concerns such as justice, magnanimity, animal welfare, use of precaution, "due diligence", accountability, transparency, enabling choice, utilization of and access to new knowledge/ technology, meaningful participation of affected parties, and acceptable use of the technology in manipulating life.

Broader/Other - (Societal interests and international considerations) - Includes international relations, distribution of risks, costs and benefits, effects on the developing world (benefit sharing, centre of origin [i.e. the original, geographic source of a plant], food security), empowerment, trade, globalization (sovereignty, democracy, power imbalances), knowledge and technology development, and compliance with related international agreements/accords.

2 For the purposes of the Dialogue Tool, the term "ethics" is understood as a widely held system or set of principles/beliefs which provides the framework within which to make moral choices for the public good. "Values" refer to those qualities, properties or ideals deemed important, desirable, or of worth and which are/may be applied to questions of choice throughout the dialogue tool/process. Relative to ethics, the term "values" refers to commonly held moral qualities or properties deemed of worth or importance, used as criteria upon which moral decisions are/can be made. For example:
- **Ethic of equality -** all are equal; none is less equal.
- **Value of inclusion -** everyone's participation is ensured and respected, and each perspective is considered in decision-making.
- **Ethic of sustainability -** of the Planet and its resources; human life in harmony with nature and not compromising future of generations to come.
- **Value of restoration and preservation -** of a natural resource such as water, taking into account social, economic and environmental impacts of actions.

you; at the session, the facilitator may use a different method depending on factors such as the progress of the dialogue and the group's frame of mind . See Section 4 for a detailed overview of how you'll step through your dialogue process.



When to Use the Dialogue Tool

The Dialogue Tool has a variety of potential uses, but is principally designed to support expert and public consultation initiatives, policy development, dispute resolution, position development and public education activities. Even though the Dialogue Tool is still a work in progress, it shows promise as a support tool that can:

- map out or "unpack" a complex policy issue
- assist governments with helping inform and shape broad public policy
- help specific stakeholders to inform their own processes (e.g. research and development, strategic planning, position clarification)
- act as an educational tool to help improve understanding and generate potential solutions to the difficult challenges faced in the debate on biotechnology issues
- break down a complex issue into its component parts
- characterize the attributes that make a products of biotechnology more or less desirable/acceptable/beneficial to Canadian society
- aid in understanding the science behind an issue
- highlight the social and economic benefits and risks
- examine ethical issues
- explore the linkages with Canadian values
- consider the potential trade offs or conditions under which citizens would find a product or procedure to be more "acceptable"
- bring opposing viewpoints to the table and engage stakeholders who would not normally have the opportunity to examine an issue collectively
- establish common language
- help set goals for a dialogue
- explore solutions (i.e. identifying the promising directions or options for policy)
- capture observations/advice for further dialogue

It is important to clearly identify the purpose, scope and desired outcomes of a particular dialogue prior to holding a session. This preparation will help you determine if the Dialogue Tool is the best device to use for your dialogue and will allow development of an optimum session design to successfully achieve your stated goals. For instance, the scope of a dialogue may be different if the ultimate goal is education, or analysis, or the development of policy recommendations/options/future direction. And, the process requires plenty of time, often in separate phases, to allow learning to occur.

Table 1: Dialogue Tool Primary Process Steps

Primary steps	Optional added and/or alternative methods
Step 1: Defining Qualities and key features of the GMFF case study	• Risks and benefits analysis • Alternatives analysis
Step 2: Identifying issues	
Step 3: Defining risks and benefits	• Risk analysis (probability and impact) • Alternatives analysis • Weighing risks and benefits • Trade off analysis • 'What if' scenarios • Triple bottom line assessment • Sustainability Impact Assessment
Step 4: Using the Tool's Spectrum	• Assess position on spectrum at start of session, then just after defining risks and benefits (assess position for all 5 consideration areas), then after conditions have been proposed (assess 5 consideration areas and overall position) (using different ways to express degree of acceptability)
Step 5: Determining conditions for acceptability	• Assess confidence level in conditions • Explore 'what if' scenarios and how different conditions/recommendations might affect the risks, benefits, trade offs and acceptability • Assess position on spectrum after conditions defined
Step 6: Exploring promising directions (conditions, solutions, advice to the dialogue sponsor, next dialogue)	• Evaluate the dialogue and process

"Absolutely essential to Canada's ability to move forward."

— Government of Canada official
and dialogue participant

A Note about Government Regulation of

The Dialogue Tool is very flexible and could be used in support of many different expert and public consultation initiatives, policy development, dispute resolution, position development and public education activities. It was not designed to create regulations for new or existing products and procedures and is not meant to evaluate products that are moving through the regulatory system, or to 'second guess' the regulatory system by introducing another step in the current regulatory process.

Canada's regulations for products of biotechnology exceed those established by the World Health Organization (WHO) and the Organization of Economic Cooperation and Development (OECD). The determination of whether products or procedures are allowable in Canada is based on health and safety considerations that look at hard scientific data and the impact on health and on the environment. Before any product is authorized for introduction into the Canadian marketplace, it must clear the foundation level of legislative regulatory standards (e.g. the mandatory Food, Feed and Environmental Safety Assessment imposed by the Canadian Food Inspection Agency).

The Dialogue Tool is more geared to informing and supporting policy development, and in no way replaces the regulatory systems that aim to protect Canadian consumers.

Roles in the Dialogue

The dialogue process, as designed by a committee of interested stakeholders with support from CBAC, requires a number of key actors or requisite conditions. First, the process needs a sponsor or an organization that is willing to do the legwork required to create an environment for dialogue. Whether through a multi-party planning group, a stakeholder group or as an independent organization, someone must set the parameters and goals for the dialogue and determine who will participate. The sponsoring organization must be very clear about its objectives (e.g. is this a short, tightly focused dialogue or a more wide-ranging inquiry?) and has to ensure that all of the support tools are in place (e.g. orientation materials, policy case information, copies of the Dialogue Tool).

While dialogue cannot happen without participants, the nature of the dialogue can vary depending on the diversity and range of opinion within the participant group (i.e. are participants from one organization or from different stakeholder groups across the country?) Industry and government representatives will also bring their own perspectives to the dialogue. Expert and non-expert participants can work just as easily with the tool, but decisions have to be made about whether they work together or separately. (NB: The Rules of Engagement (see page 17) for the Dialogue Tool encourage people to leave their titles and traditional roles at the door. The EC members who tested the tool found that while expertise helps, dialogue sessions were more lively and productive when participants contributed as interested citizens with strictly personal views.)

The role of participants is key to successful dialogue. Participants must be willing to respect the dialogue process (e.g. design of session, time factors, etc.) and each other. They must also be willing to work to constructively advance the dialogue through active listening and contribution and by managing their personal expectations of the dialogue and the session.

The dialogue process requires competent facilitation support. One or more facilitators are required to design and manage the process flow and to document input from participants.

It is often helpful to provide background information on the case prior to the dialogue session This information should be provided only where it is relevant, unbiased (or with biases acknowledged) and will contribute positively to the dialogue. It should be provided to all participants far enough in advance of the dialogue to allow ample time to review and understand the

information. It is not necessary to provide full copies of all materials if the sponsor is able to show participants where to access the information themselves.

Lastly, given that biotechnology issues, such as the GMFF case study are complex, rooted in technical and scientific elements, participants may express a desire to have 'experts' available to them during a dialogue. While it is often helpful to provide background information on the case prior to the dialogue session, the presence of experts is more likely to stall a dialogue rather than help it as competing experts and their constituent sciences can create a paralysis of theories or models (in this context, we are not defining government regulator representatives as external experts as they may be necessary to explain how the regulatory process works and/or how it applies in the particular case discussed). One of the distinctive features of the Dialogue Tool is that it is 'participant-centred' and does not rely on the presence of experts to move a dialogue along. The tool process depends on participants to provide any expertise and information that is required during a dialogue. When necessary, the facilitator and other participants will seek contributions of participants who may have factual knowledge and experience related to the case.

As well, the tool recognizes that perceptions may be important to understanding how the case is viewed and influences society, that they may clarify where more facts or research may be needed, and that they might indicate what we know is all we can know at that point. Hence, facts and perceptions will both have a place in the dialogue, with varied relative importance at different stages of the process.

The facilitator must ensure that balance is achieved in the dialogue between ensuring factual dialogue and allowing the need for too many scientific facts to dominate the discussion. This issue will never be straightforward and how it is addressed may be different depending on the situation but it cannot be ignored or treated lightly.

Developing a Policy Case

To date, the Dialogue Tool has mainly been tested with hypothetical biotech products and procedures that are, nevertheless, scientifically credible and viable. Still, the development of a one- or two-page policy case that is compelling and will inspire debate is challenging. Sponsoring organizations should contact both experts in the field, or the stakeholders they hope to engage in the dialogue, to determine what topic, or what aspect of a topic, will produce a meaningful

"The principle that all participants have equal value is important. The process that is used should result in some clear understanding of larger views at the end of day and should be helpful regardless of the issue being discussed."

— Government of Canada official and dialogue participant

The Spectrum

As mentioned previously, the Dialogue Tool is essentially a graphic grid that allows dialogue participants to position, or map, their views within a range – from full support through to complete rejection of the product proposal. A colour code has been assigned to the spectrum too, so participants can talk about their feelings of support or unease in terms of a gradation or shades of a colour. The red end of the spectrum indicates a larger degree of caution, while the blue end of the spectrum allows for more support.

- **Fully Acceptable, Supportable, Desirable, Beneficial, etc. [deep blue to green]:** Outcomes are improved or similar on balance to existing products or practice. Meets existing standards, either no new risks/issues are introduced or are offset by a greater reduction in an existing risk/issue.
- **More Acceptable with conditions [dark green to yellow]:** Generally the policy case is viewed favourably, but participants have identified conditions or "must haves" that would improve their overall opinion about the case and allow them to endorse its forward progress.
- **Less Acceptable until certain conditions are met or more is known [yellow to orange/red]:** The risk is considered too high to be acceptable under present circumstances. Depending on the benefit/risk scenario, certain conditions may be required. Conditions may be imposed to mitigate or eliminate the risk.
- **Not acceptable, etc. under any circumstances [light red to deep red]:** Evidence of harm is conclusive and serious (i.e. destructive and irreversible, that cannot be offset by any other benefit.)

debate. During the design of the tool and process, the EC commissioned policy cases – many of them real – from experts with reliable scientific knowledge and a capacity to express the public policy dimensions of an issue.

It is important for participants to understand that the real or hypothetical case before them has either already passed or would likely pass Canada's stringent regulatory hurdles that set standards for health or environmental impacts, i.e. that the case ability to meet government regulations is not at issue in the dialogue. Furthermore, the Dialogue Tool is not intended to help shape or amend existing regulatory procedures, nor is it meant to "second guess" those standards.

Participants should also be informed of the dialogue topic well in advance of the actual session, and copies of the policy case should be forwarded along with other orientation materials. Where possible, expert advisors should be invited to provide on-site support to participants, or access should be provided to on-line resource materials that can confirm certain scientific information during the course of a dialogue.

A sample list of policy case topics developed by the Exploratory Committee is available in Appendix 3.

For more background about the Dialogue Tool, see Appendix 1.

"The Dialogue Tool is a great response to a huge challenge and it holds real promise. This session illustrated that people can reason together, learn and choose direction together."

— Government of Canada official and dialogue participant

"Participants were respectful of each other, even when there was controversy."

— Ellen Desjardins, M.H.Sc., RD,
Public Health Nutritionist, Region of Waterloo Public Health (EC Member)

4

PROCESS STEPS

PROCESS STEP	FOCUS	KEY QUESTIONS	WORKSHEETS
Preliminary Preparation *Getting Ready for the Dialogue*	The parameters of the dialogue are set, participants and their roles are determined, the policy case is selected and logistic and facilitation plans are initiated.	• What are we trying to achieve with this dialogue? • What are the outputs or products expected from this dialogue? • What is the scope of the dialogue? • How much time is set aside for the dialogue? • Who are the participants?	See Session Agenda and Participant Guide.
Session Introduction *Review Session Objectives, Process and Rules of Engagement*	The scope and objectives of the dialogue are reviewed, participants' roles and expectations are clarified, a general overview of the Dialogue Tool and its process are given and the rules of engagement are reviewed.	• Are we comfortable with the objectives set for this session? • Is the dialogue process clear and understandable? • Can we agree to actively use and follow the rules of engagement? • What are we trying to achieve with this dialogue? • What are the outputs or products expected from this dialogue? Who will receive or use the results, and for what purpose? • What is the scope of the dialogue? • How much time is set aside for the dialogue?	See Participant Guide.
Case Introduction *Overview of the Case*	A general overview of the policy case is conducted to confirm participants' understanding of it.	• Is there any clarification of the case needed?	See worksheet 1 (For samples of all worksheets, see Appendix 11).
Step One *Identifying Qualities and Key Features of the Case*	By ascribing qualities or key features to the product or process proposed in the case study in each of the consideration areas, a high-level, general view of the policy case is achieved.	• What are the qualities/key features of this policy case? • Are they unique to this case? • What features are more acceptable to Canadian society and, therefore, would favour use/adoption? • What are features less acceptable to Canadian society and, therefore, would argue against use/adoption? • What specific population groups are affected and how? • Is additional supporting information required to better understand and substantiate the feature profiles? • Is additional supporting information required to better understand and substantiate the feature profiles? • What additional information do you recommend (whether the information is factual or perceptual)?	See Worksheets 2-6.

PROCESS STEP	FOCUS	KEY QUESTIONS	WORKSHEETS
Step Two *Issue Identification*	The most critical issues from Step One are ranked, and public/societal expectations to address these issues are considered.	• What are the most critical issues? • What are the issues in each consideration area? • What are the pros and cons under each consideration? • What is the issue really about? • Which issues are the most critical and why? • What does society expect should be done and who should do it?	See Worksheets 2-6.
Step Three *Defining Risks and Benefits*	After reviewing output from the previous steps, the risks and benefits under each consideration are considered. Participants also identify the populations most likely affected by each.	• What are the risks and benefits in each area, given the profile of qualities and issues? • Is there sufficient supporting information to understand and substantiate the risk/ benefit profiles? • Are there population groups particularly affected? **Optional Questions** • How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks? • What are the trade offs that emerge when we weigh/compare the risks and benefits? • Which of these trade offs is most compelling?	See Worksheets 2-6.
Step Four *Using the Dialogue Tool's Spectrum*	The policy issue is positioned on the colour spectrum and given an overall rating regarding its acceptability or supportability.	• Given what we have learned/understand about the case at this point, on balance, for each area of consideration, which spectrum position/colour/language best fits this case? • Optional - On balance, which spectrum position/ colour/language best fits this case overall?	See Worksheets 2-6.
Step Five Determining Conditions for Acceptability	Assuming there is significant interest expressed in the middle zone of the spectrum in step 4 (green to yellow to orange colour range), the group may proceed to identify the conditions, for each consideration area (e.g. health, socio-economic, etc.) that would affect the acceptability of the case and to synthesize or combine these area conditions into an overall list.	What are the conditions or requirements that would raise confidence in the acceptability of this case or clarify its fit on the spectrum? • What are the conditions derived from each area of consideration? • How would we combine these into an overall list? • Is each condition achievable? Is each condition within the control and influence of the relevant party (e.g. case proponent or other selected party)? How can we revise the conditions to enhance the probability of achievement? • Which of these conditions are most critical to acceptability? Which would help advance acceptability (e.g. move left some degree on the spectrum)? • What are the specific actions and responsibilities to give effect to these conditions?	See Worksheets 2-6.

PROCESS STEP	FOCUS	KEY QUESTIONS	WORKSHEETS
Step Five (cont'd) *Determining Conditions for Acceptability*	Participants will also test the conditions for probability of achievement, i.e. to ensure they fall within a reasonable range of control and influence by the case proponent or other involved parties, and revise as needed, and rate the conditions as to which are most critical to confirming or improving acceptability If desired, this step ends with participants conducting a re-assessment of their position on the spectrum (for comparison with position in Step 4).	• Given the application of the proposed conditions to this case as defined to this point, on balance, for each area of consideration, which spectrum position/colour/language now best fits this case? • Given application of the proposed conditions, on balance, which spectrum position/ colour/language now best fits this case overall? • Are there conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?	
Step Six *Exploring Promising Directions*	Conditions, solutions, and/or next steps to advance both the understanding of the policy case and the dialogue are discussed.	• Are there promising directions that could be explored to advance solutions or mitigate problems? • What useful next steps might enable further in-depth understanding and dialogue on the case? • Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance)? • How could this dialogue process on this case benefit others (e.g. by contributing to policy development or in helping to educate others)? • What are the real opportunities associated with this policy case? Where are the real problems?	See Worksheet 7.
Debriefing *Evaluating the Dialogue Process*	Debrief the experience drawing out impressions, lessons and potential applications elsewhere.	• What worked in the session and what could be improved? • What impact did this dialogue have on you? • What lessons did we learn about the dialogue process and the Dialogue Tool and how might we improve it in the future? • Do you see other cases or situations where the approach and tool might be useful?	See Worksheet 8 and Appendix 8.

Each process step is outlined in detail below and includes an explanation of the step as well as tips for session participants, facilitators and organizers.

PRELIMINARY PREPARATION – Getting Ready for the Dialogue

Key Questions

- What are we trying to achieve with this dialogue? Are we trying to open up an issue or break it down? Are we starting a public consultation process? Is the dialogue intended to support a public policy development process? Are regulations already in place concerning this policy matter or procedure?
- What are the outputs or products expected from this dialogue? Who will receive or use the results, and for what purpose?
- What is the scope of the dialogue? Will it deal with one very specific biotechnology issue or a whole range? Is the dialogue intended to go into a lot of detail or just frame the issues?
- What is the focus of the dialogue? Is it a case, or a system view or the societal context for GMFFs/Biotechnology?
- How much time is set aside for the dialogue? Could the dialogue continue beyond one day or have only a few hours been set aside?
- Who are the participants? Do they already know each other/work together? Are they random members of the public? Or are they a group of stakeholders with diverse opinions?

Experience with the Dialogue Tool shows that much depends on the effort put forth prior to the dialogue session. Good preparation by dialogue organizers, facilitators and participants will result in a more effective and productive dialogue.

Purpose of this Process Step

Getting everyone ready for the dialogue is absolutely crucial. Steady and **clear communications** with participants and solid planning are a must. It is important that the following key activities occur before the dialogue starts:

- Establishment of the **parameters and/or objectives** of the dialogue session. Those who are organizing a dialogue need to ask the following questions:
  - What are we trying to achieve? Are we trying to open up an issue or break it down? Are we starting a public consultation process? Is the dialogue intended to support a public policy development process? Are regulations already in place concerning this policy matter or procedure?
  - What are the outputs or products expected from this dialogue? Who will receive or use the results and for what purpose?
  - What is the scope of the dialogue? Will it deal with one very specific biotechnology issue or a whole range? Is the dialogue intended to go into a lot of detail or just frame the issues?
  - What is the focus of the dialogue? Is it mainly on a proposed GMFF case, or on the system of development and regulation surrounding the case, or on the societal context for GMFF?
  - How much time is set aside for the dialogue? Could the dialogue continue beyond one day or have only a few hours been set aside?
  - Who are the participants? Do they already know each other/work together? Are they random members of the public? Or are they a group of stakeholders with diverse opinions?
  - Is there a long-term goal to keep participants in touch with each other through a sustained network? Will they pursue more detailed or different dialogues in the future?

- How will the group capture the output of the dialogue?
- How will the group be able to satisfy themselves that they have completed what they set out to do?

- **Identification of participants** (see Roles in the Dialogue).
- **Determination of the policy case** (real or hypothetical) that will be considered by the group.
- **Early contact** with selected participants and confirmation of their willingness to participate.
- Communications with participants about the location and timing of the dialogue, along with the provision of a proposed agenda and general orientation materials (see Resources on the following page).
- Distribution of the **Rules of Engagement** (refer to page 21) to all participants that will generally help to guide their comportment and approach to their personal participation in the dialogue. (NB: These Rules are suggestions and can be elaborated on by group participants just before the dialogue starts).
- Selection of an issue for the dialogue and the development of a policy case study (usually by subject matter experts) that can be distributed to participants as much in advance as possible.
- **Development of a facilitator's plan**, including the review/preparation of sample support tools (e.g. worksheets) and the development of situation-specific tools for participants (e.g. specific backgrounders).
- **Logistics preparation** (e.g. preparation of an agenda, room booking, audio-visual support, translation services, seating plan, etc.).

Facilitator Tips

- Review both the **Rules of Engagement** and the policy case study.
- Plan ways to ensure that the dialogue gets to the end goal set by the organizers/client.
- Consider methods to ensure dialogue participation in plenary, small groups and individually (e.g. using individual survey methods).
- Determine a small group seating plan that will provide a maximum mix of stakeholders in each group. This it to allow good exchange among stakeholders with varied views and opinions, and to encourage broadening individual and group understanding of the case.
- Delegate discussion topics to the small groups (i.e. do not allow the groups to choose the topics they prefer) in order to move participants out of their "comfort zones" and into broader dialogue.
- See Appendices 4 and 5 for examples of a facilitator guide and table facilitator guide.

Participant Tips

- Informed and knowledgeable participation from the participants in the dialogue is key to its success.
- In advance of the dialogue session, read and contemplate the orientation materials (i.e. Getting Ready for Dialogue, Participant Guide, Rules of Engagement, the Dialogue Tool, the backgrounder, etc.).
- Review and carefully consider the Rules of Engagement.
- Read the policy case study and make some notes.
- Conduct your own research and ask for the opinions of others before attending.
- When you come to the dialogue session, bring your orientation materials with you as they will be used throughout the session.

Organizer Tips

- Make sure **materials**, including the policy case, are mailed, faxed or e-mailed to participants well in advance of the dialogue event.
- Ensure you have engaged a **top quality facilitator**.
- Be clear about the **objectives** of your dialogue. It may be that you only have time to scratch the surface of the issue, but plan for ways to make people see that they have made a real contribution in whatever time is available.
- Book a **bright and open space** for your dialogue with room for break-out tables, but also the capacity to manage plenary sessions that keep everyone close and involved. Be sure that you have all audiovisual requirements in place.
- Consider having a **subject matter expert** on hand to answer questions.
- Whether you are using a trained facilitator or not, it is a good idea **to orient or train your own staff** about the dialogue tool and process before the actual dialogue session.
- A **dry run** is also a good idea.
- On the day of the session, ensure that the room set-up is accurate and that all flip charts, AV equipment and dialogue materials are on-site and functioning properly.

Resources for this Process Step

- Dialogue Tool (Full version and Overview version)
- Orientation Materials: *Getting Ready for a Dialogue Backgrounder* (see Appendix 2), *Dialogue Tool Backgrounder* (see Appendix 1), Rules of Engagement, biographical information about presenters, facilitators and experts.
- Policy case study
- Information about the Dialogue Tool posted on the CBAC web site at *http://www.cbac-cccb.ca/*.

SESSION INTRODUCTION –
Review Session Objectives, Process and Rules of Engagement

Purpose of this Process Step

The purpose of step one is to provide a general overview of the Dialogue Tool and process.

The facilitator will review the session objectives, and run through the dialogue process to provide participants with a broad understanding of the parameters, scope and objectives of the dialogue. Some time will also be spent to clarify the roles and expectations of the different participants, including the facilitator, participants, experts and any others. The facilitator will also review the Rules of Engagement or the code of conduct for the dialogue with participants.

Key Questions

- Are we comfortable with the objectives set for this session?
- Is the dialogue process clear and understandable?
- Can we agree to actively use and follow the rules of engagement?
- What are we trying to achieve with this dialogue?
- What are the outputs or products expected from this dialogue? Who will receive or use the results, and for what purpose?
- What is the scope of the dialogue?
- How much time is set aside for the dialogue?

Facilitator Tips

- Open the session by reviewing the importance of the Rules of Engagement (adding and refining them as appropriate) and the need to allow for an open, honest exchange of information and ideas.
- Remind people that their contributions and **participation will not be attributed** to their organization, nor will their personal interventions be attributed in the record.
- Encourage people to leave their organizational titles and firm stances at the door. Try to have people participate as average citizens while informed by their experience and knowledge of the subject.
- Introduce the Dialogue Tool – the Brief Overview version is best used earlier in the day when introducing the tool and the process.
- If it appears that participants have not reviewed their materials and the policy case in advance, either allow time for that reading or engage someone from the group to provide an overview.
- Participants may come to the dialogue with different expectations around the scope of the case and its associated issues. Early in the dialogue, orient participants to the idea that the process will cover both the specifics of the case and a wide set of broader issues. As the dialogue progresses, the dialogue will shift from narrow to broad and back again depending on the step in the process, the area of consideration and the case. (Also see pages 6-7.)

Participant Tips

- Consider and understand your responsibilities and those of other participants and the role of the facilitator and any expert resources present.
- Ask the facilitator to **clarify process issues** if you have concerns.

Organizer Tips

- Depending on the size of your group, make provisions for small break-out tables.
- Help the facilitator set up the flip charts where everyone can easily see and review them.
- Ensure that all AV equipment is set-up and functioning properly, with the appropriate presentations cued.
- Help the facilitator identify participants in the room with comments or questions.
- Make sure there are plenty of copies of the Rules of Engagement, the policy case and the Dialogue Tool Spectrum.
- Remind participants that there is an Evaluation Form that should be completed before the end of the day, or ask the Facilitator to provide this reminder.

Resources for this Process Step

- PowerPoint presentation about this process step (see Appendix 10 for a sample presentation)
- Session Agenda
- Rules of Engagement
- Participant Guide
- Flip charts (one for each consideration area and one for a Parking Lot)
- Dialogue Tool

NB: Samples of these resource tools are appended to this guide.

RULES OF ENGAGEMENT

The following rules of engagement will help create a dialogue setting that encourages a balanced, candid and constructive exchange about issues. The dialogue session will begin with a review of the Rules of Engagement to ensure that all participants are comfortable and in accord about how they will work together.

- **Participate Fully –** You should participate to the best of your abilities. You are here because you have something to add to this dialogue and because your views matter. We need you – and all of the participants – to engage fully, according to your conscience and from your own knowledge and experience. You should draw upon your beliefs, express your uncertainties, and utilize the knowledge base and interests of your constituency or organization to contribute to the session's objectives.
- **Open Dialogue –** Dialogue participants should participate in a thoughtful and constructive manner and help create an open, balanced and respectful dialogue by:
  - proceeding in a spirit of openness and collaboration;
  - sharing factual and substantive information that can illuminate the discussion; and
  - speaking candidly.
- **Mutual Respect –** Respect is key to making this process work. Everyone should have the opportunity to express their views and opinions. We all need to listen carefully in order to understand the different perspectives being expressed and the factors that have shaped beliefs and views on these issues. This is the key to finding balanced solutions. We can try to:
  - proceed in a spirit of mutual respect;
  - not make assumptions but listen to, respect and attempt to understand the points of view, motivations, beliefs and rationales of the other participants; and
  - respect the candidness of others and use care in representing the interactions and individual opinions of others.
- **Find Common Ground –** The Dialogue Tool is designed to help participants identify common ground among a diverse set of opinions and interests. Some form of consensus is usually the goal, but as reasonable people, we know that full agreement may prove elusive. In successful dialogue sessions, participants endeavour to seek agreement and convergence, with the goal of producing a report identifying the points of agreement, differences in principles, and unresolved matters discussed during the dialogue.
- **No Attribution –** Dialogue participants will not attribute any comments and/or views of participants after or outside the dialogue session to protect the spirit of candid and open exchange.
- **Prepare in Advance –** Dialogue participants agree to prepare for the session by reviewing all background, sample policy cases and orientation materials carefully.
- **Personal responsibility -** Dialogue participants are responsible for their own behaviour and input. This responsibility includes:
  - Respecting the process (attention to time, focus at each step, design of session)
  - Respecting each other
  - Helping to constructively advance the dialogue
  - Active listening and active contribution
  - Managing one's own expectations and contributing to meeting the session expectations

NB: Experience with the Dialogue Tool shows that each participant group will want some flexibility to adjust or tailor the Rules of Engagement according to the needs of the group and the situation/environment surrounding the dialogue.

CASE INTRODUCTION –
Overview of the Gentically Modified Food and Feed Policy Case

Key Questions

- Is there any clarification of the case needed?

Facilitator Tips

- Provide a general overview of the policy case. Ask participants to share their questions and understanding of what the case entails.
- If it appears that participants have not reviewed their materials and the policy case in advance, either allow time for that reading or engage someone from the group to provide an overview. NB: In some cases, you may wish to allow a knowledgeable presenter to bring more detailed scientific information or explanations to the group (e.g. with respect to the workings of the regulatory system).Use sample PowerPoint to facilitate understanding of each step.
- If desired, assess participants' position on spectrum at start of session before dialogue begins. This assessment will provide the basis for comparison at Step 4 and at end of step 5 (see step 4 for approach).

To ensure a common understanding of the facts of the policy case at hand, the facilitator will provide a general overview of the policy case being used for the dialogue discussion, and confirm participants' understanding of the policy case that will be considered by the dialogue group. One or more experts may be on hand to assist in answering participants' questions about the facts of the policy case.

Throughout the process, participants will be informed by background information provided on the case, by expert resources that may be present to respond to queries/ clarifications, and by the contributions of participants who may have factual knowledge and experience related to the case. As well, perceptions may be important to understanding how the case is viewed and influences society, or they may clarify where more facts or research may be needed, or to indicate what we know is all we can know at that point. Hence, facts and perceptions will both have a place in the dialogue, with varied relative importance at different stages of the process.

Optional: Before beginning an in-depth discussion of the session case/topic, the facilitator may ask participants to indicate their 'position' on the spectrum. This exercise will be undertaken again in Step 4 and at the end of Step 5 for comparison to build understanding of whether and how participants have moved in their thinking on the issue at hand. See Step 4 for approach.

Participant Tips

- Review the case beforehand and identify any aspects that may need clarifying.
- Ask the facilitator to **clarify the facts of the case** if you have concerns.
- Ask for more clarification from experts in the room, if they are available.
- Use the worksheets provided to sort out issues and to make note of your own thoughts and the comments of others.

Resources for this Process Step

- PowerPoint presentation about this process step
- Worksheets
- Policy case study
- Individual(s) knowledgeable about key aspects of the policy case under discussion (e.g. the workings of the regulatory system), if possible
- Access to on-line or print information sources, if possible.

Organizer Tips

- Help the facilitator identify participants in the room with comments or questions.
- Make sure there are plenty of copies of the policy case.

STEP ONE – Identifying Qualities and Key Features

"The dialogue tool proved its merit in terms of sequence of steps. Generous time should normally be allocated for the first step, in order not to rush the identification of issues, pro and con."

— Ellen Desjardins, M.H.Sc., RD Public Health Nutritionist, Region of Waterloo Public Health

Key Questions

- What are the qualities/features of this policy case?
- Are they unique?
- What are features more desirable/ acceptable to Canadian society and, therefore, would favour use/adoption?
- What are features less desirable/ acceptable to Canadian society and, therefore, would argue against use/adoption?
- What specific population groups are affected and how?
- Is there sufficient supporting information to understand and substantiate/support the key features or profile for this case, whether the information factual or perception?

Purpose of this Process Step

To commence the dialogue, the facilitator introduces participants to the policy case and asks them to begin to **ascribe qualities or key features** to the biotechnology product or process proposed in the case study. This is done as a first step to develop a high-level, general view of the policy case, while noting specific features under each consideration heading. By doing so, the facilitator starts to "unpack" (break down) the issue into its component parts.

Using flip charts, the facilitator asks the group to consider the general features of this new product or process in the five key consideration areas shown on the Dialogue Tool, namely health, environment, socio-economic, ethical, broader/other. Comments under each consideration column are noted on the flip charts and the facilitator gets participants to provide their input in a way that does not really make a judgement about the feature. For example, if a new pharmacological product is being proposed, participants will note that the product has intended health benefits but no other judgements are made at this step. The facilitator will also ask participants to identify if any of these qualities or features are unique or different in some way that is worth noting.

With these features listed on flip charts, the facilitator then asks participants to revisit them and divide the qualities and key features in each area of consideration according to whether they are more desirable/acceptable (i.e. would favour use/pro) or are less desirable/ acceptable to Canadian society (i.e. would argue against use/con). This is the first time that participants are asked to **make some judgements about the qualities or features. However the focus is still on identifying the qualities and not on defining or discussing the issues that arise from the case.**

Finally, participants will be asked to list those **people or populations most affected** by this proposed product, policy change or biotechnology process.

At the end of Step One, the group will have developed a **"profile"** under each of the five dialogue columns. These profiles show the favourable and unfavourable qualities that need to be explored under each of the five consideration areas.

At the end or during this sequence, the facilitator may ask the group about their confidence in the supporting information/evidence, i.e. whether there is adequate information to substantiate the profile developed or if further information would be beneficial to understanding the case and its impact.

It is important to balance the need for adequate information with the need to dialogue on the issue at hand and the need to avoid 'information overload' In some cases, especially in non-traditional research areas such as social research, 'scientific' data may not exist; perception may be more important in these instances. This should be recognized but should not limit the potential for dialogue, and such perceptions should be accepted as a core part of the group's collective views and understanding on the issue at that point in time.

Facilitator Tips

- Use a separate flip chart for each of the five "consideration" areas shown on the Dialogue Tool. (NB: Mark each page with a code, so they are easy to collate after the dialogue.)
- Set aside one extra flip chart for a **Parking Lot** where good ideas, questions and items not directly related to the process can be noted.
- Encourage use of the **worksheets**.
- Make a decision about whether some of this discussion can happen in smaller work groups reporting back to the plenary group, or if the entire discussion can happen in plenary.
- Try to discourage people from moving quickly to judgement or stating firm positions about the policy case. They will have this opportunity at later stages in the dialogue. At this point it is important to get the facts out and break down the issue. Asking participants to refocus their comments from identification of issues to a specific quality or feature may help (e.g. "You have just identified an issue related to the case; reframe your comments to identify the specific quality or feature at the heart of the issue.").
- According to the agenda and your facilitator's plan, establish some **time parameters** for each activity under Step One, and allow for breaks, especially at the end.
- Make a decision about whether to apply a risk/benefit analysis[3] and/or an alternatives analysis[4] at this stage.
- NB: In some cases, you may wish to allow a knowledgeable presenter to bring more detailed scientific information or explanations to the group (e.g. with respect to the workings of the regulatory system, or to explain the case developer's process and objectives).
- Use sample PowerPoint to facilitate understanding of each step.

3 Risks and benefits analysis identifies the risks associated with the case, typically who and what is at risk, and then identifies what the benefits are and who benefits from them.

4 An alternatives analysis asks whether there are existing alternatives to the proposed biotech product with similar qualities/attributes; whether the new case qualities are distinctive and/or add value; and, whether the impacts of the proposed biotech product case in each area of consideration are different or better than the impacts from the existing alternatives.

Participant Tips

- Try to keep an open mind to the features and qualities in the policy case provided.
- Focus on identifying the qualities/features of the case and avoid the tendency to move into issues arising from the case (which will be developed in the next step).
- Be **open to the ideas of others** in the room or in your small break-out group.
- Ask for more clarification from experts in the room, if they are available.
- Ask the facilitator to **clarify process questions** if you have concerns.
- Use the worksheets provided to sort out key ideas and to make note of your own thoughts and the comments of others.
- Try not to apply too much judgment at this stage. Step One is intended to open up the broad range of considerations associated with the proposed biotechnology (product or process) and is primarily an education stage to enable all participants to see and understand the profile of the case and its dimensions.

Organizer Tips

- Depending on the size of your group, make provisions for small break-out tables. If desired, assign 'small table facilitators' to help guide table discussions throughout the dialogue session.
- Help the facilitator set up the flip charts where everyone can easily see and review them.
- Help the facilitator identify participants in the room with comments or questions.

Resources for this Process Step

- PowerPoint presentation about this process step
- Worksheets
- Flip charts (one for each consideration area and one for a Parking Lot)
- Dialogue Tool
- Policy case study
- Access to on-line or print information sources, if possible

NB: Samples of these resource tools are appended to this guide.

STEP TWO – Issue Identification

At this stage, participants will be asked to first identify the issues arising from the Step One profiles (in each consideration area) and then will be guided to focus on two or three of the **most critical issues in each area** that arose from the qualities and attributes of the biotechnology referenced in the policy case.

While a review of the profiles created in Step One will raise a number of issues, the facilitator will endeavour to focus on two or three of the most important in each area. These issues will be ranked in terms of their importance, and the facilitator will again encourage an open discussion, either table-by-table or in plenary. Participants will be asked to consider what the issue is really about (in other words, what is really at stake), and how and why it is important. The issues highlighted at this stage will be put under further scrutiny at the next step.

To complete this process step, participants will be asked to talk about the **expectations for addressing these most critical issues.** This component of the dialogue allows participants to identify what Canadian society might expect to be addressed/done about these issues (individually or as a whole) and also to clarify who they think is most responsible or has a strong role in addressing the subject area. For example, do people think that government should act in this area? Is there a need for more scientific input? Does industry need to take action on something, or provide more information in a certain area?

