New Directions Group

Plant-based Biotechnology Project Team

Final Report

November 2005

The New Directions Group

The New Directions Group (NDG) provides an informal and neutral forum for leaders from progressive Canadian businesses and NGOs to debate potentially divisive sustainability issues. In addition to advancing policy, the purpose of the NDG is to enhance capacity building, mutual learning and collaboration on significant sustainability issues.

The NDG is a virtual entity that operates with a core group of sponsors and supporters, including Suncor Energy, Alcan, Falconbridge, Dow Chemical Canada, Pollution Probe, and the Pembina Institute for Appropriate Development. The NDG is administered through Pollution Probe. While these organizations provide the NDG's foundation, specific project teams comprise individuals from the business and NGO communities who are recognized as thought leaders on the issue to be addressed. In recent years, NDG initiatives have benefited from the input of leaders from the agricultural, chemicals, energy, forestry and mining sectors, to name a few, as well as from conservation, environmental, health and academic NGOs.

Over the years, NDG initiatives have had a direct impact on environmental policy in Canada. For example

- its inaugural report, *Reducing and Eliminating Toxic Substance Emissions: An Action Plan for Canada*, became the basis for the Accelerated Reduction/Elimination of Toxics (ARET) partnership administered by Environment Canada;
- the report, *Criteria and Principles for the Use of Voluntary or Non-regulatory Initiatives to Achieve Environmental Policy Objectives,* provided the foundation for Environment Canada's Environmental Performance Agreement Policy Framework and for the Cooperative Agreements of the Ontario Ministry of Environment and influenced the design of numerous voluntary programs in Canada and internationally;
- another report, *Developing Credible and Effective Covenants for the Management of Greenhouse Gas Emissions,* had a clear influence on the Draft Model Covenant proposed by the Large Final Emitters group of Natural Resources Canada; and
- the NDG's latest report, *Applying Precaution in Environmental Decision-Making in Canada*, was highlighted by the External Advisory Committee on Smart Regulations in its report to the Prime Minister.

In addition to dedicated projects, the NDG conducts a variety of experts' workshops and networking initiatives. NDG projects are well received because the resulting reports reflect the current thinking, if not a consensus, of leaders of Canada's business and NGO communities on topical sustainability issues. This provides valuable guidance to other businesses and NGOs, but more specifically to governments, in understanding the range of views on the issues and formulating effective policy and strategic responses.

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NDG Plant-based Biotechnology Project Sponsors

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Resource People

The NDG gratefully acknowledges the following individuals who made presentations to the NDG Plant-based Biotechnology Project Team:
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I. The NDG Plant-based Biotechnology Project

Plant-based biotechnology was identified as an issue to which the NDG could contribute at an NDG planning meeting in September 2001. The issue was seen as being complementary to the NDG's interest in precaution. In July 2002, the Canadian Institute for Environmental Law and Policy prepared a background paper on plant-based biotechnology for the NDG. An experts' workshop was held on October 1, 2002 to discuss the paper and determine whether there was a strategic opportunity for the NDG in the area of plant-based biotechnology. Participants recommended that the NDG proceed with a project but suggested that one should not be initiated until the precaution project concluded. The NDG Precaution project team completed its work in March 2004.

The New Directions Group (NDG) Plant-based Biotechnology Project team was established in September 2004. The first meeting of the team, held in Toronto in October 2004, was largely conceptual and concentrated on the scope of the discussion to follow. The team met again in November 2004, also in Toronto, to discuss the relationship between plant-based biotechnology and agricultural sustainability, receiving presentations from Dr. Clarence Swanton (University of Guelph) and Dr. Rod MacRae (Food Policy Analyst). A third meeting took place in Winnipeg in February 2005 and examined issues associated with current and future applications of plant-based biotechnology based on a presentation from Dr. Wilf Keller (National Research Council). The project team's fourth meeting was in Ottawa in April 2005 at which time Dr. Phil Macdonald (Canadian Food Inspection Agency) provided a presentation on the current regulatory approach to plant-based biotechnology in Canada and identified future challenges.

The project team was continually aware that many of the issues under discussion had been debated extensively elsewhere, although not always with a focus on public policy impacts.

The public face of this issue is a polarized debate over genetically modified foods. However, applications of plant-based biotechnology are actually much broader, and the policy and regulatory challenges posed by these rapidly evolving applications are significant. Participants felt that society should have an opportunity to provide input into how to proceed with emerging plant-based biotechnologies; several felt it was important to examine whether we are on a path we can't later depart. It was clear that many of the broader issues associated with specific applications of plant-based biotechnology (such as industrialization of agriculture and food security) arise because there is no other avenue for discussing them.

