BioPromise?

Biotechnology, Sustainable Development and Canada's Future Economy

TECHNICAL REPORT TO CBAC
(Canadian Biotechnology Advisory Committee)

from the BSDE Expert Working Party

September 2006

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TECHNICAL REPORT

September 2006

Biotechnology and Sustainable Development for Canada's Future Economy (BSDE) Expert Working Party

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This Expert Working Party was formed in 2005 to perform in-depth, independent research and analysis for the Canadian Biotechnology Advisory Committee (CBAC) on the topic of biotechnology, sustainable development and Canada's future economy. In so doing, it commissioned several small research projects, performed a significant literature review, and drew heavily on the expertise of Working Party members.

The specific charge to the BSDE Working Party was to:

- Identify opportunities for, and challenges posed by, new biotechnology applications in the future development of the Canadian economy in all relevant sectors, and appropriate regulatory approaches these new applications may require.
- Identify, to the extent possible, those areas where new applications of biotechnology can contribute to achieving sustainable development goals both domestically and internationally.
- Identify policy initiatives within and across all branches of government that will encourage further development of biotechnology applications in areas most likely to contribute to achieving sustainable development objectives, including investment and incentive policies.
- Develop a sustainable development framework for applications of biotechnology.

The BSDE Expert Working Party's opinions and findings are reported to CBAC but are not necessarily those of CBAC.

The BSDE technical report is also accessible online at www.cbac-cccb.ca.
Contact info@cbac-cccb.ca for individual background research papers.

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CHAPTER 1. No More 'Business as Usual'

Canadians face a future that will be defined by change, with many new economic opportunities, and with a growing need to build a satisfactory relationship between the environment and development. Over the past three decades, opportunity has frequently been associated with new technologies, especially ITC (information technology and communications). More recently, biotechnology has been highlighted as a potential source of long-term economic, social and environmental benefits. Proponents suggest biotechnology can be a means to help Canada meet its sustainable development objectives, such as reducing greenhouse gases, improving water quality and reducing the use of pesticides. It could also provide employment and income opportunities through new value chains in agriculture, forestry and other natural resource sectors, savings for industry through greater material- and energy-efficient manufacturing, and health benefits through reduced environmental pollution.

Sustainable Development (SD) Improving the quality of human life while living within the capacity of local and global ecosystems, with more equitable sharing of economic and social benefits among today's rich and poor, and without compromising the ability of future generations to meet their needs. (*Adapted from definitions of the World Conservation Strategy and the World Commission of Environment and Development.* The Principles and Values section of this report lays out our criteria for moving towards sustainable development goals.)

Biotechnology The application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services. *(Organisation for Economic Co-operation and Development [OECD] definition.)*

This study has been prepared by an Expert Working Party on Biotechnology and Sustainable Development for Canada's Future Economy (BSDE). The Working Party reports to the Canadian Biotechnology Advisory Committee (CBAC). The study is the first comprehensive effort undertaken in Canada to examine biotechnology prospects in relation to sustainable development. Our perspective is from now until 2020. We have maintained an impartial, analytical view toward this relationship and its implications for decision-makers. This Technical Report describes findings of the study, and presents recommendations that could be implemented quickly for longer-term gain. An accompanying Executive Report is directed to Canadian decision-makers in the Federal Government, provincial governments and local communities, and to senior business and civil society representatives.

Why single out biotechnology, given the range of possible means and technologies to address key sustainable development issues? Biotechnology is a maturing technology for which numerous environmental and sustainable development applications have been suggested.[1] There are many points of view, often strongly expressed, concerning the levels of benefits and risks associated with biotechnology, just as there have been with virtually all new forms of technology. The

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[1] See, for example: I. Serageldin and G.J. Persley (eds.), *Biotechnology and Sustainable Development: Voices of the South and the North* (Oxford: CABI Publishing, 2003); J. de la Mothe and J. Niosi (eds.), *The Economics and Social Dynamics of Biotechnology* (Norwell, Mass.: Kluwer Academic Publishers, 2000); OECD, *Biotechnology for Clean Industrial Products and Processes: Towards Industrial Sustainability* (Paris: 2002); OECD, *Biomass and Agriculture: Sustainability, Markets and Policies* (2004); United Nations, Report of the Secretary-General*, Impact of New Biotechnologies, with Particular Attention to Sustainable Development, including Food Security, Health and Economic Productivity* (2003); A. Sasson, *Industrial and Environmental Biotechnology: Achievements, Prospects, and Perceptions* (Yokohama, Japan: Institute for Advanced Studies, United Nations University, 2005).

reality is that biotechnology may take 20 to 30 more years for the full range of benefits to emerge. It is also possible that potentially harmful impacts may take as much time or more to express themselves.

Most attention and funding for biotechnology innovation in Canada and elsewhere have been directed to medicine and food. Until recently, Canada's innovation strategy and efforts towards sustainable development have generally taken parallel rather than intersecting tracks. This has recently begun to change, as evidenced by the establishment of new institutions such as Sustainable Development Technology Canada (SDTC), by renewed investment in alternative energy sources such as biofuels, and by the growing recognition that many existing technologies for protecting the environment have serious limitations.

An important lesson of technology innovation is that success is less than predictable. Therefore, whatever Canada's future holds, Canadians will need to take an *adaptive approach* in which continuous learning and application of new knowledge are central to managing processes of change. We encourage the use of adaptive management[2] because development of biotechnology for sustainable development will be neither fully predictable nor ordered. Surprises are to be expected. An adaptive management approach to a new technology gives us a means of dealing with issues that otherwise may be too complex, interwoven, and dynamic to assess with conventional risk-avoidance approaches. It allows us to move forward while providing the information needed for risk identification and risk management. Specifically, adaptive management requires "a transparent and open-minded process of social choice" in which policies and novel programs are treated explicitly as experiments, with opportunities for social learning and subsequent adjustment of practices.[3] Adaptive planning and management is reasonably established as an important approach for environmental issues and sustainable development.

We believe it to be an essential approach for the future—a means to build confidence in technology innovation, and a means to learn from "small surprises" in order to improve safety and maximize sustainable development benefits. Thus, adaptive management figures prominently in all parts of our report. However, because it is not an approach widely used by those engaged in innovation technology introductions, there is a need for capacity building on how adaptive management can be applied in a systematic fashion.

In addition to the major efforts of R&D, investment and commercialization that will be required in the years ahead, people will need to (1) recognize the role of values-driven decision-making; (2) strengthen our system of governance for addressing innovation in problem-solving; (3) establish new metrics, standards, and develop the information needed to monitor progress; and (4) build public dialogue around desirable outcomes and how we might achieve them. As individual citizens and consumers, and through many organizations, Canadians need to make informed, responsible choices about problem-solving, including the role of new technologies.

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2 Adaptive management is "a systematic process for continually improving management policies and practices by learning from the outcomes of operational programs" (B.C. Ministry of Forests and Range, Forest Practices Branch). See C.J. Walters and C.S. Holling.. "Large-Scale Management Experiments and Learning by Doing," *Ecology* 71(6) (1990), pp. 2060-2068.

3 K. Lee. *Compass and Gyroscope: Integrating Science and Politics for the Environment* (Washington, D.C.: Island Press, 1993); *Adaptive Management in the Canadian Nuclear Waste Program*, Background paper commissioned for the Nuclear Waste Management Organization (2003): www.nwmo.ca/default.aspx?DN=218,206,199,20,1,Documents.

Business, communities and governments will need to act more quickly and effectively on investment decisions, new regulatory applications and capacity building. Each of these topics is touched on in this report.

2020—Sustainable Development Vision

By 2020, the economy and environmental condition of Canada should reflect the efforts of a generation attuned to sustainable development. We have chosen this time frame for our analysis because a number of sustainable development concerns will move from "urgent" to "critical" status during this period. Canadian organizations[4] have identified a number of sustainable development concerns of major significance including: greenhouse gas reduction, diversification from our reliance on fossil hydrocarbons for energy and materials, reduction in levels of persistent pollutants, environmental restoration of contaminated areas, need for improved municipal and industrial waste utilization, maintenance of ecological integrity, biodiversity and ecosystem function, and meeting the Millennium Development Goals of the United Nations.

We express hope for sustainable development outcomes that could lead to a stronger, more resilient society in Canada. Hope for a global situation where basic human needs will be met; where there is an end to biodiversity destruction; and where progress takes place on reducing emission of greenhouse gases, among other achievements. Solutions will not come about through 'business as usual.' Thus we focus on actions that need to be taken now if we are to achieve transformative change by 2020.

Technology Choices

Clearly we are already facing major new technological choices (see Box 1-1), perhaps all of which may help support sustainable development. But the detailed technological choices are by no means easy to make, as the decade of debate over genetically-modified foods has demonstrated. Assertions about benefits and impacts can be contentious, highly optimistic or pessimistic, and highly selective or incomplete. On the other hand, if there are truly major sustainable development benefits, with costs and impacts that are less than alternative actions, then it may be in society's interests to proceed with, or even accelerate the development and commercial application of particular technologies, perhaps including some biotechnologies.

Innovative technologies are disruptive.[5] They change the fundamentals of how we do things, carry high risks and generally reveal their full range of benefits only over a long time period, 20 to 50 years or more. It is impossible to definitively identify the full range of either benefits or risks early on. People may therefore feel justified in taking strong stands for or against innovation. In part, these stands will be defined by whether individuals and groups feel they have access to benefits, or whether others profit at their expense.

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4 Information is widely available, for example on the following websites: Environment Canada's Green Lane (www.ec.gc.ca/envhome.html), The National Round Table on the Environment and Economy (www.nrtee-trnee.ca), and the International Institute for Sustainable Development (www.iisd.org).

5 See C.T. Bekar et al., *Economic Transformations. General Purpose Technologies and Long-term Economic Growth* (Oxford University Press, 2006); R. Lipsey, *Economic Growth, Technological Change, and Canadian Economic Policy* (C.D. Howe Institute, 1996).