Key Questions

- What are the most critical issues to be considered in this policy case given the features and qualities discovered in Step One?
- What are the issues in each consideration area (e.g. health issues)?
- What are the pros and cons of the policy case under each consideration/theme?
- What is the issue really about? What is at stake here?
- Which issues are the most critical and why?
- What are society's expectations about what should be done about this policy case and who should do it?

Facilitator Tips

- Ask the participants the following questions:
  - What are the issues that arise in each consideration area?
  - What is the issue really about?
  - Which issues are most critical and why?
  - What are the expectations for addressing these most critical issues and why?
- Allow each table to take time to discuss the core issues they see based on the profiles from Step One.
- Post issues on flip charts per consideration.
- Brainstorm issues in break-out groups first, then allow a plenary exchange on the list of issues.
- List all issues in all five areas first then, in the plenary session, rank in each area.
- Again in plenary, note expectations for addressing each issue in each area.
- Use five separate flip charts, one for each consideration area.
- Help the group boil things down to **two or three issues** in each consideration area, and then create an overall critical short-list.
- Remember that this step involves some ranking or priority setting within the discussion. The group is getting ready to make judgements or weigh options, but do not get to that quite yet.
- You might encourage participants to consider, at this stage, whether there are existing or potential alternatives to the GM product or process being proposed.
- Encourage them to use worksheets when working in small groups.

NB: Sometimes the discussion about a specific issue may raise concerns about a broader issue or domain. Ask the group to be clear whether they want to talk about the **specific or the global**.

Participant Tips

- Work with others at your table to define the most **pressing issues** and the **true essence of the issue**, whether it is positive or negative.
- Participate in the plenary discussion to really try to reduce the list of issues to a short-list of two or three for each area of consideration.

Organizer Tips

- Continue to support an effective facilitation process by having resources on hand (e.g. worksheets) and supporting the facilitator by taking notes, highlighting concerns or questions.
- Help the facilitator with time management and logistics issues.
- Clear flip chart sheets from Step One and label them for easy reference; post them in view of group, if possible, for easy reference as the dialogue continues.

Resources for this Process Step

- PowerPoint presentation about this process step
- Worksheets
- Flip charts (one for each consideration area and one for a Parking Lot)
- Dialogue Tool
- Policy case study
- Access to on-line or print information sources, if possible

STEP THREE – Defining Risks and Benefits

Purpose of this step

This step in the dialogue process asks participants to again review what they have learned and the profiles they have created under each of the five column headings in Step One and Step Two. In Step Three, they use that information to discuss the risks and benefits associated with the policy case under each consideration area. Specifically, participants will assess **who is at risk** due to the introduction of the new science or product, and **who benefits** should things go forward as planned. **Trade offs** could also be considered at this stage.

This step involves several sub-steps:

- Consideration of **risks and benefits per consideration area.**
- Discussion about the **population groups particularly affected.**
- Consideration of the group's **confidence in the supporting information** that supports the risk-benefit profile developed.
- The application of some **weighting** to the risks and benefits to help when weighing them together to determine if the risk is greater than the benefit (or vice versa) or if they balance each other.

Optional added sub-steps:

- Assessment of the **trade offs** associated with the case. At this step, we are asking which elements are seen as being held in balance with or against other elements in a kind of dynamic tension called a "trade off". For example, a GM procedure might have unknown long-term environmental effects but would definitely reduce present day use of pesticides a field crop.
- If there is time, participants can also **rank the trade offs** in order of priority from most compelling or valuable to least important.

Key Questions

- What are the risks and benefits in each area, given the profile of qualities and issues?
- Is there sufficient supporting information to understand and substantiate the risk/benefit profiles?
- Are there population groups particularly affected?

Optional Questions

- How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?
- What are the trade offs that emerge when we weigh/compare the risks and benefits?
- Which of these trade offs is most compelling?

Facilitator Tips

- Determine the best methodological approach to manage discussion of risks and benefits (e.g. depending on the objectives and expected outcomes of a session). The following methods provide useful frameworks from which to work:
  - Risk analysis (probability and impact)[5]
  - Alternatives analysis[6]
  - Weighing risks and benefits[7]
  - Trade off analysis[8]
  - 'What if' scenarios[9]
  - Triple bottom line assessment[10]
  - Sustainability Impact Assessment (SIA)[11]
- **Using the chosen method, model one area** (e.g. socio-economic) by discussing risks and benefits in plenary, then delegate other areas to individual tables. Ask them to get ready to bring their discussion back to the full group.
- Allow the table participants to contribute ideas back to the plenary session and track that output on flip charts.
- Walk participants through a discussion of risks and benefits five times, addressing each of the condition areas.
- Encourage participants to use the worksheets when working in small groups and during the plenary sessions.
- **Optional:** See if you can get participants to arrive at a statement or idea about how to express the risks and the benefits when they are weighed against each other. For example, if the benefits associated with the policy case are substantial, how important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?
- Weigh risks and benefits within a consideration area, as well as from one consideration area to another to define the trade offs.
- Rank trade offs from most compelling or viable, to least compelling or possible.

5 In risk analysis, the risks are identified first, then rated individually on the probability it will occur, and on the impact it would have if it occurred.
6 See footnote 3.
7 Risks and benefits are considered and weighed together as to whether one outweighs another.
8 When risks and benefits are weighed together, one identifies what the trade offs appear to be in going forward.
9 In 'what if' scenarios, various combinations and degrees of the case's associated risks and benefits are projected to consider the impact of the biotech product. This allows participants to identify which risks are most critical and where changes might be most helpful
10 Triple bottom line assessment measures performance (usually corporate) against social and environmental parameters as well as economic values and factors.
11 SIA looks at the impact of the case on sustainability against a range of selected factors (environmental, socio-economic, etc.).

Participant Tips

- Consider background information provided about risk/benefit analysis. This is not a formal or theoretical economic exercise, but it sometimes helps to have this theory as a backdrop to your discussions. Rely on those in the group with some expertise in this area.
- In some ways, the facilitator will be asking you to consider the risks and benefits together to see how they compare and contrast with each other. Find out if you have strong feelings about the relationship or balance between the risks and the benefits.

Organizer Tips

- Continue to support an effective facilitation process by having resources on hand (e.g. worksheets) and supporting the facilitator by taking notes, and noting concerns or questions.
- Help the facilitator with time management and logistics issues.
- Clear flip chart sheets from Step Two and label them for easy reference.

Resources for this Process Step

- PowerPoint presentation about this process step
- Worksheets
- Flip charts (one for each consideration area and one for a Parking Lot)
- Dialogue Tool
- Policy case study

STEP FOUR – Using the Dialogue Tool Spectrum

Key Questions

- Given what we have learned/understand about the case at this point, on balance, for each area of consideration, which spectrum position/colour/language best fits this case?
- **Optional -** On balance, which spectrum position/ colour/language best fits this case overall?

Purpose of this Process Step

This step reveals the real strength of the dialogue process. Having conducted a detailed audit and analysis of the policy case in the previous steps (by working repeatedly within the five consideration columns or rows), the group should now be developing a deeper understanding of the many layers or dimensions of the issue. At this stage, they are ready to **map the case** on the Dialogue Spectrum.

In Step Four the facilitator challenges participants to position the policy case, within each consideration area, along the spectrum that runs from "Fully Acceptable/Supportable/ Beneficial/Desirable" (blue colour) to "Not Acceptable under any circumstances"(red colour), usually running from left to right. It sometimes helps if participants use the **corresponding colour** shown on the spectrum to designate where they want to position the issue. For example, under the health consideration, an individual might say that there were concerns about long-term health effects and, therefore, the item should be situated toward the red end of the spectrum. If the middle of the spectrum is used, where conditions apply, participants are encouraged to identify the conditions for each area.

Once the case has been positioned under each of the five considerations, the facilitator will then ask the group to consider giving the case an "overall" rating for the policy case, again using the colour coding as a guide.

The overall rating can be observed at a glance by noting the positioning assigned within each consideration, or participants can be given coloured dots that they can actually place on the master spectrum document. The convergence of dots within one or more areas along the spectrum allows for final conclusions about where the group has arrived. Or there may be a wide divergence of opinion, despite the time participants have spent together discussing risks, benefits, pros and cons. In most cases, the spectrum works well to visually communicate where the group of dialogue participants has settled.

If participants have positioned the case in the middle zone of the spectrum, the facilitator will encourage them to express the conditions that are implied in that zone.

Facilitator Tips

- The facilitator's key challenge at this stage is to get the participants to say how they feel about the policy case going forward.
- Common ground needs to be noted, as does any remaining divergence of views.
- The long colour version of the Dialogue Tool is most useful at this stage for participants' use at the tables (see Appendix 6). The Brief Overview version is best used earlier in the day, when introducing the tool and the process.
- Ask participants to place a sticky dot on the poster-size version of the Dialogue Tool (showing all considerations) to illustrate their 'position' on the spectrum.

Optional: Give the policy case an overall rating regarding its acceptability or supportability using the Spectrum.

Note: If participants have positioned the case on the spectrum when the case is introduced, just before Step 1, then ask participants to re-assess their 'position' on the spectrum for comparison with their opening positions, individually and as a group, at the beginning of the session.

When reviewing the pattern of positions that are evident on the spectrum, it is important to explore the views and rationale for positions in the different zones of the spectrum, from the extreme left/blue to the extreme right/red where they exist to surface the range of beliefs at this stage and the main drivers of those beliefs.

Participant Tips

- This is the stage where **final summations** about the case are starting to form. Listen carefully to the comments of others. Review your notes.
- If you have selected a position on the colour spectrum that involves "conditions", think about the kinds of conditions that would support this position.
- On balance, which area of the spectrum best fits the case overall?

Organizer Tips

- It is critical at this stage that participants can "see" the colour spectrum portion of the Dialogue Tool well, and/or have a copy of the spectrum at their table (e.g. colour version of the Dialogue Tool).
- A poster-size copy (e.g. measuring approximately 7 feet by 5 feet) of the Dialogue Tool should be posted, with all areas of consideration showing along with a separate poster for rating the case overall (e.g. one row, approximately 7 feet by 2 feet).

Resources for this Process Step

- Poster-size copy of the Dialogue Tool, with all five considerations and overall
- PowerPoint presentation about this process step
- Worksheets
- Dialogue Tool (Colour, Long Version)
- Coloured dots (different colour for each small group)
- Policy case study

STEP FIVE – Determining Conditions for Acceptability

Key Questions

- What are the conditions or requirements that would raise confidence in the acceptability of this case or clarify its fit on the spectrum?
- What are the conditions derived from each area of consideration?
- How would we combine these into an overall list?
- Is each condition achievable? Is each condition within the control and influence of the relevant party (e.g. case proponent or other selected party)? How can we revise the conditions to enhance the probability of achievement?
- Which of these conditions are most critical to acceptability? Which would help advance acceptability (e.g. move left some degree on the spectrum)?
- What are the specific actions and responsibilities to give effect to these conditions?
- Given the application of the proposed conditions to this case as defined to this point, on balance, for each area of consideration, which spectrum position/colour/language now best fits this case?
- Given application of the proposed conditions, on balance, which spectrum position/colour/language now best fits this case overall?

Purpose of this Process Step

If there is significant interest expressed in the middle zone of the spectrum in Step 4 (green to yellow to orange colour range), it is time to proceed to identify the conditions that would affect the acceptability of the case. Participants are asked by the facilitator to outline the conditions that are affected predominantly by or derived from each consideration area (i.e. health, socio-economic, etc.).

After conditions have been identified for each consideration area, participants will synthesize or combine them into an overall list, further test them as a full set of conditions (e.g. for probability of achievement, i.e. to ensure they fall within a reasonable range of control and influence by the case proponent or other significant party, and revise them as needed.

Once participants are satisfied with the list of conditions, the facilitator will ask them to rate the conditions as to which are most critical to confirming or improving acceptability. The conditions will then be further refined to make them specifically actionable by specific parties.

If desired, one last re-assessment of spectrum positioning will be undertaken and may be compared with the positions taken at the beginning of the session (if assessed then), and at Step 4.

Participant Tips

- This is the stage where **final summations** about the case are starting to form. Listen carefully to the comments of others. Review your notes.
- Think seriously about the conditions that would affect your assessment concerning where the case fits on the spectrum.
- Decide, on balance, with the conditions in place, which area of the spectrum best fits the case overall.

Organizer Tips

- It is critical at this stage that participants can "see" the colour spectrum portion of the Dialogue Tool well. If necessary, move it to a more prominent location for the duration of this step.
- Continue to support an effective facilitation process by having resources on hand (e.g. worksheets) and supporting the facilitator by taking notes, and noting concerns or questions.
- Help the facilitator with time management and logistics issues.

Resources for this Process Step

- PowerPoint presentation about this process step
- Worksheets
- Dialogue Tool (Colour, Long Version)
- Coloured dots
- Policy case study
- Individual(s) knowledgeable about key aspects of the policy case, if possible

Facilitator Tips

- Ask participants to rate their level of confidence that the conditions can be achieved and/or their level of confidence that the impact of the proposed condition will meet expectations.
- Explore 'what if' scenarios and how different conditions/recommendations might affect the risks, benefits, trade offs and acceptability.
- Assess position on spectrum after conditions defined. If the case position was assessed at the start of the process (before step 1), there will now be 3 spectrum comparison points to observe.
- When reviewing the pattern of positions that are now placed and evident on the spectrum, it is important to explore the views and rationale for a range of example positions:
  a. To determine if people have changed their position view as a result of the conditions work step
  b. To explore remaining views in the extreme left/blue and the extreme right/red zones of the spectrum, where they exist, to determine their remaining views/rationale and possibly to explore 'what would it take to shift your position?'.

STEP SIX – Promising Directions

Key Questions

- Are there conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?
- Are there promising directions that could be explored to advance solutions or mitigate problems?
- What useful next steps might enable further in-depth understanding and dialogue on this case?
- Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance)?
- How could this dialogue process benefit others (e.g. by contributing to policy development or in helping to educate others)?
- Where are the real opportunities associated with this case? Where are the real problems?
- What worked about the dialogue process? What didn't?

Purpose of this Process Step

Step Six allows the group to provide final comments or recommendations about how this case might move forward.

This stage allows for a more thorough discussion of **what conditions** would have to apply for the group to move the item further toward the "More Acceptable, etc." end of the spectrum. Sometimes participants will say that if they had more scientific information, other study data, or a commitment to a long-term planning exercise, they would be more comfortable about accepting the new biotechnology. Other times, the majority may agree that there are no conditions under which the case should proceed.

Participants can also suggest whether the dialogue should continue in another direction, focus on a particular component (e.g. ethics), or include new and different people. Sometimes this step is used by participants to pass along directions, or notes, to other groups that may be debating this issue.

As well, the group will likely want to signal the promising directions that could be explored, especially where there is an opportunity to advance solutions or mitigate problems.

This stage, therefore, generates information about a group's common ground, summary views about the conditions that would affect "acceptability" and, finally, predicts whether the group would like to continue the dialogue in any way. The real goal is to ensure that the **essence of the dialogue is captured** so it can be revisited by participants or passed on to others.

Facilitator Tips

- The key goal at this point is to ensure that the group feels that they have come to closure about their dialogue, at least for the time being.
- Dig a bit deeper on the issue of conditions that would affect the mapping of the policy case on the spectrum and document any feedback.
- The group may have strong views about the **conditions or requirements** that would make the case stronger, or would assure their confidence as it moved forward. These need to be documented carefully.
- Make sure that they have the chance to say more about what should be passed on to others, so they don't feel that their dialogue output will be lost.
- Point out that each component of the dialogue has value and can stand on its own.

Participant Tips

- Participate in this **final summary** process with a view to thinking about how your dialogue work could benefit others (e.g. by contributing to policy development or in helping to educate others).
- Focus on what has been achieved together today.
- Think about what could come next: Where are the real opportunities? Where are the real problems?
- Provide the sponsor organization and the facilitator with comments about the process and the support materials. What worked? What didn't?

Organizer Tips

- Since this is the wrap-up stage, make sure that flip charts have been coded and numbered and are ready to be stored or typed up.
- Collect loose notes in the room.
- Pass out evaluation forms, if not included in participant's kit.

Resources for this Process Step

- Power Point Presentation about this Process Step
- Worksheets
- Dialogue Tool (Colour, Long Version)
- Coloured dots
- Policy case study
- Individual(s) knowledgeable about key aspects of the policy case, if possible

DEBRIEFING – Evaluating the dialogue and process (OPTIONAL)

Purpose of this Process Step

It is always a good idea to ask participants what they thought of their experience with the Dialogue Tool from a process and a content perspective. All of this feedback helps strengthen and adapt the tool, so its maximum potential can be realized and shared with others. To encourage learning from the process, the facilitator will lead a debrief of the dialogue experience drawing out impressions, lessons and potential applications elsewhere. A sample Evaluation Form is available in Appendix 8.

Key Questions

- What worked in the session and what could be improved?
- What impact did this dialogue have on you?
- What lessons did we learn about the dialogue process and the Dialogue Tool and how might we improve it in the future?
- Do you see other cases or situations where this approach and tool might be useful?

Participant Tips

- Provide the sponsor organization and the facilitator with comments about the process and the support materials. What worked? What didn't?

Organizer Tips

- Since this is the wrap-up stage, make sure that flip charts have been coded and numbered and are ready to be stored or typed up.
- Collect loose notes in the room.
- Pass out evaluation forms, if not included in participant's kit.

Facilitator Tips

- The key goal at this point is to ensure that the group feels that they have come to closure about their dialogue, at least for the time being.
- Use both a verbal debrief of the key questions noted above and an evaluation form to gather feedback from participants.

Resources for this Process Step

- Power Point Presentation about this Process Step
- Worksheets
- Evaluation form (See Appendix 8 for a sample evaluation form.)

Report Writing

At this stage in its evolution, the dialogue process does not come with tried and true recommendations about how to capture the output from a dialogue session. To date, facilitators have generally produced copies of the flip charts and written a generalized overview of the process and the comments of participants. As a preliminary support tool, this guide provides a sample report template that may help groups capture the nature and scope of their dialogue. This template encourages reporting about different aspects of the dialogue session:

- the design and flow of the dialogue session (i.e. which steps were used and areas of emphasis);
- logistical considerations such as the provision of support materials, the environment used for the dialogue, etc.;
- the policy case study and how well it worked to generate a constructive level of dialogue;
- the nature and quality of the dialogue itself and the actual comments/deliberations of participants.
- the summary of findings and recommendations on the way ahead.

As the Dialogue Tool is used more frequently, CBAC and the Dialogue Tool developers may develop more definitive report writing tools.

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OTHER PROCESS CONSIDERATIONS

As the Dialogue Tool and process have been tested, it has become apparent that one of its strengths is its flexibility and variety of uses. Some groups have found that just walking through Step One was helpful for work they were trying to achieve. Other groups have skipped Step One and moved quickly to defining the issues, normally done in Step Two. Sometimes there is value in tracking issues through only one of the consideration areas – health, for example – if that is a priority focus.

Time Factors

Time constraints and objectives also have an impact on how this process flows. It is completely possible that a group might decide that they have only an hour and need to work through some ethical issues, for example. Other organizations may decide to convene a rolling dialogue group that meets every week for several weeks and picks up where they left off each time. The Dialogue Tool can also be useful over time to delve into and monitor the life cycle of a product (e.g. from concept to research, production, retail, consumption and accumulated impacts). Some groups may want to revisit an issue at regular intervals to track changes in Canadians' understanding and acceptance of an issue over time, or to monitor changes in the acceptability of a case as the conditions set in an initial dialogue are achieved.

Optimizing Participation

Different people prefer to interact in different ways in group settings. To optimize participation in the dialogue, the session design should allow individuals to contribute to the discussion in the manner in which they feel most comfortable, and which allows all viewpoints to be recognized, acknowledged and captured. To accomplish this, a mix of participation techniques should be offered in a dialogue including opportunities for plenary discussion, break-out groups and individual responses. There are a variety of methods that could be used to gather individual reactions including (but not limited to) participant surveys, dot exercise, baseline testing and evaluation of the process steps. Deliberative polling may also be used to create and compare participants perceptions at the beginning and end of a dialogue. A good balance between small group and plenary interaction is advised.

Confidence in Information and Perception

A group's overall confidence in the information being presented to them could affect the confidence with which any conclusions are made for a particular dialogue. This issue may become important at different stages in the dialogue. Prior to the dialogue, for example, we need to know if information is available on the issue at hand (both for and against) and secondly, whether there are any large gaps in the type of information that is available. During the dialogue, it may be important to verify whether there is adequate information to substantiate a particular point made by a participant.

It is important to balance the need for adequate information with the need to dialogue on the issue at hand and the need to avoid 'information overload' (e.g. dialogue participants are able to absorb only a limited amount of information on an issue before being overwhelmed).

In some cases, especially in non-traditional research areas such as social research, 'scientific' data may not exist; perception may be more important in these instances. This should be recognized but should not limit the potential for a dialogue.

Transparency is a key aspect of ensuring confidence in supporting information/evidence. Information should be presented prior to a dialogue session from a variety of sources representing all dimensions of an issue in order to allow participants to learn about the issues at their own pace and to draw their own conclusions about the issue at hand. Participants are often willing to access information themselves
(e.g. online information) but dialogue organizers should ensure that participants are informed about the existence and location of information relevant to the dialogue.

The purpose of the Dialogue Tool is not to create a scientifically conclusive dialogue but to develop a more holistic approach and result. This issue could limit the potential for successful dialogue if handled improperly. Verification of a group's confidence in supporting information should be deliberately inserted in the dialogue process at appropriate junctures so that it does not provide a potential roadblock at each step of the process.

Finding Alternatives

Comparative language is used throughout the Dialogue Tool process to encourage participants to think about possible alternatives to a case and/or a desired outcome of a case. This idea of 'alternatives' could be deliberately built into a session design to focus discussion on relevant issues such as corporate concentration, intellectual property and economic pressures under our regulatory system (e.g. public support for research). It may be a challenge for the facilitator to manage such a discussion (e.g. it could become philosophical; it may be raised during discussion of risks/benefits) so ways of dealing with these issues should be identified prior to a session. Finally, discussion should not be encouraged unless participants have the same degree of confidence in information about alternatives as they do for the issue at hand.

The Dialogue Tool and process can be adapted to fit any of these scenarios. In effect, the process as explained here can be stopped and started as users desire. Each step produces its own value and the dialogue, whether long or short, also has value.

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ACKNOWLEDGEMENTS

CBAC would like to acknowledge the leadership and hard work of the members of the Exploratory Committee (EC). The Committee was established by CBAC to manage a pilot project focused on the development of the Dialogue Tool. One of the catalysts of the pilot project was the boycott of the CBAC consultation process by fifty, primarily environmental, non-governmental organizations. One of their main demands was that the Government of Canada, through Parliament, deal directly with policy around genetic engineering. Discussions about how this community could continue to be engaged led to the notion of an "acceptability spectrum", a concept that CBAC referred to a pilot project to be managed by the EC. Members of the EC include representatives from a range of CBAC stakeholders – industry, the supply chain (farmers, producers, retailers), consumers, faith and public health interests, and environmentalists.

Working together, with two expert facilitators, the EC designed and refined both the Dialogue Tool and the facilitation process, including the Rules of Engagement. Their personal commitments of time and wisdom are evident in the capacity, flexibility and sensitivity of this approach to dialogue.

Without the guidance and devotion of EC members, Canadians might have missed this chance to fully explore the implications of biotechnological advancement in the context of Canadian values and Canadian circumstances. CBAC and the Canadian public owe them a huge debt of gratitude for their vision and tireless contribution. (See Appendix 9 for a list of the EC membership.)

CBAC extends its sincere thanks to Lyle Makosky, a consultant to the committee, who helped frame the original terms of reference for the initiative, and throughout the whole project, he provided pivotal input and design expertise as he facilitated EC meetings, guided the project, and helped design and develop the Dialogue Tool and process. He was a major reason for the viability and effectiveness of the project. He was ably assisted by Kerrianne Carrasco, who provided fine facilitation and reporting support to the project.

CBAC would also like to extend thanks to two of its members, Dr. Peter Phillips and Dr. Mary Alton Mackey, who acted as resources and support to the EC and its work. A former CBAC member, Suzanne Hendricks, also needs to be acknowledged for her significant contribution of time and enthusiasm for this project.

CBAC is also indebted to members of the Canadian Biotechnology Secretariat for their provision of secretariat and project management support.

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CONCLUSION

Looking at the results of a dialogue process shows that the final conclusions and final results do not represent an absolute truth or a consensus. The dialogue journey is certainly as important as reaching the destination. As mentioned, the Dialogue Tool continues to be a work in progress.. CBAC and its Exploratory Committee continue to test the tool and look for feedback. Both are committed to developing the tool and the process so Canadians, and their governments, have more practical resources at their disposal as they set out to ask questions and evaluate Canada's biotechnology options.

When you reach the end of a dialogue exercise, you will want to ask yourself what you have achieved. The developers of this tool think you will see that the time and the dialogue were well worth it. In the end, you will reach a conclusion that reflects the orientation and priorities of your group. Another group of people might have gone in another direction. At best, your conclusion will represent a summary of what a group of informed people came to understand and wanted to put forward. These may not necessarily be the most definitive recommendations but the process and the output from a dialogue process have a role in informing public policy.

CBAC and the Exploratory Committee believe that this tool and its supporting process provide one way for Canadians to come together to deliberate about the challenging potential and pitfalls presented by biotechnology, and in particular, genetically modified food and feed. It is a new way of talking about biotechnology and it is a new way of working together to bring guidance to government, and to share knowledge and perspective Canadian to Canadian. It is neither the last word, nor the first word about the issues at hand. It is a reflection, usually insightful, of what people are thinking and what they are learning.

In some ways, it is the human dimension of this process that stands out. Participants during the pilot project phase have consistently remarked that they found the process useful and powerful. The majority says that they benefited from the experience, and felt that the process helped them better understand an issue and learn from others. They say that it tested their assumptions and their biases. Most say they felt better informed at the end and had a better appreciation of all that goes into forming good policy in these matters.

CBAC is ready to say that there are true benefits to be realized here for sponsoring organizations, governments, stakeholder organizations and members of the public. This is a very Canadian approach to keeping doors and minds open when it comes to determining our biotech future.

CBAC also wants to acknowledge again that this tool and process are the offspring of a group of committed individuals who wanted to figure out how to keep the dialogue respectful and constructive. Members of the Exploratory Committee which developed this Tool/Process are some of the stakeholders who have strong views about biotechnology, and GM foods specifically. The Dialogue Tool and process will always reflect their level of involvement, intellectual rigor and focus on what is good for Canada. Their leadership and engagement have made all of the difference. They have also helped us see that consensus is not necessarily the goal – dialogue has a value all its own.

If you would like more information about the Dialogue Tool and its supporting facilitated process you can visit the CBAC web site at *http://www.cbac-cccb.ca/* and/or reference the resource tools appended to this guide (also see Appendix 12). You can also find the Exploratory Committee's full report at this website.

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APPENDICES

APPENDIX 3 – Policy Issues List

APPENDIX 4 – Facilitator Guide

APPENDIX 5 – Sample Table Facilitator Guide

APPENDIX 6 – Dialogue Tool: Colour Version

APPENDIX 7 – Dialogue Tool: Brief Overview Version

APPENDIX 8 – Standard Evaluation Form

APPENDIX 9 – Members of the Exploratory Committee

APPENDIX 10 – Sample Facilitator's PowerPoint Presentation

APPENDIX 11– Sample Participant Worksheets

APPENDIX 12 – Additional Resources

Appendix 3
Preliminary List of Policy Issues for Consideration in Future Dialogue

Notes:

- The Exploratory Committee recognizes that many of these issues could be applied more broadly to biotechnology but they are being considered for this project in the context of GMFF case study.
- This list contains issues that are thought to be amenable to dialogue using the Dialogue Tool and is not a comprehensive list of all biotechnology issues.
- These issues could be explored as individual cases or as broad policy themes (such as with many of the technology issues), or many could be seen as individual sub-issues, in which several could be examined within a larger case (e.g. within a class of technologies).
- The issue of who benefits/who risks can apply to any of these issues.

Technology Issues

1. Crop co-existence - GM crops have been rapidly adopted by farmers around the world for their production benefits. How do we ensure that GM cropping systems can co-exist with other agricultural systems, such that we maximize the benefits to society for a diverse and sustainable agrifood production system in Canada and globally?
2. The impact of Plants with Novel Traits (PNT) on weediness - What is the potential of the PNT for out-crossing? Does the trait confer competitive advantage in unmanaged ecosystems? What is the impact of the PNT on biodiversity?
3. Transgenics – e.g., insertion of a pig gene into a food product or a human gene into a plant. What are the questions that should be addressed concerning values of different sectors of Canadian society? How can Canadians ensure informed choice?
4. Genetic Use Reduction Technologies (GURT) – “Terminator” technologies may have the ability to limit out-crossing of GM traits, limit the possible compromise of other crops (e.g., limit out-crossing and improve segregation) but may require to buy new seed supply every year. The debate here focuses on biological control systems, patent issues and freedom of choice.
5. Herbicide tolerant products - Herbicide tolerant products have been engineered to be resistant to chemical herbicides, allowing the farmer to spray the chemicals without losses to the crop. These crops have contributed to more sustainable agriculture practices and reduced costs of production for the farmer. Do the benefits of these crops outweigh risks as currently assessed by the regulatory system (e.g., for out-crossing and human health)?
6. Insect resistant products – The use of insect resistant crops have contributed to more sustainable agricultural practices and reduced costs of production for farmers who adopt the technology. What is the potential for the development of insect resistance from these crops? If resistance did develop, what would be the impact on organic and non-GM farmers? How do we ensure long-term effectiveness of all the tools at the farmers’ disposal?

7. Nutraceuticals – e.g., foods that have been enhanced to provide a nutritional benefit. How do we ensure equitable distribution of these advancements in technology? How do we ensure efficacy of these products?
8. Food Pharmaceuticals - e.g., a vegetable that expresses insulin; anti-HIV bananas.
9. Industrial Agriculture – e.g., crops engineered to produce or be a contributor to an industrial product. In the example of using corn to produce bio-diesel fuel, the primary issue is one of making it economical; an issue which applies more broadly to biotechnology. An issue more specific to GMFF is the issue of whether or not animals that have been modified for a non-food use (e.g., goats) could then be used for food uses.
10. Phytoremediation – e.g., heavy metal accumulating canola.
11. Analysis of "desirability" of emerging technologies - e.g., nanotechnology.
12. The use of food crops for molecular farming.
13. Technology necessary for tracking and surveillance.

Other Issues

14. Substantial equivalence.
15. Labeling – The need for/pros and cons and practicalities of different types of labeling regimes as mechanisms for informed choice for consumers.
16. Informed choice and transparency of information for consumers on GM and all types of foods (e.g. labels, websites)
17. Information which producers need to make decisions among GM crops and crops which use other farming practices.
18. Effects of use of GMFF biotechnology on a range of agricultural food production systems (GMO, non-GMO, organic and traditional). Issue focuses on the need to keep alternatives open including patenting of GM technologies and other intellectual property systems (e.g., genetic diversity, co-existence of different agricultural systems). Current patterns of investment may also be at issue here.
19. Security of the seed supply and the shift from public to private domain (including patenting and plant breeders rights and farmers' privilege issues) and the loss of diversity and heritage of seeds.
20. The consideration of ethics when determining which new technologies will go to the marketplace. Transgenics (particularly trans-species/kingdoms) could provide a useful example to discuss ethical issues.
21. Determining the positive and negative impacts of GM crops on Canadian agriculture and the economy (e.g., farm size and productivity, ensuring competition in the seed and food supply, imports/exports, ensuring market access). The equity of distribution of federal funding is also an issue.
22. The effect of GM crops on import/export markets, international trade and globalization. How is this effect determined?
23. Mechanisms for ensuring that GM technologies are equitably shared with the developing world. How do we ensure that GM technology is not used as a political weapon to deny food supply (e.g., Zambia)?
24. The effect of new technologies on Canadian society (e.g., urban vs. rural demographics, work burden on women, farmers' freedom of choice).
25. The use of transgenic animals for food.
26. Opportunity for input and dialogue on the future: the structure, availability and integrity of the means for dialogue (e.g. transparency, access, etc.) and consultation, as well as input to the direction of GMFFs and policy development for GMFFs, including:
    a. the approach taken by industry, NGOs/civil society, government to impact direction and policy
    b. the approaches available to citizens to influence direction and policy

27. Determining the costs to Canadian society of delaying and/or deterring innovation in the field of GMFF.
28. Segregation issues – when, why, how much and who pays? What is an appropriate tolerance level?
29. The implications of corporate concentration on food.
30. The legal responsibility for co-mingling of crops from different farming systems. Who is liable when it happens?
31. Co-mingling tolerances. What are acceptable tolerances for the co-mingling of products from different farming systems (GMO, non-GMO, organic etc.)? Who will drive the development of an international standard for trade purposes?
32. The creation of a third party/agency for managing controversies between farming systems. It could provide an alternative resolution mechanism or mediation rather than court action. It could establish a fund to compensate those who have losses as a result of co-mingling or other controversies between farming systems.

Appendix 4
Sample Facilitator Guide

NOTE: This document is attached as an example only. It was created for use at the Multi-stakeholder Pilot Session held March 17-18, 2004. Subsequent changes to the process have been made and are not reflected in this document.