As the initiative unfolded, therefore, participants began to devote their attention and energies to the policy framework required to govern current and future applications of plant-based biotechnologies. There was support for including better methods for securing independent and inclusive scientific and public input into policy and decision making. Although the focus of this project was on plant-based biotechnology, participants believe that the core issues also extend to other applications of biotechnology, such as transgenic animals, and perhaps even to other emerging technologies, such as nanotechnology. It was felt that learning from public concerns about current applications of plant-based biotechnology, and the way in which the technology is regulated, could improve risk communication and better inform how future policy addressing these emerging technologies is developed.

In summary, the project team's debates concentrated on three areas, discussed in more detail in this report:

a) developing an issue characterization process for plant-based biotechnologies;
b) examining the current regulatory framework and the challenges posed to it by newer technologies; and,
c) identifying the elements of a policy framework so that issues associated with plant-based biotechnologies can be better addressed in the future.

This document is a summation of the project team's deliberations. **The record is not intended to imply consensus on any issue except where indicated**, particularly as not all project team members were able to participate in all sessions. Rather, it serves to identify the key issues associated with the application of plant-based biotechnologies and notes areas of convergence and divergence among the business and NGO communities. Strongly held views of some participants are included to illustrate the extent of divisions that currently surround some of the issues. Where possible, attempts are made to determine the underlying reasons for these divisions and to suggest ways to resolve them in future policy debates.

2. Understanding the Risks and Benefits of Plant-based Biotechnology

2.1 Scope of Plant-based Biotechnology

The starting point for the project team's discussions was the application of rDNA technology. However, it was quickly evident that this was being supplanted by other techniques that pose new and perhaps greater challenges to regulators and to society. A key issue in structuring debates of plant-based biotechnology is the lack of agreement on which techniques constitute "biotechnology." Biotechnology can encompass everything from novel bio-based activities and the identification of molecular markers for traditional breeding to truly transformative techniques that fundamentally change a species. The project team recognized that most of the technologies within this inclusive spectrum are accepted and/or non-controversial. It is those techniques that are transformative in nature, particularly those involving the transfer of genes from one species to another, that raise the greatest concern.

New techniques developed through characterization of genomics can transform species without introducing foreign genetic material; this is done by changing gene sequences or turning on or off promoter genes. These techniques enable a high throughput for the discovery or characterization of genetic elements that could lead to hundreds of new traits being brought forward for approval. Some of the component technologies include microarrays, DNA sequencing, proteomics, transient/transgenic expression, metabolomics, and bioinformatics, all of which will challenge the regulatory system. And while much of the debate to date over plant-based biotechnologies has been focused on food production, many future applications will be in the fields of industrial bioproducts and the development of pharmaceuticals and nutraceuticals.

2.2 Understanding the Basis of Public Concern

There was considerable debate within the group about the reasons why plant-based biotechnology attracts such public concern; for example, herbicide resistant wheat was available before genetically engineered glyphosate tolerant wheat, but it was only the latter that triggered concern. Further, herbicide resistant canola has two transgenic systems and one mutagenic system. Even though all three are released into the environment and are self-replicating, only the transgenic ones are causing controversy. The emphasis on the process used to secure the end result rather than on the product itself makes it clear that there is a need for broader societal discussion of the benefits that plant-based biotechnology is expected to provide, the problems that it should be used to solve, and the associated risks that need to be managed.

Generally, industry participants argued that the application of plant-based biotechnology should be treated the same as the application of any other technology. NGO participants took the position that the far-reaching implications of plant-based biotechnology, and the fact that we are unlikely to ever know all the ramifications of releasing transgenic crops into the environment, require that society be provided the opportunity to determine whether plant-based biotechnologies should be pursued at all and, if so, under what conditions. This is based, in part, on the observation that many current environmental problems are the result of the impacts of previous new technologies. Further, the public concern currently focused on genetically modified food is partly values based and relates to the social, cultural and religious importance placed on food in addition to the potential long-term health and ecological impacts, and particularly impacts on biodiversity, of plant-based biotechnology.

It was suggested that the public is uncomfortable with biotechnology due to the extent and complexity of the debate; in these types of situations the public is usually risk averse. This led to a discussion of both the level of awareness of practices currently used on farms across Canada and the potential benefits of plant-based biotechnologies. For example, it was claimed that the use of herbicide-resistant canola in Canada has resulted in a substantial reduction in herbicide application, less tillage (therefore better soil conservation) and lower fuel consumption, all of which result in less impact on the environment. Some felt that it is necessary to overcome misconceptions about how food is produced in Canada to have a meaningful debate on the application of new technologies; some claimed that most consumers don't understand the risks of what they are currently using or consuming. One problem is that there is little information publicly available about products in development and the issues associated with them.

Conversely, there was a high degree of confidence among industry participants on the science, safety, and potential benefits to both the agricultural community and society of plant-based biotechnology. In particular, there was certainty that no significant scientific or safety issue will flare up around the current wave of plant-based biotechnologies, especially those products developed by large companies with scientific and stewardship capacity.