Box 1-1. Time frame of some new technologies

Technology	Introduction	Stage of Development
Information Technology ('IT')	1950s – 1960s	Established
Biotechnology ('Biotech')	1980s	Maturing
Hydrogen Fuel Cell Technology	1990s	Testing
Nanotechnology ('Nano')	2000s	New

Biotechnology Platforms and Approaches

Box 1-2 describes some of the biotechnologies that are the foundation of modern approaches. In the case of environmental and resource applications, it is important to recognize that biotechnology does not always mean genetic manipulation. Often it will involve a sequence of technologies, including the growing, processing and manufacturing of products. In the natural environment there is great interest in bioprospecting, for example, microbes in deep vents or other extreme ocean areas, or marine life clinging to wave-battered rocky shorelines. For shorthand, we use the term genetically engineered (GE) to describe situations where genetic material is deliberately altered, added or removed. We also recognize that various combinations of technologies are possible, for example, "GE-free" pathways to bio-products, bio-nano technologies, and bio-IT.

Box 1-2. Some biotechnologies covered under the OECD definition

- DNA (the coding): genomics, pharmacogenetics, gene probes, DNA sequencing/synthesis/amplification, genetic engineering.
- Proteins and molecules (the functional blocks): protein/peptide sequencing/synthesis, lipid/protein glyco-engineering, proteomics, hormones, and growth factors, cell receptors/signaling/pheromones.
- Cell and tissue culture and engineering: cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, embryo manipulation.
- Process biotechnologies: Bioreactors, fermentation, bioprocessing, bioleaching, bio-pulping, bio-bleaching, biodesulphurization, bioremediation, and biofiltration.
- Sub-cellular organisms: gene therapy, viral vectors.

Source: OECD, Paris

The focus in the BSDE study is on the biotechnology approaches noted in Box 1-3. We have chosen to examine applications related to agriculture, energy and sustainable natural resource management, since these are matters of great relevance to Canada. It is sometimes stated that Canada's "natural advantage" in developing biotechnology products lies in our large land and natural resource base. For example, various crops and residues could potentially be used as raw material for "biorefineries", a topic that will be discussed in more detail in Chapters 2 and 4. During the past year, major initiatives on biofuels have started throughout the world. Growing attention is being given to the possibilities of "industrial ecology", which can involve the redesign of manufacturing processes to use less energy and non-polluting biocatalysts and enzymes. Yet another area is the use of biotechnologies in Canada's growing environmental technology sector, which commands a foothold in overseas markets.

Box 1-3. Potential biotechnology and sustainable development applications

- Enhanced food and fibre production using GM techniques.
- Bioproducts (biofuels, chemicals and plastics) and biorefineries.
- Bioremediation including land and water purification using GM organisms.
- Industrial applications using bioenzymes and biocatalysts.
- Environmental monitoring tests.
- Bio-based pest and disease control.
- Community and public health applications including vaccines, medicines and molecular farming.

The significance of biotechnology in international cooperation is a sometimes hotly debated topic. There are clear points of entry, ranging, for example, from the contributions biotechnology could make to achieve the United Nations Millennium Development Goals[6], to access and benefits sharing arising from the use of biological diversity, and to the role of biotechnology in agricultural sustainability. We have placed limited emphasis on medical applications, given the considerable amount of attention given to this topic in other reports. However we recognize the significance of community health to sustainable development, including new vaccines, low cost applications for treatment of HIV-AIDS and other diseases, clean water, and ecological restoration through bio-remediation. We ask the question: What major contributions could Canadian biotechnology and sustainable development applications make internationally beyond what is currently being done?

We have not examined issues of military applications for biotechnology and bioterrorism. Clearly these are important topics, especially in the US and certain other countries. They are complex subjects in their own right, and deserve separate study.

Values and Ethics

Biotechnology, "Nature" and Sustainable Development

This section outlines what we think is possible and desirable in a values driven, ethically informed approach to the relationship between biotechnology and sustainable development. A secondary purpose is to open up for productive debate our observations on this guided approach. Below, we present basic value choices, and how we think ethical-moral judgments about biotechnology should play out within the complex context of sustainable development.

We start with the view that biotechnology, like other technology platforms, should be developed with a purpose—to meet desirable goals of society. Yet, by its very nature, biotechnology confronts us with a paradox. It promises both the increased 'naturalization of industry'—that is, the use of biodegradable materials, enzymatic catalysts, and biologically-based production systems—which we hope will help human society better integrate with natural support systems and biodiversity. But in so doing, it involves the increased 'industrialization of nature,' with its attendant issues such as animal welfare (including industrial animal agriculture), new types of human intervention in natural resource management (such as GM organisms for aquaculture and tree plantations), and intellectual property rights being applied to living beings.

[6] The Millennium Development Goals cover eight important themes important for reducing poverty worldwide. Among the themes are environmental sustainability, access to clean water and sanitation, and a number of important public health objectives. These goals are to be met by 2015. See www.un.org/millenniumgoals.

Practices associated with the increased 'industrialization of nature' challenge deeply held beliefs in many cultures about the appropriate relationship of humanity to "Nature" or to "Life". Many consider that these practices pose a fundamental ethical issue. This tension has no easy solution, and so it must remain at the forefront of the many discussions necessary to facilitate biotechnology's contribution to sustainable development and respect for life.

As far as we can determine, no Federal Government commitment currently exists to a particular set of values and ethical principles or guidelines on the subject of biotechnology and sustainable development. Ongoing discussions within the Federal Government regarding a general stewardship strategy perhaps come closest to addressing this area.

Sustainable Development—a Desirable "Outcome"

The value judgments and ethical choices found within our Report derive from one basic premise: sustainable development defines desirable, long-term Canadian and global outcomes for living within planetary ecological limits, with more equitable sharing of economic and social benefits among today's population and future generations. We also believe that respect for, and maintenance of the planet's natural biological diversity must be reflected in biotechnology innovation and development decisions. To illustrate what we mean by "living within planetary ecological limits," we present in Box 1-4 a paraphrasing of four conditions considered essential to the reduction of humanity's impact on earth.

We find these conditions useful for two major reasons: they provide clear, scientifically grounded language that is also accessible and aspirational; and they are all relevant to the sustainability outcomes that biotechnological applications promise. They allow us to make our judgments about the desirability of biotechnological innovations transparent—we have clearly laid out our terms. For example, potentially desirable biotechnology innovations would include those that reduce society's dependence on scarce or damaging material (such as fossil fuels or mercury) from the earth's crust, propose substitutes for anthropogenic substances, or reduce the impact of natural resource extraction and society's activities on the biosphere.

Box 1-4. Conditions for living within planetary ecological limits

1. Reduce and eventually eliminate activities that cause the systematic increase of substances from the earth's crust (e.g., petroleum products, heavy metals) within ecosystems at the earth's surface. *Substitute renewable for non-renewable sources of materials and energy.*
2. Reduce and eventually eliminate activities that result in the systematic increase of synthetic molecules (e.g., nuclides, persistent organic pollutants) that cannot be broken down and re-integrated into natural systems. *Make safe, biodegradable products wherever possible.*
3. Reduce and eventually eliminate activities that result in the degradation of essential ecosystem functions (e.g., soil degradation, water pollution) and biodiversity (e.g., unsustainable harvesting, invasive species). *Protect ecological goods and services while respecting nature and biological diversity.*
4. Develop societal structures and practices that ensure that basic human needs (including determinants of social and emotional health) are met worldwide. *Work cooperatively to meet the Millennium Development Goals.*

Source: Modified from Robert, K.H. et al. (2002) *Strategic Sustainable Development – Selection, Design and Synergies of Applied Tools*. J. of Cleaner Production, (10): 197-214. This article provides a unifying conceptual framework for several pre-conditions for sustainable development. The italicized text provides sample applications.

Throughout our Report, we will stress the importance of ensuring that biotechnology applications benefit both humanity and the ecosystems on which we depend. Since some biotechnology innovations draw from the commons (e.g., genetic material derived from natural biological diversity), an important ethical consideration is how these innovations can be enjoyed for the benefit of all people, and indeed, how the applications of biotechnology can, directly or indirectly, help to sustain the ecological world.

Due Process—Some Guiding Principles

A useful, coherent set of principles has been developed by the State of Queensland in Australia as part of its *Code of Ethical Practice for Biotechnology*. While not everyone agrees on the value of the overall Code, it does enjoy recognition in many circles, and the principles in particular are difficult to reject. We embrace these principles (Box 1-5) and believe they are of significant value for guiding due process in relation to biotechnology and sustainable development decisions.

Authors of the Code assure readers that Queensland will "pursue biotechnology activities with potential to improve human health, enhance quality of life, support the environment (by preserving ecosystem health and biodiversity), and promote sustainable agriculture and industry".

Box 1-5. Principles Supporting Queensland Code of Ethical Practices for Biotechnology

Integrity: Having honesty and respect for the truth.

Beneficence and non-maleficence: Achieving the greatest possible good while doing the least possible harm.

Respect for persons: Treating patients, clients, research subjects and consumers as autonomous agents having freedom of choice, dignity and human rights.

Justice: Recognizing wider community interests beyond the interests of the individual, organisation or corporation; providing redress for the vulnerable; and promoting equitable access to resources.

Respect for the law and system of government: Complying with relevant laws and standards; fostering public participation and transparency in decision making; and demonstrating accountability for actions and use of resources.

Source: Code of Ethical Practice for Biotechnology in Queensland. Also, see Evlyn Fortier and Marc Saner, 2004. *Is the Queensland Code for Biotechnology a Good Model for Canada? A Preliminary Analysis.* Institute of Governance, Ottawa, p. 44.

Governance and Public Trust

These two sets of principles notwithstanding, we remain mindful of the political and economic context in which biotechnology has emerged—one that has encouraged the development of the technology through market mechanisms, within the rubric of international intellectual property (IP) and trade regimes. While acknowledging this approach's benefits, we also believe that there is a very significant role for government to maintain public trust and to recognize, safeguard and enhance the stock of public goods. Since biotechnology can be privately owned, its owners may seek to profit from the technology without considering all potential risks to the ecosystem or communities affected by its use. Therefore we need comprehensive assessment, appropriate regulations and the right balance of enforcement and incentives to ensure various biotechnology applications do indeed meet expectations of net benefits to society, but not at the expense of the natural environment, for current or future generations.