Dialogue Tool
Multi-stakeholder Pilot Session - March 17-18, 2004
FACILITATOR GUIDE

DAY 1 - Wednesday, March 17

TIME	ACTIVITY	PROCESS NOTES
5:30 - 6:30	**ARRIVAL AND REGISTRATION** • Light buffet will be available for participants.	Cue max-mix at tables, EC members delegated, check binders for participants
6:30 - 7:10	**SESSION OPENING AND INTRODUCTION** • **Welcome** (facilitator) [1 min]	Participant list in binder
	• **Participant introductions** (fac) [10 min] - brief introductions only	PPT slides (copy in binders), reference 'Backgrounder'
	• **Overview of project genesis, goals, and progress (CBAC/CBSec)** [10 min]	PPT slides (copy in binders)
	• **Review session objectives and agenda** - Note feedback forms and role of observers. - Remind observers about their worksheets	Refer to ROE in Participant Guide (Par. Guide) ***Open exchange*** **(Facilitator/ Asst. Facilitator)**
	• **Review Rules of engagement** (fac) [20 min] - Refine, add to ROE, seek shared agreement to abide by ROE	
7:10 - 7:30	**CASE INTRODUCTION** • **Introduce policy case** (plant-made pharmaceutical) - clarify use of this case (for dialogue, no public report, summary notes only)	PPT slide (text in binder)
	- reiterate that the policy case is hypothetical and was developed for the purposes of testing the Dialogue Tool in this session	Case in binder

TIME	ACTIVITY	PROCESS NOTES
7:30 - 9:30	**QUALITIES AND KEY FEATURES (STEP 1)** • **Identify 'General Features** - What are the qualities/features? - Are they unique? • **Identify features in each area of consideration (Health, Environment, Socio-economic, Ethical, Other)** - What are features more desirable/acceptable to CDN society (favour use)? Specific population groups affected? - What are features less desirable/acceptable to CDN society (mitigate against use)? Specific population groups affected? - What specific population groups are affected and how? • **Summarize features profile, noting favorable and unfavorable qualities per consideration area** • **Identify confidence in supporting information** - Is additional supporting information required to better understand and substantiate the feature profiles? What type of information do you recommend? • **Look ahead to agenda for Day 2**	Cue Qs on screen and binder/Par. Guide. Initial profile of the case ***Plenary open exchange*** Track on one flip chart (FC) - see FC graphic **(Asst. Facilitator)** Cue Qs on screen and binder/Par. Guide. Area by area profile of the case, track as Pros and Cons for each area ***Plenary open exchange*** Track on five FCs, one per area - see FC graphic Suggest participants use work book pages **(Facilitator/Asst. Facilitator)** Note which features/profiles may need more information to substantiate the profiles and raise group confidence in the evidence (notes on FC with profiles)
	DAY 2 - Thursday, March 18	
8:30 - 8:45	**REVIEW OF DAY 1** • Provide participants with a brief opportunity to make further observations about features of the case before moving into Step 2 - Is additional supporting information required to better understand and substantiate the feature profiles? What additional information do you recommend (whether the information is factual or perceptual)? (Facilitator/Asst. Facilitator)	**(Facilitator/Asst. Facilitator)**
8:45 - 10:30	**ISSUE IDENTIFICATION (STEP 2)** • Identify issues in each area of consideration - What are the issues in each area, given the profile of qualities (pros & cons)? - What is the issue really about? • Rank the issues - Which issues are the most critical and why? • Note expectations to address - What are the expectations for addressing these most critical issues? Note: option to select most intense areas for further discussion and next steps if critical issues mainly in select areas (i.e. less than all 5 areas, say 3)	Cue Qs on screen and binder/Par. Guide. Area by area issue list, track as Issues for each area ***Brainstorm issues by table first (all areas at once), then plenary exchange*** on list of issues, area by area, clarify what really about **(EC Table Facilitator/Facilitators)** List all issues in 5 areas first, then rank in each area ***(pleanary exchange),*** **(Facilitator/Asst. Facilitator)** Then note expectations in each area ***(plenary exchange)*** Track on five FCs, one per area - see FC graphic Suggest participants use work book pages **(Facilitator/Asst. Facilitator)**

TIME	ACTIVITY	PROCESS NOTES
10:30	**BREAK**	Check progress, arrange FCs, place some content on wall
10:45 -12:15	**RISKS AND BENEFITS (STEP 3)** • Identify risks and benefits in each area of consideration. - What are the risks and benefits in each area, given the profile of qualities and issues? Are there population groups particularly affected?	Cue Qs on screen and binder/Par. Guide Area by area, track risks & benefits ***Model one area in plenary, then delegate other areas to individual tables, then tables contribute ideas in plenary*** *while fac. tracks each area* Suggest participants use work book pages **(EC Table Facilitators/Facilitator)**
	• Identify confidence in supporting information - Is there sufficient supporting information to understand and substantiate the risk/benefit profiles?	Note which features/profiles may need more information to substantiate the profiles and raise group confidence in the evidence (notes on FC with profiles) ***Plenary exchange*** **(Facilitator/Asst. Facilitator)**
	• Consider weighing risks and benefits together - How would we weigh the risks and benefits together? How important are the risk factors and to they outweigh the benefits?	Provide example(s) of weighed comparison, both within a consideration area and across two or more areas. Suggest participants use work book pages ***Table group discussion first, then plenary exchange.*** **(EC Table Facilitators/Facilitator)**
12:15 - 1:15	**LUNCH**	Organize FC notes, post on wall as ready. Check in with participants. Check in with facilitator, if needed, to review issues, problems, etc. from morning table discussions **(EC Table Facilitators/Facilitator)**
1:15 - 1:45	**TRADE OFFS (STEP 3 CONTINUED)** • What are the trade offs that emerge when we weigh the risks and benefits? - Rank the trade offs (time permitting if list quite long) • Which of these trade offs are most compelling?	Compile ideas as composite weighed statements (e.g. risk attribute x 'taken together with/compared with/vs./against' benefit attribute y results in …….) Rank trade offs for top ones. ***Table Group discussion first, then plenary exchange*** **(EC Table Facilitators/Facilitator)** Track on separate FC **(Asst. Facilitator)**
1:45 - 2:45	**USING THE DIALOGUE TOOL SPECTRUM (STEP 4)** • Identify position in Spectrum that fits the case, for each area and overall - On balance, for each area of consideration, which spectrum position/colour/language best fits this case (given all the above) ? • On balance, which spectrum position/ colour/language best fits this case overall? Note if conditions are warranted/called for then advance the conditions into next step	Cue Qs on screen and binder/Par. Guide Review spectrum column gradation, colours, & language as aids to positioning Suggest participants use work book pages ***Table discussion first, then participants place sticky dots*** on each of five coloured wall Spectrum charts. Dots are associated by colour to each table. **(EC Table Facilitators/Facilitator)** Aggregate results (count dots), ***discuss in plenary,*** note strong clustering and divergences Repeat approach for overall positioning, i.e. **participants place dot on single spectrum wall chart, discuss in plenary**

TIME	ACTIVITY	PROCESS NOTES
2:45	**BREAK**	
3:00 - 4:00	**PROMISING DIRECTIONS (STEP 5)** • Identify conditions, solutions, and/or next steps to advance understanding/dialogue on this case (as appropriate) - Are there conditions or requirements we could suggest that would raise confidence in this case or clarify its fit in the spectrum? - Are there promising directions that could be explored, to advance solutions or mitigate problems? - What might be useful next steps to enable further in depth understanding and dialogue on this case? - Are there any recommendations for the next dialogue on this case? - How could the dialogue process on this case help others?	Cue Qs on screen and binder/Par. Guide. Suggest participants use work book pages. Start with 'conditions' if spectrum positioning calls for them. ***Address all 1-3 elements (conditions, solutions, advancing the understanding/dialogue) in table groups, then track exchange in plenary*** (option to delegate different elements to specific tables,) **(EC Table Facilitators/Facilitator)**
4:00 – 4:30	**EVALUATING THE DIALOGUE AND PROCESS** • Debrief session and process - What worked in the session….and what could be improved? - What lessons did we learn about the dialogue process and the Dialogue Tool….and how might we improve both in future? - What impact did this dialogue/dialogue process have on you? - Do you see other cases or situations where this approach and tool might be useful?	Cue questions on screen. Suggest participants use workbook/Par. Guide. Track observations and suggestions against questions. ***Plenary Exchange, including observers***
4:30 – 5:00	**OUTLOOK AND ADVICE ON THE FUTURE** • Provide overview on the last phase of the project (EC member) • Seek advice on further promotion of the Dialogue Tool/Process • Seek advice on future stewardship of the Tool/Process model (further development, hosting, advisory services on use, standards maintenance, accumulation of learning, lessons learned and best practices, facilitation advice [e.g. advice for other facilitators such as whether an orientation session or training is required, etc.]) • Close the session - thanks to participants and CBAC 's interest and support (facilitator) - request to complete evaluation (in binder) (facilitator) and leave behind - remind observers to leave their worksheets behind - Close session (EC member)	**(EC member to be identified)** ***Track suggestions in plenary*** ***Track suggestions in plenary*** Reference binder for feedback form. **(EC member/Facilitator to be identified)**

Flip Chart Sequencing

	HEALTH	ENVIRONMENT	SOCIO-ECONOMIC	ETHICAL	OTHER/BROAD
	GENERAL QUALITIES AND FEATURES				
Step 1: Qualities and features [define pros and cons]	Pros (more desirable/ favour use) Cons (less desirable / mitigate against use)	Pros Cons [confidence in information]	Pros Cons [confidence in information]	Pros Cons [confidence in information]	Pros Cons [confidence in information]
Step 2: Issues [List issues Expand issues, Rank issues, Note expectations]	Issue • really about.. Issue • really about… Ranked issue list Expectations to address	Issue • really about.. Issue • really about… Ranked issue list Expectations to address	Issue • really about.. Issue • really about… Ranked issue list Expectations to address	Issue • really about.. Issue • really about… Ranked issue list Expectations to address	Issue • really about.. Issue • really about… Ranked issue list Expectations to address
	HEALTH	**ENVIRONMENT**	**SOCIO-ECONOMIC, ETC.**	**AGGREGATING EXERCISE**	
Step 3: Risks, Benefits, and Tradeoffs (on select areas) [List risks, benefits, weigh together, identify tradeoffs, rank weighed tradeoffs]	Risks Benefits Pop groups affected [confidence in information]	Risks Benefits Pop groups affected [confidence in information]	Risks Benefits Pop groups affected [confidence in information]	Weighing exercise	• weighed statement with trade off • weighed statement with trade off Most compelling weighed statements list
Step 4: Using the Tool Spectrum [Identify spectrum position for each area and overall]	Place in Spectrum (column position, selected colour, gradation terminology) Note if 'conditions' required	Place in Spectrum (column position, selected colour, gradation terminology) Note if 'conditions' required	Place in Spectrum (column position, selected colour, gradation terminology) Note if 'conditions' required	Overall impression	Overall Place in Spectrum (column position, selected colour, gradation terminology) Note if 'conditions' required
Step 5: Promising Directions [List conditions List solutions List next steps]	Conditions Conditions		Solutions Solutions		Next Steps (recs for next dialogue) Next Steps (recs for next dialogue)

Debrief exercise

- What worked….what could be improved?
- What lessons about the process and Dialogue Tool?
- What impact did this dialogue/dialogue process have on you?
- Other cases where applicable?

Appendix 5
Sample Table Facilitator Guide

NOTE: This document is attached as an example only. It was created for use at the Multi-stakeholder Pilot Session held March 17-18, 2004. Subsequent changes to the process have been made and are not reflected in this document at this time.

GMFF Dialogue Tool
Multi-stakeholder Pilot Session, March 17-18, 2004
EC TABLE FACILITATOR GUIDE

As a small group facilitator, you are responsible for the following:

1) Time Management

Each table conversation has defined time limits with outputs to produce within those time limits, so you will have to manage the proportion of time spent exploring a topic, and time spent distilling the voice of the table, or summarizing (where appropriate). You may request help from someone else at the table to let you know when your allotted times are drawing near.

2) Facilitate open conversation

We are very committed to providing the opportunity for everyone to contribute, including those who may not be the usual ones to speak up. Please manage the flow of conversation to create the space for everyone to jump in. This will mean politely encouraging those with a lot to say to make space for the rest, and drawing out those who may not have taken the opportunity to speak. You may also need to gently redirect the conversation to ensure that the discussion does not get hijacked by a 'pet issue'.

Your experience with the Dialogue Tool will make it tempting to dominate the discussion. As a table facilitator, it is your job to remain neutral, listen actively and guide the discussion where necessary to keep it moving smoothly to achieving the required outputs.

3) Produce the required output

The main elements of discussion will be captured on the flip charts by the facilitator during the plenary portions of the session. It will also be helpful for you to briefly and concisely record the main points of the table discussions on a worksheet, or ask a member of the table to do it. We do not need a summary of all the details of the whole conversation for report back since the table discussions are meant to encourage individual thinking and understanding through group conversation, allowing individuals to contribute more effectively to the plenaries. We would like you to focus on identifying common ground, divergence/variety in perspectives and the range of ideas.

DAY 1 - Wednesday, March 17

TIME	ACTIVITY	NOTES, AIDS
5:30 - 6:30	**ARRIVAL AND REGISTRATION** • Greet and welcome participants; ensure they pick up session materials and sit at designated tables. • Answer questions as needed.	**(All EC members)** Binders, participant guide
6:30 - 7:10	**SESSION OPENING AND INTRODUCTION** • Contribute to the discussion as appropriate, to enhance richness of discussion, without dominating exchange.	**(All EC members)** Rules of Engagement, Backgrounder
7:10 - 7:30	**CASE INTRODUCTION** • If asked by the facilitator during the plenary review of the policy case, provide answers to technical or process questions. • Assist participants in locating correct materials, if needed (e.g. worksheet 1)	**(All EC members)** Worksheet 1
7:30 - 9:30	**QUALITIES AND KEY FEATURES (STEP 1)** **Intent of Step 1** In general, this section will have participants contribute freely into the open exchange, so there is not a specific table group discussion structured into the process. However, the facilitator may at any point, suggest that the table groups discuss the question/topic for a few minutes to generate some starting ideas. If this occurs, then…. **Tasks** • Introduce yourself and ask participants to introduce themselves. Introduce intent of step 1 which is to create a policy case "profile" under each of the five consideration columns noting favorable and unfavorable qualities/features. • Try to discourage people from moving quickly to judgment or stating firm positions about the policy case. They will have this opportunity at later stages in the dialogue. At this point it is important to get the facts out and break down the issue. • Encourage them to keep an open mind and listen actively to the others at their table. • **Focus on the particular consideration area raised, with enough depth to record the group's ideas about the key features of the case.** **Outputs** Develop an initial profile of the case, for that area of consideration, tracked as pros and cons, with some thought given to specific population groups that might be affected. Each participant should use their worksheets to track the discussion as they like. **Next step** Participants will be asked to share their ideas about the qualities and key features of the case in plenary to develop an overall profile of the case. A consensus report from each table will NOT be required. The purpose of the table discussion is to 'get the juices flowing', to allow participants to begin 'unpacking' the case.	**(EC Table Facilitators – POSSIBLE TABLE DISCUSSIONS)** Questions will be cued on screen. Use Worksheet 2-6, top left cell (Qualities/Features). **Key Dialogue Questions** • What are the qualities/features of this policy case? • Are they unique? • **What are features more desirable/ acceptable to Canadian society and, therefore, would favour use/adoption?** • **What are features less desirable/ acceptable to Canadian society and, therefore, would argue against use/adoption?** • What specific population groups are affected and how? • Is additional supporting information required to better understand and substantiate the feature profiles? What additional information do you recommend (whether the information is factual or perceptual)?

DAY 2 - Thursday, March 18

TIME	ACTIVITY	NOTES, AIDS
8:30 - 10:30	**ISSUE IDENTIFICATION (STEP 2)** Time: 20 minutes for brainstorm **Intent of Step 2** The intent of step 2 is to focus on the most critical issues that come up in each area of consideration, based on the profiles developed in Step 1. **Tasks** • Outline amount of time allocated to the task (20 minutes) • For all areas of consideration at once, brainstorm to identify the most pressing issues that come up in the case and the true essence of each issue (e.g. what is the issue 'really' about?), whether positive or negative. • You might encourage participants to consider, at this stage, whether there are existing or potential alternatives to the GM product or process being proposed. • NB: Sometimes the discussion about a specific issue may raise concerns about a broader issue or domain. Ask the group to be clear whether they want to talk about the specific or the global. • You may wish to note the relative importance of one issue over another if the group gives you clear direction but this should not be the focus of your discussion as it will be undertaken in plenary following the brainstorming exercise. **Outputs** A list of the most important issues arising out of the case, including a statement about what the issue is really about, noting any specific expectations participants have about addressing the issues. Participants can record individually on their worksheets. **Next step** Participants will be asked to share their ideas about the issues in plenary to develop an issues profile for each consideration area. Ranking the issues will be undertaken in plenary.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, top middle cell (Issues). **Key Dialogue Questions** • **What are the issues that arise in each consideration area?** • **What is the issue really about?** Allow each table to take time to discuss the core issues they see based on the profiles from Step One. • Which issues are most critical and why? • What are the expectations for addressing these most critical issues and why? • List all issues in all five areas first then, in the plenary session, rank in each area.
10:30	**BREAK** • Report any difficulties, issues, questions, etc. to the facilitator.	**(EC Table Facilitators – Speak with Facilitator)**
10:45 -12:15	**RISKS AND BENEFITS (STEP 3)** Time: 20 minutes for table discussion **Intent of Step 3** In step 3, participants will use the profile developed in steps 1 and 2 to discuss the risks and benefits associated with the policy case under each consideration area. As well, participants will assess **who is at risk** due to the introduction of the new science or product, and **who benefits** should things go forward as planned. Your table will be assigned one of the consideration areas in the introduction to step 3. **Tasks** • Indicate the amount of time allocated to the task (20 minutes). • The facilitator will assign one of the five consideration areas to your table. Identify the risks and benefits under this consideration area, including who is at risk and who will benefit if the case goes ahead as planned. • You should also get a sense of the group's **confidence in the supporting information** that supports the risk-benefit profile developed. • Note: The assessment of trade offs will take place in plenary and should NOT be a substantial part of the table discussion.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, middle left cell (Risks/Benefits). **Key Dialogue Questions** • **What are the risks and benefits in each area, given the profile of qualities and issues?** • **Are there population groups particularly affected?** • **Will the risk-benefit profile change over time?** • **Are we generally confident that the information we have is sufficient to support or substantiate the risk and benefit profiles we developed?**

TIME	ACTIVITY	NOTES, AIDS
	Outputs A list of the risks and benefits for the consideration area under discussion, including identification of groups affected by them and an assessment of the group's confidence in the available information. Participants can record individually on their worksheets. **Next step** Your table will be asked to share its profile of the consideration area assigned to it with the larger group. Assessment and weighing of trade offs will occur following the lunch break.	
12:15 - 1:15	**LUNCH**	
1:15 - 1:45	**TRADE OFFS (STEP 3 CONTINUED)** Time: 15 minutes for table discussion **Intent of Step 3, continued** Participants will be asked to compile ideas from the risks/benefits discussion as composite weighed statements (e.g. risk attribute x 'taken together with/compared with/vs./against' benefit attribute y results in …….). **Tasks** • Indicate the amount of time allocated to the task (15 minutes) • Use the results of the risk/benefits discussion to generate statements about the trade offs that need to be made between the identified risks and benefits. • Try to capture those trade offs that may be the most compelling to your group as well. **Outputs** A list of statements about the trade offs that need to be made, with the most compelling trade offs noted in some fashion. Participants can record individually on their worksheets.	**EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, middle right cell (Risks/Benefits). **Key Dialogue Questions** • **Can the risks and benefits be weighted?** • **How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?** • **What are the trade offs that emerge when we weigh/compare the risks and benefits?** • **Which of these trade offs is most compelling?**
1:45 - 2:45	**USING THE GMFF DIALOGUE TOOL SPECTRUM (STEP 4)** Time: 20 minutes for table discussion **Intent of Step 4** This is the stage where final summations about the case are starting to form. The actual GMFF Dialogue Tool spectrum will be used to "map" or position the policy case in terms of its level of support or acceptability with participants. This table discussion is meant to help prepare participants for their task of identifying their 'position' on the spectrum. **Task** • Explain the purpose and expected outputs of this step and note the time allocated to complete the task. • Help participants identify their 'position' on the spectrum. You may allow them some 'quiet time' to consider their position of the spectrum and ask them to record it on their worksheets for each consideration area, and for the policy case overall. The long colour version of the dialogue tool is most useful at this stage. • If an individual or group has identified a position on the colour spectrum that is associated with "conditions", ensure that the conditions are identified and explained when the position on the spectrum is presented. • Listen carefully to the comments of others and note any common ground and any remaining divergence of views. • Ask participants, when they are ready, to place their coloured dot in the desired position on the wall chart spectrum.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, bottom cell, and long colour version of the GMFF Dialogue Tool. **Key Dialogue Questions** • **On balance, for each area of consideration, which spectrum position/colour/language best fits this case?** • On balance, which spectrum position/ colour/language best fits this case overall? • **Where conditions are called for, what are the conditions and the rationale?**

TIME	ACTIVITY	NOTES, AIDS
	Outputs Encourage participants to record their position on the spectrum on their worksheets for each consideration area and for the policy case overall and then to do the same on the wall chart, using the sticky dots provided. The results will be aggregated and discussed in plenary.	
2:45	**BREAK**	
3:00 – 4:00	**PROMISING DIRECTIONS (STEP 5)** Time: 15 minutes for table discussion **Intent of Step 5** The step gives participants additional opportunity to discuss the conditions that would affect the acceptability of the policy case., e.g. express the conditions (if warranted or called for) required to move the case on the spectrum toward a more "acceptable" status. They will also discuss how the dialogue could be or should be extended, by this group or another. **Task** • Address all key dialogue questions (conditions, solutions, advancing the understanding/dialogue) as a group. • The group may have strong views about the conditions or requirements that would make the case stronger, or would assure their confidence as it moved forward. Please document these carefully. • Make sure that participants have the chance to say more about what should be passed on to others, so they don't feel that their dialogue output will be lost. **Outputs** Encourage participants to record their/the group's ideas on their worksheets. **Next step** Review and evaluation of the process and Dialogue Tool will be undertaken next (in plenary). Ensure that all table members have a copy of the evaluation form and worksheet 8.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 7. **Key Dialogue Questions** • **Are there conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?** • **Are there promising directions that could be explored to advance solutions or mitigate problems?** • **What useful next steps might enable further in-depth understanding and dialogue on this case?** • **Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance, facilitation advice)?** • **How could this dialogue process on this case benefit others (e.g. by contributing to policy development or** in helping to educate others)? • Where are the real opportunities associated with this policy case? Where are the real problems?
4:00 – 4:30	**EVALUATING THE DIALOGUE AND PROCESS** • Provide overview of the last phase of the project. • Listen carefully to the feedback being provided by participants and take notes to provide your own feedback for the EC final report to CBAC. • Contribute to the discussion if appropriate, to enhance richness of discussion, without dominating exchange.	**(EC member to be identified)** **(All EC members)**
4:30 – 5:00	**OUTLOOK AND ADVICE ON THE FUTURE** • Listen carefully to the feedback being provided by participants and take notes to provide your own feedback for the EC final report to CBAC. • Contribute to the discussion if appropriate, to enhance richness of discussion, without dominating exchange.	**(All EC members)**
5:00	**SESSION CLOSE** • Provide brief closing remarks.	**(EC member to be identified)**

Appendix 6
Dialogue Tool: Colour Version

Spectrum

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Health Considerations**	Clear evidence of improved human health outcomes. **Examples:** • improved food safety - reduced risk chemical residues - removal of allergens or toxins • improved nutritional outcomes • clear health benefits - introduction of a vaccine or other means to combat disease • production of an essential pharmaceutical	Similar health outcomes to existing products and/or evidence of improved health outcomes or offsetting risk/benefits. **Examples:** • reduced allergenicity but diminished nutritional benefit, flavour, utility • CONDITIONS could include: - product information (labelling) - monitoring	While the evidence of harm to human health is not conclusive, the identified risks are significant and must be addressed by more information or conditions. **Examples:** • specific studies are required to address identified risks or information gaps • CONDITIONS could include: - labelling to identify risk for certain groups - use restrictions	Clear evidence of unacceptable risk to human health not offset by any other health benefit. **Examples:** • introduction of a new allergen or toxin • serious diminution in nutritional value • evidence of harm through excess consumption of micro-nutrients in some sub-groups
Environmental Considerations**	Clear evidence of improved environmental outcomes. **Examples:** • improved agricultural practices (significant reduction in the use of pesticides, irrigations, tilling, etc.) • enhanced habitat protection • protection of endangered species (Comment – addressed above)	Similar environmental outcomes to existing products and/or evidence of improved environmental outcomes or offsetting risk/benefits. **Examples:** • use of herbicides but reduced tillage • reduced effect of pollen on bees/butterflies but increased risk of outcrossing • CONDITIONS could include: - stewardship requirements - product information (labelling) - geographical restrictions - containment procedures - monitoring	While the evidence of harm to the environment is not conclusive, the identified risks are significant and must be addressed through more information or conditions. **Examples:** • specific studies are required to address identified risks or information gaps • CONDITIONS could include: - monitoring - limited/controlled introduction - use restrictions - delay in market approval until studies are complete	Clear evidence of unacceptable risk to the environment not offset by any other environmental benefit **Examples:** • irreversible or threatening effect on biodiversity • contamination or pollution • ecosystem degradation, etc.

Spectrum				
CRITERIA*	**Fully "acceptable, supportable, desirable, beneficial, etc."**	**More "acceptable, etc." possibly with conditions**	**Less "acceptable, etc." with conditions or more information required**	**Not "acceptable, etc." under any circumstances**
Socio-economic Considerations	Clear evidence of improved socio-economic outcomes. **Examples:** • enhanced productivity, diversity in production or improved trade • improved outcomes for consumers such as reduced costs, enhanced choice, improved shelf life, etc. • outcomes are especially positive for producers (large and small)	Similar socio-economic outcomes to existing products and/or evidence or improved socio-economic outcomes or offsetting risk/benefits. **Examples:** • improved consumer outcomes (cost, choice, etc.) but diminished trade opportunities • the introduction of the product, while on the whole desirable, creates socio-economic issues for some groups of producers or consumers • CONDITIONS could include: - product information (labelling) - guidelines/restrictions for product introduction - legislative or standards changes to protect interests of affected groups - international competitiveness	While the evidence of harm is not conclusive, the identified risks are significant and must be addressed through more information or conditions. **Examples:** • studies or further consultation needed to address risks or information gaps • CONDITIONS could include: - product information (labelling) - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups - trade agreements - delay market introduction until studies/consultations are complete and risk addressed	Clear evidence of unacceptable soci-economic outcomes that cannot be otherwise addressed or mitigated. **Examples:** • denial of access to traditional or future export markets • increased food costs, on a full-cost accounting basis • effects on small producers that cannot be mitigated, etc.

Spectrum				
CRITERIA*	**Fully "acceptable, supportable, desirable, beneficial, etc."**	**More "acceptable, etc." possibly with conditions**	**Less "acceptable, etc." with conditions or more information required**	**Not "acceptable, etc." under any circumstances**
Ethical Considerations* **	Clear evidence that ethical considerations have been fully and carefully weighed, and the decision-making criteria for ethical considerations are clear. **Examples:** • the process of development has been guided by precaution and national standards • based on principles of justice, equity, transparency, accountability and inclusion • introduction of the product, after broad consultation, is deemed to enhance the preservation of biodiversity • improves quality of human life	Similar ethical outcomes to existing products with evidence or improved ethical outcomes or offsetting risk/benefits. **Examples:** • improved food supply for indigenous peoples but achieved with their consent to forego traditional agricultural methods • CONDITIONS could include: - implementation of mechanisms to promote choice or otherwise increase beneficence - diligence, timely, full broad and meaningful consultation - disclosure, verification (3rd party independent), enforceability - risk/benefit consultation	While the evidence of harm is not conclusive, the identified risks raise ethical concerns that may be difficult to address at present or unless and until societal norms change or may be addressed with more information or under certain conditions. **Examples:** • insertion of human genes into plants or animals • creation of new species • patenting of higher life forms, etc. • CONDITIONS could include: - product information (labelling) - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups • delay market intro until studies/ consultations are complete and risk addressed	Clear evidence that introduction of the product raises ethical concerns that cannot be addressed now or in the foreseeable future. **Examples:** • species extinction • creation of a threatening species • unacceptable effect on animal welfare • threat to human well-being and sustainable communities • widening of povery gap and access to affordable food supply, etc.

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Broader Considerations (Societal Interests and International Considerations)	Clear evidence of improved outcomes for the broader society and world, including full, meaningful and wide consultation and compliance with relevant international agreements. **Examples:** • empowers developing country producers • broad improvements in agricultural practices • improves benefit sharing between developed and developing countries, rich and poor classes, or women and men • greatly improves food security globally, especially in developing countries • meets a great societal need • distribution of benefits and risks overtime and across generations	Similar societal outcomes to existing products, with evidence of improved societal outcomes or offsetting risk/benefits. **Examples:** • improved food security in developing world but with greater economic concentration • improved agricultural production in developing world but trade blockage from developed world • CONDITIONS could include: - international agreements that protect vulnerable citizens - international compensation, increased aid, or subsidies to developing countries to allow for adjustment, increase market access for their products, or to compensate for use of traditional knowledge	While the evidence of harm is not conclusive, the identified risks are significant and difficult to address at present. **Examples:** • unresolved issues of ownership • compensation for traditional knowledge • changes in traditional practices/societal norms (this is environmental) • CONDITIONS could include: - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups - delay market introduction until studies/consultations are complete and risk addressed - international agreements in place	The introduction of the product is not acceptable from a societal perspective now or in the foreseeable future. **Examples:** • unacceptable threat to food security • appropriation or redundancy of traditional or indigenous knowledge and practice • elimination of markets for developing world producers • evidence that there would be unacceptable risks to future generations

* These Criteria, where applicable, should reflect outcomes both unique to a GMFF or in general for a technology, research area, product, etc. They apply to all stages of the life cycle – from research and development, through confined trials, production, handling, processing, transportation, consumption and waste disposal. Outcomes may be relative to existing products, standards and practices and may be influenced by whether credible alternatives exist.

** Health and safety considerations presume the foundational level of legislated regulatory clearance, i.e., Canada requires a mandatory Food, Feed and Environmental Safety assessment and clearance before any GMFF product is authorized for market introduction. Canadian regulatory standards exceed WHO and OECD standards for safety evaluation.

*** For the purposes of the Dialogue Tool, the term "ethics" is understood as a widely held system or set of principles/beliefs which provides the framework within which to make moral choices for the public good. "Values" refer to those qualities, properties or ideals deemed important, desirable, or of worth and which are/may be applied to questions of choice throughout the dialogue tool/process. Relative to ethics, the term "values" refers to commonly held moral qualities or properties deemed of worth or importance, used as criteria upon which moral decisions are/can be made. For example:

- **Ethic of equality -** all are equal; none is less equal.
- **Value of inclusion -** everyone's participation is ensured and respected, and each perspective is considered in decision-making.
- **Ethic of sustainability -** of the Planet and its resources; human life in harmony with nature and not compromising future of generations to come.
- **Value of restoration and preservation -** of a natural resource such as water, taking into account social, economic and environmental impacts of actions.

Positions along the spectrum

- **Acceptable/Supportable -** Outcomes are improved or similar on balance to existing products or practice. Meets existing standards, either no new risks/issues are introduced or are offset by a greater reduction in an existing risk/issue.
- **More Acceptable with conditions, to Less Acceptable until certain conditions are met or more is known -** Outcomes are similar to existing situation, there exists evidence of improved outcomes and/or evidence of risk to varying degrees, or the risk is considered too high to be acceptable under present circumstances. Depending on the benefit/risk scenario certain conditions may be required. Conditions may be imposed to mitigate or eliminate the risk.
- **Not acceptable under any circumstances -** Evidence of harm is conclusive and serious i.e., destructive and irreversible, that cannot be offset by any other benefit.

Considerations

- **Human Health Considerations -** Includes toxicity, allergenicity, nutritional value and potential long term impacts on health (e.g. post-market monitoring of effects on obesity levels, dietary habits, etc.). They may apply to the population as a whole or to specific sub-groups.
- **Environmental Considerations -** Includes effects on biodiversity, pollution and sustainability, including effects on targeted and non-targeted species, changes in biological/ecological fitness (such as outcrossing [i.e. pollens crossing from one crop to another], or invasiveness).
- **Socio-economic Considerations -** Economic effects include trade, costs/benefits, productivity, education, economic growth and economies of scale. Social effects include distribution of income, effect on small and large farms, regional effects and consumer choice.
- **Ethical Considerations -** Include ethical or moral concerns such as justice, magnanimity, animal welfare, use of the precaution, due diligence, accountability, transparency, enabling choice, utilization of and access to new knowledge/technology, meaningful participation of affected parties, and acceptable use of the technology in manipulating life.
- **Broader Considerations (societal interests and international considerations) –** Includes international relations, distribution of risks, costs and benefits, effects on the developing world (benefit sharing, centre of origin [i.e. the original geographic source of a plant], food security), empowerment, trade, globalization (sovereignty, democracy, power imbalances), knowledge and technology development, and compliance with related international agreements/accords.

Example Approach to Use of Dialogue Tool Overview

Assuming there is a biotechnology product or process subject to discuss, which may be a technology, or proposed research in a new area, or a type of product, etc., the subject would be considered using the following sequence:

1. Identify the qualities or features of the product, are the qualities or features unique to the GMFF subject, and list them in relation to the five areas of consideration (i.e., Health considerations, etc).
2. Define the issues that arise when considering the subject qualities in each area.
3. Engage in a dialogue on the issues, seeking clarity, better understanding and a sense of which issues are the most critical/have the most impact, and the expectations there are/may be for addressing these issues.
4. Identify the risks and benefits of the product in each area of consideration and determine if these are unique to the product or also relate to other products of biotechnology.

5. Weigh the risks and benefits together and consider the potential trade offs in and across the areas of consideration.
6. Using the spectrum breakout, identify which area of the spectrum best fits the subject, after discussing and weighing all the factors above – do this for each consideration area, and then overall.
7. Choose the preferred language (see below) that best describes the position of the product in each consideration area and then the overall position of the product (note: if 'conditions' are called for, then suggest the type of conditions or further information that could be called for).
8. Provide any advice on how to further consider the future of this product.

Preferred Language Options

- At the left end of the spectrum
  - fully acceptable/supportable and/or desirable/beneficial
- At next position (left to right)
  - acceptable/supportable
  - acceptable/supportable with some conditions
- At next position (left to right)
  - not acceptable at this time
  - not acceptable without conditions or more information
- At the right end of the spectrum
  - not acceptable under any circumstances

Appendix 7
Dialogue Tool (Brief Overview)

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Health Considerations				
Environmental Considerations				
Socio-economic Considerations				
Ethical Considerations				
Broader Considerations (Societal Interests and International Considerations)				

Appendix 8
Sample Evaluation Form

FEEDBACK on the Dialogue Tool
Multi-stakeholder Pilot Session

Thank you for your contribution to the development of the Dialogue Tool. We would appreciate if you could take a few moments to provide us with some feedback. Please fill out this form and leave it at the back of the room when you leave.

1. **What impact did today's dialogue have on you?**

2. **What worked in the session…. and what could be improved?**

3. **Could the Dialogue Tool be helpful in your work? How?**

4. **Do you see cases or situations in addition to Dialogue Tool where this approach might be useful?**

5. **What are your suggestions on how CBAC could promote the Dialogue Tool?**

6. **Did you find the organization and facilitation of the session to be effective?**

Very Poor	Poor	Satisfactory	Good	Excellent
☐	☐	☐	☐	☐

Comments and/or suggestions for improvement?

7. **You received some background documents prior to the Pilot Session as well as several hand-outs and worksheets during the session. How useful was this information to you?**

	Not Useful	Somewhat Useful	Very Useful
Background Documents	☐	☐	☐
Hand-outs and Worksheets	☐	☐	☐

Comments and/or suggestions for improvement?

8. **Other comments:**

If you are interested in receiving additional information about the Dialogue Tool and the dialogue process, please provide us your name, telephone number and e-mail address.

Please send any additional comments about the Dialogue Tool, the dialogue process and today's pilot session to **<insert contact name>** at **<e-mail address>** by **TUESDAY, MARCH 23, 2004.**

Name:

Telephone number:

E-mail address:

Appendix 9
Members of the Exploratory Committee

Herb Barbolet
Ellen Desjardins
Denise Dewar
Conor Dobson
Jennifer Hillard
Martin Jamieson
Joy Kennedy
Elizabeth May
Don McCabe
Elbert van Donkersgoed
Geoff Wilson

CBAC

Mary Alton Mackey
Peter Phillips

Facilitators

Lyle Makosky
Kerrianne Carrasco

Appendix 10
Sample Facilitator's Powerpoint Presentation to guide Primary Steps

NOTE: This document is attached as an example only. It was created for use at the Multi-stakeholder Pilot Session held on March 17-18,2004. Subsequent changes to the process have been made and are not reflected in this document at this time.