These organizations face a substantial risk to their business and reputation should things go wrong. Major producers have principles, codes of ethics and/or advisory committees to assist in their efforts. SemBioSys, for example, initially started its plant molecular farming work with canola but realized that the risk of out-crossing to other canola meant that field releases would not be accepted in Canada so the technology was switched to safflower. It was suggested that the activities of small companies, government labs, and other countries out of the mainstream public, regulatory and technical debate could conceivably pose a greater risk than do those of larger, publicly traded companies. And while much public concern is focused on the application of plant-based biotechnology to food production, industry generally believes that there are fewer concerns in this area than with pharmaceutical and industrial applications, which to date have received far less public attention.

Due to the lack of agreement surrounding the risks and benefits of plant-based biotechnologies, the project team spent a considerable amount of time on risk communication issues. It was suggested that a national risk communication strategy for plant-based biotechnologies is required. There is a need for a credible, objective intermediary to take all the available knowledge and information, interpret it, and package it for public consumption. This will facilitate a broader societal discussion of the advantages, effectiveness and potential risks of new technologies versus alternative approaches to determine whether these technologies ought to be pursued.

3. Assessing Alternatives to Plant-based Biotechnology

A large part of the project team's discussions centred on how to deal with alternatives to plant-based biotechnology. Clarity is needed in what critics mean by alternatives — alternatives to plant-based biotechnology writ large, a particular application (such as plant molecular farming), a specific trait (such as herbicide tolerance), or a product (such as a modified oil or protein) — to ensure that the debate takes place in the proper context.

The issue of alternatives is fundamental for people who want to know whether there are other ways of delivering similar benefits to society. It was pointed out that many companies already do a detailed assessment of alternatives as part of their in-house testing programs. It was also stressed that evaluating a new product against existing riskier alternatives is easier than evaluating a new product that represents innovation. Others stated that, in many ways, biotechnology it is not inherently riskier than other sectors or technologies, with the exception of the unique risk of the ability of organisms generated through plant-based biotechnology to propagate. It was suggested that considering alternatives should be built in to risk management decisions when there are scientific reasons to question a product that causes risk. It was argued that this may work for food and feeds applications of biotechnology but plant molecular farming is itself an alternative technology that some believe may be less risky than current approaches to producing pharmaceuticals.

There was also concern expressed by some that all alternative technologies should be subject to the same assessments and processes as plant-based biotechnologies rather than being assumed to be safer by default; for example, organic products have been associated with product recalls.

4. Issue Characterization in Plant-based Biotechnology

As introduced in Section 2, the project team discussed a wide range of issues associated with plant-based biotechnology. Much of the discussion about plant-based biotechnology usually results from other things. Those external drivers (e.g., the power of multinationals, the future of the family farm) are pushing the issue. Upon reflection, it was possible to group the issues into three broad categories:

- proxy issues (related to the future direction of agriculture in general and not specifically concerned with biotechnology);
- exposure issues (the extent of risks presented to human health or the environment due to the release of the product, who bears them and who accepts liability); and,
- application issues (whether the application of biotechnology is warranted, and whether the technology is the most effective means of achieving the desired outcome).

4.1 Biotechnology as a Proxy: Relationship to Agricultural Sustainability

It was observed that, when plant-based biotechnology became an issue in Europe, it was the perfect proxy for a debate of broader structural issues in the agricultural sector that weren't being addressed anywhere else. In Canada, currently, this is reflected in a fundamental dichotomy between proponents and critics of plant-based biotechnology based in large part on divergent visions of what constitutes sustainability, particularly agricultural sustainability. While these issues do not apply uniquely to the application of plant-based biotechnology, they do define the context in which many of the debates over plant-based biotechnology take place.

Plant-based biotechnologies are perceived by critics to negatively impact on agricultural sustainability and the options available to Canadian farmers. NGOs strongly believe in the need to contrast applications of plant-based biotechnologies with alternative ways of achieving similar results. Many NGOs see plant-based biotechnology as reinforcing the industrial agriculture paradigm and compromising other agricultural approaches, such as organic farming. Industry representatives countered that biotechnology is a tool that can be an effective component of sustainable agriculture approaches and can assist in meeting the challenges of feeding the world's growing population.

The issues of control and equity were also raised regarding plant-based biotechnologies. One view holds that the capital requirements of rDNA technology favour centralized control while selective breeding remains within the reach of the individual farmer. It was argued that plant-based biotechnologies may thus favour large landholders at the expense of smaller ones. The other holds that, while many farmers save and reuse their own seed, farmers are not plant breeders, especially of major crops, and that biotechnology can reduce operating costs, thus favouring smaller landowners.

It was stated that the stereotype of industrial agriculture often presented by critics does not exist; the vast majority of farms in Canada are family-owned. It was claimed that there is a general lack of awareness about current best management practices that support agricultural stewardship on Canadian farms and this negatively influences debates on a range of issues.