The development of biotechnology in support of sustainable development requires integrated action leading to transformative changes in governance, management and business practices. To bring about these longer-term desirable changes, we must work within the current models of governance, intellectual property (IP) and business practice, and also consider options to change such practices. In the process, consumer behaviour and consumption patterns may also be influenced towards more sustainable pathways.

A Systems Approach

In assessing biotechnology's contribution to sustainable development, we will be taking a "cradle-to-cradle" complex systems approach. The "cradle-to-cradle" concept might be likened to what in Germany, Japan and China is called a "Circular Economy". In other words, even at the disposal stage for products there can be further transformation into new products or uses, so that waste is kept to an absolute minimum. This concept is consistent with emerging thinking about value chains involving bioproducts and biorefineries (see Box 1-6).

Taking a complex systems approach in relation to values and ethics requires acknowledging that different ways of measuring the 'same' things can lead to different moral conclusions, and that value choices cannot be made in isolation, but must take into account the multiplicity of other related choices that will arise within a biotech product's life-cycle. However, such complexity will not prevent us from making choices, but will help us consider interrelations as we make choices. It will also help us establish that appropriate monitoring and feedback can take place.

The complex system approach links with the notion of adaptive planning and management, which recognizes that technology introductions and development are experimental, requiring expectation of surprises (both good and bad in nature), learning and extensive dialogue.[7]

Box 1-6. Bioproduct value chains and biorefineries

The bioproduct value chain may include growing industrial crops tailored to specific characteristics (with or without GM content), intermediate biorefineries operated in rural communities to produce transportable products such as bioethanol, and a smaller number of biorefineries designed to produce a broader range of products than in a conventional petroleum refinery, including plastics, biofuels and fine chemicals. Biorefineries will be energy efficient through processes using GM enzymes and catalysts and with limited or no fossil fuel consumption. Their products will be biodegradable at the end of their life cycle and have lower environmental impacts by comparison to alternatives such as products from hydrocarbons.

These new supply chains raise issues of ecological impacts on crop lands, environmental assessment of the biorefinery location and operations, and trade considerations concerning final products. And, of course, the social and economic considerations of who will actually benefit, and whether economic viability is possible. This level of complexity requires a systematic approach for analysis, and some tools such as life cycle analysis (LCA) have been developed. There are significant social and economic considerations. Will farmers and rural communities be significant beneficiaries and therefore willing to participate fully, and can these value chains operate without new patterns of agricultural and industrial subsidies?

Source: Notes abstracted from a November 2005 OECD meeting on Bioproducts. Ghent, Belgium.

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7 A good entry point for this complex system-adaptive management approach appears to be BIOCAP, Canada's new (2005-2006) Research Integration Program, which covers a variety of approaches to leading-edge agriculture, forest, and climate change opportunities related to biotechnology: www.biocap.ca/rif/RIP_Insights_Final_June_8.pdf.

Being Clear About Values

The foundational values we advocate and upon which we have based our research and analysis include: the *consequences* or *ends* to which we want biotechnology to contribute; and the *process* or *means* to achieve these ends. We think that being clear on the values that underpin our notion of "moral" is very important, especially in light of the challenges that biotechnology innovation makes to deeply-held cultural values related to "Nature" and its relation to human intervention.

Methods and Report Content

Our year-long examination has been multidisciplinary, drawing upon a great amount of existing material through the Canadian Biotechnology Secretariat, other parts of the Federal Government, business case studies, independent research by Expert Working Party Members, and international perspectives drawn from studies undertaken by the EU and agencies of various European countries, the US, Japan, China, various UN bodies, the OECD, and other organizations. The work has included interviewing people in a number of relevant organizations, attending Canadian and international meetings, and overseeing original research conducted by various contractors.

In Chapters 2 to 8, the main body of findings is presented. A prospective look at biotechnology (Chapter 2) identifies the current and projected status of transformative possibilities for biotechnology and sustainable development based on the categories in Box 1.3. This Chapter provides a survey of the leading edge—where R&D, private investment and government action are converging to promote specific initiatives and outcomes such as biofuels and bioremediation of damaged ecosystems. And it covers topics where policy decisions are needed in coming years.

We take the view in Chapter 3 that Canadians wish to live in healthy, sustainable communities, and that they do recognize the need for healthy ecosystems, able to provide a variety of services and goods, and protected for their intrinsic values. What are the potential contributions of biotechnology for meeting these needs? How much do we need to know about social and ecosystem effects of transformative technologies before they are introduced? And how can we move towards an adaptive planning and management approach?

The particular innovation lens we use to understand how biotechnology applications are developed and brought into use was developed by the Conference Board of Canada. It is used by the Board's research team to ask the key question of the value of biotechnology applications for defining new economic opportunities for Canadians living in rural areas (Chapter 4).

What do we need to realistically assess biotechnology for sustainable development? An integrative approach covering environmental, social and economic considerations would be appropriate, but is not currently available. And, for those situations where biotechnology appears to offer better options for achieving sustainable development goals, how can we fast-track solutions that might otherwise take 20 years or perhaps never make it to an implementation stage? A framework for examining biotechnology development using sustainable development criteria is proposed in Chapter 5.

The turmoil that surrounded the introduction of GM crops is an exercise not to be repeated. Clearly there is a need for both public literacy and dialogue concerning the broad range of biotechnology options highlighted in this report. How can this need be addressed in a fashion that helps to shape knowledge, areas of genuine risk, acceptable applications, etc.? We have undertaken e-dialogues, on an experimental basis, using the power of the Internet, to demonstrate how we might structure on-going dialogue (Chapter 6).

Canada's needs for international cooperation in relation to biotechnology and sustainable development are complex. Our actions will be guided by international development objectives such as the Millennium Development Goals and by other Canadian commitments, such as to the Framework Conventions on Biodiversity and on Climate Change. Canada has been one of the leaders in the OECD on issues of both biotechnology and sustainable development. How can we best contribute and position ourselves to benefit from our international cooperation efforts, including our work with developing and industrial nations and with international organizations? In Chapter 7, we examine a number of the most critical matters related to knowledge, development assistance, international obligations under laws and agreements, and our comparative advantages and competitiveness.

Governance is a central theme of the report, and in Chapter 8, we present a review of the current situation and several recommendations for how governance of the biotechnology and sustainable development relationship could be strengthened. The proposed changes to a very considerable extent are based on alterations within the existing institutional framework of regulation and policy development.

While we would like to be in a position today to make definitive predictions about the best technologies for the future, and to declare how such information could make sustainable development possible in Canada and globally, the reality is much more complex. The outcomes will be determined by many interacting factors, including public opinion, success in renovating dated regulatory systems and putting in place incentives, R&D, etc. We need to be adaptive in our thinking and actions, to identify the values and ethics that can appropriately guide our societal decisions, and to build the public literacy and dialogue that will support the necessary change, as well as continuity, to achieve desired goals. In Chapter 9, we summarize our key policy recommendations that will help move us towards the necessary conditions for making the relationship between biotechnology and sustainable development productive.

CHAPTER 2. BioPromise?

Promise and Premise

This chapter is about possibilities, especially the possibilities that researchers, governments and industry representatives see for biotechnology. There is a lot of promise, but there is certainly an abundance of premise to go along with it! In this chapter, we hope to highlight both aspects of biotechnology's future, exploring possible outcomes and strategic interventions, keeping our premises conservative without discounting the value of the promises. A fundamental premise of the SD-biotech relationship is that it should be driven by changing values in society towards less environmentally damaging lifestyles and consumption, and by favourable economics and social outcomes.

Consider the following three points about the global spread of interest in biotechnologies: (1) In 2005, approximately 90 million hectares (ha) of genetically engineered crops were planted, compared to 2 million a decade ago.[8] (2) Growth rates are currently greater than 30% per year for biodiesel and about 6.5% per year for bioethanol.[9] By 2020, bioethanol use for transportation might increase from current levels of 35 billion litres to 120 billion litres.[10] (3) Perhaps up to 80% of the almost 14 billion kg of environmentally undesirable conventional solvents used globally each year could be replaced by green chemistry/biobased solvents such as ethyl lactate, which are much less toxic.[11] Each of these examples, and others, present challenges to established ways, and the case for each has to be developed in very specific ways.

The promise of biotechnology for sustainability is described in thousands of company web sites, at scientific and trade gatherings, and in the marketing of many products. Proponents of biotechnology for sustainable development make the case that transformative change and *not* business as usual is already happening, and big time!

One of the thoughtful proponents is a supplier of industrial and commercial GE enzyme products, the multinational Novozymes A/S, considered one of the world's top 100 sustainable development companies. Novozymes talks of "Unlocking the Magic of Nature" with a vision to support the world with "sustainable, biological solutions that create the necessary balance between better business, a cleaner environment and better lives."[12] This forward-looking approach has served the company well, most recently in a 2005 research breakthrough converting biomass into fermentable sugars for fuel ethanol with a reduction in the cost of enzymes from over $5 to between $0.10 and $0.18 per gallon of cellulosic ethanol."[13] This type of good-news story appears almost daily in the current rush of firms to capitalize on biofuels as an alternative to high hydrocarbon prices.

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8 www.gmo-compass.org
9 www.marketresearch.com
10 www.iea.org
11 J.C. Warner et al., "Green Chemistry," *Environmental Impact Assessment Review* 24 (2004), pp. 775-779.
12 www.novozymes.com
13 www.novozymes.com/en/MainStructure/PressAndPublications/PressRelease/Novozymes+response+to+the+state+of+the+union.htm

But many of the stories are still mainly about hopeful R&D efforts that have not yet been turned into commercially viable products. Even for a major field of endeavour such as industrial applications of enzymes, the world market only grew from a billion to US$1.5 billion in the period from the mid-90s to 2000 – in the world of industrial chemistry, this is a drop in the bucket.[14] On some topics of great excitement, for example GE bioremediation, it is very difficult to obtain meaningful statistics. Environmental remediation is a fragmented market of perhaps $20 billion or more worldwide, bioremediation accounts for perhaps US$1.5 or 2 billion of this market, and GE bioremediation is only a small fraction of total bioremediation activities. These figures remind us that, while there is a great deal of intriguing news, turning that information into sustainable development outcomes can be a decades-long struggle.