Slide 1

Slide 2

Slide 3

Slide 4

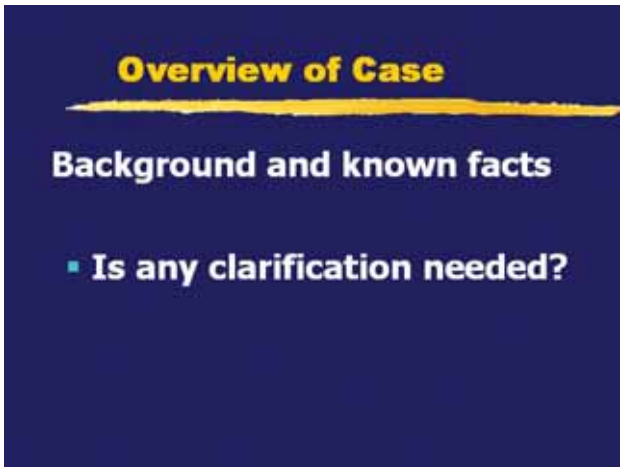
Slide 5

Slide 6

Slide 7

Slide 8

Slide 9



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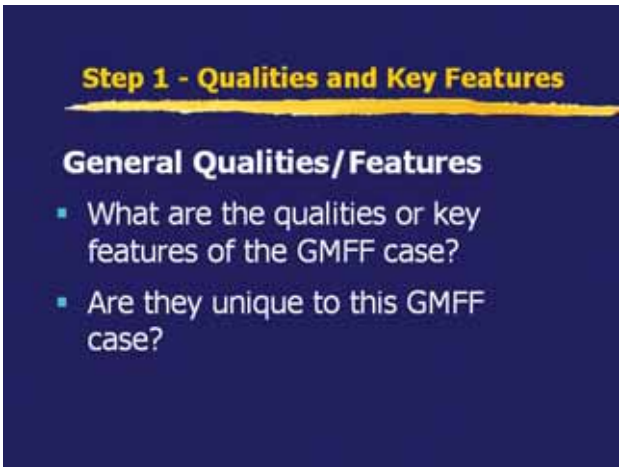

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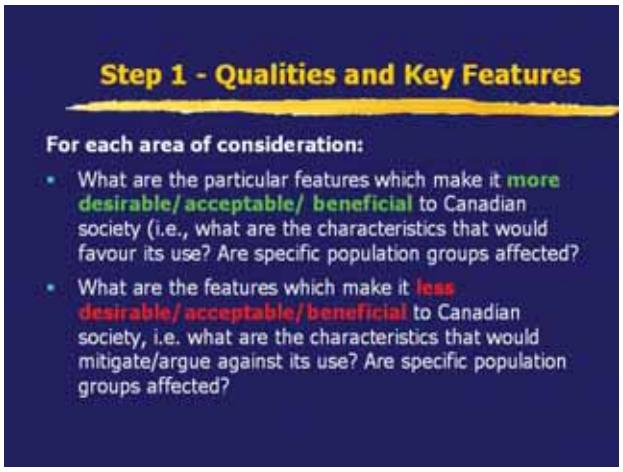

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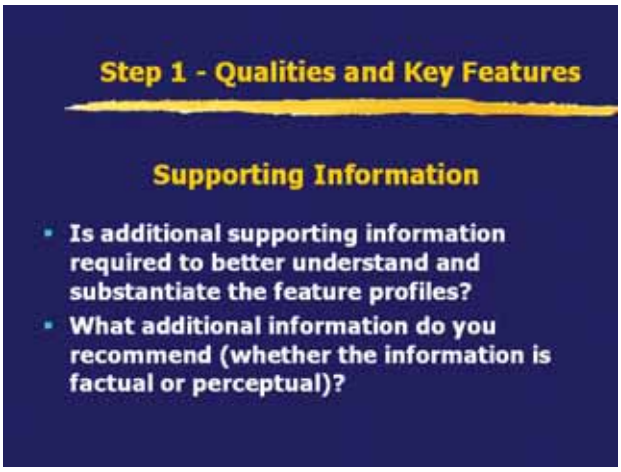

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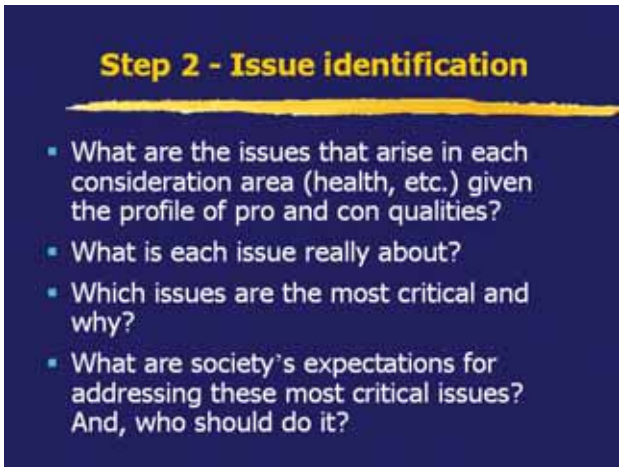

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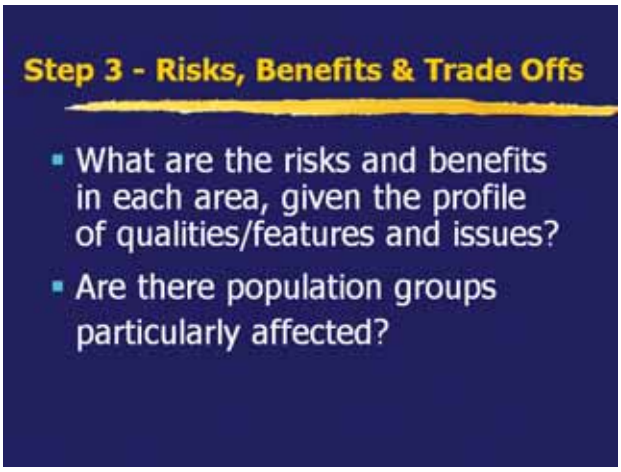

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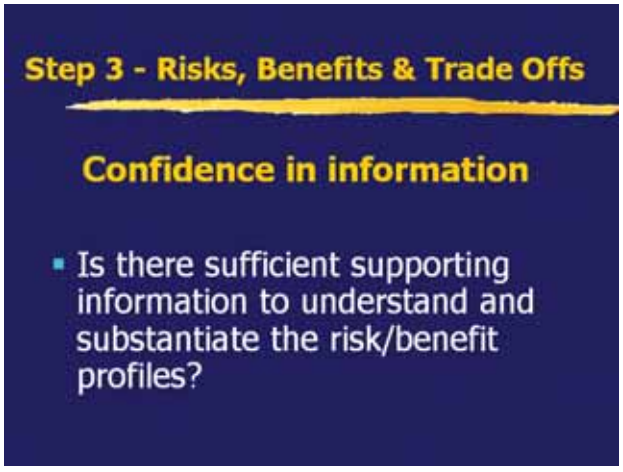


Slide 16

Slide 17

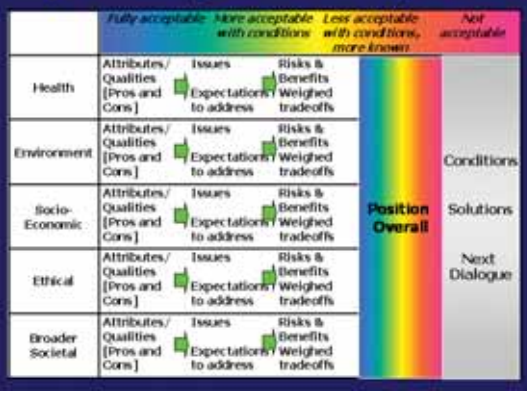
Step 4 - Using the Tool's Spectrum

- On balance, for each area of consideration, which spectrum position/colour/language best fits this case?
- On balance, which spectrum position/ colour/language best fits this case overall?

Note: specify where conditions warranted, and explain what the conditions might look like

Slide 18

Step 4 - Using the Tool's Spectrum



Slide 19

Step 5 - Promising Directions

- Are there **conditions or requirements** we could suggest that would raise confidence in this case or clarify its fit in the spectrum?
- Are there promising directions that could be explored, to **advance solutions** or mitigate problems?
- What useful **next steps might** enable further in-depth **understanding and dialogue** on this case?
- Are there **recommendations for the next dialogue** on this case?
- How could this dialogue process **benefit others**?

Slide 20

Evaluating the dialogue and process

- What worked in the session….and what could be improved?
- What lessons did we learn about the dialogue process and the Dialogue Tool…and how might we improve in future?
- What impact did this dialogue/dialogue process have on you?
- Do you see other cases or situations where this approach and tool might be useful?

Slide 21

Outlook and advice on the future

- **Overview** on last phase of project
- Do you have advice on further promotion, exposure, use of the tool?
- Are there observations or suggestions on the future stewardship of the Tool/process? (e.g. further development, hosting, advisory services on use, standards maintenance, accumulation of learning, lessons and best practices on method, facilitation, etc.)

Slide 22

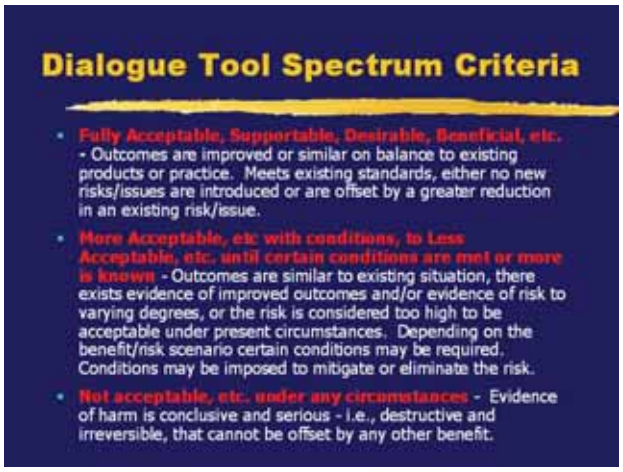
Closing

- Summary
- Next Steps
- Appreciation
- Complete and leave evaluation

Slide 23

Slide 24

Slide 25



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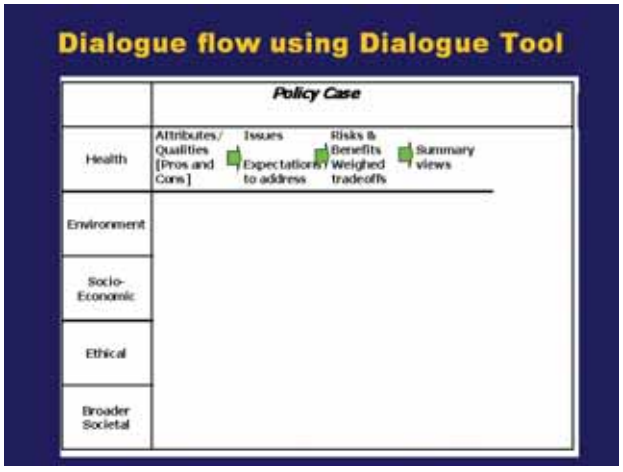

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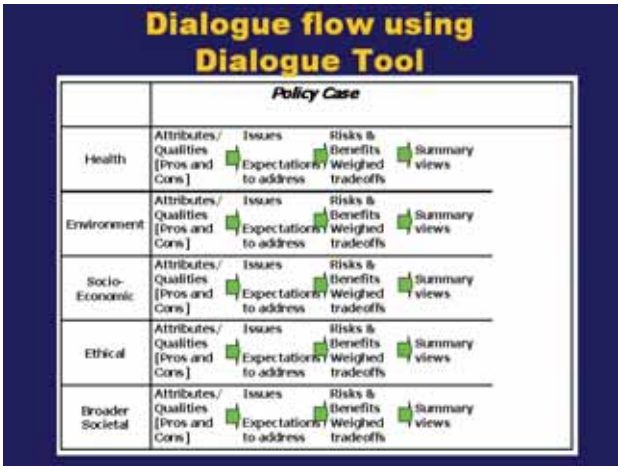

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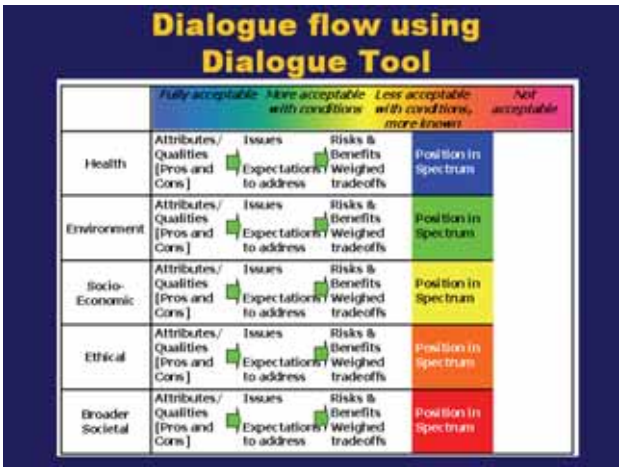

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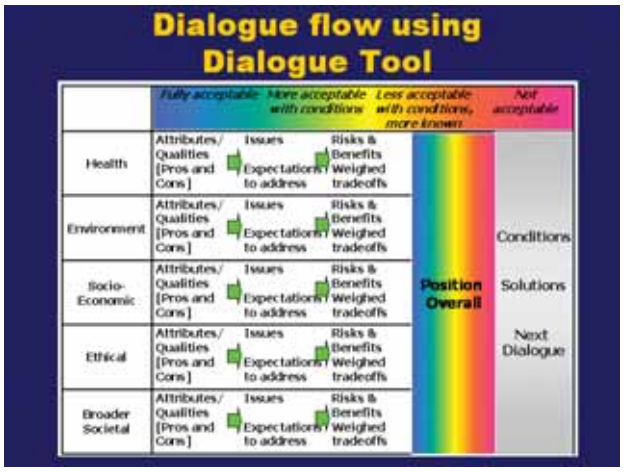

Appendix 11
Dialogue Tool
Sample Participant Worksheets

Worksheet 1 – Policy Case

Example Case: Plant-made Pharmaceutical Generated in Food-grade Soybeans

N.B.: The following case is completely hypothetical (although grounded in existing science) and was developed solely for the purposes of testing the dialogue tool at the Multi-stakeholder Pilot Session on March 17-18., 2004 in Ottawa, Ontario. It is included here to offer a model for a case description.

Introduction

A pharmaceutical company wishes to produce a new blood thinning agent. While the drug could be produced chemically, the company believes that a plant-made pharmaceutical (PMP) may provide a significant therapeutic advantage related to the purity of the active ingredient. Production of the protein would require genetic modification of a plant – and in this case, the most desirable host plant is also a food. The company has a patent on the active ingredient.

The company is concerned about the potential public reaction to this proposal. It understands that some members of the public may have concerns with genetically modified (GM) foods in general and that most citizens have concerns about whether proper safeguards will be in force. The public is aware of a few, well-publicized incidents of transgenic crop violations involving other food crops (e.g., Starlink and Prodigene products).

The company does not wish to invest a considerable sum in developing the PMP if public opposition will make it impractical to produce. It has heard about a new approach to dialogue on GM Foods, called the Dialogue Tool and has asked two facilitators to guide a dialogue session, with a wide range of participants, to discuss the potential product, to discern their underlying views and issues, and identify the conditions under which the acceptance of the product might be improved.

As the product has not yet been developed, the regulators – either Health Canada or Canadian Food Inspection Agency – have not reviewed it.

The Case

The case for discussion is genetically engineered food-grade soy, grown to produce a patented pharmaceutical – a blood thinning protein derived from pig spleens. The crop is to be grown by farmers in five locations in Ontario – 4 hectares each for a total of 20 hectares – under contract for a major pharmaceutical company. It will be grown in open fields and appropriate safeguards will be required to ensure both isolation and containment, such as full segregation, buffer zones within season and buffer crops.

Even though some would consider these safeguards sufficient to satisfy regulatory requirements, the developer intends to take an additional step to prevent outcrossing – namely the use of Genetic Use Reduction Technology (GURT), also known as the terminator gene. In this case, the developer intends to use a Varietal GURT or V-GURT to make the plant sterile. While the introduction of GURT may allay some concerns, it could also introduce new ones such as the theoretical potential for cross-pollination with traditional varieties leaving progeny sterile, and related concerns for biodiversity.

The soy is not intended for consumption as a food – either for humans or animals. It is not considered toxic, but inadvertent consumption of unusually large amounts may cause a pharmacological effect – the thinning of the blood. Hence, good farming practices and other management systems will be required to ensure that the entire crop is used as a pharmaceutical input, and that none of it ends up as food or feed. This should be in the company's best interest as the crop will be very expensive.

Example Case: Plant-made Pharmaceutical Generated in Food-grade Soybeans

Comments/Thoughts:

Worksheet 2

HEALTH CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits	Weighing Risks and Benefits	
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully ‘acceptable, supportable, beneficial, desirable’, etc.	More ‘acceptible’, etc., possibly with conditions	Less ‘acceptable’, etc., with conditions or more information required	Not ‘acceptable’ etc. under any circumstances

Worksheet 3

ENVIRONMENTAL CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks

Benefits

Population Group(s) Affected

Trade Offs **Most Compelling**

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 4

SOCIO-ECONOMIC CONSIDERATIONS

Qualities/Features Pros Cons	Issues	Ranking	Expectations to Address

Risks Benefits Population Group(s) Affected		Trade Offs	Most Compelling
	Weighing Risks and Benefits		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 5

ETHICAL CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits		
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 6

BROADER CONSIDERATIONS

Qualities/Features	Issues	Ranking	Expectations to Address
Pros			
Cons			

Risks	Trade Offs	Most Compelling
Benefits		
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 7

PROMISING DIRECTIONS

Identify conditions, solutions, and/or next steps to advance understanding/dialogue on this case (as appropriate):

Conditions - Are there conditions or requirements we could suggest that would raise confidence in this case or clarify its fit in the spectrum?

Solutions - Are there promising directions that could be explored to advance solutions or mitigate problems?

Help Advance Dialogue - What might be useful next steps to enable further in-depth understanding and dialogue on this case?

Help Advance Dialogue – Do you have any recommendations for the next dialogue undertaken on this case? (e.g. areas or questions to focus on, further research in advance, etc.)

Help Advance Dialogue – How could this dialogue process on this case benefit others? (e.g. by contributing to policy development or helping to educate others, etc.)

Help Advance Dialogue – Where are the real opportunities associated with this case? Where are the real problems?

Worksheet 8

DEBRIEF DIALOGUE SESSION AND PROCESS

What worked in the session….and what could be improved?

What impact did this dialogue have on you?

**What lessons did we learn about the dialogue process and the Dialogue Tool….
and how might we improve both in future?**

Do you see other cases or situations where this approach and tool might be useful?

Notes

Appendix 12
Additional Resources

Experienced Users of the Dialogue Tool

1. Exploratory Committee (see Appendix 9 for list)
   c/o Canadian Biotechnology Secretariat
   235 Queen St.
   Ottawa ON K1A 0H5

   Canadian Biotechnology Advisory Committee
   http://www.cbac-cccb.ca

Experienced Dialogue Tool Facilitators

2. Lyle Makosky
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   1404 – 1 Nicholas Street
   Ottawa, ON K1N 7B7
   Ph: (613) 241-1001
   E-mail: ggreene@stratos-sts.com

Other Relevant Resources

1. **Canadian General Standards Board. 2001.** Voluntary Labelling and Advertising of Foods That Are, or Are Not, Products of Gene Technology.
2. **Conseil de la science et de la technologie (Québec). 2002.** *OGM et alimentation humaine : impacts et enjeux pour le Québec.*
3. **Donaldson, L. May R. 1999.** *Health Implications of Genetically Modified Foods.* Report for the Ministerial Group on Biotechnology (MISC 6), Department of Health. United Kingdom.
4. **European Commission. 2001.** *Toward a Strategic Vision of Life Sciences and Biotechnology.* Consultation Document.
5. **Farmers Legal Action Group, Inc. (FLAG). 2001.** *GMO Liability Threats for Farmers: Legal Issues Surrounding the Planting of Genetically Modified Crops.*
6. **Food and Agriculture Organization and World Health Organization. 1996.** *Biotechnology and Food Safety.* Report of the Joint FAO/WHO Expert Consultation, September 30-October 4. Rome.
7. **Food and Agriculture Organization and World Health Organization. 2000.** *Safety Aspects of Genetically Modified Foods of Plant Origin.* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, May 29-June 2. Geneva, Switzerland.
8. **Food and Agriculture Organization and World Health Organization. 2001.** E*valuation of Allergenicity of Genetically Modified Foods.* Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, January 22-25.
9. **Food and Agriculture Organization and World Health Organization. CODEX Alimentarius Commission. 2002.** *Principles for the Risk Analysis of Foods Derived from Biotechnology.*
10. **Food Policy Institute of the Consumer Federation of America. 2001.** Breeding Distrust: *An Assessment and Recommendations for Improving the Regulation of Plant-derived Genetically Modified Foods.*
11. **IFT. 2000a.** IFT expert report on biotechnology and foods: Introduction. *Food Technology* 54: 124-36.
12. **IFT. 2000b.** Expert report on biotechnology and foods: Human food safety evaluation of r-DNA biotechnology-derived foods. *Food Technology* 54 (9): 53-61.
13. **IFT. 2000c.** Expert report on biotechnology and foods: Labelling of r-DNA biotechnology-derived foods. *Food Technology* 54 (9): 62-74.
14. **IFT. 2000d.** Expert report on biotechnology and foods: Benefits and concerns associated with recombinant DNA biotechnology-derived foods. *Food Technology 54* (10): 61-80.
15. **Institute on Governance. 2002.** *Linking In, Linking Out, Linking Up: Exploring the Governance Challenges of Biotechnology.*
16. **New Zealand. 2001.** *Report of the Royal Commission on Genetic Modification.*
17. **Organisation for Economic Co-operation and Development. 2000.** *GM Food Safety: Facts, Uncertainties, and Assessment.* The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods.
18. **Organisation for Economic Co-operation and Development. 2000.** *Report of the Task Force for the Safety of Novel Foods and Feeds.* 86/ADDI. Paris: OECD, May 17.
19. **Privy Council Office. 2001.** *A Canadian Perspective on the Precautionary Principle.* Discussion Document.
20. **Royal Society of Canada Expert Scientific Panel. 2001.** *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada,* Ottawa (http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf).
21. **Royal Society of London. 1998.** *Genetically Modified Plants for Food Use.*
22. **Royal Society of London. 2002.** *Genetically Modified Plants for Food Use and Human Health: An Update.* Policy Document 4/02. February. (http://www.royalsoc.ac.uk)

23. **United States. Environmental Protection Agency. 2000.** Biopesticides Registration Action Document: Preliminary Risks and Benefits Sections *Bacillus thuringiensis* Plant Pesticides.
24. **United States. National Academy of Sciences. 2002.** European Union/United States *Biotechnology Consultative Forum: Final Report. December 2000.* (http://europa.eu.int/comm/external_relations/us/biotech/report.pdf)
25. **United States. National Academy of Sciences. 2002.** *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.* (http://www.nap.edu/books/0309082633/html)
26. **United States. National Research Council. 1989.** *Field Testing Genetically Modified Organisms: Framework for Decisions.* Washington, DC: National Academy Press.
27. **United States. National Research Council. 2000.** *Genetically Modified Pest Protected Plants: Science and Regulation.* Washington, DC: National Academy Press.
28. **World Intellectual Property Organization. 1999.** *Intellectual Property Needs and Expectations of Traditional Knowledge Holders.* Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge.

Websites

1. **AgBios:** http://agbios.com/main.php
2. **AgBio Forum:** http://www.agbioforum.org/
3. **CBAC GM Foods:** http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/h_ah00103e.html
4. **CBAC Dialogue Tool:** http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/h_ah00350e.html
5. **Canadian Food Inspection Agency:** http://www.inspection.gc.ca/english/toce.shtml
6. **European Community Sponsored Research on Safety of GMOs:** http://europa.eu.int/comm/research/quality-of-life/gmo/index.html
7. **GM Nation:** http://www.gmnation.org.uk/
8. **Health Canada - Regulation of Novel foods:** http://www.hc-sc.gc.ca/english/protection/ novel_foods.html
9. **Canadian Agri-Food Research Council:** http://www.carc-crac.ca/english/index.htm
10. **Nuffield Council on Bioethics:** http://www.nuffieldbioethics.org/gmcrops/index.asp
11. **The Royal Society:** http://www.royalsoc.ac.uk/policy/index.html
12. **World Health Organization:** http://www.who.int/health_topics/food_genetically_modified/en/ and http://www.who.int/foodsafety/biotech/en/
13. **Food Safety Network:** http://www.foodsafetynetwork.ca/
14. **Plant Biotechnology Institute:** http://www.pbi.nrc.ca/en/pbi.htm

SECTION 3

Dialogue
Participant Guide

SECTION 3

Pages

Dialogue Tool

Participant Guide

Canadian Biotechnology Advisory Committee

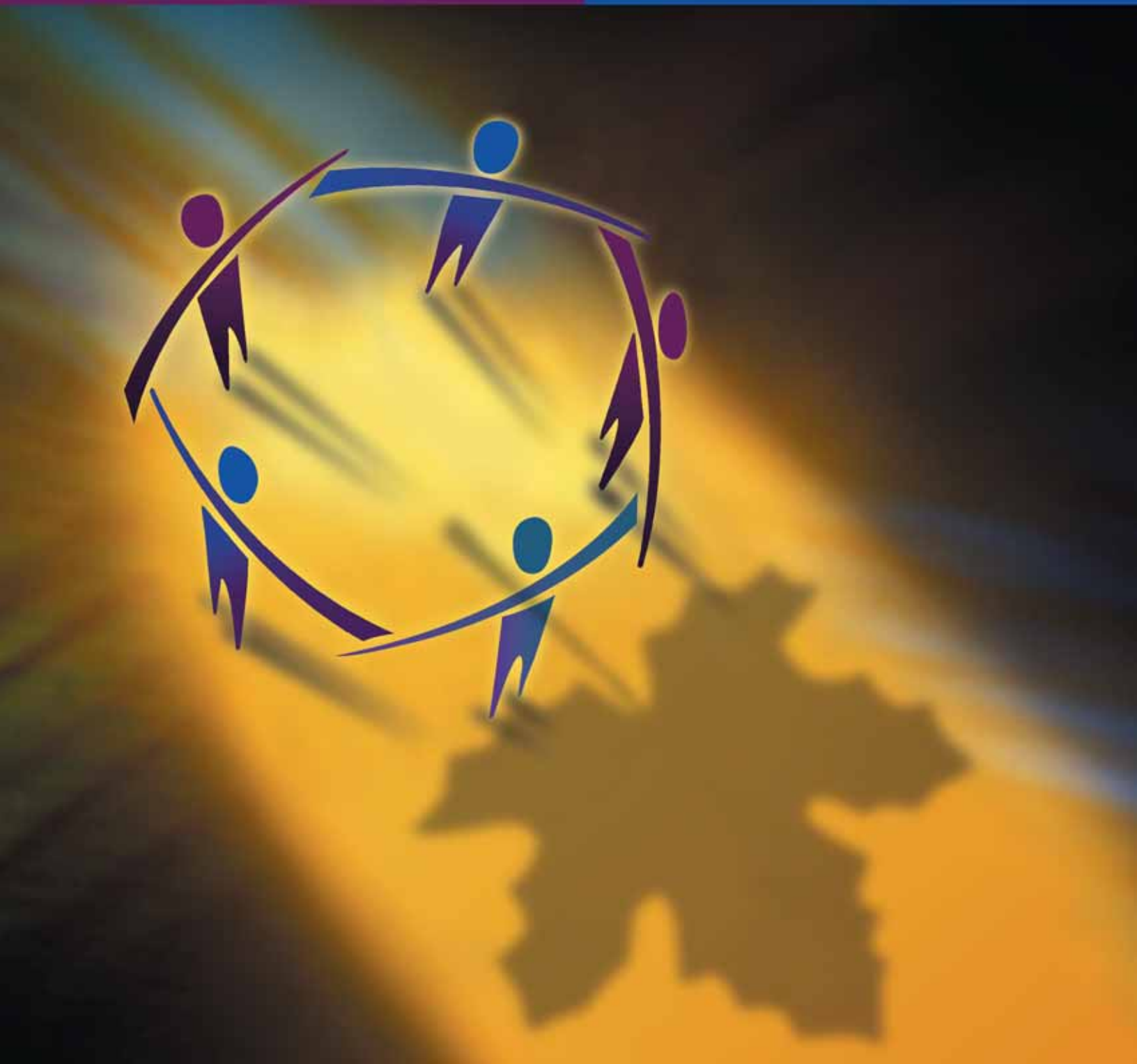


Table of Contents

1

INTRODUCTION TO THE DIALOGUE TOOL

The Dialogue Tool is a simple, printed matrix that helps a group of people "unpack" one or more of the complex issues associated with Genetically Modified Food and Feed. It helps participants walk through a series of process steps and arrive at the heart of some of the most complex scientific and ethical issues likely to be considered by citizens and their governments. The tool lets them view an issue from different angles. It enables examination of a wide range of broad issues as well as specifics and narrower questions. It affords expert and non-expert inputs. It looks for alternatives. It encourages respectful dialogue and education. But most importantly, it allows the group to determine what they like, what they do not like, what they are concerned about and where they finally "sit" vis-à-vis the biotehnology issue at hand. A real or hypothetical policy case provides the substance of the dialogue. The tool and process do not necessarily produce full consensus, but common ground is often found among participants with widely divergent interests and opinions.

The Dialogue Tool is a unique, "Made-in-Canada" public discourse device. It borrows from other public consultation methodologies and extends beyond traditional public opinion polls or focus groups. The Dialogue Tool is used to look at issues associated with biotechnology though the lens of five "considerations" or "themes" – health, environment, socio-economic considerations, ethical considerations and broader considerations such as international implications. Best of all, it was designed and tested by many of the stakeholders who had asked for new and different ways to be engaged by government on the issue of genetically modified food & feed (GMFF). A committee of individuals drawn from the food producing sector, the biotech industry, growers, public interest groups (including consumer and public health groups), faith organizations and environmental groups have devoted considerable time over the past few years refining the tool and the process that it supports.

The dialogue approach involves a 6-step process, guided by an expert facilitator, where participants explore all dimensions of a biotechnology case study, including a product's features, risks and benefits, issues and implications, and then propose

The Dialogue Tool is all about creating constructive discussion about biotechnology issues in Canada. Policy makers, industry leaders, not-for-profit organizations and academics can all use the tool. It can be used to inform policy making, while also serving as an educational tool. And it can be used by individual stakeholder groups or by a group of stakeholders to aid in decision-making processes. By helping to identify central issues, underlying value questions, possible solutions, areas of compromise and Canadian values, it encourages different points of views to be heard.

summary observations and suggestions on the future for the case example. In this approach, participants discuss ideas in small groups, exchange views in plenary session with the whole group, note their opinions in individual survey instruments, and record their individual views in a private workbook as appropriate.

Definition of GM/GMFF

For the purposes of this dialogue approach, the focus will be on a case study of genetically modified crops and livestock for food and feed (either as individual products or classes of products). This has been shortened to 'Genetically Modified Food and Feed', and in this document will be represented by the acronym GMFF. As it is commonly understood, the term "genetically modified" refers to food or feed that has been produced using recent advances in gene technology, such as cloning, gene splicing and the introduction of single genes into plants (or animals) through a process called transformation. These and other techniques are often collectively referred to as recombinant DNA (rDNA) technology and they define a set of tools for "genetically engineering" organisms (e. g. plants, animals and bacteria). The dialogue approach will generally focus on cases that are the result of such genetic engineering as defined here.

While the focus of this tool is on food products modified using rDNA techniques, the developers of this Tool are aware that many other new and traditional techniques are being used to modify food and feed products. It should be understood that similar issues exist for all techniques used in the modification of food and this tool can be used to help the open discussion of these issues, regardless of the modification technique under discussion.

2

THE DIALOGUE TOOL MODEL AND APPROACH

What is the Dialogue Tool?

The Dialogue Tool is a printed matrix or grid, with strong visual components that aid understanding and dialogue (see Appendix 1). The tool includes an "spectrum" that is designed to help people figure out the degree to which they find a biotechnology product acceptable or suitable in the Canadian context. The tool uses comparative terminology (e.g. "acceptable/supportable/beneficial/desirable" through to "unacceptable"), as well as colour to differentiate those degrees of support. In some ways, the Dialogue Tool provides a "temperature reading" of the views about a specific GM initiative. It also allows stakeholders with different points of view to build bridges between their respective positions.

Five Ways to Look at a GMFF Policy Case Study

More importantly, the tool and the dialogue process help people break down or "unpack" what would appear to be a highly complex and often confusing subject matter. Specifically, participants using the tool are challenged to look at a real or hypothetical biotechnology policy case study through the lens of five different themes – health, environment, socio-economic considerations, ethical considerations and broader societal considerations.

Dialogue Tool – Five Considerations

- **Human Health -** Includes toxicity, allergenicity, nutritional value and potential long term impacts on health (e.g. effect on obesity levels, dietary habits, etc.). These considerations may apply to the population as a whole, or to specific sub-groups.
- **Environment -** Includes effects on bio-diversity, pollution and sustainability, including effects on targeted and non-targeted species, changes in biological/ecological fitness (such as outcrossing [i.e. pollens crossing from one crop to another], or invasiveness).
- **Socio-economic -** Economic effects include trade, costs/benefits, productivity, education, economic growth and economies of scale. Social effects include distribution of income, effect on small and large farms, regional effects and consumer choice.
- **Ethical[1] -** Includes ethical or moral concerns such as justice, magnanimity, animal welfare, use of precaution, "due diligence", accountability, transparency, enabling choice, utilization of and access to new knowledge/ technology, meaningful participation of affected parties, and acceptable use of the technology in manipulating life.
- **Broader/Other -** (Societal interests and international considerations) - Includes international relations, distribution of risks, costs and benefits, effects on the developing world (benefit sharing, centre of origin [i.e. the original, geographic source of a plant], food security), empowerment, trade, globalization (sovereignty, democracy, power imbalances), knowledge and technology development, and compliance with related international agreements/accords.

1 For the purposes of the Dialogue Tool, the term "ethics" is understood as a widely held system or set of principles/beliefs which provides the framework within which to make moral choices for the public good. Relative to ethics, the term "values" refers to commonly held moral qualities or properties deemed of worth or importance, used as criteria upon which moral decisions are/can be made. For example: the Ethic of equality - all are equal; none is less equal; and the Value of inclusion - everyone's participation is ensured and respected, and each perspective is considered in decision-making.

The Spectrum

The Dialogue Tool is essentially a graphic grid that allows dialogue participants to position, or map, their views within a range – from full support through to complete rejection of the biotechnology product proposal. A colour code has been assigned to the spectrum too, so participants can talk about their feelings of support or unease, in terms of a gradation or shades of a colour. The red end of the spectrum indicates a larger degree of caution, while the blue end of the spectrum allows for more support.

- **Fully Acceptable, Supportable, Desirable, Beneficial, etc. [deep blue to green]:** Outcomes are improved or similar on balance to existing products or practice. Meets existing standards, either no new risks/issues are introduced or are offset by a greater reduction in an existing risk/issue.
- **More Acceptable with conditions [dark green to yellow]:** Generally the policy case is viewed favourably, but participants have identified conditions or "must haves" that would improve their overall opinion about the case and allow them to endorse its forward progress.
- **Less Acceptable until certain conditions are met or more is known [yellow to orange/red]:** The risk is considered too high to be acceptable under present circumstances. Depending on the benefit/risk scenario, certain conditions may be required. Conditions may be imposed to mitigate or eliminate the risk.
- **Not acceptable, etc. under any circumstances [light red to deep red]:** Evidence of harm is conclusive and serious (i.e. destructive and irreversible, that cannot be offset by any other benefit.)

With the help of a facilitator, participants take a first pass down the matrix and create "profiles" for the sample policy case in each of the five consideration areas. In a second pass, participants identify the issues arising from these profiles. On a third pass, they begin to consider the policy case in terms of its risks and benefits, and the apparent "trade offs" that emerge. Eventually, they are asked to comment on the "acceptability" or "supportability" of the policy case within the spectrum based on what they have now learned or explored by moving through the dialogue process.

The Dialogue Tool considers a spectrum of possible outcomes for each consideration theme (each represents a visual area within the spectrum of acceptability) – acceptable/supportable/beneficial/desirable; acceptable with certain conditions; unacceptable at the present time and until more is known or a given standard is met; or not acceptable under any circumstances. A real world parallel to the category "not acceptable under any circumstances" might be an unconditional prohibition (i.e. a ban). "Not acceptable until more is known" might be likened to a moratorium.

Participants work together to determine if there are 'conditions' for acceptability and what those conditions might be, both for each consideration area and for the case overall. They also 'test' the conditions to ensure that it is realistic to expect the case proponent or other parties involved to achieve the conditions, and then contemplate which conditions are most critical to confirming or improving acceptability. The last stage looks at 'promising directions' including suggested conditions, new thinking on solutions to mitigate problems that were identified, and guidance for future dialogue on this case.

As you use the Dialogue Tool, keep in mind that the goal is not necessarily to achieve consensus but to inspire and encourage dialogue, to bring different viewpoints to the table and to share expertise and perspective. In some cases, people using the tool have changed their minds or admitted that they learned something new. And sometimes consensus has been achieved. Most people said the dialogue was worth it for what they learned, how they were able to listen to others, and how free they were to put their own views forward. Participants have also commented that they are able to break down complicated, often highly scientific, information so they can become more comfortable about their level of understanding and appreciation of the many impacts of new technologies.

A Note about Government Regulation of Biotechnology Products and Processes

The Dialogue Tool is very flexible and could be used in support of many different expert and public consultation initiatives, policy development, dispute resolution, position development and public education activities. It was not designed to create regulations for new or existing biotechnology products and procedures and is not meant to evaluate products that are moving through the regulatory system, or to 'second guess' the regulatory system by introducing another step in the current regulatory process.

Canada's regulations exceed those established by the World Health Organization (WHO) and the Organization of Economic Cooperation and Development (OECD). The determination of whether these products or procedures are allowable in Canada is based on health and safety considerations that look at hard scientific data and the impact on health and on the environment. Before any biotechnology product, such as genetically modified food & feed, is authorized for introduction into the Canadian marketplace, it must clear the foundation level of legislative regulatory standards (e.g. the mandatory Food, Feed and Environmental Safety Assessment imposed by the Canadian Food Inspection Agency).

The Dialogue Tool is more geared to informing and supporting policy development, and in no way replaces the regulatory systems that aim to protect Canadian consumers.

3

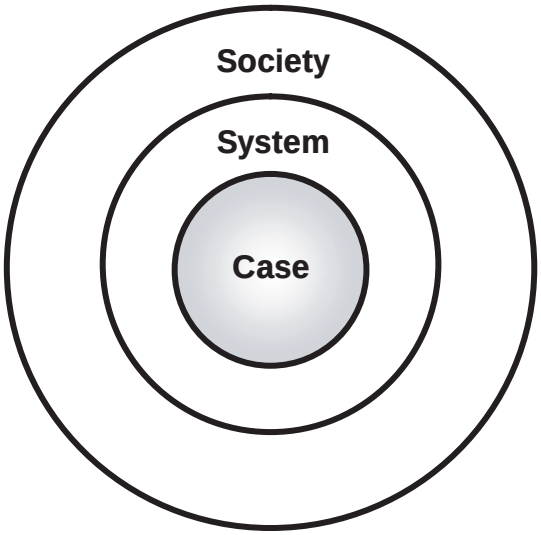
AN OVERVIEW OF THE DIALOGUE PROCESS

A trained facilitator will walk participants through the dialogue process. As you get ready to participate, it sometimes helps to consider how the dialogue process is designed. Using the coloured version of the Dialogue Tool, a small group of dialogue participants will consider a sample, or real, policy case associated with developments in genetically modified food and/or feed. Facilitation staff will keep track of your comments and the "profiles" you build as you progress through the discussion. In the end, you may not have reached consensus, but you will have plumbed the depths of the issue and considered many of the ways – positive, negative or neutral — it could possibly affect Canadians, and contemplated what it means for the future and offered suggestions for the way ahead.

Using the Dialogue Tool, participants are guided through a process to see how a complex biotechnology policy case, either real or hypothetical, can be "unpacked" into more understandable components. Participants will move between assessing specifics of the case and a range of broader issues derived from the case, and back again. The test policy case is examined from the perspectives of health, environment, socio-economic, ethical and other broader considerations (e.g. international). Participants consider the risks, impacts, benefits, implications and possible trade offs under each of these themes or considerations. They then assess the relative degree of "acceptability" or "supportability" for each consideration.