In summary, critics view plant-based biotechnology as the epitome of the industrial agriculture model. They argue it will serve to enshrine and promote that paradigm at the expense of other approaches, and will contribute to further corporate control of the industry. Proponents see plant-based biotechnologies as tools that can service any agricultural paradigm. They believe these technologies can provide immediate social, economic and environmental benefits, even to small landowners, and are complementary to sustainable agriculture systems.

To explore this divide, the project team discussed the perceived polarity between agroecology and conventional agricultural practices. NGOs argued that plant-based biotechnology favoured the latter and hindered the uptake of the former. Industry representatives stated that many farmers are adopting a range of agroecological techniques and deserve recognition, not criticism, for their efforts. There is, though, a distinction between the adoption of selected agroecology techniques and the practice of agroecology as a paradigm for managing all farm operations. A resolution to the divergent views is difficult as participants were unaware of any long-term, large-scale pilots of agroecology that could be used for comparison with current agricultural approaches. It was suggested that organic agriculture could provide some insights, but organic agriculture and agroecology are not synonymous; agroecology has broader application. Further, some argued that agroecology should be subject to the same sustainability tests being demanded of other approaches; i.e., how can it be fully applied when farm social and economic viability could be placed at risk by doing so?

There was general agreement among the project team that agricultural practices are evolving rapidly and that there is little opportunity for public debate on their impacts. Agriculture is moving beyond the production of foods, feeds and fibre to the development of new products and feedstocks for industrial processes and this is having an impact on the landbase; for example, tobacco could become a much more important field crop as it is non-food, manipulable, high in protein, and readily transformable into an industrial crop to produce plant-based pharmaceuticals.

Further, it was suggested that the high potential for applying biotechnology to address short-term societal imperatives may lead to pressure to override some agricultural sustainability considerations. Others countered that this was all the more reason to consider the long-term implications of future applications of plant-based biotechnologies as the technologies of today usually lead to the problems of tomorrow. Society needs to be very clear on the problems that it is trying to "fix" and the appropriateness of biotechnology as the means to address them.

4.2 Exposure Issues: Who Bears the Risks and Liabilities?

The project team spent some time exploring why the risks and liabilities of some applications of biotechnology were apparently acceptable to society while others weren't. For example, for 20 years insulin has been produced through genetic engineering (insertion of a human protein into a bacterium) but this application, although intuitively more controversial than plant-based biotechnologies approved to date, has not been a subject of widespread concern. It was pointed out that the bacteria used to produce insulin aren't released into the field, there is a demonstrated health benefit, the process reduces the use of laboratory animals, and any adverse effects affect only a small portion of diabetics, therefore the benefits obviously outweigh the risks. With genetically modified foods, there is no agreement on the extent of the benefits they provide and it is perceived that the risks could be more external and borne by society at large. Furthermore, in a whole food, unintended changes in the genome might cause negative health or ecological effects.

It was claimed by industry and government participants that Canada has ten years of experience consuming genetically modified foods with no documented illnesses or environmental incidents. It was asked whether any long-term studies of this have been done. Lacking a way to identify a product that may be causing a problem (e.g., labelling), such studies are difficult to carry out. Others reported that Europeans have spent $150 million on studies that conclude there is no difference between transgenic and unmodified crops, and asked how much more testing is needed to satisfy the critics. According to some NGOs, scientific questions that still need to be addressed with plant-based biotechnologies include the safety of genetic promoters and vectors, antibiotic markers, long-term genetic stability of rDNA, and whole food testing (as opposed to testing for isolated proteins). Further, genetically modified foods are creating using technologies that are rapidly being replaced by newer approaches; while some of the expressed concerns regarding vectors and promoters may not exist with newer technologies, other concerns may emerge.

A principal concern with plant-based biotechnologies is that once products are released into the environment they can't be brought back; the full impacts of a technology will never be known in advance of its application. However, biotechnology may not be unique in this regard. From a regulatory perspective, the self-replicating nature of plant-based biotechnology remains the key difference between it and other technologies; this is considered in the regulatory review to attempt to restrict any potential damage. One fear is the possibility that genes may "escape" to contaminate wild populations or domestic species. Industry representatives stated that they and the regulators understand that genes can move; industry's experience in managing their movement needs to be taken into account. Further, it was pointed out that Canada is a centre of origin for sunflowers, but not for other crop species. Therefore, the risk of genes contaminating wild populations is not seen to be an issue for anything except sunflowers, although the possibility of contaminating domestic species remains.

The project team had an extended discussion over who should bear responsibility for the risks associated with plant-based biotechnology. This discussion is summarized in Section 5.1.3.

4.3 Application Issues: Matching Benefits to Risks

It was suggested during the discussions that one issue has acted as an impediment to the acceptance of plant-based biotechnology: its initial applications addressed problems that weren't high priorities and that may have been solved through other means. Critics see this as the technology driving the issues ("Look what we can do") as opposed to finding the best solution to an identified priority. Others see these early applications as critical to innovation and as enabling the technology to be applied to more pressing issues in the future. They claim that, though the benefits are largely hidden from consumers, the application of biotechnology in canola, soy and corn created incremental advantages for farmers to grow these crops.