The major areas of biotechnology are sometimes described as red (health), green (agriculture, natural resources and environment), blue (marine) and white (industrial biotechnology). The relative proportion of biotechnology applications differs considerably depending on the country. For example, in 2002 in Germany[15] they were: red 86%, green 9% and white 5%. In the US and Canada, because of relatively strong agricultural biotechnology industries, the proportion labeled green would be larger. These distinctions, though useful, also create differences in a field that is characterized by much convergence in terms of methods, tools and approaches to problem solving. The CEO of Dupont, for example, sees "agricultural or green biotechnology as central and indispensable to the development of red and white biotechnology, as well as the application of biotechnology in other fields."[16] Seeking such synergies will become more and more important at all levels, from basic R&D on the building blocks of life, to integrated operations for producing an array of products such as food and drugs, plastics and fibres, and energy.

Box 2-1. Distribution of Canadian biotech firms by sector

Human Health	53%
Agricultural Biotechnology	18%
Food Processing	11%
Environment	8%
Natural Resources	4%
Aquaculture	3%
Bioinformatics	3%

Source: Statistics Canada. *Biotechnology Use and Development Survey* 2003

Statistics Canada surveys the biotech industry; its 2003 survey is widely quoted. In relation to the overall portfolio covered in the survey it is clear that health, agriculture and food processing lead, with over 50% of the total activity as measured by number of firms (see Box 2-1). What is most striking though is the concentration of R&D spending: 89% was spent on human health, and only 6% on agriculture and food processing. Environment, natural resources and bioinformatics accounted for only 5%. The survey does not fully cover industrial biotechnology applications, so these figures do not tell the complete story. But it is very clear that health applications have garnered the greatest support.

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[14] T. Schäfer, *Industrial Enzymes: An Overview about Companies, Markets, and Key Technologies,* Abstract for Presentation, Bio-logical Futures III (Saskatoon: October 2006): www.biologicalfutures.ca.

[15] Deutsche Bank Research, *Green Biotechnology: Europe Needs a Way Out of the Impasse,* Current Issues (February 5, 2004): www.dbresearch.com.

[16] www2.dupont.com/Media_Center/en_US/speeches/holliday_04_13_05.html

In this Chapter, our focus is on what could be accomplished in Canada over the coming decade plus. We say "decade plus" because we would expect the really significant outcomes from investments started now to happen in the decade after 2015. We review some specific sectors and topics that Canada needs to consider carefully:

- bioproducts, including biofuels, agriculture and forest product possibilities;
- the role of the biorefinery as a driver towards production of a wide variety of chemicals, bioplastics and energy;
- marine biotechnology (including bioprospecting of the oceans and why this is so significant for Canada), diagnostic testing and monitoring, disease control and other aspects of fish and aquaculture management;
- industrial applications of biotechnology; and
- bioremediation.

In the limited space available for this Chapter, we can hardly do justice to these major areas of development. We try to identify key points and barriers important for policies and implementation, and to identify overarching considerations affecting all the areas. We pay special attention to biofuels because this emerging component of the renewable energy sector is now the leading edge of resource-oriented biotechnology applications, and the first to be specifically mandated by governments around the world, including Canada and several provinces.

Well-established biotechnology applications such as GE crops, pest control and medical applications are not given much treatment, although they are important to sustainable development outcomes. We wish to concentrate our efforts on the novel areas that are still at an early stage of development and understanding.

Finally, we set the stage for later chapters by considering timelines and barriers that may influence the roll-out of various BSDE possibilities.

We conclude with an excerpt from a scenario we developed for our Executive Report—a possible outcome for BSDE by 2020.

Bioproducts

A rising star among Canadian biotechnology activities is the area of industrial bioproducts.[17] The strategic importance of bioproducts is that conceivably they can be used in a wide number of industries as substitutes for petroleum-based or toxic chemicals. There are possibilities for creating value-added products from agricultural and forest wastes, including the development of new biomaterials. They could also reduce both costs and environmental impacts of various manufacturing processes by the use of bioproducts and bioprocesses such as enzyme catalysts, bio-sensors for process control, and microbial or other systems for waste cleanup.

A central theme heard from those who promote bioproducts is that Canada has a natural biomass advantage. This is clear from our large land mass, with some 10% of the world's forests, the great volume of agricultural wastes (potential resources), and products from the sea. Based on BIOCAP Canada (a research organization specializing in bioproducts) analysis, it is suggested that

[17] Federal Working Group on Bioproducts, *Industrial Bioproducts for Sustainable Growth and Competitiveness,* Outline of a Common Briefing for Federal Departments (December 2004).

"agricultural and forest biomass could supply all of our feedstock requirements for production of organic chemicals and a significant portion of our needs for transportation fuels." This clearly represents a significant production potential.

Another point in favour of developing a Canadian bioproduct industry is that the development and marketing work often can be done through existing companies that have access to capital and incentive to seek value-added products and processes. Thus, 150 companies involved in some aspect of bioproduct manufacturing have revenues of some C$15 billion with R&D investment of $600 million, and total employment of 39,000. Core bioproduct activities are still small within these firms: $500 million in revenues, $80 million in R&D, and 2,000 people employed.[18] Another point in their favour is that the industry does not face some of the daunting regulatory hurdles that other sectors such as health and food face. A premise is that the time to commercialize bioproducts is shorter than for medical biotechnology products—3 to 7 years, compared to the extended development and trial period in medicine that can stretch into a decade or longer.

A significant driver for bioproducts has been the high price of fossil hydrocarbons, significant for both bioproduct-based fuels and biomass-based feedstocks for chemicals and plastics. Another driver is Canada's ongoing resolve to improve competitiveness and industrial productivity in a manner strongly aligned with both stewardship and sustainability, including sustainable forestry, agriculture and ocean management practices. Because bioproducts promise cleaner processes, there is the possibility for, and a strong interest in creating, "triple win" situations. Existing wastes are turned into value-added products, or in the case of industrial biotechnology, the use of both toxic substances and energy are reduced or eliminated. Environmental impacts and GHG emissions are substantially reduced, and new employment opportunities are created, especially in rural areas.

Some of the most interesting initiatives currently under development or commercialization reflect this need to consider sustainability and competitiveness. In some cases they are cast in a regional context, and are referred to as "eco-industrial clusters." These clusters consist of co-located businesses whose products or waste serve as feedstock for neighbouring firms. An example of this is the Ottawa Biotechnology Incubation Centre.[19] This site includes a variety of firms dedicated to bioproducts, in what might be described as a mutualistic relationship. Topia, which produces glycerol as a biodiesel byproduct, can provide the glycerol to Ensyn, a co-located firm, which produces bio-oil as a feedstock for other chemical products. A firm in nearby Moose Creek, LaFleche Environmental, which operates a landfill, is working with Ensyn and Topia to provide wood waste feedstock for both their operations instead of disposing it in the landfill. There are numerous other opportunities within this region to build a localized eco-industrial base, supported by R&D activities from the incubation centre and other sources. This is likely the way forward—not spectacular advances, but cooperative ventures gradually introducing changed practices with a biotechnology and sustainability slant.

[18] Ibid.

[19] R. Goodfellow, personal communication; S. Foster, "Biotech Leaders See Benefits of Industry Cluster", *Ottawa Business Journal* 31 (May 2004).

Biofuels[20]

There is a very concerted effort underway to develop the biofuel sector in Canada, as well as other regions and countries, through the use of generous subsidies and various other incentives.[21] This approach, coming at a time of collapse of WTO talks on reducing agricultural subsidies could be seen as a harbinger of a whole new round of rural support mechanisms, with the added twist of seeking to link these initiatives to fuel security and to environmental benefits. These "first-generation biofuel" investments have the potential to lock countries into choices and longer-term financial and environmental costs that are not desirable. These issues need to be considered carefully.[22]

There are many ways to create bioethanol. The current, most common way is by fermentation of wheat, cornstarch, sugar beets, or molasses followed by distillation that creates fuel grade ethanol. These crops are usually varieties that can also be used for food or feed purposes; specialized varieties are being developed for fermentation to fuel-grade products. In calculating their conversion efficiency, it becomes clear that fossil fuel used in their production and transportation is considerable. Processing into ethanol ideally will take place close to farmers to reduce transportation cost, with the important advantage of providing additional income to rural areas from processing.

A second strategy, promised soon at commercial scale, is the use of steam pressure and enzymatic pre-treatment to convert cellulosic – woody, fibrous plant material – into the sugars that the fermentation process can use. This "cellulosic" ethanol promises to be cheaper than the traditional

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[20] The following references used in the preparation of this section are a selection of recent views on a complex subject. A.M. Walburger et al., *Policies to Stimulate Biofuel Production in Canada: Lessons from Europe and the United States* (Biocap Canada Foundation, March 2006); Agra CEAS Consulting, *How Canada Ranks: A Comparative Study of National Biofuels Policies World-wide*, Report for the Canadian Renewable Fuels Association (March 2006); BusinessWeek Online, *Ethanol: A Tragedy in Three Acts* (April 27, 2006); Commission of the European Communities, *An EU Strategy for Biofuels* (February 8, 2006); A. Farrell et al., "Ethanol Can Contribute to Energy and Environmental Goals", *Science* (January 27, 2006); *Popular Mechanics*, "The Truth about Biofuels. Can Oil Alternatives Really Power America?" (May 2006); D. Sandalow. "Ethanol: Lessons from Brazil," *A High Growth Strategy for Ethanol* (Aspen Institute: May 2006); Worldwatch Institute, *Biofuels for Transportation* (June 2006); International Energy Agency (IEA), various reports: www.iea.org.

[21] The most comprehensive support packages being proposed are by the Canadian Renewable Fuels Association in their *Canadian Renewable Fuels Strategy* (July 25, 2006), which calls for changes to tax credits for ethanol and biodiesel production, accelerated depreciation, initial support for a commodity production incentive during start-up and, for smaller producers, an additional tax credit for a portion of their production. In addition, it is proposed that matching funds on a dollar-to-dollar basis be provided to increase participation by farmers (up to $75,000 per producer, with a limit of $20 million per ethanol project and $10 million per biodiesel project). The emphasis in these proposals is on conventional food crops including grain, corn and canola, although use of waste materials such as cellulosic ethanol is not excluded. The purpose of these incentives is to create an industry that could be competitive with subsidized US first-generation biofuels.