Toward the end of the dialogue, the group explores possible conditions that could affect the receptivity of the case in question. Participants conclude by making suggestions for further work that could improve understanding and subsequent societal dialogue on the policy case.

Throughout the process, participants will be informed by background information provided on the case prior to the dialogue session and/or by the contributions of participants who may have factual knowledge and experience related to the case. As well, perceptions may be important to understanding how the case is viewed and influences society, or they may clarify where more facts or research may be needed, or to indicate what we know is all we can know at that point. Hence, facts and perceptions will both have a place in the dialogue, with varied relative importance at different stages of the process.



It is a challenge in any dialogue process, especially involving complex subjects such as GMFFs or other products of biotechnology, to balance discussion between the topic at hand and broader societal issues without shortchanging either. To some participants, it is most desirable to focus discussion on the issue/case at hand. They feel that enlarging the debate beyond case facts (e.g. health/safety issues) only confuses the dialogue. To others, it is difficult, if not impossible, to discuss a policy issue without a larger societal/systemic context.

This question should be clarified by clear agreement beforehand on what the dialogue session is focused on and trying to achieve, i.e. if the objective is feedback on the **case** then a predominant focus on the case is desirable; however if

the goal is to understand the concerns for how a case is dealt with in the developmental and regulatory system then a focus on the **system** is warranted; and if the intent is to explore and appreciate the larger **societal context** and the impact of a product of biotechnology then a larger view focus is desirable. The predominant focus selected will also affect the focus, tangibility and influence of improvements and recommendations that a dialogue group might suggest.

The following are the main steps in the dialogue process and the key questions that need to be explored at each stage. A facilitator will guide the discussion throughout, either in small break-out groups or in a full plenary session.

Table 1 shows a quick overview of how you'll step through your dialogue process. The dialogue process is outlined in detail below as well.

Table 1 – Summary of the Dialogue Process

SESSION INTRODUCTION – Review Session Objectives, Process and Rules of Engagement

FOCUS
- Set the parameters/scope/objectives of the dialogue.
- Clarify roles and participant expectations.
- Provide general overview of the Dialogue Tool and process.
- Review Rules of Engagement or the code of conduct for the dialogue.

KEY QUESTIONS
- Are we comfortable with the objectives set for this session?
- Is the dialogue process clear and understandable?
- Can we agree to actively use and follow the rules of engagement?
- What are we trying to achieve with this dialogue?
- What are the outputs or products expected from this dialogue? Who will receive or use the results, and for what purpose?
- What is the scope of the dialogue?
- How much time is set aside for the dialogue?

CASE INTRODUCTION – Overview of the GMFF Policy Case Study

FOCUS
- Provide a general overview of the policy case being used for the dialogue discussion.
- Confirm participants' understanding of the policy case that will be considered by the dialogue group.

KEY QUESTIONS
- Is there any clarification of the case needed?

STEP 1 – Qualities and Key Features of the Case

FOCUS
- Ascribe qualities or key features to the biotechnology product or process proposed in the case study, first in general as a brief profile, and then in each area of consideration (health, environment, socio-economic, ethical, other).
- Develop a high-level, general view of the policy case, while noting specific features under each of the five consideration headings
- Identify the people or populations most affected by the policy case.
- Create a policy case "profile" under each of the five consideration columns noting favorable and unfavorable qualities/features.

KEY QUESTIONS
- What are the qualities/key features of this policy case?
- Are they unique?
- What are features more desirable/acceptable to Canadian society and, therefore, would favour use/adoption?
- What are features less desirable/acceptable to Canadian society and, therefore, would argue against use/adoption?
- What specific population groups are affected and how?
- Is additional supporting information required to better understand and substantiate the feature profiles?
- What additional information do you recommend (whether the information is factual or perceptual)?

STEP 2 - Issue Identification

FOCUS
- Focus on the most critical issues that come up in each area of consideration, based on the profiles developed in Step One.
- Rank the issues.
- Discuss public/societal expectations to address these issues.
- Identify those populations most affected by the policy case.

KEY QUESTIONS
- What are the issues to be considered in this policy case given the features and qualities discovered in Step One (i.e. the pros and cons of the policy case under each consideration/theme)?
- What are the issues in each consideration area (e.g. health)?
- What is the issue really about? What is at stake here?
- Which issues are the most critical and why?
- What are society's expectations about what should be done about this policy case, and these critical issues in particular, and who should do it?

STEP 3 – Defining Risks and Benefits

FOCUS
- Review output from Step One and Step Two.
- Consider risks and benefits under each consideration/theme.
- Identify populations most affected by each.

KEY QUESTIONS
- What are the risks and benefits in each area, given the profile of qualities and issues?
- Is there sufficient supporting information to understand and substantiate the risk/benefit profiles?
- Are there population groups particularly affected?

OPTIONAL QUESTIONS
- How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?
- What are the trade offs that emerge when we weigh/compare the risks and benefits?
- Which of these trade offs is most compelling?

STEP 4 - Using the Dialogue Tool's Spectrum

FOCUS
- Use the actual Dialogue Tool spectrum to "map" or position the policy case in terms of its level of support or acceptability with participants.
- Use the colour code of the spectrum to characterize the degree of support for the policy case, first in each area of consideration.

KEY QUESTIONS
- Given what we have learned/understand about the case at this point, on balance, for each area of consideration, which spectrum position/colour/language best fits this case?
- Optional - On balance, which spectrum position/ colour/language best fits this case overall?

STEP 5 - Determining Conditions for Acceptability

FOCUS
- Assuming there is significant interest expressed in the middle zone of the spectrum in step 4 (green to yellow to orange colour range), proceed to identify the conditions that would affect the acceptability of the case
- Outline the conditions that are affected predominantly by or derived from each consideration area (i.e. Health, socio-economic, etc.)
- Synthesize or combine these area conditions into an overall list
- Test the conditions for probability of achievement, i.e. to ensure they fall within a reasonable range of control and influence by the case proponent or others involved, and revise as needed
- Rate the conditions as to which are most critical to confirming or improving acceptability
- Further define the conditions so they are specifically actionable and by whom.
- Re-assess position on spectrum for comparison with position in Step 4. What are the conditions or requirements that would raise confidence in the acceptability of this case or clarify its fit on the spectrum?

KEY QUESTIONS
- What are the conditions derived from each area of consideration?
- How would we combine these into an overall list?
- Is each condition achievable? Is each condition within the control and influence of the relevant party (e.g. case proponent or other selected party)? How can we revise the conditions to enhance the probability of achievement?
- Which of these conditions are most critical to acceptability? Which would help advance acceptability (e.g. move left some degree on the spectrum)?
- What are the specific actions and responsibilities to give effect to these conditions?
- Given the application of the proposed conditions to this case as defined to this point, on balance, for each area of consideration, which spectrum position/colour/language now best fits this case?
- Given application of the proposed conditions, on balance, which spectrum position/ colour/language now best fits this case overall?

STEP 6 – Exploring Promising Directions

FOCUS

- Spend more time discussing the conditions that would affect the acceptability of the policy case., e.g. express the conditions (if warranted or called for) required to move the case on the spectrum toward a more "acceptable/supportable/beneficial/desirable" status.
- Identify conditions, solutions, and/or next steps to advance both the understanding of the policy case and the dialogue about it.
- Review the entire dialogue and try to capture the essence and high-level conclusions.
- Talk about how the dialogue could be or should be extended, by this group or another.

KEY QUESTIONS

- Are there further conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?
- Are there promising directions that could be explored to advance solutions or mitigate problems?
- What useful next steps might enable further in-depth understanding and dialogue on this case?
- Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance)?
- How could this dialogue process on this case benefit others (e.g. by contributing to policy development or in helping to educate others)?
- Where are the real opportunities associated with this policy case? Where are the real problems?

DEBRIEFING - Evaluating the Dialogue and Process (OPTIONAL)

FOCUS

- Debrief the experience drawing out impressions, lessons and potential applications elsewhere.

KEY QUESTIONS

- What worked in the session and what could be improved?
- What impact did this dialogue have on you?
- What lessons did we learn about the dialogue process and the Dialogue Tool and how might we improve it in the future?
- Do you see other cases or situations where this approach and tool might be useful?

4

The Dialogue Process

PRELIMINARY PREPARATION- Getting Ready for the Dialogue

Participant Tips

- Read and contemplate the dialogue orientation materials prior to the dialogue session.
- When you come to the dialogue session, bring your orientation materials with you as they will be used throughout the session.
- Review and carefully consider the Rules of Engagement

Experience with the Dialogue Tool shows that much depends on the effort put forth prior to the dialogue session. Good preparation by dialogue organizers, facilitators and participants will result in a more effective and productive dialogue.

Your informed and knowledgeable participation in the dialogue is key to its success. It is therefore important for you to read and contemplate the dialogue orientation materials (i.e. this Guide, rules of engagement, the Dialogue Tool, the back-grounder) in advance of the dialogue session. It would also be useful for you to read the policy case and make some notes, and if you desire, to conduct your own research and ask for the opinions of others before attending to ensure your understanding of the issues for discussion.

Additional information about the Dialogue Tool is posted on the CBAC web site at http://www.cbac-cccb.ca/.

SESSION INTRODUCTION – Review Session Objectives, Process and Rules of Engagement

Key Dialogue Questions

- Are we comfortable with the objectives set for this session?
- Is the dialogue process clear and understandable?
- Can we agree to actively use and follow the rules of engagement?
- What are we trying to achieve with this dialogue?
- What are the outputs or products expected from this dialogue? Who will receive or use the results, and for what purpose?
- What is the scope of the dialogue?
- How much time is set aside for the dialogue?

The purpose of step one is to provide a general overview of the Dialogue Tool and process.

The facilitator will review the session objectives, and run through the dialogue process to provide participants with a broad understanding of the parameters, scope and objectives of the dialogue. Some time will also be spent to clarify the roles and expectations of the different participants, including the facilitator, participants, experts and any others. The facilitator will also review the Rules of Engagement or the code of conduct (see Table 2, pg.12) for the dialogue with participants.

Participant Tips

- Consider and understand your responsibilities and those of other participants and the role of the facilitator and any expert resources present.

Required Materials

- Session Agenda
- Rules of Engagement
- Participant Guide

CASE INTRODUCTION - Overview of the GMFF Policy Case Study

To ensure a common understanding of the facts of the policy case at hand, the facilitator will provide a general overview of the policy case being used for the dialogue discussion, and confirm participants' understanding of the policy case that will be considered by the dialogue group. One or more experts may be on hand to assist in answering participants' questions about the facts of the policy case.

Optional Added and/or Alternative Methods

Before beginning an in-depth discussion of the session case/topic, the facilitator may ask participants to indicate their 'position' of this case on the spectrum. This exercise will be undertaken again in Step 4 and at the end of Step 5 for comparison to build understanding of whether and how participants have moved in their thinking on the issue at hand. (see step 4 for approach).

Key Dialogue Question

- Is there any clarification of the case needed?

Required Materials

- Policy Case
- Worksheet 1

Participant Tips

- Review the case beforehand and identify any aspects that may need clarifying.

Rules of Engagement

The following rules of engagement will help create a dialogue setting that encourages a balanced, candid and constructive exchange about the issues associated with a biotechnology product or process. The dialogue session will begin with a review of the rules of engagement to ensure that all participants are comfortable and in accord about how they will work together.

Participate Fully – You should participate to the best of your abilities. You are here because you have something to add to this dialogue and because your views matter. We need you – and all of the participants – to engage fully, according to your conscience and from your own knowledge and experience. You should draw upon your beliefs, express your uncertainties, and utilize the knowledge base and interests of your constituency or organization to contribute to the session's objectives.

Open Dialogue – Dialogue participants should participate in a thoughtful and constructive manner and help create an open, balanced and respectful dialogue by:

- proceeding in a spirit of openness and collaboration;
- sharing factual and substantive information that can illuminate the discussion; and
- speaking candidly.

Mutual Respect – Respect is key to making this process work. Everyone should have the opportunity to express their views and opinions. We all need to listen carefully in order to understand the different perspectives being expressed and the factors that have shaped beliefs and views on these issues. This is the key to finding balanced solutions. We can try to:

- proceed in a spirit of mutual respect;
- not make assumptions but listen to, respect and attempt to understand the points of view, motivations, beliefs and rationales of the other participants; and
- respect the candidness of others and use care in representing the interactions and individual opinions of others.

Find Common Ground – The Dialogue Tool is designed to help participants identify common ground among a diverse set of opinions and interests. Some form of consensus is usually the goal, but as reasonable people, we know that full agreement may prove elusive. In successful dialogue sessions, participants endeavour to seek agreement and convergence, with the goal of producing a report identifying the points of agreement, differences in principles, and unresolved matters discussed during the dialogue.

No Attribution – Dialogue participants will not attribute any comments and/or views of participants after or outside the dialogue session to protect the spirit of candid and open exchange.

Prepare in Advance – Dialogue participants agree to prepare for the session by reviewing all background, sample policy cases and orientation materials carefully.

Personal responsibility – Dialogue participants are responsible for their own behaviour and input. This responsibility includes:

- respecting the process (attention to time, focus at each step, design of session)
- respecting each other
- helping to constructively advance the dialogue
- active listening and active contribution
- managing one's own expectations and contributing to meeting the session expectations.

STEP ONE -
Identifying Qualities and Key Features

To commence the dialogue, the facilitator introduces participants to the policy case and asks them to begin to **ascribe qualities or key features** to the biotechnology product or process proposed in the case study. This is done as a first step to develop a high-level, general view of the policy case, and then by noting specific features under each consideration heading. By doing so, the facilitator starts to "unpack" (break down) the issue into its component parts.

Using a flip chart, the facilitator asks the group to consider the general features of this new product or process. Comments are noted on the flip chart and the facilitator gets participants to provide their input in a way that does not really make a judgment about the feature. For example, if a new pharmacological product is being proposed, participants will note that the product has intended health benefits but no other judgments are made at this step as to the desirability or efficacy of such a benefit. The facilitator will also ask participants to identify if any of these features are unique or different in some way that is worth noting.

Next, the facilitator asks the group to consider the features of this product or process in the five key consideration areas shown on the Dialogue Tool, namely health, environment, socio-economic, ethical, broader/other. Comments under each consideration column are noted on separate flip charts, by sorting the qualities and features in each area of consideration according to whether they are more desirable/acceptable (i.e. would favour use/pro) or are less desirable/ acceptable to Canadian society (i.e. would argue against use/con). This is the first time that participants are asked to **make some judgements about the qualities or features. However the focus is still on identifying the qualities and not on defining or discussing the issues that arise from the case.**

Finally, participants will be asked to list those **groups of people or populations most affected** by this proposed product, policy change or biotechnology process.

At the end of Step One, the group will have developed a "profile" in each of the five rows of the matrix. These profiles show the favourable and unfavourable qualities that need to be explored under each of the five consideration areas.

Required Materials

- Worksheets 2-6
- Dialogue Tool (colour)
- Policy Case

Participant Tips

- Try to keep an open mind to the features and qualities in the policy case provided.
- Focus on identifying the qualities/features of the case and avoid the tendency to move into issues arising from the case (which will be developed in the next step).
- Be **open to the ideas of others** in the room or in your small break-out group.
- Ask for more clarification from experts in the room, if they are available.
- Ask the facilitator to **clarify process questions** if you have concerns.
- Use the worksheets provided to sort out key ideas and to make note of your own thoughts and the comments of others.
- Try not to apply too much judgment at this stage. Step One is intended to open up the broad range of considerations associated with the proposed biotechnology (product or process) and is primarily an education stage to enable all participants to see and understand the profile of the case and its dimensions.

Key Dialogue Questions

- What are the qualities/features of this policy case?
- Are they unique?
- What are features more desirable/acceptable to Canadian society and, therefore, would favour use/adoption?
- What are features less desirable/ acceptable to Canadian society and, therefore, would argue against use/adoption?
- What specific population groups are affected and how?
- Is additional supporting information required to better understand and substantiate the feature profiles?
- What additional information do you recommend (whether the information is factual or perceptual)?

Optional Added and/or Alternative Methods

- Apply a risks and benefits analysis[2]
- Apply an alternatives analysis[3]

At the end or during this sequence, the facilitator may ask the group about their confidence in the supporting information/ evidence, i.e. whether there is adequate information to substantiate the profile developed or if further information would be beneficial to understanding the case and its impact.

It is important to balance the need for adequate information with the need to dialogue on the issue at hand and the need to avoid 'information overload'. In some cases, especially in non-traditional research areas such as social research, 'scientific' data may not exist; perception may be more important in these instances. This should be recognized but should not limit the potential for dialogue, and such perceptions should be accepted as a core part of the group's collective views and understanding on the issue at that point in time.

2 Risks and benefits analysis identifies the risks associated with the case, typically who and what is at risk, and then identifies what the benefits are and who benefits from them.

3 An alternatives analysis asks whether there are existing alternatives to the proposed product with similar qualities/attributes; whether the new case qualities are distinctive and/or add value; and, whether the impacts of the proposed product in each area of consideration are different or better than the impacts from the existing alternatives.

STEP TWO -
Issue Identification

At this stage, participants will be asked to first identify the issues arising from the Step One profiles (in each consideration area) and then will be guided to focus on two or three of the most critical issues in each consideration area, that arose from the qualities and attributes of the policy case.

While a review of the profiles created in Step One will raise a number of issues, the facilitator will endeavour to focus on two or three of the most important in each area. These issues will be ranked in terms of their importance, and the facilitator will again encourage an open discussion, either table-by-table or in plenary. Participants will be asked to consider what the issue is really about (in other words, what is really at stake), and how and why it is important. The issues highlighted at this stage will be put under further scrutiny at the next step.

To complete this process step, participants will be asked to talk about the **expectations for addressing these most critical issues.** This component of the dialogue allows participants to identify what Canadian society might expect to be addressed/done about these issues (individually or as a whole) and also to clarify who they think is most responsible or has a strong role in addressing the subject area. For example, do people think that government should act in this area? Is there a need for more scientific input? Does industry need to take action on something, or provide more information in a certain area?

Key Dialogue Questions

- What are the issues to be considered in this policy case given the features and qualities discovered in Step One (i.e. the pros and cons of the policy case under each consideration/theme)?
- What are the issues in each consideration area (e.g. health issues)?
- What is the issue really about? What is at stake here?
- Which issues are the most critical and why?
- What are society's expectations about what should be done about this policy case, and these critical issues in particular, and who should do it?

Required Materials

- Worksheets 2-6
- Dialogue Tool (colour)
- Policy Case

Participant Tips

- Work with others at your table to define the most **pressing issues** and the **true essence of the issue**, whether it is positive or negative.
- Participate in the plenary discussion to really try to reduce the list of issues to a short-list of two or three for each area of consideration.

Key Dialogue Questions

- What are the risks and benefits in each area, given the profile of qualities and issues?
- Is there sufficient supporting information to understand and substantiate the risk/benefit profiles?
- Are there population groups particularly affected?

Optional Questions

- How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?
- What are the trade offs that emerge when we weigh/compare the risks and benefits?
- Which of these trade offs is most compelling?

Required Materials

- Worksheets 2-6
- Dialogue Tool (colour)
- Policy Case

Participant Tips

- In some ways, the facilitator will be asking you to consider the risks and benefits together to see how they compare and contrast with each other. Find out if you have strong feelings about the relationship or balance between the risks and the benefits.

STEP THREE – Defining Risks and Benefits

This step in the dialogue process asks participants to again review what they have learned and the profiles they have created under each of the five column headings in Step One and Step Two. In Step Three, they use that information to discuss the risks and benefits associated with the policy case under each consideration area. As well, participants will assess **who is at risk** due to the introduction of the new science or product, and **who benefits** should things go forward as planned.

This step involves several sub-steps:

- Consideration of **risks and benefits per consideration area**.
- Discussion about the population groups **particularly affected**.
- Consideration of the group's **confidence in the supporting information** that supports the risk-benefit profile developed.
- The application of some **weighting** to the risks and benefits to help when weighing them together to determine if the risk is greater than the benefit (or vice versa) or if they balance each other.

Optional Added and/or Alternative Methods

Depending on the objectives and expected outcomes of a session, the facilitator may choose to use other methods to manage discussion of risks and benefits, such as:

- Risk analysis (probability and impact)[4]
- Alternatives analysis[5]
- Weighing risks and benefits[6]
- Trade off analysis[7]
- 'What if' scenarios[8]
- Triple bottom line assessment[9]
- Sustainability Impact Assessment (SIA)[10]

4 In risk analysis, the risks are identified first, then rated individually on the probability each will occur, and on the impact each would have if it occurred.

5 See footnote 3.

6 Risks and benefits are considered and weighed together as to whether one outweighs another.

7 When risks and benefits are weighed together, one identifies what the trade offs appear to be in going forward.

8 In 'what if' scenarios, various combinations and degrees of the case's associated risks and benefits are projected to consider the impact of the product. This allows participants to identify which risks are most critical and where changes might be most helpful

9 Triple bottom line assessment measures performance (usually corporate) against social and environmental parameters as well as economic values and factors.

10 SIA looks at the impact of the case on sustainability against a range of selected factors (environmental, socio-economic, etc.).

STEP FOUR –
Using the Dialogue Tool Spectrum

This step reveals the real strength of the GMFF dialogue process. Having conducted a detailed audit and analysis of the policy case in the previous steps (by working repeatedly within the five consideration columns or rows), the group should now be developing a deeper understanding of the many layers or dimensions of the case. At this stage, they are ready to **map the case** on the Dialogue Tool Spectrum.

In Step Four the facilitator challenges participants to position the policy case, within each consideration area, along the spectrum that runs from "Fully Acceptable/Supportable/ Beneficial/Desirable" (blue colour) to "Not Acceptable under any circumstances"(red colour), usually running from left to right. It sometimes helps if participants use the **corresponding colour** shown on the spectrum to designate where they want to position the issue. For example, under the health consideration, an individual might say that there were concerns about long-term health effects and, therefore, the item should be situated toward the red end of the spectrum. If the middle of the spectrum is used, where conditions apply, participants are encouraged to identify the conditions for each area.

Once the case has been positioned under each of the five considerations, the facilitator will then ask the group to consider giving the case an "overall" rating for the policy case, again using the colour coding as a guide.

The overall rating can be observed at a glance by noting the positioning assigned within each consideration area, or participants can be given coloured dots that they can actually place on the master spectrum document. The convergence of dots within one or more areas along the spectrum allows for final conclusions about where the group has arrived. Or there may be a wide divergence of opinion, despite the time participants have spent together discussing risks, benefits, pros and cons. In most cases, the spectrum works well to visually communicate where the group of dialogue participants has settled.

If participants have positioned the case in the middle zone of the spectrum, the facilitator will encourage them to express the 'conditions' that are implied in that zone.

Required Materials

- Worksheets 2-6
- Dialogue Tool (colour)
- Policy Case

Participant Tips

- This is the stage where **final summations** about the case are starting to form. Listen carefully to the comments of others. Review your notes.
- Think seriously about the conditions that would affect your assessment concerning where the case fits on the spectrum.
- On balance, which area of the spectrum best fits the case overall?

Key Dialogue Questions

- Given what we have learned/understand about the case at this point, on balance, for each area of consideration, which spectrum position/colour/language best fits this case?
- **Optional -** On balance, which spectrum position/ colour/language best fits this case overall?

Note: If participants have positioned the case on the spectrum when the case is introduced, just before Step 1, then the facilitator will ask participants to re-assess their 'position' on the spectrum for comparison with their opening positions, individually and as a group, at the beginning of the session.

Key Dialogue Questions

- What are the conditions or requirements that would raise confidence in the acceptability of this case or clarify its fit on the spectrum?
- What are the conditions derived from each area of consideration?
- How would we combine these into an overall list?
- Is each condition achievable? Is each condition within the control and influence of the relevant party (e.g. case proponent or other selected party)? How can we revise the conditions to enhance the probability of achievement?
- Which of these conditions are most critical to acceptability? Which would help advance acceptability (e.g. move left some degree on the spectrum)?
- What are the specific actions and responsibilities to give effect to these conditions?
- Given the application of the proposed conditions to this case as defined to this point, on balance, for each area of consideration, which spectrum position/colour/language now best fits this case?
- Given application of the proposed conditions, on balance, which spectrum position/ colour/ language now best fits this case overall?

Optional Added and/or Alternative Methods

- Assess confidence level in conditions[11]
- Explore 'what if' scenarios and how different conditions/recommendations might affect the risks, benefits, trade offs and acceptability[12]
- Assess position on spectrum after conditions defined.[13]

STEP FIVE – Determining Conditions for Acceptability

If there is significant interest expressed in the middle zone of the spectrum in Step 4 (green to yellow to orange colour range), it is time to proceed to identify the conditions that would affect the acceptability of the case. Participants are asked by the facilitator to outline the conditions that are affected predominantly by or derived from each consideration area (i.e. health, socio-economic, etc.).

After conditions have been identified for each consideration area, participants will synthesize or combine them into an overall list, further test them as a full set of conditions (e.g. for probability of achievement, i.e. to ensure they fall within a reasonable range of control and influence by the case proponent or other significant party), and revise them as needed.

Once participants are satisfied with the list of conditions, the facilitator will ask them to rate the conditions as to which are most critical to confirming or improving acceptability. The conditions will then be further refined to make them specifically actionable by specific parties.

If desired, one last re-assessment of spectrum positioning will be undertaken and may be compared with the positions taken at the beginning of session (if assessed then) and after Step 4.

Participant Tips

- This is the stage where **final summations** about the case are starting to form. Listen carefully to the comments of others. Review your notes.
- Think seriously about the conditions that would affect your assessment concerning where the case fits on the spectrum.
- On balance, with the conditions in place, which area of the spectrum best fits the case overall?

Required Materials

- Worksheets 2-6
- Dialogue Tool (colour)
- Policy Case

11 Participants rate their level of confidence that the conditions can be achieved and/or their level of confidence that the impact of the proposed condition will meet expectations.

12 See footnote 8 for a definition of 'what if' scenarios.

13 If the case position was assessed at the start of the process (before step 1), there will now be 3 spectrum comparison points to observe.

STEP SIX –
Promising Directions

Step Six allows the group to provide final comments or recommendations about how this case might move forward. This stage allows for a more thorough discussion of **what conditions** would have to apply for the group to move the item further toward the "More Acceptable" end of the spectrum. Sometimes participants will say that if they had more scientific information, other study data, or a commitment to a long-term planning exercise, they would be more comfortable about accepting the new biotechnology. Other times, the majority may agree that there are no conditions under which the case should proceed.

Participants can also suggest whether the dialogue should continue in another direction, focus on a particular component (e.g. ethics), or include new and different people. Sometimes this step is used by participants to pass along directions, or notes, to other groups that may be debating this issue. As well, the group will likely want to signal the promising directions that could be explored, especially where there is an opportunity to advance solutions or mitigate problems.

This stage, therefore, generates information about a group's common ground, summary views about the conditions that would affect "acceptability" and, finally, predicts whether the group would like to continue the dialogue in any way. An important goal is to ensure that the **essence of the dialogue is captured** so it can be revisited by participants or passed on to others.

Required Materials

- Worksheet 7
- Dialogue Tool (colour)
- Policy Case

Key Dialogue Questions

- Are there conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?
- Are there promising directions that could be explored to advance solutions or mitigate problems?
- What useful next steps might enable further in-depth understanding and dialogue on this case?
- Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance)?
- How could this dialogue process on this case benefit others (e.g. by contributing to policy development or in helping to educate others)?
- Where are the real opportunities associated with this case? Where are the real problems?

Participant Tips

- Participate in this **final summary process** with a view to considering what new thinking or approach might address the critical issues that have arisen and how your dialogue work could benefit others (e.g. by contributing to policy development or in helping to educate others).
- Focus on what has been achieved together today.
- Think about what could come next: Where are the real opportunities? Where are the real problems?

DEBRIEFING – Evaluating the Dialogue and Process (OPTIONAL)

Debrief the experience drawing out impressions, lessons and potential applications elsewhere.

Key Dialogue Questions

- What worked in the session and what could be improved?
- What impact did this dialogue have on you?
- What lessons did we learn about the dialogue process and the Dialogue Tool and how might we improve it in the future?
- Do you see other cases or situations where this approach and tool might be useful?

Participant Tips

- Provide the sponsor organization and the facilitator with comments about the process and the support materials. What worked? What didn't?

Required Materials

- Worksheet 8
- Dialogue Tool (colour)
- Evaluation Form

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CONCLUSION

Looking at the results of a dialogue process shows that the final conclusions and results do not represent an absolute truth nor perhaps even a consensus. The dialogue journey is certainly as important as reaching the destination.

When you reach the end of a dialogue exercise, you will want to ask yourself what you have achieved. The developers of this tool think you will see that the time and the dialogue were well worth it. In the end, you will reach a conclusion that reflects the orientation and priorities of your group. Another group of people might have gone in another direction. At best, your conclusion will represent a summary of what this group of informed people came to understand and wanted to put forward. These may not necessarily be the most definitive recommendations, but the process and the output from a dialogue process have a role in informing public policy.

CBAC also wants to acknowledge again that this tool and process are the offspring of a group of committed individuals who wanted to figure out how to keep the dialogue respectful and constructive. Members of the Exploratory Committee which developed this Tool/Process are some of the stakeholders who have strong views about biotechnology, and GM foods specifically. The Dialogue Tool and process reflects their level of involvement, intellectual rigor and focus on what is good for Canada. Their leadership and engagement have made all of the difference. They have also helped us see that consensus is not necessarily the goal – dialogue has a value all its own.

If you would like more information about the Dialogue Tool and its supporting facilitated process you can visit the CBAC web site at http://www.cbac-cccb.ca/ and/or reference the resource tools appended to this guide. You can also find the Exploratory Committee's full report at this website.

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TABLE FACILITOR GUIDE

NOTE: This document is attached as an example only. It was created for use at the Multi-stakeholder Pilot Session held March 1718, 2004. Subsequent changes to the process have been made and are not reflected in this document.

Table Facilitator Guide

As a small group facilitator, you are responsible for the following:

1) Time Management

Each table conversation has defined time limits with outputs to produce within those time limits, so you will have to manage the proportion of time spent exploring a topic, and time spent distilling the voice of the table, or summarizing (where appropriate). You may request help from someone else at the table to let you know when your allotted times are drawing near.

2) Facilitate open conversation

We are very committed to providing the opportunity for everyone to contribute, including those who may not be the usual ones to speak up. Please manage the flow of conversation to create the space for everyone to jump in. This will mean politely encouraging those with a lot to say to make space for the rest, and drawing out those who may not have taken the opportunity to speak. You may also need to gently redirect the conversation to ensure that the discussion does not get hijacked by a 'pet issue'.

Your experience with the Dialogue Tool will make it tempting to dominate the discussion. As a table facilitator, it is your job to remain neutral, listen actively and guide the discussion where necessary to keep it moving smoothly to achieving the required outputs.

3) Produce the required output

The main elements of discussion will be captured on the flip charts by the facilitator during the plenary portions of the session. It will also be helpful for you to briefly and concisely record the main points of the table discussions on a worksheet, or ask a member of the table to do it. We do not need a summary of all the details of the whole conversation for report back since the table discussions are meant to encourage individual thinking and understanding through group conversation, allowing individuals to contribute more effectively to the plenaries. We would like you to focus on identifying common ground, divergence/variety in perspectives and the range of ideas.

DAY 1 - Wednesday, March 17

TIME	ACTIVITY	NOTES, AIDS
5:30 - 6:30	**ARRIVAL AND REGISTRATION** • Greet and welcome participants; ensure they pick up session materials and sit at designated tables. • Answer questions as needed.	**(All EC members)** Binders, participant guide
6:30 - 7:10	**SESSION OPENING AND INTRODUCTION** • Contribute to the discussion as appropriate, to enhance richness of discussion, without dominating exchange.	**(All EC members)** Rules of Engagement, Backgrounder
7:10 - 7:30	**CASE INTRODUCTION** • If asked by the facilitator during the plenary review of the policy case, provide answers to technical or process questions. • Assist participants in locating correct materials, if needed (e.g. worksheet 1)	**(All EC members)** Worksheet 1
7:30 - 9:30	**QUALITIES AND KEY FEATURES (STEP 1)** **Intent of Step 1** In general, this section will have participants contribute freely into the open exchange, so there is not a specific table group discussion structured into the process. However, the facilitator may at any point, suggest that the table groups discuss the question/topic for a few minutes to generate some starting ideas. If this occurs, then…. **Tasks** • Introduce yourself and ask participants to introduce themselves. Introduce intent of step 1 which is to create a policy case "profile" under each of the five consideration columns noting favorable and unfavorable qualities/features. • Try to discourage people from moving quickly to judgment or stating firm positions about the policy case. They will have this opportunity at later stages in the dialogue. At this point it is important to get the facts out and break down the issue. • Encourage them to keep an open mind and listen actively to the others at their table. • **Focus on the particular consideration area raised, with enough depth to record the group's ideas about the key features of the case.** **Outputs** Develop an initial profile of the case, for that area of consideration, tracked as pros and cons, with some thought given to specific population groups that might be affected. Each participant should use their worksheets to track the discussion as they like. **Next step** Participants will be asked to share their ideas about the qualities and key features of the case in plenary to develop an overall profile of the case. A consensus report from each table will NOT be required. The purpose of the table discussion is to 'get the juices flowing', to allow participants to begin 'unpacking' the case.	**(EC TABLE FACILITATORS – POSSIBLE TABLE DISCUSSIONS)** Questions will be cued on screen. Use Worksheet 2-6, top left cell (Qualities/Features). **Key Dialogue Questions** • What are the qualities/features of this policy case? • Are they unique? • What are features more desirable/acceptable to Canadian society and, therefore, would favour use/adoption? • **What are features less desirable/acceptable to Canadian society and, therefore, would argue against use/adoption?** • What specific population groups are affected and how? • Is additional supporting information required to better understand and substantiate the feature profiles? What additional information do you recommend (whether the information is factual or perceptual)?