Views may change if the application of plant-based biotechnologies provides demonstrable benefits to consumers or is framed differently, i.e., applied to real problems for which there are no current alternatives, such as fusarium-resistant wheat or late blight resistance in potatoes. Many felt that there is a need to tie plant-based biotechnology into a more positive strategy to generate public support, rather than constantly reacting to the campaigns of critics. For example, the need to meet the targets of the Kyoto Protocol could lead to a multitude of opportunities through plant-based biotechnologies. Other opportunities may exist in areas such as improved plant nutrition and reduced phosphate use that lower costs and improve the environment.

This raised the question of who decides what is to be beneficial before a product is approved, especially as there is a need to reconcile benefits with time, i.e., there may be short-term benefits but long-term risks. Some questioned how far society should go in demanding testing for everything and where the lines ought to be drawn. NGOs argued that too much assessment of benefits is left to public choice in the marketplace, where the tools may not exist to make sound decisions; not enough assessment is done through the regulatory process. Some felt that it was important to assess biotechnology against other options for achieving similar objectives. It was also suggested that better economic impact assessments and greater opportunity for public involvement are required.

One tool that may contribute positively to debates over the application of plant-based biotechnologies without stifling innovation is life cycle assessment. Many companies are already doing this in other areas and are ahead of regulatory processes. The tools and techniques for life cycle assessment are well developed, but are not yet legitimized. The private sector has to further develop the tools (e.g., eco-efficiency) and government decision-making structures have to be modernized to incorporate them.

It was pointed out that it is difficult to pick and choose among biotechnologies until the conditions that would lead to broad societal acceptance are understood. A fundamental problem in Canada is that an acceptable framework for discussing what types of biotechnologies would be in the best interest of Canadian agriculture, industry and citizens does not yet exist. This is further explored in Section 6.

5. Regulating Plant-based Biotechnology in Canada

Although Canada has a regulatory process for addressing plant-based biotechnology, there was general agreement among all participants that this process could be enhanced, particularly to address future challenges that plant-based biotechnologies and other new technologies will present. It was pointed out that care has to be taken in making changes as the current system complies with WTO rules and other international agreements. Some participants went so far as to suggest that a moratorium on the commercialization of new varieties should be introduced until the regulatory system improves.

The project team acknowledged that Canada has ten years' experience with the release of plant-based rDNA technology and this should be used to address public concerns and to prepare to regulate future, more challenging biotechnologies. In Canada the Canada Food Inspection Agency (CFIA) and Health Canada regulate all new plant-based agricultural products on the basis of novelty, including those arising through biotechnology. The current process is a science-based risk assessment and is not equipped to address non-health and non-safety issues. With the emergence of new technologies, regulators will need greater policy direction and understanding. There is a real potential for the gap between the available technologies and Canada's regulatory capacity to widen; for example, elements of plant molecular farming (PMF) present a new paradigm (non-food/feed industrial use of agricultural crops) that is outside that within which the CFIA operates.

The CFIA has years of experience with monitoring small (one hectare) field trials; however, it is not equipped to oversee a multitude of larger sites. To protect the environment, conditions imposed on applicants for confined field trials in Canada are very restrictive. Few proposals are turned down because proponents are unlikely to attempt to obtain approval for something that would not meet the requirements for environmental release. All field trials are monitored. Information on these can be found at www.inspection.gc.ca/english/plaveg/bio/triesse.shtml.

It was suggested that CFIA statistics on approvals, rejections, and so on, as well as more detailed information on testing methodology and results, should be made publicly available, perhaps complemented by anonymous case studies (to protect proprietary information), so that the public could better understand how the regulatory system works.

Some concern was expressed that the current approach to regulating plant-based biotechnologies is designed to foster competitiveness and innovation and that this may come at the expense of considering the values of Canadians as well as long-term health and ecological impacts. It was argued that a way forward is needed that recognizes that some applications of plant-based biotechnologies (and some plant-based biotechnologies themselves) are more beneficial and acceptable to society than others. Canada needs to know how to make decisions as to which technologies will be pursued and approved, and ensure that appropriate alternatives are considered. It was stated that Canadians understand that competition from other countries, and diminishing resources, are going to require changes and innovation in our society, but there needs to be a way to engage the public effectively and act on their concerns, ensuring awareness, understanding and inclusivity.

5.1 Enhancing the Regulatory Process

As with many emerging technologies or products of innovation, plant-based biotechnology challenges the capacity of regulatory processes, particularly when processes or products do not fit within existing paradigms. Participants discussed four aspects of this challenge.

5.1.1 Risk Assessment

rDNA technologies are considered as novel traits in Canada. Some felt this was inappropriate as rDNA technologies may introduce unique risks not associated with novel traits produced through other means. The Canadian risk assessment process considers both the product and the process and is designed to be inclusive rather than exclusive. Concerns were expressed as to whether, given the complexity of the issue, the regulatory system is designed properly and is really able to fully detect anomalies or unexpected consequences of the release of plant-based biotechnologies.