[22] S. Dimas (EU Commission Member), *A Sustainable Bio-fuels Policy for the European Union,* Presentation to Goethe Institute (Brussels: June 7, 2006); Worldwatch Institute, *Review of Biofuels* (June 2006); A.E. Farrell et al., "Ethanol Can Contribute to Energy and Environmental Goals," *Science* 311 (2005), pp. 506-508.

ethanol because it uses material that would otherwise be residual, such as corn stalks or wheat straw. The use of cellulosic ethanol also allows the forestry industry to become involved in generating ethanol, as wood waste can be used.

A Canadian company, Iogen, leads the world in cellulosic ethanol technology, and has attracted international partners, including Royal Dutch/Shell PLC and the investment firm Goldman Sachs. The choice of where to locate their $260 million plant to commercialize the technology will be based on which government provides the best incentives—Canada, the US or perhaps a European nation are all options. The US wants to make cellulosic ethanol competitive within 6 years and is setting out grants and loan guarantees. Iogen points out that "*We've got to share the risk with the government—whichever government"* (Globe and Mail, 29 May 2006). It is a fast-moving business, thus it will be extremely hard for any one company to maintain a lead.

Other regions and countries are seeking their position in biofuel markets, on both the demand and supply sides. Europe and the US, as well as countries like China and Indonesia, have strong interests in biodiesel and bioethanol. The efficiency of converting palm oil into biodiesel is high, and it is hard to imagine that Canada could compete with tropical producers on this basis. In fact, Canadian canola producers already export canola to Europe for biodiesel production. Europe is unlikely to come even close to meeting its relatively modest, mandated goals for biodiesel and bioethanol, unless there is considerable imported product from countries such as Brazil, Indonesia, Malaysia and Africa.

We believe that biofuels can be useful for Canada and others as an important entry point to the broader industrial transformation favouring bioproducts. However, both immediately and for the long run, it is sensible to encourage technologies that utilize, at a sustainable level, residues and wastes. This strategy would place emphasis on accelerating production efficiency and achieving well-defined environmental benefits. In particular, it would require a focus on commercially successful cellulosic ethanol and lignocellulose from wood and crop residues. It is a strategy that would stimulate use of currently available materials such as commercially collected food wastes, livestock wastes and municipal wastes. This approach will require further R&D investment and support to move from pilot-stage plants to large-scale, integrated commercial biorefinery facilities capable of providing a range of products. Other countries with defined mandates (e.g., US goal to support mainstreaming cellulosic ethanol over the coming six years) and incentives (e.g., Ireland's use of carbon credits that could be applied to an integrated biorefinery) may provide a better investor environment that will lure away businesses started in Canada.

Bioethanol-gasoline mixes are promoted as a cleaner fuel, as a way to reduce dependence on costly oil imports, and as a means to stimulate sagging rural economies. Not everyone agrees about the magnitude and cost of benefits. For example, conventionally produced bioethanol is considered to be a very expensive way to lower greenhouse gas emissions and has a relatively high draw on fossil fuels in its production. Ecologists worry about long-term impacts on ecosystems if large amounts of forest and agricultural residual biomass are removed in order to produce it, and biodiversity impacts if conservation habitat is turned into industrial harvesting operations. There are practical and moral-ethical concerns if too much of the world's agricultural lands are converted to supplying fuel. Economists worry about the levels of subsidies being provided by governments becoming entrenched, as well as the effects of challenges to these subsidies under WTO or regional trade arrangements.

We treat most of these concerns as unanswered questions at the moment—good reason to apply an adaptive planning and management approach. They will become most pertinent globally and in Canada once biofuel blending goes beyond 15%, and is applied to all ground transportation fuel. Only Brazil has achieved that level today; the US plans to reach 20% by 2020, but Canada certainly will not reach those levels for at least 10 years.

We predict a steep learning curve ahead concerning biofuels, with a need to move rapidly beyond first-generation operations in all countries into more innovative approaches, not only for biofuels but also for other bioproducts. We have focused attention on biofuels in most of our chapters since the precedents that will be set in their development and use will be important for other biotechnology and sustainable development initiatives.

Central Importance of Biorefineries

The concept of a biorefinery is as old as the mass production of wine and spirits and as new as the complex, integrated multiproduct facilities built by companies such as Dupont[23]. For the purposes of our discussion, a biorefinery is an industrial plant that takes biological material as its input, transforms the material into mixtures of valuable chemicals and then separates and purifies them, yielding multiple valuable products and often a large amount of energy as a byproduct, with minimum waste and pollution.[24] The biorefinery ultimately defines the range of products, the conversion efficiency from raw materials, and also just which raw materials can be economically used. Thus biorefineries should be at the centre of any bioproduct sectoral strategy. Many are still on the drawing board, or laboratory bench. But others are at a pilot stage or beyond. And some are at the full commercial production stage.[25]

Whether advanced integrated biorefineries will be located in Canada is critical to the future of bioproducts here. The EU countries will press hard for locating facilities in countries like Germany, the Netherlands and Belgium where there are established research efforts and a long history of chemistry innovation and production. The size of markets and capacity to bankroll these expensive operations from public and private funds in the US make it certain that advanced operations are likely to spring up, quite possibly based in part on R&D achievements funded and developed from elsewhere.

Where then might Canada have advantages? There are several possibilities: the Canadian lead in cellulosic ethanol via Iogen, the presence in Canada of some major multinational corporations such as Dupont with an interest in biorefineries, Canada's pulp and paper industry, and possibly the marine bioproducts sector. Once upon a time, Canada supplied the cod liver oil pills dreaded by all children, but now there is a range of health, food and industrial chemicals such as omega-3 oils and many other products that find their way into everything from ice cream to industrial lubricants.

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[23] Dupont has been engaged with various partners since 2003 in development of "the world's first integrated biorefinery" capable of using corn and corn stover for the production of various chemicals such as Bio-PDO, the intermediate product for polymers with various applications, and biofuel.

[24] A very good source of information on current biorefinery activities is the First International Workshop on Biorefineries held in 2005, jointly sponsored by the US and the EU: www.biorefineryworkshop.com.

[25] The largest facility is a $200 million biorefinery investment by Cargill (originally with Dow Chemical) to produce polylactide polymers from corn and from this stock, biodegradable plastics: www.natureworksllc.com.

Pulp and paper mills already are strategically important as proto-biorefineries. They produce chemicals from wastes, along with a significant amount of energy for their own use and for sale to others. This would appear to be an area of advantage for Canada and also a prime area for urgent R&D. Yet, with the exception of a few companies such as Tembec, which is producing high-quality cellulosic products, food-grade ethanol, a range of lignin byproducts and other chemical products at its Temiscaming site, Canadian mill owners are not embarking on an integrated biorefinery approach. With new investment and engineering re-design, it has been suggested that very significant new revenue streams could be established.[26] Major technical breakthroughs may well take place in European or US rather than Canadian operations. The double-barrelled barrier of recent low revenues in pulp and paper and limited investment presents a dilemma, since biotechnology innovation could help reduce costs over the long run, while providing value-added chemical and additional energy product streams.

Biorefineries using residual materials, including residual plant material, manure, food processing or municipal compostables, could operate at small or large scale. An intriguing integrated thermal-based facility capable of switching among waste sources ranging from turkey processing wastes to rubber tires has been developed in the US.[27] Over the coming decade there will be many advances and much greater efficiency of production, with lower prices and a greater range of products. Think of a PC produced in 1990 and those available today!

Other opportunities in Canada could be cited, although progress is slow. These include dealing with urban organic and food wastes, manure from feedlots, and the scaling-up of cellulosic ethanol and chemicals from agricultural residues. Much will depend upon whether the current provincial and federal commitment to biofuels broadens into a more general shift to bioproducts. Clearly, there will be a need to attract multinational companies now just beginning to develop biorefineries in order to produce platform chemicals for various synthetic products.

An important feature to consider for biorefineries is the range of products that can be produced. Scale is another big issue. Ideally smaller ones located in rural areas should be under the control of local cooperatives, or other farmer-operated arrangements, so that value beyond the growing of crops can be captured directly. But these still require millions of dollars in investment. There are some successful operations of this type in the US. It is also possible to consider intermediate biorefineries located close to producers, which then ship the feedstock product such as ethanol to larger facilities where final products including fuels, fine chemicals and plastics would be manufactured. At the high end of the commodity production scale are vertically integrated operations for biofuel, such as those owned by Archer Daniels Midland, a company sometimes described as the "Exxon of corn."

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[26] G. Cosset et al., *The Integrated Forest Products Biorefinery* (2005): www.biorefineryworkshop.com; P. Gunther, *Capturing Canada's Natural Advantage,* Workshop Report. Alberta Research Council, Paprican (Canadian Forest Innovation Council: 2005): www.arc.ab.ca; P. Stuart, *"The Forest Biorefinery. Survival Strategy for Canada's Pulp and Paper Sector?" Pulp & Paper Canada* (June 2006); W.E. Mabee et al., "Assessing the Emerging Biorefinery Sector in Canada," *Appl Biochem Biotechnol* (Spring 2005), pp. 121-124:765-78; F.D. Haagensen. *Enzymes for Biomass and Forestry*: www.cnr.ncsu.edu/wps/documents/Haagensen.pdf.

[27] B. Lemley, "Anything into Oil," *Discover* 27(4) (April 2006): www.discover.com/issues/apr-06/features/anything-oil.

At the moment, with the exception of biofuel efforts, there is no dedicated federal program effort to ensure that biorefineries do indeed emerge as part of Canada's future industrial fabric. Practical barriers include the need for further R&D effort, stable investment funding, a transition to new bio-based engineering and plant management capacity, an integrated approach to regulatory decisions, and, very likely, improved federal-provincial coordination for creating attractive development situations. There will be a period of perhaps five to ten years when many, perhaps most, biorefineries are unlikely to be profitable. Other nations face the same challenges. The US, China and countries in Europe are investing through public and private funding. Canada will need to follow through with stronger enabling measures, including streamlined decision-making processes and incentives in what will be an internationally competitive environment.