DAY 2 - Thursday, March 18

TIME	ACTIVITY	NOTES, AIDS
8:30 - 10:30	**ISSUE IDENTIFICATION (STEP 2)** **Time: 20 minutes for brainstorm** **Intent of Step 2** The intent of step 2 is to focus on the most critical issues that come up in each area of consideration, based on the profiles developed in Step 1. **Tasks** • Outline amount of time allocated to the task (20 minutes) • For all areas of consideration at once, brainstorm to identify the most pressing issues that come up in the case and the true essence of each issue (e.g. what is the issue 'really' about?), whether positive or negative. • You might encourage participants to consider, at this stage, whether there are existing or potential alternatives to the GM product or process being proposed. • NB: Sometimes the discussion about a specific issue may raise concerns about a broader issue or domain. Ask the group to be clear whether they want to talk about the specific or the global. • You may wish to note the relative importance of one issue over another if the group gives you clear direction but this should not be the focus of your discussion as it will be undertaken in plenary following the brainstorming exercise. **Outputs** A list of the most important issues arising out of the case, including a statement about what the issue is really about, noting any specific expectations participants have about addressing the issues. Participants can record individually on their worksheets. **Next step** Participants will be asked to share their ideas about the issues in plenary to develop an issues profile for each consideration area. Ranking the issues will be undertaken in plenary.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, top middle cell (Issues). **Key Dialogue Questions** • **What are the issues that arise in each consideration area?** • **What is the issue really about?** Allow each table to take time to discuss the core issues they see based on the profiles from Step One. • Which issues are most critical and why? • What are the expectations for addressing these most critical issues and why? • List all issues in all five areas first then, in the plenary session, rank in each area.
10:30	**BREAK** • Report any difficulties, issues, questions, etc. to the facilitator.	**(EC Table Facilitators – Speak with Facilitator)**
10:45 -12:15	**RISKS AND BENEFITS (STEP 3)** **Time: 20 minutes for table discussion** **Intent of Step 3** In step 3, participants will use the profile developed in steps 1 and 2 to discuss the risks and benefits associated with the policy case under each consideration area. As well, participants will assess **who is at risk** due to the introduction of the new science or product, and **who benefits** should things go forward as planned. Your table will be assigned one of the consideration areas in the introduction to step 3. **Tasks** • Indicate the amount of time allocated to the task (20 minutes). • The facilitator will assign one of the five consideration areas to your table. Identify the risks and benefits under this consideration area, including who is at risk and who will benefit if the case goes ahead as planned. • You should also get a sense of the group's **confidence in the supporting information** that supports the risk-benefit profile developed.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, middle left cell (Risks/Benefits). **Key Dialogue Questions** • **What are the risks and benefits in each area, given the profile of qualities and issues?** • **Are there population groups particularly affected?** • **Will the risk-benefit profile change over time?** • **Are we generally confident that the information we have is sufficient to support or substantiate the risk and benefit profiles we developed?**

TIME	ACTIVITY	NOTES, AIDS
	RISKS AND BENEFITS (STEP 3 CONTINUED) • Note: The assessment of trade offs will take place in plenary and should NOT be a substantial part of the table discussion. **Outputs** A list of the risks and benefits for the consideration area under discussion, including identification of groups affected by them and an assessment of the group's confidence in the available information. Participants can record individually on their worksheets. **Next step** Your table will be asked to share its profile of the consideration area assigned to it with the larger group. Assessment and weighing of trade offs will occur following the lunch break.	
12:15 - 1:15	**LUNCH**	
1:15 - 1:45	**TRADE OFFS (STEP 3 CONTINUED)** **Time: 15 minutes for table discussion** **Intent of Step 3, continued** Participants will be asked to compile ideas from the risks/benefits discussion as composite weighed statements (e.g. risk attribute x 'taken together with/compared with/vs./against' benefit attribute y results in …….). **Tasks** • Indicate the amount of time allocated to the task (15 minutes) • Use the results of the risk/benefits discussion to generate statements about the trade offs that need to be made between the identified risks and benefits. • Try to capture those trade offs that may be the most compelling to your group as well. **Outputs** A list of statements about the trade offs that need to be made, with the most compelling trade offs noted in some fashion. Participants can record individually on their worksheets.	**(EC TABLE FACILITATORS - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, middle right cell (Risks/Benefits). **Key Dialogue Questions** • **Can the risks and benefits be weighted?** • **How would we weigh the risks and benefits together? How important are the risk factors and do they outweigh the benefits that have been noted? Are the benefits as significant as the risks?** • **What are the trade offs that emerge when we weigh/compare the risks and benefits?** • **Which of these trade offs is most compelling?**
1:45 - 2:45	**USING THE DIALOGUE TOOL SPECTRUM (STEP 4)** **Time: 20 minutes for table discussion** **Intent of Step 4** This is the stage where **final summations** about the case are starting to form. The actual Dialogue Tool spectrum will be used to "map" or position the policy case in terms of its level of support or acceptability with participants. This table discussion is meant to help prepare participants for their task of identifying their 'position' on the spectrum. **Task** • Explain the purpose and expected outputs of this step and note the time allocated to complete the task. • Help participants identify their 'position' on the spectrum. You may allow them some 'quiet time' to consider their position of the spectrum and ask them to record it on their worksheets for each consideration area, and for the policy case overall. The long colour version of the dialogue tool is most useful at this stage.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 2-6, bottom cell, and long colour version of the GMFF Dialogue Tool. **Key Dialogue Questions** • **On balance, for each area of consideration, which spectrum position/colour/language best fits this case?** • On balance, which spectrum position/ colour/language best fits this case overall? • **Where conditions are called for, what are the conditions and the rationale?**

TIME	ACTIVITY	NOTES, AIDS
	USING THE DIALOGUE TOOL SPECTRUM (STEP 4 CONTINUED) • If an individual or group has identified a position on the colour spectrum that is associated with "conditions", ensure that the conditions are identified and explained when the position on the spectrum is presented. • Listen carefully to the comments of others and note any common ground and any remaining divergence of views. • Ask participants, when they are ready, to place their coloured dot in the desired position on the wall chart spectrum. **Outputs** Encourage participants to record their position on the spectrum on their worksheets for each consideration area and for the policy case overall and then to do the same on the wall chart, using the sticky dots provided. The results will be aggregated and discussed in plenary.	
2:45	**BREAK**	
3:00 - 4:00	**PROMISING DIRECTIONS (STEP 5)** **Time: 15 minutes for table discussion** **Intent of Step 5** The step gives participants additional opportunity to discuss the conditions that would affect the acceptability of the policy case., e.g. express the conditions (if warranted or called for) required to move the case on the spectrum toward a more "acceptable" status. They will also discuss how the dialogue could be or should be extended, by this group or another. **Task** • Address all key dialogue questions (conditions, solutions, advancing the understanding/dialogue) as a group. • The group may have strong views about the conditions or requirements that would make the case stronger, or would assure their confidence as it moved forward. Please document these carefully. • Make sure that participants have the chance to say more about what should be passed on to others, so they don't feel that their dialogue output will be lost. **Outputs** Encourage participants to record their/the group's ideas on their worksheets. **Next step** Review and evaluation of the process and Dialogue Tool will be undertaken next (in plenary). Ensure that all table members have a copy of the evaluation form and worksheet 8.	**(EC Table Facilitators - TABLE DISCUSSION)** Questions will be cued on screen. Use Worksheet 7. **Key Dialogue Questions** • **Are there conditions or requirements that would raise confidence in this case or clarify its fit on the spectrum?** • **Are there promising directions that could be explored to advance solutions or mitigate problems?** • **What useful next steps might enable further in-depth understanding and dialogue on this case?** • **Are there any recommendations for the next dialogue undertaken on this case (e.g. areas or questions to focus on, further research in advance, facilitation advice)?** • **How could this dialogue process on this case benefit others (e.g. by contributing to policy development or** in helping to educate others)? • Where are the real opportunities associated with this policy case? Where are the real problems?

TIME	ACTIVITY	
4:00 – 4:30	**EVALUATING THE DIALOGUE AND PROCESS** • Provide overview of the last phase of the project. • Listen carefully to the feedback being provided by participants and take notes to provide your own feedback for the EC final report to CBAC. • Contribute to the discussion if appropriate, to enhance richness of discussion, without dominating exchange.	**(EC member to be identified)** **(All EC members)**
4:30 – 5:00	**OUTLOOK AND ADVICE ON THE FUTURE** • Listen carefully to the feedback being provided by participants and take notes to provide your own feedback for the EC final report to CBAC. • Contribute to the discussion if appropriate, to enhance richness of discussion, without dominating exchange.	**(All EC members)**
5:00	**SESSION CLOSE** Provide brief closing remarks.	**(EC member to be identified)**

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APPENDICES

APPENDIX 1 – Dialogue Tool: Full Colour Version

APPENDIX 2 – Dialogue Tool: Brief Overview Version

APPENDIX 3 – Example Policy Case Study

APPENDIX 4 – Dialogue Tool Sample Participant Worksheets

Appendix 1
Dialogue Tool: Colour Version

Spectrum

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Health Considerations**	Clear evidence of improved human health outcomes. **Examples:** • improved food safety - reduced risk chemical residues - removal of allergens or toxins • improved nutritional outcomes • clear health benefits - introduction of a vaccine or other means to combat disease • production of an essential pharmaceutical	Similar health outcomes to existing products and/or evidence of improved health outcomes or offsetting risk/benefits. **Examples:** • reduced allergenicity but diminished nutritional benefit, flavour, utility • CONDITIONS could include: - product information (labelling) - monitoring	While the evidence of harm to human health is not conclusive, the identified risks are significant and must be addressed by more information or conditions. **Examples:** • specific studies are required to address identified risks or information gaps • CONDITIONS could include: - labelling to identify risk for certain groups - use restrictions	Clear evidence of unacceptable risk to human health not offset by any other health benefit. **Examples:** • introduction of a new allergen or toxin • serious diminution in nutritional value • evidence of harm through excess consumption of micro-nutrients in some sub-groups
Environmental Considerations**	Clear evidence of improved environmental outcomes. **Examples:** • improved agricultural practices (significant reduction in the use of pesticides, irrigations, tilling, etc.) • enhanced habitat protection • protection of endangered species (Comment – addressed above)	Similar environmental outcomes to existing products and/or evidence of improved environmental outcomes or offsetting risk/benefits. **Examples:** • use of herbicides but reduced tillage • reduced effect of pollen on bees/butterflies but increased risk of outcrossing • CONDITIONS could include: - stewardship requirements - product information (labelling) - geographical restrictions - containment procedures - monitoring	While the evidence of harm to the environment is not conclusive, the identified risks are significant and must be addressed through more information or conditions. **Examples:** • specific studies are required to address identified risks or information gaps • CONDITIONS could include: - monitoring - limited/controlled introduction - use restrictions - delay in market approval until studies are complete	Clear evidence of unacceptable risk to the environment not offset by any other environmental benefit **Examples:** • irreversible or threatening effect on biodiversity • contamination or pollution • ecosystem degradation, etc.

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Socio-economic Considerations	Clear evidence of improved socio-economic outcomes. **Examples:** • enhanced productivity, diversity in production or improved trade • improved outcomes for consumers such as reduced costs, enhanced choice, improved shelf life, etc. • outcomes are especially positive for producers (large and small)	Similar socio-economic outcomes to existing products and/or evidence or improved socio-economic outcomes or offsetting risk/benefits. **Examples:** • improved consumer outcomes (cost, choice, etc.) but diminished trade opportunities • the introduction of the product, while on the whole desirable, creates socio-economic issues for some groups of producers or consumers • CONDITIONS could include: - product information (labelling) - guidelines/restrictions for product introduction - legislative or standards changes to protect interests of affected groups - international competitiveness	While the evidence of harm is not conclusive, the identified risks are significant and must be addressed through more information or conditions. **Examples:** • studies or further consultation needed to address risks or information gaps • CONDITIONS could include: - product information (labelling) - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups - trade agreements - delay market introduction until studies/consultations are complete and risk addressed	Clear evidence of unacceptable soci-economic outcomes that cannot be otherwise addressed or mitigated. **Examples:** • denial of access to traditional or future export markets • increased food costs, on a full-cost accounting basis • effects on small producers that cannot be mitigated, etc.

Spectrum				
CRITERIA*	**Fully "acceptable, supportable, desirable, beneficial, etc."**	**More "acceptable, etc." possibly with conditions**	**Less "acceptable, etc." with conditions or more information required**	**Not "acceptable, etc." under any circumstances**
Ethical Considerations* **	Clear evidence that ethical considerations have been fully and carefully weighed, and the decision-making criteria for ethical considerations are clear. **Examples:** • the process of development has been guided by precaution and national standards • based on principles of justice, equity, transparency, accountability and inclusion • introduction of the product, after broad consultation, is deemed to enhance the preservation of biodiversity • improves quality of human life	Similar ethical outcomes to existing products with evidence or improved ethical outcomes or offsetting risk/benefits. **Examples:** • improved food supply for indigenous peoples but achieved with their consent to forego traditional agricultural methods • CONDITIONS could include: - implementation of mechanisms to promote choice or otherwise increase beneficence - diligence, timely, full broad and meaningful consultation - disclosure, verification (3rd party independent), enforceability - risk/benefit consultation	While the evidence of harm is not conclusive, the identified risks raise ethical concerns that may be difficult to address at present or unless and until societal norms change or may be addressed with more information or under certain conditions. **Examples:** • insertion of human genes into plants or animals • creation of new species • patenting of higher life forms, etc. • CONDITIONS could include: - product information (labelling) - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups • delay market intro until studies/ consultations are complete and risk addressed	Clear evidence that introduction of the product raises ethical concerns that cannot be addressed now or in the foreseeable future. **Examples:** • species extinction • creation of a threatening species • unacceptable effect on animal welfare • threat to human well-being and sustainable communities • widening of povery gap and access to affordable food supply, etc.

Spectrum				
CRITERIA*	**Fully "acceptable, supportable, desirable, beneficial, etc."**	**More "acceptable, etc." possibly with conditions**	**Less "acceptable, etc." with conditions or more information required**	**Not "acceptable, etc." under any circumstances**
Broader Considerations (Societal Interests and International Considerations)	Clear evidence of improved outcomes for the broader society and world, including full, meaningful and wide consultation and compliance with relevant international agreements. **Examples:** • empowers developing country producers • broad improvements in agricultural practices • improves benefit sharing between developed and developing countries, rich and poor classes, or women and men • greatly improves food security globally, especially in developing countries • meets a great societal need • distribution of benefits and risks overtime and across generations	Similar societal outcomes to existing products, with evidence of improved societal outcomes or offsetting risk/benefits. **Examples:** • improved food security in developing world but with greater economic concentration • improved agricultural production in developing world but trade blockage from developed world • CONDITIONS could include: - international agreements that protect vulnerable citizens - international compensation, increased aid, or subsidies to developing countries to allow for adjustment, increase market access for their products, or to compensate for use of traditional knowledge	While the evidence of harm is not conclusive, the identified risks are significant and difficult to address at present. **Examples:** • unresolved issues of ownership • compensation for traditional knowledge • changes in traditional practices/societal norms (this is environmental) • CONDITIONS could include: - guidelines/restrictions on market introduction - legislative or standards changes to protect interests of affected groups - delay market introduction until studies/consultations are complete and risk addressed - international agreements in place	The introduction of the product is not acceptable from a societal perspective now or in the foreseeable future. **Examples:** • unacceptable threat to food security • appropriation or redundancy of traditional or indigenous knowledge and practice • elimination of markets for developing world producers • evidence that there would be unacceptable risks to future generations

* These Criteria, where applicable, should reflect outcomes both unique to a GMFF or in general for a technology, research area, product, etc. They apply to all stages of the life cycle – from research and development, through confined trials, production, handling, processing, transportation, consumption and waste disposal. Outcomes may be relative to existing products, standards and practices and may be influenced by whether credible alternatives exist.

** Health and safety considerations presume the foundational level of legislated regulatory clearance, i.e., Canada requires a mandatory Food, Feed and Environmental Safety assessment and clearance before any GMFF product is authorized for market introduction. Canadian regulatory standards exceed WHO and OECD standards for safety evaluation.

*** For the purposes of the Dialogue Tool, the term "ethics" is understood as a widely held system or set of principles/beliefs which provides the framework within which to make moral choices for the public good. "Values" refer to those qualities, properties or ideals deemed important, desirable, or of worth and which are/may be applied to questions of choice throughout the dialogue tool/process. Relative to ethics, the term "values" refers to commonly held moral qualities or properties deemed of worth or importance, used as criteria upon which moral decisions are/can be made. For example:

- **Ethic of equality -** all are equal; none is less equal.
- **Value of inclusion -** everyone's participation is ensured and respected, and each perspective is considered in decision-making.
- **Ethic of sustainability -** of the Planet and its resources; human life in harmony with nature and not compromising future of generations to come.
- **Value of restoration and preservation -** of a natural resource such as water, taking into account social, economic and environmental impacts of actions.

Positions along the spectrum

- **Acceptable/Supportable -** Outcomes are improved or similar on balance to existing products or practice. Meets existing standards, either no new risks/issues are introduced or are offset by a greater reduction in an existing risk/issue.
- **More Acceptable with conditions, to Less Acceptable until certain conditions are met or more is known -** Outcomes are similar to existing situation, there exists evidence of improved outcomes and/or evidence of risk to varying degrees, or the risk is considered too high to be acceptable under present circumstances. Depending on the benefit/risk scenario certain conditions may be required. Conditions may be imposed to mitigate or eliminate the risk.
- **Not acceptable under any circumstances -** Evidence of harm is conclusive and serious i.e., destructive and irreversible, that cannot be offset by any other benefit.

Considerations

- **Human Health Considerations -** Includes toxicity, allergenicity, nutritional value and potential long term impacts on health (e.g. post-market monitoring of effects on obesity levels, dietary habits, etc.). They may apply to the population as a whole or to specific sub-groups.
- **Environmental Considerations -** Includes effects on biodiversity, pollution and sustainability, including effects on targeted and non-targeted species, changes in biological/ecological fitness (such as outcrossing [i.e. pollens crossing from one crop to another], or invasiveness).
- **Socio-economic Considerations -** Economic effects include trade, costs/benefits, productivity, education, economic growth and economies of scale. Social effects include distribution of income, effect on small and large farms, regional effects and consumer choice.
- **Ethical Considerations -** Include ethical or moral concerns such as justice, magnanimity, animal welfare, use of the precaution, due diligence, accountability, transparency, enabling choice, utilization of and access to new knowledge/technology, meaningful participation of affected parties, and acceptable use of the technology in manipulating life.
- **Broader Considerations (societal interests and international considerations) -** Includes international relations, distribution of risks, costs and benefits, effects on the developing world (benefit sharing, centre of origin [i.e. the original geographic source of a plant], food security), empowerment, trade, globalization (sovereignty, democracy, power imbalances), knowledge and technology development, and compliance with related international agreements/accords.

Example Approach to Use of Dialogue Tool Overview

Assuming there is a biotechnology product or process subject to discuss, which may be a technology, or proposed research in a new area, or a type of product, etc., the subject would be considered using the following sequence:

1. Identify the qualities or features of the product, are the qualities or features unique to the GMFF subject, and list them in relation to the five areas of consideration (i.e., Health considerations, etc).
2. Define the issues that arise when considering the subject qualities in each area.
3. Engage in a dialogue on the issues, seeking clarity, better understanding and a sense of which issues are the most critical/have the most impact, and the expectations there are/may be for addressing these issues.
4. Identify the risks and benefits of the product in each area of consideration and determine if these are unique to the product or also relate to other products of biotechnology.

5. Weigh the risks and benefits together and consider the potential trade offs in and across the areas of consideration.
6. Using the spectrum breakout, identify which area of the spectrum best fits the subject, after discussing and weighing all the factors above – do this for each consideration area, and then overall.
7. Choose the preferred language (see below) that best describes the position of the product in each consideration area and then the overall position of the product (note: if 'conditions' are called for, then suggest the type of conditions or further information that could be called for).
8. Provide any advice on how to further consider the future of this product.

Preferred Language Options

- At the left end of the spectrum
  - fully acceptable/supportable and/or desirable/beneficial
- At next position (left to right)
  - acceptable/supportable
  - acceptable/supportable with some conditions
- At next position (left to right)
  - not acceptable at this time
  - not acceptable without conditions or more information
- At the right end of the spectrum
  - not acceptable under any circumstances

Appendix 2
Dialogue Tool (Brief Overview Version)

CRITERIA*	Fully "acceptable, supportable, desirable, beneficial, etc."	More "acceptable, etc." possibly with conditions	Less "acceptable, etc." with conditions or more information required	Not "acceptable, etc." under any circumstances
Health Considerations				
Environmental Considerations				
Socio-economic Considerations				
Ethical Considerations				
Broader Considerations (Societal Interests and International Considerations)				

Appendix 3
Example Policy Case Study

Plant-made Pharmaceutical Policy Case

N.B.: The following case is completely hypothetical (although grounded in existing science) and was developed solely for the purposes of testing the Dialogue Tool at the Multi-stakeholder Pilot Session on March 17-18., 2004 in Ottawa, Ontario. It is included here to offer a model for a case description.

Introduction

A pharmaceutical company wishes to produce a new blood thinning agent. While the drug could be produced chemically, the company believes that a plant-made pharmaceutical (PMP) may provide a significant therapeutic advantage related to the purity of the active ingredient. Production of the protein would require genetic modification of a plant – and in this case, the most desirable host plant is also a food. The company has a patent on the active ingredient.

The company is concerned about the potential public reaction to this proposal. It understands that some members of the public may have concerns with genetically modified (GM) foods in general and that most citizens have concerns about whether proper safeguards will be in force. The public is aware of a few, well-publicized incidents of transgenic crop violations involving other food crops (e.g., Starlink and Prodigene products).

The company does not wish to invest a considerable sum in developing the PMP if public opposition will make it impractical to produce. It has heard about a new approach to dialogue on GM Foods, called the Genetically Modified Food and Feed (GMFF) Dialogue Tool and has asked two facilitators to guide a dialogue session, with a wide range of participants, to discuss the potential product, to discern their underlying views and issues, and identify the conditions under which the acceptance of the product might be improved.

As the product has not yet been developed, the regulators – either Health Canada or Canadian Food Inspection Agency – have not reviewed it.

The Case

The case for discussion is genetically engineered food-grade soy, grown to produce a patented pharmaceutical – a blood thinning protein derived from pig spleens. The crop is to be grown by farmers in five locations in Ontario – 4 hectares each for a total of 20 hectares – under contract for a major pharmaceutical company. It will be grown in open fields and appropriate safeguards will be required to ensure both isolation and containment, such as full segregation, buffer zones within season and buffer crops.

Even though some would consider these safeguards sufficient to satisfy regulatory requirements, the developer intends to take an additional step to prevent outcrossing – namely the use of Genetic Use Reduction Technology (GURT), also known as the terminator gene. In this case, the developer intends to use a Varietal GURT or V-GURT to make the plant sterile. While the introduction of GURT may allay some concerns, it could also introduce new

ones such as the theoretical potential for cross-pollination with traditional varieties leaving progeny sterile, and related concerns for biodiversity.

The soy is not intended for consumption as a food – either for humans or animals. It is not considered toxic, but inadvertent consumption of unusually large amounts may cause a pharmacological effect – the thinning of the blood. Hence, good farming practices and other management systems will be required to ensure that the entire crop is used as a pharmaceutical input, and that none of it ends up as food or feed. This should be in the company's best interest as the crop will be very expensive.

Background

Normally, after a cut or injury, blood clots to stop bleeding; however, blood may sometimes clot when it is not supposed to, forming inside a blood vessel, the lung or the heart. A thromboembolism is a blood clot that breaks off and travels through the bloodstream to another part of the body, potentially stemming the flow of blood and causing damage. A blood clot formed in the heart can travel to almost any organ in the body. When lodged in the brain, it can cause a stroke. In other cases, it can cause heart attack or kidney damage. Prompt treatment is essential in order to prevent serious complications or death.

Blood thinning medications, known as anticoagulants, are used to treat and prevent blood clots associated with conditions such as deep vein thrombosis (DVT) – a blood clot in veins embedded deeply in the muscle mass of the legs or lower abdomen, or pulmonary embolism – a blood clot that has travelled through the bloodstream to the lungs. They generally work by decreasing the synthesis of vitamin K dependent clotting factors.

As with all medications, there is risk of adverse effects. Anticoagulants may prevent normal blood coagulation, thereby increasing the risk of bleeding complications. Many of these complications are minor, such as bleeding from gums, but some may be severe and life-threatening, including bleeding into the brain.

There are two commonly used anticoagulants to stop existing clots from growing and new ones from developing. The first anticoagulant (A) is derived from pig spleens and administered orally. It effectively treats blood clots, but is slow acting and interferes with the normal blood clotting, increasing the risk of bleeding. Anticoagulant B (also derived from animals), administered subcutaneously, is fast-acting, helps prevent existing clots from growing and stops the formation of new ones, albeit less effectively than anticoagulant A. Its major advantage is that its half-life is shorter than that of anticoagulant A, thereby making it less likely to cause severe bleeding, especially after finishing treatment.

A well known clinical trial compared the two medications in the treatment of DVT in 68 patients. Nine of 35 patients receiving medication B, but none of 33 patients receiving medication B, had new episodes of venous thromboembolism. However, seven patients on medication A had bleeding complications of which 4 were considered major. This contrasts with no adverse incidents using medication B. The study concludes as follows: "Thus, adjusted dose A is more effective than low dose B in preventing recurrent venous thromboembolism, but its use is accompanied by a significant risk of bleeding."

Pharmaceutical companies have tried to develop a new medication that would combine the benefits of both drugs – effectiveness and oral administration with minimal bleeding, especially after stopping treatment.

However, attempts to do so using normal pharmacology have proven unsuccessful. The quality of supply of the active ingredient from animal sources has been inconsistent. The company has therefore decided to try to stabilize supply by planting a genetically modified protein inside the genome of food-grade soy.

Appendix 4
Dialogue Tool
Sample Participant Worksheets

Worksheet 1 – Policy Case

Example Case: Plant-made Pharmaceutical Generated in Food-grade Soybeans

N.B.: The following case is completely hypothetical and was developed solely for the purposes of testing the dialogue tool.

Introduction

A pharmaceutical company wishes to produce a new blood thinning agent. While the drug could be produced chemically, the company believes that a plant-made pharmaceutical (PMP) may provide a significant therapeutic advantage related to the purity of the active ingredient. Production of the protein would require genetic modification of a plant – and in this case, the most desirable host plant is also a food. The company has a patent on the active ingredient.

The company is concerned about the potential public reaction to this proposal. It understands that some members of the public may have concerns with genetically modified (GM) foods in general and that most citizens have concerns about whether proper safeguards will be in force. The public is aware of a few, well-publicized incidents of transgenic crop violations involving other food crops (e.g., Starlink and Prodigene products).

The company does not wish to invest a considerable sum in developing the PMP if public opposition will make it impractical to produce. It has heard about a new approach to dialogue on GM Foods, called the Dialogue Tool and has asked two facilitators to guide a dialogue session, with a wide range of participants, to discuss the potential product, to discern their underlying views and issues, and identify the conditions under which the acceptance of the product might be improved.

As the product has not yet been developed, the regulators – either Health Canada or Canadian Food Inspection Agency – have not reviewed it.

The Case

The case for discussion is genetically engineered food-grade soy, grown to produce a patented pharmaceutical – a blood thinning protein derived from pig spleens. The crop is to be grown by farmers in five locations in Ontario – 4 hectares each for a total of 20 hectares – under contract for a major pharmaceutical company. It will be grown in open fields and appropriate safeguards will be required to ensure both isolation and containment, such as full segregation, buffer zones within season and buffer crops.

Even though some would consider these safeguards sufficient to satisfy regulatory requirements, the developer intends to take an additional step to prevent outcrossing – namely the use of Genetic Use Reduction Technology (GURT), also known as the terminator gene. In this case, the developer intends to use a Varietal GURT or V-GURT to make the plant sterile. While the introduction of GURT may allay some concerns, it could also introduce new ones such as the theoretical potential for cross-pollination with traditional varieties leaving progeny sterile, and related concerns for biodiversity.

The soy is not intended for consumption as a food – either for humans or animals. It is not considered toxic, but inadvertent consumption of unusually large amounts may cause a pharmacological effect – the thinning of the blood. Hence, good farming practices and other management systems will be required to ensure that the entire crop is used as a pharmaceutical input, and that none of it ends up as food or feed. This should be in the company's best interest as the crop will be very expensive.

Comments/Thoughts:

Worksheet 2

HEALTH CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits	Weighing Risks and Benefits	
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 3

ENVIRONMENTAL CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits	Weighing Risks and Benefits	
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully ‘acceptable, supportable, beneficial, desirable’, etc.	More ‘acceptible’, etc., possibly with conditions	Less ‘acceptable’, etc., with conditions or more information required	Not ‘acceptable’ etc. under any circumstances

Worksheet 4

SOCIO-ECONOMIC CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits		
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 5

ETHICAL CONSIDERATIONS

Qualities/Features	Issues	Ranking	Expectations to Address
Pros			
Cons			

Risks	Trade Offs	Most Compelling
Benefits		
Population Group(s) Affected		

Weighing Risks and Benefits

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 6

BROADER CONSIDERATIONS

Qualities/Features Pros	Issues	Ranking	Expectations to Address
Cons			

Risks	Trade Offs	Most Compelling
Benefits		
Population Group(s) Affected		

APPLY THE DIALOGUE TOOL SPECTRUM:

Fully 'acceptable, supportable, beneficial, desirable', etc.	More 'acceptible', etc., possibly with conditions	Less 'acceptable', etc., with conditions or more information required	Not 'acceptable' etc. under any circumstances

Worksheet 7

PROMISING DIRECTIONS

Identify conditions, solutions, and/or next steps to advance understanding/dialogue on this case (as appropriate):

Conditions - Are there conditions or requirements we could suggest that would raise confidence in this case or clarify its fit in the spectrum?

Solutions - Are there promising directions that could be explored to advance solutions or mitigate problems?

Help Advance Dialogue - What might be useful next steps to enable further in-depth understanding and dialogue on this case?

Help Advance Dialogue – Do you have any recommendations for the next dialogue undertaken on this case? (e.g. areas or questions to focus on, further research in advance, etc.)

Help Advance Dialogue – How could this dialogue process on this case benefit others? (e.g. by contributing to policy development or helping to educate others, etc.)

Help Advance Dialogue – Where are the real opportunities associated with this case? Where are the real problems?

Worksheet 8

DEBRIEF DIALOGUE SESSION AND PROCESS

What worked in the session….and what could be improved?

What impact did this dialogue have on you?

**What lessons did we learn about the dialogue process and the GMFF Dialogue Tool….
and how might we improve both in future?**

Do you see other cases or situations where this approach and tool might be useful?

Notes

SECTION 4

Final Report of the Exploratory Committee to CBAC on the Dialogue Tool Pilot Project

SECTION 4

Pages

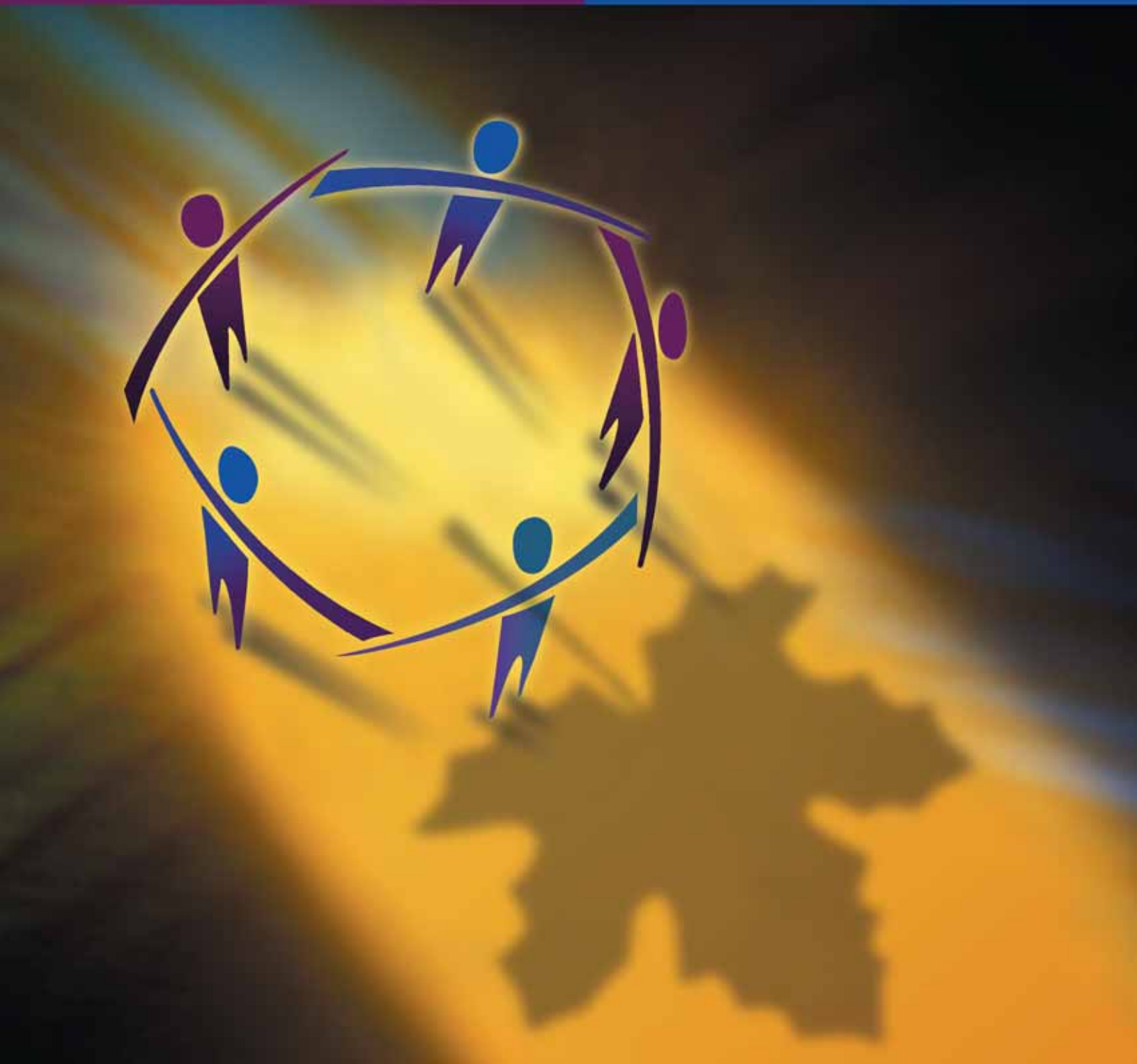
Dialogue Tool

Final Report

of the Exploratory Committee to CBAC on the Dialogue Tool Pilot Project

APRIL 2004

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE



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APPENDICES

Executive Summary

This is the final report to the Canadian Biotechnology Advisory Committee (CBAC) on the Dialogue Tool Pilot Project. The Dialogue Tool was formerly named the "Acceptability Spectrum". This report and the related material fulfill the following functions:

- report on the third and last phase of the pilot project, including the lessons learned, and assess whether the project's objectives were achieved[1];
- provide final materials for conducting a dialogue session[2];
- make final recommendations for any further work, including promoting its use in Canada and abroad; and
- provide broad findings and recommendations on the future of the Dialogue Tool and CBAC's proposed role in that future.

In 2002, the Canadian Biotechnology Advisory Committee undertook a special pilot project to develop the Dialogue Tool and to assess its viability and usefulness. At the outset, CBAC established and delegated authority to an Exploratory Committee (EC) to enable and guide the pilot project. The EC was comprised of individuals from a range of stakeholders interested in biotechnology issues including industry, the supply chain (farmers, producers, retailers), consumers, faith and public health interests, and environmentalists. The co-chairs of the GM Food Committee of CBAC also served ex officio on the committee.[3]

The pilot project had three primary objectives:

1. To create a space that facilitates a dialogue among key stakeholders on key issues in concerning biotechnology products, and to assess the viability of extending the space and dialogue for future deliberations on products of biotechnology.
2. To test the relevance, viability and usefulness of the proposed Dialogue Tool among stakeholders with a wide range of views, and to assess the ability to explore and understand key issues, underlying principles and values questions using the Tool.
3. To bring these stakeholders together to understand the issues and to look toward approaches that meet the needs of society.

The final phase was undertaken to conduct two important events needed to fully test the Dialogue Tool and refine its elements - a Government of Canada (GoC) session (held November 21, 2003) and a Multi-Stakeholder Session (held March 17-18, 2004).

1 The previous Report of the Exploratory Committee to CBAC, dated May 2003, ("Report to the Canadian Biotechnology Advisory Committee on the progress to date of the Pilot Project formerly called the Acceptability Spectrum") covered the first two phases of the pilot project.

2 This document also provides references to and attaches the final materials developed for the Dialogue Process including the GMFF Dialogue Tool, Participant Guide, Orientation Guide, and other supporting materials.

3 CBAC representatives participated in the discussions of the Exploratory Committee but the stakeholder participants (non-CBAC) were responsible for deciding the path of the pilot project within a set of guidelines.

The GoC session was deemed by participants to be very successful; highlighting the potential of the Dialogue Tool to achieve the three above objectives. Participants were particularly impressed with the innovation of the Dialogue Tool, such as providing a structured, logical and intuitive approach for dialogue around five consideration areas. Participants also noted other qualities such as its capacity to keep people engaged in civil, constructive dialogue, its flexibility, its ability to unpack a policy case and its ability to gently challenge participants' assumptions, allowing participants to shift their attitudes on an issue.

The multi-stakeholder session was held March 17-18, 2004 with an objective to test the Tool and its process fully. The session provided an opportunity for a range of stakeholders to experience the Dialogue Tool in a "hands-on" dialogue session and to provide their advice on a number of issues, including improving the Dialogue Tool, further promotion, application and uses of the tool, and stewardship of its future. Approximately thirty participants attended the session, drawn from a range of constituencies including public health, faith, developers, consumers, farmers, producers/retail, and environmentalists. Federal government officials, CBAC members and staff, and the Exploratory Committee participated in the session as observers, tasked with monitoring the session and offering advice for improvement to the tool and process.

Participants contributed actively to the session and concluded that the Dialogue Tool was extremely useful for 'unpacking' an issue and improving their understanding of other viewpoints. Participants and observers were impressed at how quickly an open dialogue atmosphere was established, allowing participants to freely and honestly share their viewpoints. Participants and observers endorsed the Dialogue Tool as a useful tool for providing meaningful dialogue.

They also recommended further work to improve the Tool as an assessment tool for gauging the overall acceptability of a GMFF case. This is explored in depth in Sections 3.3 and Annex X of this Report.

Four key challenges were raised regarding the overall Dialogue Tool process:

a. the tug between the need to focus discussion on the specific issue/case at hand and the desire to discuss broader societal issues;
b. the need to identify and provide adequate supporting information;
c. the appropriate involvement of 'experts' in the dialogue, and
d. the need to find an achievable balance between reaching a common understanding of the central issue and developing a constructive outlook on the future.

Section 3.3 provides greater detail on these challenges and identifies possible solutions.

The Exploratory Committee provides its overall findings and recommendations on the future of the tool in Section 4, in particular:

- The Participant Guide and Orientation Guide should be organized to present the six Primary steps with a selection of optional methods to enable varied design emphasis to respond to different dialogue design requirements
- That the Tool/Dialogue Process be further developed and made available, not only to the GMFF field through the range of opportunities outlined but to the other complex issues in biotechnology as well. Furthermore, that the model be made available to other policy areas with comparably complex profiles for adaptation and application.
- As a first priority, in preparation for further use of the Tool/Dialogue Process, a Facilitator Guide and basic information package be developed.
- As a next priority, three prototype designs should be developed that explore a particular focus on each of a case, the system, and societal context for GMFFs.

- CBAC share the Tool/Process with institutions in government, or agencies that support public policy development and dialogue, and who are engaged in respectful dialogue processes dealing with compelling policy questions, such as the National Round Table on the Environment and Economy (NRTEE), Public Policy Forum, Canadian Policy Research Networks, and the International Association for Public Participation.

The Exploratory Committee concludes that the Dialogue Project objectives have been achieved and provides the following summary recommendations and findings. The full set of recommendations can be found in Section 5.