Concern was also expressed that testing protocols assume that genes work in a linear function, with one gene coding for one trait (i.e., inserting a gene into bacteria, testing the protein produced and then assuming that because the protein is safe that the new plant created through rDNA is safe), and do not take a more holistic approach. The need for independence and transparency in testing and whistle blower protection was stressed repeatedly.

One current safeguard in Canada is that there must be a statistically relevant data set over multiple generations of observations in field trials before a product can be released from a contained system. Some of the risks identified for rDNA technologies are also experienced with mutagenesis or classical breeding. The question, for some, is confidence on whether CFIA risk assessment procedures are independent, thorough and adequate and are informed by the best available science.

5.1.2 Managing Innovation

It was suggested that many problems posed by plant-based biotechnologies result because government and society don't handle innovation well, and when innovation gets ahead of society everyone struggles. Innovation happens in the laboratory and then society decides what happens when attempts are made to market the resulting product or technology or deploy it in the field. This is inefficient as significant money can be spent innovating only to have the results rejected.

It was suggested that government can best stimulate innovation by creating clear principles and standards rather than being directly involved in the industry. Fostering a climate of innovation should not take precedence over ensuring public safety. Political leadership on plant-based biotechnology is thus required, but policy makers must be cognizant of societal debate, otherwise politicians will bear huge risks.

There was some discussion of the specific challenges posed by innovation in plant-based biotechnology and the adequacy of current regulatory systems for future governance. A particular focus of concern is plant molecular farming (PMF): Only two approvals for confined field trials (for safflower and tobacco) have been given recently by the CFIA, although earlier approvals for several small confined field trials of flax and canola expressing PMF traits were given. Currently, few Canadian groups are working with PMF at a field scale; thus, there has been no unconfined release in Canada and no widespread consultation. A well-developed, transparent regulatory system will facilitate innovation, as the rules are clear.

5.1.3 Reconciling Risk and Responsibility

A major regulatory challenge is the uncertainty associated with understanding all of the effects of plant-based biotechnologies. A growing number of tools are available to assist in risk assessments of biotechnology. These are allowing much more information to be secured at lower cost, but the function of every gene in the genome and how they work in combination is unknown. It was pointed out that plant-based biotechnology often provides better molecular characterization than mutagenesis, thus there may be a better understanding of why things happen. The question is how to determine the value of getting complete and perhaps irrelevant information to address all possible uncertainties in cases where the benefits of the technology are clear.

Some claimed that even if everything on the market today was completely safe it would not indicate that the current regulatory system could guarantee the safety of future products, particularly those developed through newer technologies. While industry does test products extensively before they are introduced into the regulatory process and that is why few products are rejected, critics contend that confidence would be further enhanced if the testing done through the regulatory process was independent and transparent.

The project team had an extended discussion over who should bear responsibility for the risks associated with plant-based biotechnology. As all products are approved by government, it was suggested that industry should not bear liability alone. While some argued that those who profit from a technology should also bear liability for its ill effects, government also has an obligation to protect public safety and should similarly be held accountable.

It was stressed that while the major companies in this field won't accept the business implications of putting a product on the market when the risks are unknown or unmanageable, newer biotechnologies will challenge some societal structures. Modifications will be needed to accommodate their impacts; for example, it may not be possible to sustain the current risk management system in which government is seen as the principal manager of risk on behalf of society. Greater ownership of risk among those sectors of society that develop or apply the technologies may need to be encouraged.

5.1.4 Incorporating Socioeconomic Concerns

Government representatives stated that Canada currently has no legal authority for anything other than health or safety issues when regulating plant-based biotechnology. They asked what model could be used to incorporate other values into decision making. Clear policy direction is required. For example, a decision to not pursue a product that the vast majority of stakeholders oppose is fairly straightforward; it is not clear how consistent decisions will be made when stakeholders are split on an issue.

Although crop quality standards and the potential for market harm are part of CFIA's Variety Registration, the current regulatory process has no mandate to deal with socioeconomic questions. For many critics such questions are the nub of the challenge posed by plant-based biotechnologies. Developing an enhanced process to accommodate these issues will be very difficult due to fragmented authority and the fact that most, if not all, stakeholders wish the regulatory decision-making process to remain science based. One such process, based on a previous NDG project addressing precaution, is described in Section 5.3.

5.2 Achieving Greater Transparency in Decision Making

All participants noted that, except through the media, there is currently no forum for public debate of issues associated with plant-based biotechnology. Some felt that better mechanisms are needed to enable public input into the regulatory system; there are many cases where a public review prior to the application of plant-based biotechnology is warranted. It was noted that there is an initiative being developed as part of the *Canadian Environmental Protection Act* review that will include consultation on biotechnology.