Forests: GE Trees

The argument can be made that enhancing forest growth is a contribution to sustainable development for several reasons. First, the amount of land in timber production might be decreased since productivity would be much greater. This would protect nature, and possibly also reduce the amount of energy necessary for transportation, logging construction, etc. Second, local economic opportunities in rural areas would be increased due to the high value of forest crops. Third, greenhouse gas emissions might be reduced by the increased carbon sequestration. And enhanced forest growth is only one attribute that might be modified. Others include enhanced insect or disease resistance, and for pulp species, a reduction in lignin.

The most ardent opponents believe that most of the arguments in support of GE trees are spurious, and call for a global moratorium.[28] Canada has faced past problems over forest practices in some forest product export markets, and can ill-afford any such intervention around issues of GE tree products. It is not clear just how strong such opposition is within Canada, but some conservation and environmental organizations have taken strongly negative positions.

The Canadian Forest Service (CFS) maintains an active program of biotechnology research. This program has numerous components, with only a limited focus on transgenic activities. These activities are described as follows:[29]

> "The CFS was the first organization to successfully produce genetically engineered (transgenic) black spruce, *Picea mariana* (Mill.) BSP, and tamarack, *Larix laricina* (Du Roi) … Since then, the CFS has also produced transgenic white spruce, *P. glauca* (Moench) Voss, and European larch, *L. decidua* (Mill.), and is now working on transferring genes for pest and disease tolerance.
>
> To advance research in tree molecular biology, the CFS is developing protocols for gene delivery in various tree tissues such as flower parts and pollen. This will allow research scientists to bypass the long life cycle of tree species to verify patterns of expression of the introduced genes in mature tissues.

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28 C. Lang, *Genetically Modified Trees: The Ultimate Threat to Forests* (World Rainforest Movement and Friends of the Earth International: 2004): chrislang.blogspot.com/2004_12_20_chrislang_archive.html.

29 Natural Resources Canada, Canadian Forest Service, Biotechnology Research: www.nrcan-rncan.gc.ca/cfs-scf/science/resrch/biotechnology_e.html.

> Future goals include the introduction of genes for flower sterility into conifer species to minimize gene flow to related trees. The CFS is also conducting research with deciduous hardwood species such as poplar, aspen, and willow, with the aim of producing hardier and faster-growing trees."

CFS has restricted its field trials on GE trees to one field site in Quebec. The rules for such trials and also for any environmental release (unconfined field trial) would be enforced by the Canadian Food Inspection Agency (CFIA) in the same way as for GE food crops.

There will be other commercial pressures to release GE trees. These pressures may come from companies interested in fast-growing trees suitable for pulp and paper, fruit trees, and possibly for ornamental species. And Canada will have to decide how to address the possibility that GE trees could enter, either as seeds or seedlings, from other countries that will embrace GE tree technology.

While there may be many other applications of genetic engineering involving forest use – including GE pest control and GE micro-organisms for use both in pulp processing and to reduce energy and pollution from chemical processing – the widespread, commercial-scale use of GE trees for either reforestation, plantations optimized for pulp and paper, or other timber use, is unlikely for the coming 10 to 15 years in Canada. It may not be desirable at all from a sustainable development perspective. Much depends on the ability to contain gene flow and ensure that forestry plantations do actually deliver on environmental benefits.

Oceans: Marine Biotechnology and Marine Aquaculture

The potential of marine biotechnology is just beginning to be understood, in Canada and elsewhere. With three oceans and a great variety of conditions found in Canada's 200-mile zones and along our extensive coastlines, plus an ocean economy of at least $20 billion, this nation has every reason to take a comprehensive view of marine resources. Comparatively little is known about the microbial life of the oceans, currently one of the hottest prospects for marine biotechnology. Recently, the National Research Council (NRC) prepared an Oceans Technology Roadmap, including biotechnology possibilities. There is also an active Canadian ocean technology network starting to share experience in many aspects of marine R&D.

We examine some of the possibilities at the leading edges of ocean biotechnology, and also review marine aquaculture, where lines have been drawn quite definitively between proponents and those who are wary about this maturing industry.

Ocean Biotechnology

Marine organisms represent a new, and potentially one of the most significant remaining frontiers for scientists screening for unusual biological characteristics. Applications for medicine, industry, environmental remediation and food have been identified. Yet, it has not been possible to study as many as perhaps 99% of marine microbial organisms, let alone screen them for chemical products of potential commercial application. Some of the properties of interest unique to marine organisms include:

- Bioluminescence;
- The ability to live under extreme temperature or high sulphur conditions (e.g., around the hydrothermal vents), yielding material with pressure-resistant and heat-stable conditions of value for genetic engineering of industrial enzymes or in hazardous waste cleanup;[30]
- Novel chemicals including toxins, chemicals that will deter or attract other organisms, chemical bonding agents of interest as bioadhesives, and antifreeze of extreme cold water fishes.

Marine bioprospecting, that is, sampling marine biodiversity for future testing in the lab, on the scale proposed by many scientists from industrialized countries, raises a number of important considerations including:

- Benefit sharing with source countries, which often are poorer developing countries but certainly includes Canada as nation with three high biodiversity oceans;
- Conservation strategies, especially if significant amounts of the resource are removed;
- Impacts of cultivation where aquaculture methods are employed, as in the case of some algae culture; and
- Arrangements with local communities and indigenous groups.

It has been suggested by some that the arduous process of marine bioproduct commercialization should be accompanied by earmarking "a portion of future financial windfalls for support of marine conservation and sustainable coastal development, thus preserving as-yet-undiscovered marine bioproducts for the benefit of future generations".[31]

It should be pointed out that, while the *Law of the Sea* has exhaustively considered certain categories of resources, especially fish and mineral resources, it was written prior to the current understanding of biochemical properties and biotechnology of sea creatures was fully appreciated. Discussions are ongoing in this forum to frame the issue of bioprospecting appropriately, and then to develop solutions that work for all. It is instructive that the high-visibility, international marine bioprospecting expedition launched by Craig Venter in 2003 started on its world-wide sampling voyage from Halifax, Nova Scotia.[32] Canada will need to define how it wishes to manage the use of all forms of life in its oceans, including the microbes that are potentially as valuable to the world as the fish and other resources we seek to manage.

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[30] R. Colwell, "Fulfilling the Promise of Marine Biotechnology," *Marine Biotechnology in the Twenty-first Century: Problems, Promise and Products* (Wash., D.C.: National Academy Press, 2002).

[31] D. Gerhart, "Commercialization of Marine Bioproducts: Intellectual Property and Technology Transfer Issues," *Marine Biotechnology in the Twenty-first Century* (2005).

[32] www.sorcerer2expedition.org/version1/HTML/main.htm

In 2002, the global market for marine biotechnology products was about US$2.4 billion, with an annual growth rate of about 10%.[33] The interest in this sector continues to grow. In 2005, the International Marine Biotechnology Conference (IMBC 2005) took place in St. John's, Newfoundland. Almost 500 presentations were made to this state-of-the-art meeting, covering a wide range of topics. Box 2-3 lists some of the titles of promising research and applications. Clearly this is a topic that deserves careful tracking and possibly more policy attention.

Marine biotechnology is a topic that is of particular importance to Canada for a number of reasons:

- Canada's three oceans possess very diverse characteristics, including extreme conditions and rich biodiversity, the characteristics that attract Canadian and foreign bioprospectors;
- Ocean uses in Canada are increasing in both intensity and variety, placing increasing pressure on biodiversity and habitat. Ocean monitoring using biosensors, DNA analysis for fish stock identification and for enforcement evidence, and bioremediation for oil, metal and chemical cleanup are examples where biotechnology can help to manage ocean uses;
- Seafood safety, including pathogen detection, use of enzymes for reducing wastes in cage culture of seafood;
- Vaccines and other means of disease control for aquaculture, fish food from biofuel and other biorefinery residual materials, utilization of fish processing wastes in local biorefineries;
- Issues of transgenic organisms being introduced into Canada's oceans either through aquaculture or as alien invasive species;
- Commercialization, of products and scale as most activities are undertaken by small and medium-sized enterprises (some large fish processing plants are an exception);
- Access and benefits sharing with governments, local institutions and aboriginal knowledge and rights holders, for example those living in arctic areas; and
- Fostering of economic activities through marine biotechnology clusters in a number of Canada's coastal cities and provinces.

It is fair to say that attention given by Canada to policies for marine biotechnology have been minimal to this point. It is only in the past few years that Canada ratified the *Law of the Sea Convention*, thus ensuring a place at future negotiations.

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[33] Biobridge Ltd., *A Study into the Prospects for Marine Biotechnology Development in the United Kingdom* (January 2005): www.dti.gov.uk/sectors/biotech/agribusiness/biosciencemarine/page10522.html.

Box 2-3. Selected presentations at the 2005 International Marine Biotechnology Conference

Bioprospecting

Genomic and Proteomics of Magnetic Bacteria for Nano-Biotechnology

Marine Bacteria: A Potential Source of Anti-Angiogenic Compounds

Molecular Biomedical Prospecting of Sponges

New Anticancer Compounds from Marine Actinomycetes

Enzymes and Enzymatic Hydrolysates from Invertebrates of the Barents Sea

Economically Important Traits of Aquacultured Species

Aquaculture Genomics of Salmonid Fishes: Linkage Mapping, QTL, and Candidate Genes

Marine Nutraceuticals and Omega-3 Oils

Developing Transgenic Finfish and Crustaceans Resistant to Microbial Pathogens

A Re-evaluation of Triploid Bay Scallop Induction Methodology

Engineering Long-Chain, Omega-3 Fatty Acid Biosynthesis in Plants

Transgenic Salmon: Ideas to Market

Invasive Species (including Aquaculture Escapees)

Recombinant Approaches for Managing the Impacts of Invasive Species

Monitoring and Identification

New Analytical Technologies in the Hunt for Red Tide Toxins

Marine Biotoxin Monitoring and Research in New Zealand

Molecular Approach and Application to Identification and Traceability of Fish Product: An Example with Shark Fin Processed Products

The 'Fish Chip': A DNA Microarray-based Identification Tool for Fish Species in the North Sea

Molecular Phylogenetics of Gadidae [cod] Based on Complete Motochondria DNA Sequences

BOD [Biochemical Oxygen Demand] Chip Sensor with Marine Luminous Microorganisms

Bioremediation and Detoxification

Uptake and Detoxification of the Explosive TNT in Seawater by a Genetically Engineered Seaweed

Marine Extremophiles: Enzymes for Bioremediation Applications

Degradation of Endocrine Disrupters by Marine Bacterium

Oxidation of Gaseous Hydrocarbons by Marine Microorganisms

Waste Utilization

Processing of Marine Waste: Production of Hydrolysates Harbouring Specific Biological Properties

Source: IMBC 2005CIBM Abstracts www.imbc2005.org

Aquaculture

Aquaculture of species such as Atlantic salmon is an important and growing economic activity on both the Pacific and Atlantic coasts of Canada. Experimental work has demonstrated that GE salmon and likely many other species could grow faster and/or to a larger size. This would enhance profitability, especially if the fish can be raised on either a diet with less animal protein, or by needing less food altogether through greater efficiency in food utilization. There are other desired characteristics that appear amenable to genetic interventions, for example, ability to withstand very cold conditions, and better survival rates under the stressful conditions of intensive cage culture.