1. The Dialogue Tool and Process is ready for immediate use and continues to be a work in progress.
2. The Exploratory Committee strongly urges CBAC to promote the Tool/Process immediately in order to encourage the active and timely use of the Tool, with aggregated feedback and learning achieved across several constituencies by the end of 2004.
3. The Exploratory Committee strongly urges CBAC to select and establish a host/steward that would manage the Tool/Process including the central concepts and materials, advisory services, a lessons learned and best practices searchable database, and the maintenance of quality standards for the Tool/Process.
4. The Exploratory Committee is willing to continue to advise on and assist the future development and promotion of the tool if desirable and helpful, and in particular to provide advice to the transition process over the balance of 2004. [And, in any case, the EC would appreciate feedback on the future course selected.]
5. Individual members of the Exploratory Committee are committed to seeing the tool used widely and to that end intend to actively promote the tool and pursue individual opportunities to engage dialogue sessions using the tool.

In concluding this initiative, and tabling this final report to the Canadian Biotechnology Advisory Committee, the Exploratory Committee extends its appreciation to CBAC for their support of this project, for the mandate and freedom provided to the Exploratory Committee, and for the foresight and innovation in having initiated and championed this important project which has the potential to enable a more open constructive dialogue, to foster compelling solutions and outlooks on the future, and to inform the policy environment the potential of these benefits have made this initiative worthwhile, encouraging and very satisfying to the members of the Committee.

April 16, 2004
The Exploratory Committee

1

Purpose of Report

This is the final report on the Dialogue Tool Pilot Project[4]. The Dialogue Tool was formerly named the "Acceptability Spectrum".

The Pilot Project consisted of three phases of work and was undertaken by an Exploratory Committee. This report covers the third and last phase of the Pilot Project including the Government of Canada session (November 21, 2003) and the Multi-Stakeholder Session (March 17-18, 2004).[5] It reviews the third phase results and lessons learned and assesses whether and to what extent the project objectives were achieved. It makes recommendations on the work remaining to bring the Dialogue Tool to a fully finished product and to promote its use in Canada and internationally. Finally it provides broad findings and recommendations on the future of the Dialogue Tool and CBAC's proposed role in that future.

This document also provides references to and attaches the final materials developed for the GMFF Dialogue Process including the Dialogue Tool, Participant Guide, Orientation Guide, and other supporting materials.

4 For the purposes of this dialogue approach, the focus will be on genetically modified crops and livestock for food and feed, either as individual products or classes of products. This has been shortened to 'Genetically Modified Food and Feed', and in this document will be represented by the acronym GMFF. As it is commonly understood, the term "genetically modified" refers to food or feed that has been produced using recent advances in gene technology, such as cloning, gene splicing and the introduction of single genes into plants (or animals) through a process called transformation. These and other techniques are often collectively referred to as recombinant DNA (rDNA) technology and they define a set of tools for "genetically engineering" organisms (e. g. plants, animals and bacteria). The GMFF dialogue approach will generally focus on cases that are the result of such genetic engineering as defined here.

While the focus of this tool is on food products modified using rDNA techniques, the Exploratory Committee is aware that many other new and traditional techniques are being used to modify food and feed products. It should be understood that similar issues exist for all techniques used in the modification of food and this tool can be used to help the open discussion of these issues, regardless of the modification technique under discussion.

5 The previous Report of the Exploratory Committee to CBAC, dated May 2003, ("Report to the Canadian Biotechnology Advisory Committee on the progress to date of the Pilot Project formerly called the Acceptability Spectrum") covered the first two phases of the pilot project.

2

Purpose and Objectives of the Project

In 2002, the Canadian Biotechnology Advisory Committee (CBAC) undertook a special pilot project to develop the Dialogue Tool and to assess its viability and usefulness. To guide the pilot project, CBAC established and delegated authority to an Exploratory Committee (EC) to enable and guide the pilot project. The EC was comprised of individuals from a range of stakeholders interested in biotechnology issues including industry, the supply chain (farmers, producers, retailers), consumers, faith and public health interests, and environmentalists. The co-chairs of the GM Food Committee of CBAC also served ex officio on the committee.[6]

The role of the Exploratory Committee was to:

1. Agree on the objectives for the project;
2. Create a design for the overall process and a general model for individual stakeholder sessions;
3. Outline principles and ground rules for the conduct of the project and sessions (incorporating a code of conduct);
4. Identify case studies or stylized examples of GM Foods or products and example assessment criteria to be used in the dialogue and examination of the 'acceptability spectrum';
5. Outline participant selection criteria for the stakeholder sessions, and develop and implement a strategy to invite and engage stakeholders in stakeholder sessions;
6. Consider the results of the stakeholder sessions and advise on whether a subsequent multi- stakeholder session would be useful and productive;
7. Advise on whether and in what ways the learning, model and tools (principles, criteria, case examples, etc.) should and could be made more available to other groups and the public to promote better understanding, and to further assess and improve their viability and usefulness.

The committee was guided by a lead facilitator, who was dedicated to the project for all phases and led the delivery of pilot dialogue sessions. He was aided by an assistant facilitator and by secretariat services provided by the Canadian Biotechnology Secretariat.

6 CBAC representatives participated in the discussions of the Exploratory Committee but the stakeholder participants (non-CBAC) were responsible for deciding the path of the pilot project within a set of guidelines.

2.1 Objectives of the Project

The pilot project had three primary objectives:

1. To create a space that facilitates a dialogue among key stakeholders on key issues in GM foods and feed (GMFF), and to assess the viability of extending the space and dialogue for future deliberations in GM foods and feed.
2. To test the relevance, viability and usefulness of the proposed Dialogue Tool among stakeholders with a wide range of views, and to assess the ability to explore and understand key issues, underlying principles and values questions using the Tool.
3. To bring these stakeholders together to understand the issues and to look toward approaches that meet the needs of society.

2.2 Desired Outputs/Results from the Project

The pilot project aimed to achieve the following results:

1. A more developed Dialogue Tool with probing questions/criteria that span both risks/negative impacts and benefits/positive impacts, and which identifies central issues across a range of considerations.
2. An assessment of the relevance, viability and usefulness of the Dialogue Tool, the preferred conditions/requirements for successful use, and the further development that should be pursued as the Tool moves toward informing policy making.*
3. An assessment of the ability to create a space that facilitates a dialogue on GM foods and which enhances understanding of the issues, risks and benefits, from different perspectives, and the opportunity to explore approaches that meet the needs of society. This dialogue should enable people to have a structured conversation that helps ameliorate the complexity of the subject.
4. An initial outline of those key questions/issues that are most amenable to examination and dialogue using the Dialogue Tool/approach (and those that are not).
5. A set of design principles to accompany the Dialogue Tool. These would be used to guide the design of future dialogue processes using the approach and Dialogue Tool developed by this project. Examples of design principles would include a code of conduct for the dialogue process, and the importance and examples of adequate background information/briefing to enable an informed dialogue.

2.3 Three Phases to the Pilot Project

The pilot project was divided into three phases. In Phase I, the Exploratory Committee designed the project process, identified possible case studies and example assessment criteria to use in the testing process, and identified potential participants for the single stakeholder sessions planned for Phase II. In Phase II, six individual, facilitated stakeholder group sessions were held to consider the proposed concepts and criteria and to apply the dialogue approach developed by the Exploratory Committee. The tool and processes were further refined based on the lessons learned in these sessions.

* 'Policy' is intended to be broadly defined, including stakeholder/constituency policy as well as public policy.

After completion of Phases I and II, the EC found the tool effective in finding common ground, breaking down barriers to dialogue, and creating common language and purpose between and among stakeholders with shared or conflicting views – particularly when conducted with expert facilitation, good advance planning and strong information sources. Accordingly, the EC reported back to CBAC in the spring of 2003, requesting CBAC's further support for completing the third and final phase of the pilot project. This was to include conducting a Government of Canada orientation session and a multi-stakeholder meeting, the completion of supporting materials and the production of a final report to CBAC on the outcome of the pilot project. CBAC agreed to provide support and Phase III was undertaken. This report provides an overview of Phase III, including recommendations for the future of the Dialogue Tool.

2.4 Projected uses of the resulting tool/dialogue process

The Exploratory Committee believed from the start that the scope of potential uses of the Dialogue Tool/Process would be open to how others wished to utilize and pursue its benefits, once the model dialogue process and Tool were considered mature enough for release. Notwithstanding this, the Committee noted the following potential uses for the Tool/Process.

The Tool/Process could:

a. Be a vehicle to inform and guide policy discussion, policy development, and decision-making on national policies affecting GM foods and feeds, especially early in the development of policy or the development of potential GMFFs (e.g., to identify policy gaps and key issues to be addressed);

b. Be a vehicle for creating dialogue on a broader scope to inform decision-making in the policy environment;

c. Help to incorporate socio-economic and ethical considerations and provide the context for economic and social issues to shape policy;

d. Engage and support public dialogue and be an aid to assess public will, values and priorities with regard to broad types of new technologies or products such as GM foods and feeds;

e. Inform and support individual stakeholder groups in consideration of their own policy-making and direction (e.g., to identify Research and Development priorities, draw on as a basis for codes of practice);

f. Inform the public on GMFFs with respect to risks and benefits, issues of interest or concern, current regulations and policies and, if and where there are gaps or unnecessary duplication, to address them; and

g. Provide a model for deliberative dialogue and consultation in a broad range of biotechnology subjects.

3

Phase 3 Overview

At the completion of Phases I and II of the pilot project, the Exploratory Committee endorsed the tool as a means to encourage a full airing of issues, helpful input and interventions, and constructive dialogue. The group recommended that CBAC continue the project through to the end of Phase III.

The third, and final, phase of the Dialogue Tool project expanded the process to take into account the collective view of many stakeholder groups. Two additional pilot sessions were proposed for Phase III; a Government of Canada orientation and pilot dialogue session, followed by a full testing of the tool with multiple stakeholders (which had not yet occurred as planned in Phase II). In preparation for the Phase III sessions, the Exploratory Committee used the results of the single stakeholder sessions from Phase II and the lessons learned from them to refine the Dialogue Tool and process. Then, they held the Government of Canada session to further test the Tool.

3.1 Government of Canada (GoC) Preview Session

An orientation and pilot dialogue session was held in November 2003 involving participants from several Government of Canada departments. Participants were selected due to their interest and/or involvement in programs and regulatory work related to GM foods and feed and included representatives from Agriculture and Agri-food Canada, Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, Department of Foreign Affairs and International Trade, Health Canada, Industry Canada, Justice Canada, Natural Resources Canada and the Privy Council Office[7].

The session program was divided into two components: an Overview Session that explained the genesis of the Dialogue Tool and the work of both CBAC and the Exploratory Committee; and a practical “hands on” dialogue session working with the Dialogue Tool and a policy case study developed specifically for the event. The intent of the session was to gauge interest and reaction from federal officials, while raising awareness of the Dialogue Tool. CBAC and the Exploratory Committee were particularly interested to know if the Dialogue Tool and process could be endorsed for use in a government setting and whether it could be applied in other fields and disciplines. The session was also used to educate departments that had sponsored the pilot project in its earlier phases. As well, the Government of Canada session was intended as a precursor to a more complex multi-stakeholder trial planned for later in Phase III.

The GoC Preview Session was deemed successful from nearly all points of view and achieved all of its stated objectives. The session successfully demonstrated the potential success and use of the Dialogue Tool. Participants in the hands-on session were impressed with the ability of the Dialogue Tool to provide a structured, logical and intuitive approach for dialogue around very complex issues. They felt that the structure around the five consideration areas is innovative and gives the tool additional strength for addressing difficult public policy issues. Other strengths of the tool noted by GoC participants included its capacity to keep people engaged in civil, constructive dialogue, its process flexibility, its ability to unpack a policy case and its ability to gently challenge participants’ assumptions, showing people where they might possibly shift their attitudes a bit on an issue.

7 A full participant list is attached to the final report of the GoC session which can be found at: http://www.cbac-cccb.ca/

Overall, all participants felt that the Dialogue Tool and its facilitated process had merit. It was well received as a multi-purpose tool that could be used to build and sustain dialogue on complex and/or controversial topics in a variety of venues, including consultations, dispute resolutions and educational sessions. A full GoC Session report is available at http://www.cbac-cccb.ca/.

3.2 Multi-stakeholder Pilot Session

Following the GoC Preview Session, the Exploratory Committee hosted a multi-stakeholder session in March 2004 to fully test the Tool and its process. The purpose of this session was to provide an opportunity for a range of stakeholders to experience the Dialogue Tool in a "hands-on" dialogue session and to provide their advice on improving the Dialogue Tool, further promotion, application and uses of the tool, and stewardship of its future. A hypothetical policy case was developed and used as the basis of discussion to test the Dialogue Tool (See Annex 1).

The session was attended by approximately 30 people from a range of constituencies including public health, faith, developers, consumers, farmers, producers/retail, and environmentalists. Several government department representatives, CBAC and the Exploratory Committee also participated in the session as observers who monitored the session and offered their advice for improvement to the tool and process. A participant list is included in Annex 2.

The Multi-stakeholder session marked the first time that the dialogue process had been fully tested from beginning to end. Participants contributed actively to the session and concluded that the Dialogue Tool was extremely useful for 'unpacking' an issue and improving their understanding of other viewpoints. Participants and observers were impressed at how quickly an open dialogue atmosphere was established, allowing participants to freely and honestly share their viewpoints. The rules of engagement helped to establish this rapport, especially the non-attribution rule and the rules for inclusivity. Participants and observers endorsed the Dialogue Tool as a useful tool for providing meaningful dialogue.

They also recommended further work to improve the Tool as an assessment tool for gauging the overall acceptability of a GMFF case. Participants found that the beginning of the process (e.g. introduction, qualities and features, and issues) was well-developed and recommended a few changes to improve the process at these stages in the dialogue, including additional consideration of inviting experts to a dialogue and more reflection on the amount of supporting information required for a successful dialogue. Furthermore, the final steps in the process, which are intended to identify mitigating conditions and to develop potential solutions that address stakeholder concerns, were not fully addressed (in large part given time constraints) and as a result, there was no consensus on potential solutions. Consideration should be given to how this stage can be further developed (this is addressed in section 4.1.2, in the annex on a strengthened step 5 dealing with conditions, and will be strengthened in the various accompanying Tool guides). As well, several participants questioned the use of a risk/benefit analysis as the only or best option in Step 3 and recommended consideration of other models such as the triple bottom line and the Sustainability Impact Assessment (SIA). These issues are discussed in more detail below in sections 3.3 and Annex 3.

More significant refinements were recommended for Step 4, titled 'Using the Spectrum'. The general intent of this step was found to be useful but additional work is required to fine tune it to avoid creating confusion and cynicism, and to ensure meaningful dialogue results. Participants requested a deeper examination of 'conditionality' at this step. They further noted that Step 5, 'Promising Directions', had the potential for improving the way ahead and could be pursued in greater depth. These changes are addressed in section 4.1.2

3.3 Four Key Challenges for the Dialogue Tool Process

Four key challenges were raised regarding the overall Dialogue Tool process:

a. the tug between the need to focus discussion on the specific issue/case at hand and the desire to discuss broader societal issues;

b. the need to identify and provide adequate supporting information;

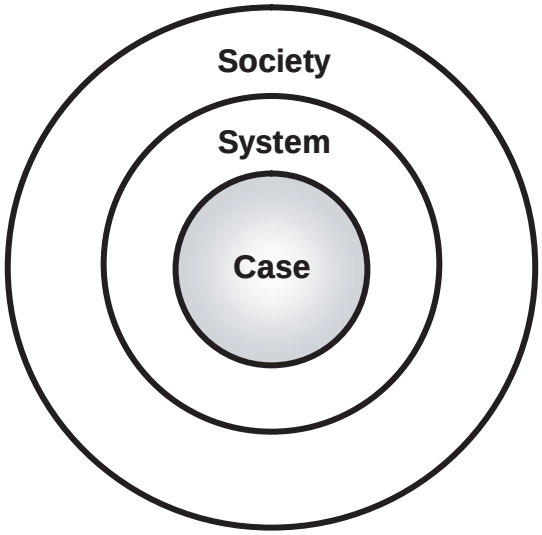
c. the appropriate involvement of 'experts' in the dialogue, and

d. the need to find an achievable balance between reaching a common understanding of the central issue and developing a constructive outlook on the future.

The Exploratory Committee, observers and participants struggled with the best way to address these issues. Balance must be achieved between providing enough direction to support a successful dialogue (e.g. through dialogue focus, the provision of adequate and appropriate information, and so on) without overwhelming participants. Each of these challenges is discussed in detail below.

3.3.1 Focusing discussion on the specific issue and/or on broader societal issues

At the multi-stakeholder session, participants experienced a tug between the need to focus discussion on the issue/case at hand and the desire to discuss broader societal issues. To some participants it is difficult, if not impossible, to discuss a policy issue without a larger societal/systemic context. To others, enlarging the debate beyond the case facts (or health/safety issues) just "muddied the water". In the multi-stakeholder session, broader issues quickly dominated discussion and it was questioned whether this was a result of the hypothetical case or the mix of stakeholders participating.



It will remain a challenge in any dialogue to provide guidance on the case and related broader issues without shortchanging either. This question should be clarified by clear agreement beforehand on what the dialogue session is focused on and trying to achieve, i.e. if the objective is feedback on the case then a predominant focus on the **case** is desirable; however if the goal is to understand the concerns for how a case is dealt with in the developmental and regulatory **system** then a focus on the system is warranted; and if the intent is to explore and appreciate the larger **societal context** and the impact of GMFFs then a larger view focus is desirable. The predominant focus selected will also affect the focus, tangibility and influence of improvements and recommendations that a dialogue group might suggest. *(Addressed in section 4.3.1 c.)*

Participants noted that the dialogue process, clear session objectives and the facilitator helped to bring discussion back to the case where necessary; these will be key elements in ensuring focused discussion in future dialogues. Other ways of focusing discussion may be to include additional process questions in the dialogue process to deliberately address the relationship, or possible direct linkages, between broad societal issues and the policy case/issue under discussion (e.g. What do your concerns about this broader societal issue mean for this topic at hand? Which aspects of this issue directly affect this policy case, and how?). The addition of a parking lot to separate out issues specific to the discussion topic and ones that are broader in nature would also be helpful. *(These issues will be addressed in the Facilitator, Participant and Orientation Guides.)*

3.3.2 Supporting information

The issue of providing the right amount of information (e.g. background, answers to questions on the case, clarification of how the current regulatory system works, etc.) before and during the session, is another key challenge. The process should be based on factual information, without allowing the information to become the central focus of the dialogue or to paralyze the dialogue by the lack of, or contradictory, information. *(Addressed in sections 4.2.2 e. and 4.3.1 b., and Recommendation 5.)*

3.3.3 Role of experts in the dialogue process

The issue of the desired role, if any, of experts in the Dialogue Tool process was raised again at the multi-stakeholder session. There was a clear need for additional technical information regarding the case, the developmental process, the regulatory system, and GMFF technology and its environmental, social, health and ethical implications. The dialogue suffered from a lack of basic information even amongst a largely informed and in-touch group of knowledgeable participants. Some of this information could be provided with additional supporting information (see 3.3.2). However, some participants and observers felt that it would have been helpful to have experts available to answer questions and to clarify misunderstandings or estimations of 'how things worked'. Others remained concerned about the risk of dialogue degenerating into a debate about "my science versus your science" and noted that a benefit of the Dialogue Tool process is its reliance on the expertise, experience and knowledge of participants, not 'experts'. It was also noted that the authority of an expert may be questioned for reasons such as perceived bias, unsubstantiated research or philosophical differences; these issues should be considered prior to the dialogue and must be managed by the facilitator at the session. The facilitator also must ensure that balance is achieved in the dialogue between ensuring factual dialogue and not allowing experts to dominate the discussion with too many scientific facts or non -facts or the focus to be dominantly on the science questions. If the case in discussion is likely to implicate questions or considerations about the regulatory system and how the case has already, or may engage the regulatory process, then it will be important to provide basic information on the system beforehand, and to consider having knowledgeable, informed representatives from the relevant regulatory agencies present to answer questions, etc. The presence of such representatives was not seen as a part of the 'expert inclusion' question assessed here.

This issue will never be straightforward and the way it is addressed may be different depending on the situation but it cannot be ignored or treated lightly. Given the complexity of the topic, and acknowledging that discussion of GMFF issues is rooted in scientific and technical elements, it is still important to have relevant, solid background information available even though it may not be advisable to invite 'experts' to a dialogue. For future dialogue in GMFF, depending on the topic, strong effort should be made to ensure that participants have, or are provided with a basic level of knowledge about the subject and the system. It was also suggested that an extra day could be added to the dialogue process in order to make this possible. If a dialogue sponsor decides that additional background or technical information is required for a dialogue, it should be provided to participants in written form, prior to the dialogue session (e.g. technical papers, websites, etc.). All background and technical information must be provided in an unthreatening, unbiased manner. *(Addressed in sections 4.2.2 e. and 4.3.1 b., and Recommendation 5.)*

3.3.4 Desired Outcome of Dialogue

A dialogue conducted with this Tool/Process can have various outcomes. In some cases, the dialogue organizers/sponsors may be content to enable a dialogue without any particular objectives or results in mind. More often than not, however, specific objectives will be defined for the session along with associated desired outcomes. Although the dialogue process is based on a primary set of process steps, nevertheless the design can be fine tuned to fit each set of circumstances/issues and hence offers some options for tailoring its design to achieve desired outcomes related to the objectives set for the session. But, how far should a session be expected to proceed in the period available (i.e. beyond improved common understanding) and what is the extent of recommendations, solutions, or advice that is desirable and achievable? On balance, participants, observers and Exploratory Committee members felt it reasonable to expect the session to not only bring an improved

understanding and appreciation of the case, and the issues and the reasons behind stakeholder views, but also to achieve some degree of convergence on an outlook to the future including a level of advice to the session sponsors and/or key parties implicated in the case/policy issue. This desire would affect the design of a session and calls for careful attention to the relative emphasis and time allotted to profiling the case, exploring issues/challenges, positioning the case, and developing recommendations and observations for the future including the analysis of conditions needed to support the case. *(Advice on this issue will be incorporated into the Facilitator Guide and Orientation Guide.)*

For a full report of the observations and advice arising from the multi-stakeholders session, see Annex 3.

4

Overall Findings and Recommendations

4.1 Findings and Recommendations Dealing with Features and the Overall Dialogue Process Design

4.1.1 Features and benefits of the Tool and Dialogue Process

a. The Dialogue Tool is a printed matrix or grid, with strong visual components that aid understanding and dialogue. The tool includes an "acceptability spectrum" that is designed to help people figure out the degree to which they find a GMFF proposal acceptable or suitable in the Canadian context. The tool uses comparative terminology (e.g. "acceptable/supportable/beneficial/desirable" through to "unacceptable"), as well as colour to differentiate those degrees of support.

b. The Dialogue Tool helps a group of people "unpack" one or more of the complex issues associated with Genetically Modified Food and Feed. It helps participants walk through a series of process steps and arrive at the heart of some of the most complex scientific and ethical issues likely to be considered by citizens and their governments. The tool lets them view an issue from different angles.

c. The nature and design of the Tool enables and guides participants to engage in a dialogue that incorporates a broad range of issues affecting GMFFs, as well as focusing on specifics related to the case or issue under discussion. The art in the process is to ensure the right balance relative to the objectives of the dialogue and to manage the transition in focus from broad to narrow and back, as needed to bring insight on how both affect the acceptability of the case and its future.

d. The Dialogue Tool affords expert and non-expert inputs. It looks for alternatives. It encourages respectful dialogue and education. But most importantly, it allows the group to determine what they like, what they do not like, what they are concerned about and where they finally "sit" vis-à-vis the GM issue at hand. A real or hypothetical policy case provides the substance of the dialogue. The tool and process do not necessarily produce full consensus, but common ground is often found among participants with widely divergent interests and opinions.

e. The Dialogue Tool is a unique, "Made-in-Canada" public discourse device. It borrows from other public consultation methodologies and extends beyond traditional public opinion polls or focus groups. The Dialogue Tool is used to look at issues associated with genetically modified food and feed though the lens of five "considerations" or "themes" – health, environment, socio-economic considerations, ethical considerations and broader considerations such as international implications.

f. In essence, the Dialogue Tool is a Dialogue Tool, not a consultation tool, in the sense that it intends to provide outcomes and benefits for all participants rather than simply a result mainly for a consultation sponsor.

g. The Tool enables a more holistic examination of policy questions and GMFF cases, incorporating areas and subjects that are implicated and important, (such as social and economic impacts, and ethical questions) and which are not part of Canada's science based regulatory safety review and not easily or successfully incorporated into traditional consultation to date in GMFFs.

h. The dialogue approach involves a 6-step process, guided by an expert facilitator, where participants explore all dimensions of a GMFF case, including its features, risks and benefits, issues and implications, and then propose summary observations and suggestions on the future for the case example. In this approach, participants discuss ideas in small groups, exchange views in plenary session with the whole group, note their

Recommendation 1:

That further development and promotion of the Tool/Dialogue Process build upon and deepen the features designed to date, in particular the ability: to create an open, candid, and engaging dialogue environment; to create a dialogue that has outcomes for all participants; to unpack complex issues through an iterative series of deliberative dialogue steps; to enable dialogue that is focused on broad issues as well as narrow specifics; to include risks as well as benefits; to view issues through a wide range of considerations (from Health, Environment, Social, Economic, Ethical, and Broader considerations); to assess relative 'acceptability' from a spectrum of alternatives; a nd to suggest conditions that enable solutions for the case.

opinions in individual survey instruments, and record their individual views in a private workbook as appropriate.

i. The goal is not necessarily to achieve consensus but to inspire and encourage dialogue, to bring different viewpoints to the table and to share expertise and perspective. In some cases, people using the tool have changed their minds or admitted that they learned something new. And sometimes consensus has been achieved. Most people said the dialogue was worth it for what they learned, how they were able to listen to others, and how free they were to put their own views forward. Participants have also commented that they are able to break down complicated, often highly scientific, information so they can become more comfortable about their level of understanding and appreciation of the many impacts of new technologies.

4.1.2 Primary Dialogue Process Steps

a. The primary dialogue process steps will consist of the following six steps. Optional additional steps within the overall sequence of the six core steps (which can also be used as alternative approaches to the primary step in certain circumstances), are outlined in the right column and can be selected depending on the design objectives and the time available.

Primary steps	Optional added and/or alternative methods
Step 1: Defining Qualities and key features of the GMFF case	• Risks and benefits analysis • Alternatives analysis
Step 2: Identifying issues	
Step 3: Defining risks and benefits	• Risk analysis (probability and impact) • Alternatives analysis • Weighing risks and benefits • Trade off analysis • 'What if' scenarios • Triple bottom line assessment • Sustainability Impact Assessment
Step 4: Using the Tool's Spectrum	• Assess position on spectrum at start of session, then just after defining risks and benefits (assess position for all 5 consideration areas), then after conditions have been proposed (assess 5 consideration areas and overall position) (using different ways to express degree of acceptability)
Step 5: Determining conditions for acceptability (see Annex 4 for overview of new step 5)	• Assess confidence level in conditions • Explore 'what if' scenarios and how different conditions/recommendations might affect the risks, benefits, trade offs and acceptability • Assess position on spectrum after conditions defined
Step 6: Exploring promising directions (conditions, solutions, advice to the dialogue sponsor, next dialogue)	• Evaluate the dialogue and process

Recommendation 2:

The Participant Guide and Orientation Guide be organized to present the six Primary steps with a selection of optional methods to enable varied design emphasis to respond to different dialogue design requirements.

4.2 Findings and Recommendations Dealing with Use and Principles Underpinning the Use

4.2.1 Utility and Applications

The Exploratory Committee had projected the potential uses early in its development and have concluded that this range of potential applications still stands and provides great opportunities for creative application now that the model dialogue process and Tool are considered mature enough for release. This scope of uses suggests that the Tool/Process can:

a. be a vehicle to inform and guide policy discussion, policy development, and decision-making on national policies affecting GM foods and feeds, especially early in the development of policy or the development of potential GMFFs.

b. provide broader scope for decision-making in the policy environment.

c. help to incorporate socio-economic and ethical considerations and provide the context for economic and social issues to inform policy development.

d. engage and support public dialogue and be an aid to assess public will, values and priorities with regard to broad types of new technologies or products such as GM foods and feeds.

e. inform and support individual stakeholder groups in consideration of their own policy making and direction.

f. inform the public on GMFFs with respect to risks and benefits, issues of concern, current regulations and policies and, if and where there are gaps or unnecessary duplication, to address them.

g. provide a model for deliberative dialogue and consultation in a broad range of biotechnology subjects.

Applications in other fields

In addition, the Exploratory Committee suggests that the Tool/Process could provide a model for deliberative dialogue and consultation in other public policy areas which have a profile of complexity and multidimensionality, have impacts on health, environment, socio-economic and ethical domains, are related to a public good and are regulated (or even non regulated) (e.g. these could include introduction of new agricultural products, new food products or processes, cloning, health products, fisheries management, sustainable development, nuclear energy, etc.).

Recommendation 3:

That the Tool/Dialogue Process be further developed and made available, not only to the GMFF field through the range of opportunities outlined but to the other complex issues in biotechnology as well. Furthermore, that the model be made available to other policy areas with comparably complex profiles for adaptation and application.

NOTE: if the Tool is used in areas other than biotechnology, it will likely be useful to change the name to a more generic form, e.g. The Spectrum Dialogue Tool, Dialogue Tool Unpacked, Dialogue Unplugged, The Spectrum View Dialogue Tool, The Future Acceptability Dialogue Tool, etc.

4.2.2 Principles and limitations in the use of the Tool/Process

a. It is important to the success of the dialogue session, to be clear on the objectives, scope and focus of the dialogue on a GMFF, so that an appropriate design can be outlined that meets expectations and best fits the conditions.

b. It is critical to be clear about the purpose and expected outcomes of a dialogue in the development phase, at the stage of invitation to participants, and throughout a dialogue process. Transparency and accountability are key to success. If the objectives and scope of the dialogue cannot be clarified and agreed in the design and participants acceptance of the invitation, it will be dangerous to proceed as participants may differ widely in where they wish to focus their discussion and assessments of acceptability, conditionality and improvements for the future.

c. The process must establish rules of engagement or a code of conduct in the lead up to the dialogue and these must be agreed to by participants in principle beforehand, and in practice at the start of the session. Without this, one will not have a confident basis for a civil dialogue that ensures mutual respect, in which case the session should not proceed.

d. The Dialogue Tool/Process may be less or not appropriate in situations,

- Where the issues are fairly one dimensional, and do not have complexity or require unpacking;
- To assess only the Health and/or Environmental risks associated with a product, as this is the purview of the regulatory regime;
- In an uninformed participant group without good background, scientific facts, and adequate preparation as users could draw erroneous or superficial conclusions, or become paralyzed with widely different estimations of the case and context;
- Where the question is set up for debate with winners and losers.

e. Following are key design principles for a dialogue session that should guide development.

(a) Informed participation is essential. Before undertaking a dialogue, it is essential to ensure that adequate background information is available for informed dialogue.

(b) The content of background materials must be presented, with a balanced representation of the issue. Balance must also be found between offering enough information to inform participants but not enough to confuse or overwhelm them.

(c) The Dialogue Tool could be useful in a variety of processes and for a variety of audiences. Be explicit about the context of the dialogue, including purpose, audience, expected output and outcomes and how they will be used.

(d) Be explicit about whether the issues dialogue focuses on hypothetical or current reality.

(e) It is important to identify all stakeholders who should be involved in a particular dialogue.

(f) The process flow involving group make-up, group work, plenary round table and individual reflection has been carefully designed to foster interaction across constituencies and lateral ‘out of box/out of comfort zone’ thinking and should be maintained despite participant inclinations to focus on areas of comfort or preconceived issues.

(g) The report of a dialogue session should fairly present the scope and focus of the dialogue, should reflect the areas of relative convergence or agreement as well as any areas of substantive difference, and should indicate the make-up and balance of interests/representation of the stakeholder participants

(h) The process is very resource-intensive (time, money and effort). Dedication and willingness to undertake a dialogue is essential.

(i) A skilled facilitator should be engaged to guide a dialogue process.

Recommendation 4:

The descriptive, instructive and promotional material on the Tool/Process should outline the preferred focus and uses, while indicating applications and topics that would likely not be useful, as well as any selection criteria and preconditions that should be satisfied to optimize success.

(j) Trust, creativity and flexibility in the approach are important.

(k) Participants must be willing to participate in dialogue in an open, respectful manner.

(l) Participants must commit to participating full time for the whole of the dialogue process.

Note: An understood desired outcome of the dialogue process is to raise public confidence (for instance that a constructive dialogue that elicits helpful solutions is possible), and to provide relevant and useful policy advice. This means that the dialogue process should attend to and strive for quality outcomes that both inform and increase confidence that a progressive and useful approach to the case and its context has been developed. This means for instance, that step 5 dealing with conditions, must be well and diligently done, striving to produce conditions that are compelling, useful and achievable. In the longer term, this also means that we need a means to aggregate the learning from these dialogues so the collected wisdom can help inform the policy environment in a constructive and ongoing manner using accumulating results (see section 4.3.3 e).

4.3 Findings and Recommendations Dealing with Further Development and Hosting

4.3.1 Areas for further future work to enhance and advance the Dialogue Tool/Process

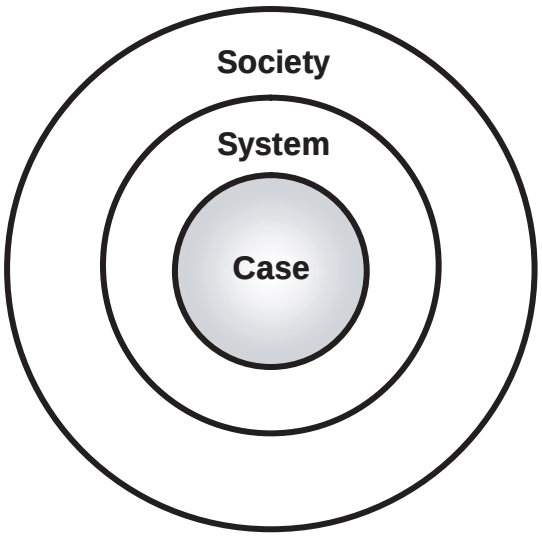
a. Prepare a Facilitator Guide for use in future sessions, containing a complete review of the primary dialogue process, with select variations on the primary process, and including guidance on the methodology of each step, tips and techniques, etc. This will be necessary to support and guide any new groups who undertake dialogue events using the Tool/Process.

b. Develop a basic background information package for preparation of future participants including:

- a generic outline of the lifecycle of a GMFF from research to consumption, with an indication of roles of key stakeholders involved at each stage of the life cycle;
- a detailed overview of the Canadian regulatory system that applies to GMFF cases, which federal agencies are involved and what the system tests for;
- a summary of the elements and steps of a GMFF developmental and regulatory review process and what tests and requirements are required at each step of development; and
- a comprehensive and balanced list of accessible public information sources on GMFFs, including websites, published papers and bibliography, international sources, etc.
- **Note:** other potential information that could be added to the package depending on the particulars of the case include information on international regulatory regimes e.g. OECD and a listing of products already on the market in Canada and elsewhere where relevant.

c. Develop dialogue design prototypes for three different core objectives, i.e.

- focused predominantly on a particular GMFF **case** where the objective is to enable exchange and provide advice on the acceptability of the proposal, what specific conditions might be needed to enable degrees of acceptability and observations on what this means for policy making with these types of cases; and/or
- focused predominantly on the **'system'** in which the GMFF exists including the development, regulation, supply chain and policy makers where the objective is to enable exchange and provide advice on the processes that occur in this system, on the roles and practices of key stakeholders and how they might be enhanced; and/or



- focused predominantly on the **societal context** for GMFFs including broader considerations at a domestic and international level where the objective is to enable exchange, observations and insights on how GMFFs impact societal norms, beliefs, practices and relationships with the opportunity to explore how their place in society could be addressed in more constructive and helpful ways.
- **Note:** while dialogue events could be designed to address two or all three of these domains/objectives, this increases the complexity significantly and will make it much more difficult to gain a degree of closure on any one of the objectives. Furthermore, understanding how the design parameters would change for the different prototypes will assist the designer to focus on what is desired and most useful for the event and to appreciate how the dialogue would proceed in the different approaches.

Recommendation 5:

As a first priority, in preparation for further use of the Tool/Dialogue Process, a Facilitator Guide and basic information package be developed.

Recommendation 6:

As a next priority, three prototype designs should be developed that explore a particular focus on each of a case, the system, and the societal context for GMFFs.