While there was general support for greater transparency with respect to policy and regulation applicable to plant-based biotechnology, there was some concern as to how open processes should be structured. Some participants wondered how anyone could determine with certainty what "society" wanted from a decision-making process and how to determine who speaks for society. It was pointed out that Canadians as a whole rarely make decisions on anything and decisions are usually taken by those leading the debate. For example, it was argued that it wasn't the general public that led to the decision to not use pest-resistant potatoes containing Bt; rather, McCain made a marketing decision based in part on pressure from NGOs. It was pointed out, though, that when government and industry make decisions without public input it predisposes this type of activity, as public interest groups have no other avenues for influencing decisions. Failing to engage public interest groups or engaging them late in a process makes it more difficult and expensive to address their concerns. It was suggested that the costs of undertaking a productive consultation also need to be weighed against the ongoing costs of processes and consultations that do not lead anywhere.

To reinforce this point, the group was warned that public complacency should not be taken as a sign that there are no concerns or problems with plant-based biotechnology. The importance of constructing a robust policy and regulatory system that addresses socioeconomic as well as other societal concerns can thus not be overstated. While some suggested that an increased emphasis on process may send negative signals to investors and venture capitalists, others argued that the absence of a clear understanding of how to address controversial issues was more of an impediment to product development; a clear decision-making process would provide greater certainty for proponents and investors.

In terms of the current regulatory process, it was claimed that decision documents for approved genetically engineered crops do not provide much information. In response, one participant indicated that plant-based biotechnology guidelines are supplementary to existing breeding requirements, which require rigorous multiple tests; it takes ten to twelve years to introduce a new variety of crop. The Notices of Submissions Pilot Project is a new project that notifies the public of applications for new agricultural products. It requires new traits to be posted on the CFIA website so that people with a scientific interest in these matters can pose questions.

The project team discussed means of securing greater input into the development of the regulatory system. The idea of an independent scientific advisory body was accepted by all participants. It was agreed that a similar structure would be valuable to address non-science, non-safety issues up front as new technology emerges in order to inform and prepare policy makers. This would need to be an open, inclusive and transparent process that should make clear what problems are being fixed with the technology and whether there are other means of addressing them. It was offered that forthcoming technical workshops could host a public dialogue between PMF

proponents, the CFIA and scientists to develop a regulatory framework for PMF. It was suggested that PMF is ripe for public consultation because, while some elements of the regulatory framework are already in place (e.g., Canada has experience in conducting field trials), PMF poses new challenges to regulatory authorities.

5.3 Applying Precaution

Given the range of issues associated with plant-based biotechnology and, in particular, the level of uncertainty associated with some current and future applications, ways to make the decision-making process more robust to "precaution" was discussed in detail. Despite public concern and the views of NGOs regarding certain plant-based biotechnologies and/or their application(s), there appears to be no fundamental concern within industry and government over the release of genetically engineered plants. Issues, then, must be addressed on a case-by-case basis and assessments must continue to be trait and crop specific.

5.3.1 Multiple Approaches to Regulating Plant-based Biotechnology

In March 2004, the New Directions Group released the report *Applying Precaution in Environmental Decision-Making in Canada* (www.newdirectionsgroup.org/projects/precaution.php). Participants in this NDG project concluded that the approach to regulating a product or process ought to be adaptive to the associated level of risk and scientific uncertainty. To illustrate this concept, the NDG described three differing regulatory "tracks" (see Appendix I). Where there is an established risk assessment/risk management (RA/RM) process, it should be evaluated to determine its robustness to precaution and enhanced where warranted. These "Standard RA/RM" processes are suitable for addressing situations in which there is little uncertainty, even if there may be significant risks.

At the other extreme are issues for which there is very high risk and a high level of uncertainty. These issues can be addressed through an "Alternative to RA/RM" track, which, while science based, may result in a political decision regarding the acceptability of the product or process or the constraints placed upon it.

Much of the attention of the NDG Precaution project team centred on the grey area between these two tracks, where risks and uncertainty may be high and potential benefits may be significant, i.e., situations that may be too complex or controversial for the "standard" track but not so complex or controversial to warrant the "alternative" approach. The Precaution Project Team suggested that such situations warranted a "Negotiated RA/RM" track, which, while based on the "Standard RA/RM" track, allowed greater public input into issue characterization and faster movement of the risk assessment process into risk management options where warranted.

5.3.2 Issue Characterization

Given the range and types of issues associated with plant-based biotechnologies, as described in Sections 2 and 4, and the need for greater transparency in decision making, the "issue characterization" stage of the Negotiated RA/RM track outlined in Appendix I is especially important. As described by the NDG Precaution Project Team, this stage involves

- identifying the type and degree of scientific uncertainty
- assessing the level of public and/or scientific controversy surrounding the issue
- determining the questions that need to be asked or the additional information required in the chosen decision-making process
- evaluating the potential need for immediate introduction of some elements of risk management (e.g., an interim decision).