The problem, of course, is that intermingling of wild fish and escapees from fish pens could produce situations where new genetic material is introduced into the wild gene pool, possibly to the detriment of existing wild stocks. This situation is considered untenable by many scientists and conservation organizations. On the West Coast of Canada there are some 9600 genetically distinct stocks of salmon, so the issue cannot be taken lightly. And on the East Coast, where most wild stocks are imperilled, there is concern that salmon with novel genetic traits could take over habitat and make restoration of wild stocks more difficult or impossible. One possible solution is to move any such aquaculture onto self-contained land-based facilities, greatly reducing the risk, although increasing production costs.

The GE aquaculture issue was reviewed in 2002 by the Department of Fisheries and Oceans (DFO) in response to a petition by Greenpeace to the Office of the Auditor General, Commissioner on Environment and Sustainable Development. At that time, DFO indicated it was preparing regulations. As of June 2004, in a CESD follow-up report[34], DFO indicated that it could not give a timeline for completing the regulations. In the absence of regulations, it is doubtful that GE fish will appear in open cages, but there certainly will continue to be demands for introduction of fast- growing fish, and likely even stronger demands for a ban on such activities.

Aqua Bounty Technologies Inc., and its Canadian subsidiaries located in Newfoundland and PEI have developed fast growing Atlantic salmon and fish with a capacity to withstand cold winter water conditions. They would like to see these fish introduced into Canadian aquaculture, and present the case for their contribution to sustainability[35]:

> "The advent of technologies such as those being developed by Aqua Bounty Farms will allow the aquaculture industry to be an even more environmentally beneficial technology, providing sufficient seafood to the world's consumers at low cost. These objectives are in keeping with a commitment to what Aqua Bounty Farms calls the Blue Revolution: Bringing together technology from the biological sciences and engineering to produce an aquaculture industry capable of large-scale, low-cost production that is independent of proximity to the oceans and less invasive to the environment. Increased growth rates, enhanced resistance to disease, better food-conversion rates, alteration of breeding cycles, and more efficient use of indoor water-recycling plants are all aspects of this revolution."

[34] Office of the Auditor General of Canada, *Timelines Set by Fisheries and Oceans Canada for Completing Regulations on GE Fish,* Report of the Commissioner of the Environment and Sustainable Development (2004): www.oag-bvg.gc.ca/domino/reports.nsf/html/c20041006se02.html.

[35] Aqua Bounty Farms. *Technology for Sustainability:* www.aquabounty.com/.

The case for GE aquaculture will continue to be made, although there will be many opponents. However, there will be other countries that will see introductions. Much of the opposition will focus on the key question of sustainability, especially in relation to impact of aquaculture on the food chain. What will Canadian policy be towards the marketing of products in Canada, and will we be effective in monitoring the arrival of imported broodstock or accidental releases (including young specimens of temperate zone GE fish that might be introduced via the aquarium trade)?

There are other ways in which Canada can excel in aquaculture biotechnology that are likely to be of great value to aquaculturalists here and elsewhere in the world. These applications include development of vaccines and disease control measures; continued efforts to broaden the use of monitoring tools for identification of fish stocks and for ocean environmental monitoring within and around aquaculture areas; and the development of new feed and use of wastes. Initiatives such as these will create added value for fish farmers and processors, and likely have beneficial environmental impacts such as reduced pollution, reduced need for antibiotics and chemicals, and reduced amount of fish sourced for aquaculture feed.

Cooperative Approach for Ocean Biotechnology

The oceans cover most of the planet and form the largest global commons. Their health is a concern, yet scientists have barely started to understand the rich genetic makeup of sea life, and potential benefits and management needs. What stands out is the need for a cooperative approach to make the best use of marine biotechnology, and to define applications that will assist in a number of areas such as sustainable aquaculture. This was an important theme at the 2005 St. John's IMBC meeting, and in Canada there are promising endeavours such as AquaNet[36], which supports research in sustainable aquaculture.

Industrial "White" Biotechnology

Industrial biotechnology is in many ways the "sleeper" among the array of biotechnologies. Far less controversial than green biotechnology since, with products such as industrial enzymes, there is little that finds it way into final products, or has the possibility of living in the natural environment. Furthermore, there is an up-front effort to promote industrial biotechnology as a major contributor to industrial sustainability. Industrial biotechnology may offer a triple win—"good for the planet, profits and people." The leading edge initiatives, based on closed loop systems, are often labelled "Industrial Ecology."[37]

The field of industrial biotechnology is actually a very complex aggregation of technologies. Some are linked to medical biotechnology, since medical R&D can serve both areas. Green technologies are highlighted, since utilization of agricultural and forest products and wastes is an important industrial component, leading to "bioproducts." Beyond these examples, there is huge potential for transforming industrial processes by substituting biological processes for existing multi-stage synthesis of chemicals or manufactured products such as plastics.

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[36] Networks of Centres of Excellence on Aquaculture hosted at Memorial University and University of British Columbia, supported by NSERC and other research organizations.

[37] R. Côte et al. (eds), *Linking Industry and Ecology: A Question of Design* (Vancouver: UBC Press, 2006); International Society for Industrial Ecology: www.yale.edu/isie/.

The notion of "white biotechnology" is being promoted in Europe and the US.

> "It uses living cells—from yeast, moulds, bacteria and plants—and enzymes to synthesize products that are easily degradable…The benefits of exploiting natural processes and products are manifold: They do not rely on fossil fuels, are more energy efficient and their substrates and waste are biologically degradable, which all helps to decrease their environmental impact." [38]

There are numerous examples of such applications already in use, or in experimental stages of development. Transgenic *E. coli* used in large fermentation tanks for the production of human insulin is one. Use of enzymes instead of harsh chemicals for the scouring process to remove brown, non-cellulose parts of cotton for textiles is another. Polymers and bulk chemicals are areas where commercialized products are most likely to be found at present. But in future, the emphasis will also be on "fine chemicals," for example biological pharmaceuticals that are focusing on antibody-based cancer treatment. Another category is specialty chemicals, such as production of flavours and fragrances, where there already is use of enzymes and fermentation processes. McKinsey and Company believe that by 2010 perhaps 10 to 20% of all chemicals sold will involve biotechnology applications. For fine chemicals, the share could be as great as 60%.[39]

As efforts intensify to address greenhouse gases and other impacts of fossil fuel, the industrial use of biotechnology will increase. This provides much of the basis for what is called, in Canada and the US, the "bio-based economy". The notion of moving away from a hydrocarbon-based economy to a "carbohydrate-based economy" is not new. But many obstacles remain, including financial costs (plastics so derived may still be 5 to 10 times as expensive to produce), environmental costs in terms of pesticide, fertilizer and water needed to grow the extra biomass, and conversion efficiencies from biomass into bioproducts and energy. The complexity of these considerations has yielded some dubious whole life-cycle results, and make clear-cut analysis very challenging.

There is no single focus for industrial biotechnology. We have looked at a number of examples already in this Chapter, including the role of enzymes, pulp and paper opportunities, and biorefineries. The opportunities are spread over a number of other fields, such as chemical production, pharmaceuticals, textiles, agrifood, and mining (bioleaching). The OECD has produced very useful studies promoting the possibilities of industrial biotechnology. Interest and investment in "white" biotechnology appear greatest in Europe, with the US, Japan and China as strong competitors.[40] Where Canada fits into this picture is not very clear, unless one examines specific sectors in detail. Even so, there is not a sense of priority for this topic within Canada, by comparison to the attention given in Europe. The 3rd World Congress on Industrial Biotechnology

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38 European Molecular Biology Organization, 2003. *White Biotechnology.* EMBO Reports 4 (9): 835-837.

39 EuropaBio, *White Biotechnology: Gateway to a More Sustainable Future* (2003): www.europa-bio.be/.

40 See reviews of this subject including: OECD, *Biotechnology for Clean Industrial Products and Processes: Towards Industrial Sustainability* (1998); OECD, *The Application of Biotechnology to Industrial Sustainability* (2001); A. Sasson, *Industrial and Environmental Biotechnology, Achievements, Prospects and Perceptions*, (Yokohama, Japan: Institute for Advanced Studies, United Nations University: 2005); EuropaBio, *Industrial or White Biotechnology. A Driver of Sustainable Growth in Europe*, Working Document as Input for European Technology Platform in Sustainable Chemistry: www.europa-bio.be/TPWhite/IB_Vision.pdf.

and Bioprocessing took place in Toronto in July 2006. It was billed as a convergence of biotechnology, chemistry and agriculture to create new value chains. Perhaps that is the way we might think most clearly about this complex set of endeavours.

Bioremediation

Of the various main themes concerning biotechnology and sustainable development, bioremediation would appear to present a compelling case. The problem, in Canada and elsewhere, is clear enough. According to the National Round Table on the Environment and the Economy (NRTEE), there may be as many as 30,000 brownfield sites in Canada. These are defined as "abandoned, idle or underutilized commercial or industrial properties where past actions have caused known or suspected environmental contamination, but where there is an active potential for redevelopment." [41] High profile cleanups such as the Sydney Tar Ponds consume hundreds of millions of dollars. Thousands are of a much smaller scale, for example, gasoline station storage tanks requiring soil remediation, mine sites with acid drainage, and small industrial or commercial sites. Government lands and military bases sometimes require extensive remediation, for example the network of DEW Line sites[42] in the arctic. There is a strong financial commitment on the part of the Federal Government and also from other levels of government to address these needs. It will take decades to fully address the problem.