Recommendation 7:

As part of any next stage of development, another pilot dialogue could be undertaken to assess the approach to the latter steps in the process, in particular dealing with the 'use of conditions'. As well, a case preparation overview should be developed and included in the Orientation Guide, and optional dialogue designs and prototypes be developed that incorporate variations in timeframes and stakeholder clients.

d. Conduct another pilot with a special focus on process steps 3-5 dealing with the use of the spectrum, conditions and recommendations on the way ahead

e. Develop a description of the key elements of a case model for use in the dialogue sessions, the qualities of a good case, and how the case should be developed with some examples for pilot use and include the case overview in the Orientation Guide.

f. Develop dialogue design options that are delivered over different time frames depending on the objectives and focus of the dialogue project, e.g. one day event; a multi-stage project in 3 stages over 1 month with learning/research/follow-up after each stage that informs and prepares the next stage; a longitudinal project where a selected constituency group follows and advises on a case over the life cycle of the case.

g. Develop dialogue design prototypes for different stakeholders, e.g. for the general public; for policy makers; and for single stakeholders (e.g. to enable developers to identify the degree of acceptability and conditionality associated with a proposed case, for consumers to explore how consumers could relate to GMFFs).

4.3.2 Exposing and promoting the Tool/Dialogue Process in Canada and internationally

a. CBAC Members

In order to help CBAC members better understand the Dialogue Tool, a plan should be developed to allow the members to use the tool themselves and/or to enable CBAC to experience a GMFF dialogue session designed especially for them, or CBAC could sponsor a dialogue with outside participants on an issue relevant to CBAC. As well, with the reports from the GoC and multi-stakeholder sessions in hand, along with a recommendation from the EC, CBAC should consider making a public statement or issuing a press release about the future of the tool.

b. Government of Canada Involvement

A strategy should be developed to further engage Government of Canada (GoC) departments, especially BACC members, to consider applications in their related policy domains. This should build on the strong success of the GoC Preview Session held in November 2003 and could include hosting another GoC session and inviting the seven biotechnology departments along with officials from other departments and agencies. The focus would be on the more advanced view of how the Dialogue Tool and process can be used in multi-stakeholder sessions, including the different design options and a review of other advanced collateral products such as the Participant Guide.

c. Single Constituency Promotions

Some Exploratory Committee members have indicated an interest in presenting the Dialogue Tool at one of their conferences/national meetings etc. This would help market the Dialogue Tool and other collateral products and provides greater outreach to key target audiences.

d. International

With the assistance of CBAC and EC members, the Dialogue Tool could be promoted to an international audience through government-to-government exchanges, international conferences, publishing an article on its evolution and present use, etc. Approaches to international channels could include: UNEP, Commission on Sustainable Development, UN Committee for Trade and Development.

e. MP Kit

Members of Parliament (MPs and Senators) would benefit from an in-depth briefing and access to information about the Dialogue Tool. A kit that ‘tells the story” of the Dialogue Tool should be designed and MPs should be directed to

Recommendation 8:

CBAC share the Tool/Process with institutions in government or agencies that support public policy development and dialogue, and who are engaged in respectful dialogue processes dealing with compelling policy questions, such as the National Round Table on the Environment and Economy (NRTEE), Public Policy Forum, Canadian Policy Research Networks, and the International Association for Public Participation.

Recommendation 9:

CBAC develop and execute a strategy to expose and promote the Tool and its use in Canada and internationally. The Exploratory Committee urges CBAC to promote the Tool immediately in order to encourage the active and timely use of the Tool, with aggregated feedback and learning achieved across several constituencies by the end of 2004.

more information about the dialogue process and tool at the CBAC web site. MPs may even be interested in encouraging use of the tool with organizations in their communities.

f. Information Kit

A general information kit should be developed that would be similar to the MP kit and would be distributed more extensively across the federal government (including to Director Generals of communications and those involved in public engagement exercises).

g. Web Site

A web site plan should be developed that positions the dialogue process and tool as a knowledge tool accessible to all Canadians. The advisory services described in section 5.7 should be web enabled as well and part of this web site.

h. Media Relations

Once CBAC is clear about how it wishes to further promote the dialogue process and tool, a media relations plan should be developed. This might involve the development of a press kit, targeted briefings and/or editorial board briefings, and even media roundtables with journalists covering biotechnology issues.

4.3.3 Stewardship and Hosting of the Tool/Dialogue Process

a. Wherever the Tool/Dialogue Process concept and support materials proceed following the receipt of this report by CBAC, they will benefit from further development, in particular provision of a facilitator guide, background information package, descriptive process on how to develop a case/topic for dialogue and optional dialogue designs to fit varied conditions and objectives.

b. The Tool/Process will be most useful if supported by a level of advisory services that can respond to requests for background information, for the best design/approach to fit a situation/objectives, lessons from other experiences, do's and don'ts, contacts for other case experiences, contacts for facilitation, etc. Preferably, this will be web enabled.

c. The advisory services are the logical place to receive, track, and catalogue lessons learned in dialogue experiences, and to make them accessible to other users. Over time, this would form the basis of a 'best practices' database that should be web accessible.

d. It will be important to ensure that there are standards defined and maintained for the Tool/Process. While open access and use should be encouraged, this must be balanced with a desire for continued high quality and consistency in the presentation and use of the tool.

e. In this report, the Exploratory Committee has provided advice to CBAC on how the Dialogue Tool and its related process can be systematically applied in the long term to enhance Canadian society's understanding of and ability to inform the policy environment related to the area of GMFFs (e.g. to enable Canadians' understanding of the issues and to begin to improve the situation). Comparison and cumulative learning from a number of dialogues is key and a framework (with appropriate administrative system, infrastructure and responsibility centres) must be developed to facilitate learning across dialogues and time. This responsibility centre could be established in association with CBAC, a government department, or via an independent third party.

f. The Exploratory Committee urges CBAC to explore and select an appropriate host to become the steward of this Tool/Process, to encourage BACC members to participate in this process, and to select from among attractive candidates including: CBAC itself given its interest, role and experience to date; NGOs that are concerned with governance, or policy development such as the Institute on Governance, Canadian Policy Research Networks; agencies providing consultation and facilitation services such as the Simon Fraser University Dialogue Centre.

Recommendation 10:

CBAC select and establish a host/steward that would manage the Tool/Process including the central concepts and materials, advisory services, a lessons learned and best practices searchable database, and the maintenance of quality standards for the Tool/Process. Further, CBAC work with another party to advocate for and to develop a framework and a capacity to facilitate learning across dialogues over time, to maximize the benefit to the policy environment and to Canadians.

Note: CBSec should report back to BACC members (including staff who attended the GoC Preview Session and the Multi-stakeholder Pilot Session) on the results of Phase III and the going forward outlook, so they know the Tool/Process is complete enough for immediate use and that they can participate/contribute in the search for and selection of a host.

g. Following are suggested criteria for the selection of hosts for the Tool/Process. The host should be:
   - recognized, with profile and convening power
   - adequately resourced
   - appreciative of dialogue and good process design
   - objective with a neutral stance
   - active and has influence (credibility and presence) in public policy networks
   - has potential/possibility to look out and act on an international level.

5

Recommendations and Summary on the Future of the Dialogue Tool and Process

5.1 Summary of Recommendations

Recommendations dealing with features and the overall dialogue process design

- **Recommendation 1:** That further development and promotion of the Tool/Dialogue Process build upon and deepen the features designed to date, in particular the ability: to create an open, candid, and engaging dialogue environment; to create a dialogue that has outcomes for all participants; to unpack complex issues through an iterative series of deliberative dialogue steps; to enable dialogue that is focused on broad issues as well as narrow specifics; to include risks as well as benefits; to view issues through a wide range of considerations (from Health, Environment, Social, Economic, Ethical, and Broader considerations); to assess relative 'acceptability' from a spectrum of alternatives; and to suggest conditions that enable solutions for the case.
- **Recommendation 2:** The Participant Guide and Orientation Guide be organized to present the six Primary steps with a selection of optional methods to enable varied design emphasis to respond to different dialogue design requirements.

Recommendations dealing with use and principles underpinning the use

- **Recommendation 3:** That the Tool/Dialogue Process be further developed and made available, not only to the GMFF field through the range of opportunities outlined but to the other complex issues in biotechnology as well. Furthermore, that the model be made available to other policy areas with comparably complex profiles for adaptation and application.
- **Recommendation 4:** The descriptive, instructive and promotional material on the Tool/Process should outline the preferred focus and uses, while indicating applications and topics that would likely not be useful, as well as any selection criteria and preconditions that should be satisfied to optimize success.

Recommendations dealing with further development and hosting

- **Recommendation 5:** As a first priority, in preparation for further use of the Tool/Dialogue Process, a Facilitator Guide and basic information package be developed.
- **Recommendation 6:** As a next priority, three prototype designs should be developed that explore a particular focus on each of a case, the system, and societal context for GMFFs.
- **Recommendation 7:** As part of any next stage of development, another pilot dialogue could be undertaken to assess the approach to the latter steps in the process, in particular dealing with the 'use of conditions'. As well, a case preparation overview should be developed and included in the Orientation Guide, and optional dialogue designs and prototypes be developed that incorporate variations in timeframes and stakeholder clients.

- **Recommendation 8:** CBAC share the Tool/Process with institutions in government, or agencies that support public policy development and dialogue, and who are engaged in respectful dialogue processes dealing with compelling policy questions, such as the National Round Table on the Environment and Economy (NRTEE), Public Policy Forum, Canadian Policy Research Networks, and the International Association for Public Participation.
- **Recommendation 9:** CBAC develop and execute a strategy to expose and promote the Tool and its use in Canada and internationally. The Exploratory Committee recommends and urges CBAC to promote the Tool/Process immediately in order to encourage the active and timely use of the Tool, with aggregated feedback and learning achieved across several constituencies by the end of 2004.
- **Recommendation 10:** CBAC select and establish a host/steward that would manage the Tool/Process including the central concepts and materials, advisory services, a lessons learned and best practices searchable database, and the maintenance of quality standards for the Tool/Process. Further, CBAC work with another party to advocate for and to develop a framework and a capacity to facilitate learning across dialogues over time, to maximize the benefit to the policy environment and to Canadians.

5.2 Conclusion and Summary Recommendations by the Exploratory Committee

1. The Dialogue Tool Project objectives have been achieved (see section 2.1). The conduct of the developmental process by the Exploratory Committee was noteworthy in its respectful communication among EC members, in the constructive nature of the exchange despite fundamental differences to start, in the enhanced confidence that the process built among the group and in the overall productive and promising outputs/results.
2. The Dialogue Tool and Process is ready for immediate use and continues to be a work in progress.
3. The Exploratory Committee strongly recommends and urges CBAC to promote the Tool/Process immediately in order to encourage the active and timely use of the Tool, with aggregated feedback and learning achieved across several constituencies by the end of 2004.
4. The Exploratory Committee strongly recommends and urges CBAC to select and establish a host/steward that would manage the Tool/Process including the central concepts and materials, advisory services, a lessons learned and best practices searchable database, and the maintenance of quality standards for the Tool/Process.
5. The Exploratory Committee is willing to continue to advise on and assist the future development and promotion of the tool if desirable and helpful, and in particular to provide advice to the transition process over the balance of 2004. [And, in any case, the EC would appreciate feedback on the future course selected.]
6. Individual members of the Exploratory Committee are committed to seeing the tool used widely and to that end intend to actively promote the tool and pursue individual opportunities to engage dialogue sessions using the tool.

In concluding this initiative, and tabling this final report to the Canadian Biotechnology Advisory Committee, the Exploratory Committee extends its appreciation to CBAC for their support of this project, for the mandate and freedom provided to the Exploratory Committee, and for the foresight and innovation in having initiated and championed this important project which has the potential to enable a more open constructive dialogue, to foster compelling solutions and outlooks on the future, and to inform the policy environment……the potential of these benefits have made this initiative worthwhile, encouraging and very satisfying to the members of the Committee.

April 16, 2004

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Lyle Makosky (lead facilitator)
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Appendix 1
Policy Case for the Multi-stakeholder Pilot Session

NOTE: The following case is completely hypothetical and has been developed solely for the purposes of testing the Dialogue Tool.

Introduction

A pharmaceutical company wishes to produce a new blood thinning agent. While the drug could be produced chemically, the company believes that a plant-made pharmaceutical (PMP) may provide a significant therapeutic advantage related to the purity of the active ingredient. Production of the protein would require genetic modification of a plant – and in this case, the most desirable host plant is also a food. The company has a patent on the active ingredient.

The company is concerned about the potential public reaction to this proposal. It understands that some members of the public may have concerns with genetically modified (GM) foods in general and that most citizens have concerns about whether proper safeguards will be in force. The public is aware of a few, well-publicized incidents of transgenic crop violations involving other food crops (e.g., Starlink and Prodigene products).

The company does not wish to invest a considerable sum in developing the PMP if public opposition will make it impractical to produce. It has heard about a new approach to dialogue on GM Foods, called the Genetically Modified Food and Feed (GMFF) Dialogue Tool and has asked two facilitators to guide a dialogue session, with a wide range of participants, to discuss the potential product, to discern their underlying views and issues, and identify the conditions under which the acceptance of the product might be improved.

As the product has not yet been developed, the regulators – either Health Canada or Canadian Food Inspection Agency – have not reviewed it.

The Case

The case for discussion is genetically engineered food-grade soy, grown to produce a patented pharmaceutical – a blood thinning protein derived from pig spleens. The crop is to be grown by farmers in five locations in Ontario – 4 hectares each for a total of 20 hectares – under contract for a major pharmaceutical company. It will be grown in open fields and appropriate safeguards will be required to ensure both isolation and containment, such as full segregation, buffer zones within season and buffer crops.

Even though some would consider these safeguards sufficient to satisfy regulatory requirements, the developer intends to take an additional step to prevent outcrossing – namely the use of Genetic Use Reduction Technology (GURT), also known as the terminator gene. In this case, the developer intends to use a Varietal GURT or V-GURT to make the plant sterile. While the introduction of GURT may allay some concerns, it could also introduce new ones such as the theoretical potential for cross-pollination with traditional varieties leaving progeny sterile, and related concerns for biodiversity.

The soy is not intended for consumption as a food – either for humans or animals. It is not considered toxic, but inadvertent consumption of unusually large amounts may cause a pharmacological effect – the thinning of the blood. Hence, good farming practices and other management systems will be required to ensure that the entire crop is used as a pharmaceutical input, and that none of it ends up as food or feed. This should be in the company's best interest as the crop will be very expensive.

Background

Normally, after a cut or injury, blood clots to stop bleeding; however, blood may sometimes clot when it is not supposed to, forming inside a blood vessel, the lung or the heart. A thromboembolism is a blood clot that breaks off and travels through the bloodstream to another part of the body, potentially stemming the flow of blood and causing damage. A blood clot formed in the heart can travel to almost any organ in the body. When lodged in the brain, it can cause a stroke. In other cases, it can cause heart attack or kidney damage. Prompt treatment is essential in order to prevent serious complications or death.

Blood thinning medications, known as anticoagulants, are used to treat and prevent blood clots associated with conditions such as deep vein thrombosis (DVT) – a blood clot in veins embedded deeply in the muscle mass of the legs or lower abdomen, or pulmonary embolism – a blood clot that has travelled through the bloodstream to the lungs. They generally work by decreasing the synthesis of vitamin K dependent clotting factors.

As with all medications, there is risk of adverse effects. Anticoagulants may prevent normal blood coagulation, thereby increasing the risk of bleeding complications. Many of these complications are minor, such as bleeding from gums, but some may be severe and life-threatening, including bleeding into the brain.

There are two commonly used anticoagulants to stop existing clots from growing and new ones from developing. The first anticoagulant (A) is derived from pig spleens and administered orally. It effectively treats blood clots, but is slow acting and interferes with the normal blood clotting, increasing the risk of bleeding. Anticoagulant B (also derived from animals), administered subcutaneously, is fast-acting, helps prevent existing clots from growing and stops the formation of new ones, albeit less effectively than anticoagulant A. Its major advantage is that its half-life is shorter than that of anticoagulant A, thereby making it less likely to cause severe bleeding, especially after finishing treatment.

A well known clinical trial compared the two medications in the treatment of DVT in 68 patients. Nine of 35 patients receiving medication B, but none of 33 patients receiving medication B, had new episodes of venous thromboembolism. However, seven patients on medication A had bleeding complications of which 4 were considered major. This contrasts with no adverse incidents using medication B. The study concludes as follows: "Thus, adjusted dose A is more effective than low dose B in preventing recurrent venous thromboembolism, but its use is accompanied by a significant risk of bleeding."

Pharmaceutical companies have tried to develop a new medication that would combine the benefits of both drugs – effectiveness and oral administration with minimal bleeding, especially after stopping treatment.

However, attempts to do so using normal pharmacology have proven unsuccessful. The quality of supply of the active ingredient from animal sources has been inconsistent. The company has therefore decided to try to stabilize supply by planting a genetically modified protein inside the genome of food-grade soy.

Appendix 2
Participant List for the Multi-stakeholder pilot session

March 17-18, 2004

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Bob Main
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Appendix 3
Observations and Advice Arising from the Multi-stakeholder Session

Specific recommendations from participants and observers of the Multi-stakeholder Pilot Session, Exploratory Committee members, CBAC members, Canadian Biotechnology Secretariat staff and the facilitation team has been captured in this section and includes comments on the overall process and design, the policy case, session logistics and the future of the Dialogue Tool. Many of these observations and suggestions are directly addressed in the Exploratory Committee's recommendations in Section 4 while others will be considered when the Participant Guide, Orientation Guide and Facilitator Guide are revised. Where possible, cross-references to section 4 have been included below.

3.4.1 Features and benefits of the Tool and Dialogue Process

a. Rules of engagement were key to the success of the dialogue. Participants suggested that it would be useful to have the rules of engagement prominently displayed throughout the dialogue as reminder to participants. One observer suggested that "no grandstanding" should be added as one of the rules of engagement. *(This issue is addressed in section 4.2.2 c. and will be further incorporated into the Facilitator and Orientation Guides.)*

b. The process steps worked well in leading the group through the dialogue process in a logical manner. This "pull" is needed in the process in order to guide a diverse group and a difficult topic to a successful dialogue conclusion. The definition of a successful dialogue conclusion may change depending on the desired outcomes identified prior to a dialogue, but it is important for a group to feel that there is an end to the dialogue even if full clarity around an issue has not been achieved. *(See section 4.1.1 i.)*

c. Expert facilitation is essential to the success of the dialogue as was evidently present in this session. The facilitator's ability to clarify and articulate participants' issues in a concise, understandable manner is crucial.

d. One of the benefits of the dialogue process is that participants meet other people interested in the same issues as they are but who may have a different perspective or who may be from a different stakeholder group than one that participants would normally come in contact with. One participant suggested that additional time for 'informal' discussion (e.g. longer breaks) would be useful.

3.4.2 Overall Dialogue Process Design

One of the goals of the Multi-stakeholder session was to assess the design and flow of the dialogue session; looking at how effectively each step, and the process overall, produced expected results. Feedback about this aspect of the multi-stakeholder session included the following comments/observations.

General Comments

a. Transparency and accountability are key to success. Be clear about the purpose and expected outcomes of a dialogue upfront, and throughout the dialogue process. If possible, clarify how the use of the tool may translate into public confidence and policy advice. *(This issue is addressed in section 4.2.2 a. and 4.2.2 b. and will be further incorporated into the Facilitator and Orientation Guides.)*

b. The mix of group and plenary discussions was useful and helped raise participants' comfort levels with each other and advanced the dialogue. One participant, with some agreement from others, suggested that participants be allowed to choose their own discussion table rather than being assigned a discussion topic (e.g. health, environment, etc.). Balance of representation at each table should be maintained if this option is allowed. *(This issue is addressed in section 4.2.2 e. and will be further incorporated into the Facilitator and Orientation Guides.)*

c. Additional clarity about the purpose of each step and the relationship and differences between steps is required throughout the dialogue, especially at the beginning of the process. Some overlap was noted between steps 1 and 2 and questions were raised about the differences between pros and cons and risks and benefits (step 1 and 3). It is also important to continually keep the objective of the dialogue in mind as a means of maintaining focus in the dialogue.

   It might be useful to include a step at the beginning of the dialogue for participants to indicate their starting position on the spectrum. This would be compared to the positions indicated in Step 4 after participants have benefited from the dialogue. *(See Section 4.1.2 and Recommendation 2 for further recommendations on improving this stage of the dialogue process.)*

d. One participant questioned whether the use of categories (e.g. health, environment, socio-economic, etc.) potentially limits discussion or patronizes participants. In response, others stated that the criteria serve to stimulate dialogue, identify key issues and improve understanding among diverse stakeholders by encouraging attention on, and legitimizing, issues beyond the more traditionally considered issues of health and safety, and legitimizing them, and that it also helps considerably in unpacking complex cases and enables participants to understand and focus on particular dimensions of the issue.

e. A modified open space technology methodology might be useful for some stages of the dialogue to allow more participant choice in the identification and scoping of issues discussed (e.g. allow participants to self-select the criteria they would like to discuss). *(Advice on this issue will be incorporated into the Facilitator and Orientation Guides.)*

Step One Qualities and Features

f. This step in the process is essential and appeared to foster greater common understanding of the case. The tool appears to work well, at this stage, by giving people "permission" to voice their opinions, observations, ideas and concerns (listed as "features" of GMFF on a series of flipcharts). The process serves to legitimize the feelings and values of the participating stakeholders in a structured format. It reveals the collective points as a mixture of benefits and challenges.

g. An observer noted that it is difficult for participants to remain focused on identifying features and qualities as their tendency is to jump right into an issues discussion and that it is difficult for the facilitator and the participants to limit the amount of value-laden commentary that surfaces during this step. Further understanding of the purpose and process of this step might be precipitated through the use of one or two examples when the process step is introduced.

h. At this stage, it is also important for the facilitator to keep the discussion fixed, as much as possible, on the policy case rather than on broader societal issues. The facilitator must manage participation across stakeholder groups as much as possible as an imbalance of identified pros and cons can result if one stakeholder group is more vocal than another. One observer noted that most participants come with negative viewpoints (e.g. the negative effects of the proposed drug on health, environment, etc.) making it more challenging to identify and discuss positive attributes. *(Advice on this issue will be incorporated into the Facilitator and Orientation Guides.)*

Step 2 Issues

i. Additional time could be given to this step to better flesh out the issues and to allow a group to better group/synthesize the identified issues into themes, or common issue groups. This could help make process steps 3 and 4 more manageable.

Step 3 Risks, Benefits and Trade Offs

j. Participants did not dispute the benefit of this step but several questioned the use of a risk/benefit/trade off analysis at this point in the dialogue. They felt that the terms 'risk', 'benefit' and 'trade off' all have negative connotations and may not adequately address the need to fully consider the relationship between different aspects of the issue. In addition, participants felt that they had insufficient information available to effectively consider trade offs in this policy case; this could be partially addressed through expanded dialogue in step 2 as suggested above, or by allowing additional time between steps 2 and 3 to gather further information about risks and benefits.

k. It would be useful for the facilitator to have different methodologies available from which to choose depending on the nature and purpose of a specific dialogue. The concepts of sustainability impact assessment or triple bottom line were recommended as well as the risk/benefit analysis currently proposed.

l. Clarify the purpose of this step and its relationship to the pros and cons identified in Step One.

m. Include discussion of alternatives at this point in the dialogue. Discuss some "what if" scenarios and how different conditions/recommendations might affect the risks, benefits or trade offs, and consequently, how they might change participants' reactions to them.

n. Conclude the discussion with an articulation of the priority issues, risks, benefits and trade offs that need to be addressed. (e.g. identify the areas where unacceptable risks exist, areas where further work is required by the proponent, etc.).

   (See Section 4.1.2 and Recommendation 2 for further recommendations on improving this stage of the dialogue process.)

Step 4 Using the Spectrum

Overall, participants found this to be a problematic step although they acknowledged the value in undertaking it. The expectations and intent of Step 4 were unclear to participants as was the meaning and weight of the dots they were placing (what exactly does each dot represent and is it the same for everyone?). Further work is needed to clarify the purpose of the step, the meaning and intent of "conditions", assessment of conditions, and the language on the spectrum. Participants and observers made the following recommendations to improve this step:

o. Conditions are a critical aspect of this step and more time to address/discuss conditions is required. At the multi-stakeholder session, there was not complete agreement on what the conditions were (although a compelling range of conditions had been suggested), which ones were most important, which ones were achievable, and whether participants had any confidence that the conditions could/would be achieved at all. In the future, more attention needs to be paid to the types of conditions that might apply to a case study, what the conditions might look like, how they might be prioritized and who should undertake to achieve them.

   If participants believe it is impossible to meet the conditions, the tool has a limited future. This could lead participants to feel that they have participated in a false process and that their participation/positions have been 'betrayed' at this step. Accurately and completely recording results is key to avoiding the problem of participants feeling betrayed by the process at this stage in the dialogue. Even if it is difficult to assess whether conditions are capable of resolving the issue or of being implemented (to some degree this may require regulators or other experts to assess), nevertheless if proposed , and then reviewed and critiqued rigorously in the dialogue, it can still identify where there is convergence on types of solutions or the way ahead.

p. The step should conclude with the development of recommendations for future action to the dialogue sponsor (in this dialogue event's case, the developer). Dialogue participants should clarify and articulate their positions on the spectrum and their discussions in such a way that the dialogue sponsor can gather practical advice from them for moving forward (e.g. would they be best advised, given this dialogue, to halt development of this pharmaceutical, or to move forward while acting on the following conditions, etc.)

q. Clarify the vocabulary at the top of the spectrum (e.g. acceptable with conditions...)

r. Interesting variations on this step could include:

- Undertake a series of "votes" to determine the initial position of a group, their position if conditions were in place, if only some conditions were in place, etc.
- Undertake a 2-step process with 2 votes – one without consideration of specific conditions and then assuming specific conditions in place.
- Ask participants to identify one condition that would move them over a colour on the spectrum (i.e. toward the left on the grid)
- Allot dot colours by sector rather than by table group.

(See Section 4.1.2 and Recommendation 2 for further recommendations on improving this stage of the dialogue process.)

Step 5 Promising Directions

s. Participant energy levels could be either high or low at this point in the dialogue, depending on how intense the dialogue has been and what the result of the spectrum analysis was. This may be an opportunity for letting the group decide how they would prefer moving through the next dialogue step, rather than following the design process too closely. For instance, instead of asking for "promising directions", a question could be, "What does it all mean?". Or, this step could possibly be merged with the "debriefing step" to simplify the process. *(Further advice on this issue will be incorporated into the Facilitation and Orientation Guides.)*

t. This step can be improved to provide clearer advice to the sponsor of a dialogue (e.g. in this case, the developer) about where to act next i.e. What are the non-negotiables? Is further dialogue needed? Should they proceed with development? What are the exact conditions that need to be met?, etc.

u. Closing the dialogue can be tricky. Further discussion is needed to determine how the dialogue can be guided into a meaningful closure, with a sense of purpose. *(Further advice on this issue will be incorporated into the Facilitation and Orientation Guides.)*

Policy Case Study *(See Appendix 1 for outline of the case used.)*

Overall, participants and observers felt that the policy case (a plant-made pharmaceutical generated in food-grade soybeans) worked well and inspired constructive dialogue around many issues relevant to genetically modified foods and feed, and biotechnology. Many noted that case preparation is essential to a successful dialogue as it guides the nature of discussion.

v. At this session, there were several requests for additional information about the magnitude of the problem being addressed and for technical information such as the number of Canadians who use blood thinning medications, how soybeans grow and reproduce, how GURT works, the steps in the regulatory process, and basic farming practices. An observer also noted how easy it was for incorrect information to be introduced (and remain unchallenged) by participants and the difficulties this injects into the process.

In addition, several participants highlighted a need to understand how the case study would fit into the existing regulatory system, the issues a regulator would consider most important and the path forward for a developer considering this type of product. This policy case rightly raised issues that a regulator/evaluator would have to consider as part of a risk assessment – both scientific and social/scientific — but did not adequately outline the process that would be undertaken to bring the proposed pharmaceutical to market.

Two possible ways of addressing these issues were raised in the session. First, it was suggested that additional background information could be provided with the policy case. This raised concerns about the amount of information that is provided to participants and its ability to either clarify or confuse the issues under discussion. They noted that balance must be achieved between providing enough information to incite discussion of issues but not so much that participants become confused and unable to identify important issues and concerns.

Second, some participants suggested that it would be useful to have experts on hand at the session to answer technical questions about these issues. Others felt that having experts present at a dialogue means there is a strong potential to stop dialogue due to a perceived lack of information or an emphasis on a dialogue among experts. Other solutions such as creating a mechanism for identifying information needs and answering such questions prior to a dialogue session were suggested (e.g. online discussion groups, use of reference studies).

Regardless of the amount of information provided, it must be factual, unbiased and must recognize the existence of any assumptions underlying the case.

(These issues are addressed in section 3.3.2, 3.3.3, 4.2.2 and 4.3.1, and in Recommendation 5.)

Logistics

Participants and observers provided the following feedback with respect to the session structure including the provision of support materials, the venue and the selection of participants. Advice and discussion on these issues will be incorporated into the Facilitator and Orientation Guide.

a. It was effective to have discussion questions projected at all times. The Rules of Engagement should also be prominently posted throughout the session.

b. Fully developed materials distributed both prior to the session and at the session contributed to the success of the dialogue. The worksheets were used and considered useful by nearly all participants.

c. It was useful to post an enlarged Dialogue Tool colour spectrum on the wall. Participants felt this was an excellent aid that was well-presented. At the end of the session, take a photograph of the spectrum for the session report and future use.

d. Resources to hold a dialogue could become an issue as the process has proven to be resource intensive (e.g. provision of staff, professional facilitation, materials, equipment, etc.) both in terms of time and funding.

e. Information management throughout the session was a key issue. The use of flip charts was essential although many participants found them difficult to see. The flip chart set-up – using one flip chart for each criteria area – was useful as were the labels on each flip chart indicating its topic area (e.g. health, environment, etc.).

f. It may be of benefit during future dialogue sessions to use an electronic, on-screen presentation of text along with flip charts. Copies of the text could be printed when participants are working together in groups or on breaks and distributed periodically to each group so that the issues – past and present – are catalogued and readily available within each work environment. This type of scenario would require two session reporters.

g. The selection of an appropriate venue is important. Issues such as auditory quality and lighting need to be considered prior to a session.

h. Depending on the topic/case, care must be taken to ensure the full representation of relevant stakeholders at a session (e.g. including youth, Aboriginal representation). The gender balance at this session was noticeably good and should be a quality goal/criteria in future sessions. The range of stakeholders may change depending on the scope and objectives of a dialogue. The strategy used for identifying participants for a particular dialogue should be clearly identified to the participants.

3.4.3 Use and Principles Underpinning Use of the Tool

a. The orientation guide should offer advice on the best situations in which to successfully employ the Dialogue Tool (e.g. best stage in product development, for decision-making in uncertainty, etc.). The guide should clearly outline the purpose of the tool and its potential uses and benefits as well as the expected benefit of using this tool over other dialogue methodologies. *(This will be incorporated into the Orientation Guide.)*

b. The facilitator guide should note that participants, especially at the beginning of a session, are likely to be more cautious and conservative in the comments they make so the nature of the dialogue will be cautious as well. The facilitator may need to take extra care to minimize possible undercurrents of dissatisfaction with the dialogue that may result among participants in a cautious dialogue. *(This will be incorporated into the Facilitator Guide.)*

c. Dialogue takes time and adequate time and resources must be applied to ensure successful dialogue...the more complex the case, the more time is required to unpack it. There was some concern that most people who should be involved in a dialogue would not have the time, or be willing to spend the time, required for a full dialogue process. Others observed that additional time is required to undertake steps 3 and 4 more thoroughly. Two days was considered a more appropriate amount of time for this particular policy case. Some also suggested that it would be useful to hold a dialogue broken into several sessions over time (e.g. a period of weeks). *(See section 4.2.2 e.)*

d. Any dialogue held using the Dialogue Tool is time sensitive (e.g. values change over time, making the results of the dialogue valid and useful only for a certain amount of time).

3.4.4 Further Development and Future of the Tool

Feedback from the multi stakeholder session about possible future uses of the Tool included the following comments/observations.

a. Several observers recommended additional investment of time and money into further testing of the Dialogue Tool. The following test cases were proposed:
    a. Improve steps 3 and 4 based on lessons to date and hold 2-3 additional multi-stakeholder sessions to further test the tool.
    b. Use a real case.
    c. To test the amount of information required to optimize dialogue, undertake a series of three sessions, using the same basic case, with different amounts of information (e.g. session 1 – short case with no background information; session 2, case with some background information; session 3 – case with extensive technical information and background data available).

b. The following questions were also posed in consideration of the future of the Dialogue Tool:
    a. How useful, or transferable, is the tool to other cultures (e.g. Quebec)?
    b. How might a dialogue session be used by the media and public interest groups (e.g. by taking a sensational twist, media could easily derail the original intent of open dialogue). How can the political risk of this tool be minimized?

c. Give the Dialogue Tool a more generic title to make it more useful in different situations addressing different issues (e.g. the use of the term “GMFF” in the title potentially limits its use), and to give it a ‘catchier’ title. *(This is addressed in Recommendation 3.)*

It was noted that there will be potential confidentiality issues to be dealt with in some dialogues (e.g. intellectual property issues or patenting issues within industry). *(Advice on this issue will be incorporated into the Facilitator and Orientation Guides.)*

Appendix 4
New Step 5 in Participant Guide and Orientation Guide (Summary version)

Step 5 – Determining conditions for acceptability

Focus

- Assuming there is significant interest expressed in the middle zone of the spectrum in step 4 (green to yellow to orange colour range), proceed to identify the conditions that would affect the acceptability of the case
- Outline the conditions that are affected predominantly by or derived from each consideration area (i.e. Health, socio-economic, etc.)
- Synthesize or combine these area conditions into an overall list
- Test the conditions for probability of achievement, i.e. to ensure they fall within a reasonable range of control and influence by the sponsoring party, and revise as needed
- Rate the conditions as to which are most critical to confirming or improving acceptability
- Further define the conditions so they are specifically actionable and by whom

Key Questions

- What are the conditions or requirements that would raise confidence in the acceptability of this case or clarify its fit on the spectrum?
- What are the conditions derived from each area of consideration?
- How would we combine these into an overall list?
- Is each condition achievable? Is each condition within the control and influence of the relevant party (e.g. sponsoring or other selected party)? How can we revise the conditions to enhance the probability of achievement?
- Which of these conditions are most critical to acceptability? Which would help advance acceptability (e.g. move left some degree on the spectrum)?
- What are the specific actions and responsibilities to give effect to these conditions?

Appendix 5
Useful Supporting Documents for the Dialogue Tool Process

The following aids and support materials have been created to guide and facilitate the Dialogue Tool process. The purpose and content of each product is briefly described below. Copies of these documents and further information about the Dialogue Tool project can be found under the "Dialogue Tool" button on CBAC's website at http://www.cbac-cccb.ca/.

1. **Getting Ready for a Dialogue Session –** This document helps prepare participants for a session by providing details about the dialogue process, elements of a successful dialogue and the expected role of participants at a dialogue session. It is provided to participants by the session sponsor prior to a dialogue, usually with the letter of invitation.
2. **Backgrounder –** This 5-page document briefly describes the process by which the Dialogue Tool was developed, including a chronology of the project. The Backgrounder also provides a description of the Tool itself (e.g. what it does and how it works) and why it was developed.
3. **The Dialogue Tool –** A brief outline of the Dialogue Tool and how it works.
4. **Participant Guide –** The Participant Guide walks participants through the dialogue process step-by-step and includes copies of all documents that participants will use in the session including worksheets, rules of engagement and the Dialogue Tool spectrum.
5. **Dialogue Tools (long and short) –** The Dialogue Tool is used to look at biotechnology issues associated with genetically modified food and feed though the lens of five "considerations" or "themes" – health, environment, social considerations, ethical considerations and broader considerations such as international implications. Two versions of the Tool have been developed for use in a dialogue session. The "short version shows the Tool in its most basic matrix form with space for participants to complete their own observations about the spectrum. The "long" version includes additional visual components (e.g. colour, vocabulary) which are intended to aid understanding and dialogue.
6. **Dialogue session slide deck –** The dialogue process proceeds through a series of steps, each with guidelines, engagement questions and worksheets. This slide deck in Power Point can be used to guide the participants with slides describing each step and the engagement questions. This deck version was used with the multi stakeholder session using 5 steps.
7. **Facilitator Guide –** Sessions using the Dialogue Tool are facilitated by a trained and expert facilitator to help the participants maintain momentum through the dialogue and to capture their thinking. A very brief facilitator guide was developed for the multi-stakeholder session. A more complete guide should be developed to aid facilitators in planning, facilitating and follow-up of a session.
9. **Table Group Facilitation Guide –** Depending on the specific session design used for any given dialogue, facilitators may be required to facilitate table groups throughout a dialogue. A brief table group facilitation guide was developed for the multi-stakeholder session. A more complete guide should be developed to assist table facilitators with their duties.

9. **Orientation Guide –** The Orientation Guide outlines the GMFF Dialogue process for those who are interested in learning more about the process for their own dialogue needs. It outlines the process, describes the tool, suggests opportunities in which the tool might be usefully applied (e.g. to policy making, strategic planning, issue development), and offers advice on the best ways to apply the tool and tool process to ensure successful dialogue.
10. **Terms of Reference for the Exploratory Committee –** Refer to: *http://cbac-cccb.ca/*