The issue characterization process assesses the level of scientific knowledge, societal values, regulatory and policy aspects of the issue, and market considerations. The decision-making authority should

- make use of all relevant information from the proponent
- consider the best practices of companies who undertake internal issue characterization processes
- ensure formal opportunities for input by stakeholders that are inclusive and transparent, as internal screens may not bring the full range of perspectives to an issue.

5.3.3 Precaution and Plant-based Biotechnology

The NDG Plant-based Biotechnology project team was informed that a "Standard RA/RM" process exists for rDNA technology in Canada, and has been in place for over 10 years through the current approach of the CFIA and Health Canada. Precaution is triggered already by the Plants with Novel Traits regulations; proponents have to apply for field trials and for regulatory approval. As indicated earlier, some argued that the existing regulatory process in Canada has many gaps and can still be improved in terms of addressing socioeconomic concerns, enhancing transparency, and improving the scientific basis for decisions.

Depending on the particular plant-based biotechnology and its applications, there is potential for any of the three "tracks" to be utilized in decision making, according to the levels of risk, uncertainty and benefit. While some future technologies may push the envelope of the existing policy and regulatory approach and will need to be dealt with through the "Alternative to RA/RM" track, some argued that it may be possible to take a less cautious approach to approve products developed through proven technologies. As described by the NDG Precaution Project Team, all products or processes ought to be subject to an initial screening by the decision maker to determine the ability of the existing regulatory process (the "Standard RA/RM" track) to deal with them. The outcome of this screen could include simple modifications to the regulatory process to address minor deficiencies and considerations or it could recommend that the issue be addressed through a "Negotiated RA/RM" or "Alternative to RA/RM" process where issues are more complex or uncertainty is greater.

The "Negotiated RA/RM" track may provide one avenue for securing greater public input and incorporating non-health or non-safety issues into the process while maintaining a science-based approach to decision making.

6. Moving Towards a National Policy Framework for Plant-based Biotechnology

In reviewing their discussions, members of the NDG's Plant-based Biotechnology Project Team agreed that one contribution they could make to furthering the development of public policy would be to outline a policy framework for plant-based biotechnology that could be offered to the federal government. Among other things, the policy framework should empower national advisory bodies, identify clear "no go" situations and establish public processes that create legitimacy for the ensuing decisions.

Based on the foregoing, a preliminary outline of a policy framework for plant-based biotechnology would take the following format:

6.1 Policy Context

- How does the pursuit of the technology link to/support/implement agricultural policy in Canada?
- Which agencies are principally responsible for federal policy regarding the technology?
- How do the risks and benefits of the technology compare to other means of producing the product?
- What are the likely products of the technology and the potential benefits and risks associated with them?
- How will the socioeconomic considerations of the technology be evaluated and addressed within a science-based, decision-making context?
- How does Canada ensure innovation is not stifled and investment in Canada continues to be encouraged?

6.2 Science

- What science bodies are to be recognized in the assessment of the technology?
- Is there a role for a national science advisory body on plant-based biotechnology?
- What is the state of scientific knowledge surrounding the technology and its impacts?
- What are the major scientific uncertainties, how can they be resolved, and who will be responsible for resolving them?
- What weight is to be given to information used in assessments by other jurisdictions?

6.3 Public Consultation

- Is there a role for a national advisory committee and, if so, how will it operate and where will it intersect with the decision-making process?
- What forms of broader public consultation will be pursued and under what conditions (i.e., timeframe)?
- How will continuity of public input be assured over a lengthy decision-making process?
- How will participants in the process be provided with appropriate information in order to have an informed consultation?

6.4 Regulatory Approach

- What is the scope of the technology and the applications to be regulated?
- What is the capacity of the current regulatory approach for novel traits to regulate the technology?
- How do other jurisdictions (e.g., USA and EU) approach regulation?
- How will precaution be applied through the decision-making process (is there a

role for the multiple track approach suggested by the NDG, for example)?
- Will socioeconomic considerations be reflected in the regulatory process?
- Is there a role and opportunity for Smart Regulations in addressing the technology?
- Will alternative technologies be considered where risk appropriate?

6.5 Risk Communication

- What provisions will be made to enhance the transparency of the regulatory process?
- Who is responsible for risk communication and how will risks and benefits be balanced?
- What information will be made publicly available regarding the success or failure of the regulatory process (e.g., publication of statistics/reporting)?
- How will the results of the regulatory process and the reasons for decisions be communicated to the public?

The project team was cautioned that a policy framework is not the last word on how a decision is taken. It was also stated that the need for a societal debate on plant-based biotechnologies should not constrain moving forward on applications that are proven or non-controversial.

Finally, while a policy framework is intended for policy development, and not for product decisions, it was suggested that PMF could provide a timely focus for developing such a framework and could serve as an example of how Canada could approach other policy challenges relating to biotechnology.

Appendix 1: NDG Architecture for Applying Precaution in Risk-based Decision-making Processes