Meanwhile, accidents do happen. Coastal oil spills present a case where bioremediation works. Microbes are highly effective for these cleanups and other purposes. Thus, bioremediation will be needed even after the backlog of problems from the past is cleaned up. The examples of research concerning "marine extremophiles" noted in Box 2-3 cover microorganisms that can thrive on certain pollutants, even breaking down explosives left over from ordnance on the ocean floor. And it is in this context that genetic engineering becomes important, since it would be desirable to have traits helpful for the breakdown of waste placed into microbes or into larger plants (macrophytes) optimized for various environmental conditions. Fast-growing trees that could extract heavy metals from contaminated soil is one example. Another is seaweed able to remove toxic wastes.

There are many researchers around the world and some in Canada engaged in GE bioremediation. One of the leading centres is the NRC Biotechnology Research Institute (NRC-BRI) in Montreal. An example of their research is the breakdown, by GE bacteria, of a groundwater and soil contaminant, the fuel additive MTBE:

> "The genes controlling an MTBE degradation pathway have been isolated from a strain of *Mycobacterium austroafricanum,* a bacterium that possesses the rare ability to use MTBE as a sole carbon and energy source. The genes have been sequenced and expressed in a heterologous micro-organism in order to confirm their role. A biological barrier using this micro-organism has also been developed for the bioremediation of MTBE-contaminated water sources."[43]

[41] NRTEE, *Cleaning Up the Past, Building the Future. A National Brownfield Redevelopment Strategy for Canada* (2003): www.nrtee-trnee.ca/Publications/PDF/SOD_Brownfield-Strategy_E.pdf.

[42] The "DEW (Distant Early Warning) Line" is a set of 58 surveillance sites, primarily using radar constructed during the Cold War to detect incoming attacks: www.lswilson.ca/dewline.htm#C.

[43] National Research Council of Canada, *Biotechnology Research Institute: A Global Player*, 2004/2005 Annual Report: www.bri.nrc-cnrc.gc.ca/files/ar_04-05_eng.pdf.

There are many similar examples that could be cited. All face an uphill struggle about release of genetically engineered organisms into natural environments. The case of bioremediation has not attracted the same level of public attention as GE crops and foods. However, ecological scientists are wary. The Ecological Society of America includes bioremediation on its list of possible areas of concern related to GE organisms and the environment.[44]

For reasons of precaution, the availability of alternatives, such as screening and use of natural organisms from the forest floor, ocean bottom and soil, and a range of other methods such as increasing air circulation or oxygen flow to enhance breakdown, acceptance of GE biotechnology in bioremediation has been slow.[45] We believe that this will continue to be the case, but the tools, whether or not they involve GE organisms, deserve careful attention and research. Over time the arsenal of commercially available, highly effective, but also highly controlled bioremediation agents will contribute to environmental improvement.

Timelines

What kind of timelines are we expecting for the mainstreaming of BSDE? Our timeline table is based on extensive review of current initiatives and projections worldwide. It shows biotechnology innovations from 1995 to date, along with our outlook for 2007 to 2020. In reality, timelines will depend on regulatory and investment decisions, and on public and consumer acceptance of products. Nevertheless, we will likely possess the necessary scientific and technological knowledge for each category within the timeframes noted. We envisage that by 2012, BSDE will have become a mainstream technological and economic activity.

We place considerable emphasis on bioproducts and biorefineries, since these are likely to be most significant in terms of policy decisions, and in terms of need for new assessment processes. Industrial use of enzymes will proceed at rates determined by industrial R&D and re-tooling of industrial processes. Bioremediation, while in use for activities such as oil spill cleanup, may be introduced rather slowly, as specific techniques are developed.

[44] A.A. Snow et al., "Genetically Engineered Organisms and the Environment: Current Status and Recommendations," *Ecological Applications* 15(2) (2005), pp. 377-404.
[45] M. Watanabe, "Can Bioremediation Bounce Back?" *Nature Biotechnology* 19 (2001), pp. 1111-1115.

Timeline for Canadian BSDE Applications

1995	2005	2015	2020
Agriculture			
GE crops, bioengineered pest control			
	Bioethanol/biodiesel		
		Cellulosic ethanol	
		Advanced biorefineries (chemicals, plastics)	
		"Molecular pharming" (drugs, industrial feedstock)	
Forestry			
Pulp and paper use of black liquor for chemicals			
		Forest processing advanced biorefineries	
Bioengineered forest pest control			
			GE trees?
	Gasification of waste wood (energy and chemicals)		
Aquaculture			
DNA analysis of stock characteristics			
		Marine medical bioproducts	
		Biodiagnostic testing	
		Bioengineered vaccines & medicines	
		GE aquaculture products	
Industrial biotechnology			
	Widespread use of enzymes		
Bioremediation			
GE microbes for oil spill cleanup			
	GE microbes for brownfield cleanup		
	GE macrophytes for brownfield cleanup		

Conclusion – Just Imagine in 2020 …

We start our BSDE Executive Report with a scenario that covers both promises and premises around which we might build the relationship between biotechnology and sustainable development, to provide a good level of benefits for Canadians by 2020. We wish to end this Chapter with some excerpts from the scenario.

Just Imagine ... in 2020 …

A Canadian society where:

> *A flourishing rural economy supplies one-quarter of Canada's fuel, chemical and synthetic product needs from renewable biomass sources…*
>
> *A 50 percent reduction occurs in the use of harmful chemicals that accumulate in the environment and in peoples' bodies…*
>
> *A successful national strategy of "biowaste to bioproduct" is implemented in cities and rural communities across the country, based on the conversion of commercial food wastes, household compostable wastes, manure, aquaculture, agriculture and forest residues into biofuels and feedstocks for use in newer, cleaner chemical processes that reduce fossil fuel consumption…*
>
> *A well-established and successful eco-efficiency effort exists within Canadian industries—partly based on the use of new enzymes to prevent pollution, and reduce material and energy use by three or four percent each year per unit of manufactured product…*
>
> *An end occurs to contaminated industrial, mining and other "brownfield" sites, assisted by new biological remediation techniques for cleaning up past messes and treating current operations…*
>
> *An effective national network is in place for monitoring the health of local ecosystems, relying not only on inexpensive biosensor monitoring tools, but also on the commitment and involvement of local communities and citizen groups…*
>
> *A concerted effort by Canadian researchers, entrepreneurs, businesses, and government officials leads to new vaccines, crop varieties and environmental technologies needed to meet the Millennium Development Goals[46] for global sustainable development—including biological control for human, fish, plant and livestock diseases; drought-resistant crop varieties; and advanced water pollution control for communities and industry…*

These actions are driven by a growing realization of the magnitude of environmental and development challenges Canada and the world face. Our society embraces rigorous principles to reduce and eliminate environmental damage, and to improve quality of life.

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[46] Eight goals, to which all countries and international development institutes agree, for meeting key needs of the world's poorest people by 2015: www.un.org/millenniumgoals.

Biotechnology is a major contributor to each of these seven imagined 2020 outcomes—a means *to achieve important sustainable development goals of environmental quality, new economic opportunities and improved quality of life for Canadians and people elsewhere. But these new biotechnology applications are quite different from innovations such as the early genetically modified crop introductions of the 1990s. These new applications are far more integrated into the mainstream of industrial and community activities and decisions. Most are multiple-step initiatives, where biotechnology and other innovations are introduced at various stages. Some stages involve genetically engineered organisms, others do not. Many applications, such as industrial enzymes, operate in closed environments, or, as in the case of genetically engineered vaccines, are unlikely to affect the natural environment.*

Just Imagine in 2020 … Four Big Trends

The following four trends helped the transition involving biotechnology and sustainable development:

- *Cellulosic ethanol production leading to biorefineries.*
- *Canada's stringent approach towards eco-efficiency and persistent chemical contaminants.*
- *Community and industry-led initiatives for seeking value-added uses of wastes and contaminated sites.*
- *Greater integration of science and technology applications into international development problem-solving.*

We believe that *Just Imagine ... 2020 ...* is attainable. In fact, through Canada's investments in scientific R&D at Canadian universities and research centres such as the NRC and the International Development Research Centre (IDRC), and through provincial innovation centres and the private sector, we have starting points for each of the outcomes mentioned. Yet, make no mistake: achieving these outcomes will take concerted effort on the part of several sectors, public acceptance, and strategic use of political energies. The effort should be worthwhile.

CHAPTER 3. Healthy Ecosystems, Healthy Communities

Most Canadians recognize that they and their communities are integral parts of ecosystems at both local and global levels, and that their activities therefore affect the functioning of ecosystems. Since the publication of Rachel Carson's *Silent Spring* in the early 1960s, the complex linkages between human and ecosystem health have been recognized—with increasing concern over toxic chemicals and, now, growing concern over the magnitude of the ecological footprint[47] of our communities. But the relationship is, of course, much broader, extending to the impacts of poorly managed watersheds on downstream communities; the loss of biodiversity through intensive agricultural practices, and carbon emissions arising from forest fires in Canada's boreal forests, for example.

The issues at stake are becoming clearer, based on many studies, for example, the half century of detailed ecosystem research on the Great Lakes and St. Lawrence River and their surrounding lands; studies on the accumulation of organic pollutants and heavy metals in the ecosystem and bodies of people living in arctic ecosystems; the economy of communities affected by ecological change such as the damage created by the pine bark beetle; and the effects of smog in some large cities such as Toronto.[48] Problems also occur at a smaller scale—drinking water quality in smaller towns and isolated native communities, clean-up of contaminated sites surrounding mines and industrial sites such as Britannia Beach in BC, and the Sydney tar ponds in Nova Scotia.

As noted in Chapter 2, the types of problems indicated above and others may represent opportunities for biotechnology applications. But is Canada well placed to realize potential biotechnology benefits in addressing clean, healthy ecosystems and communities? And what fundamental knowledge is needed for citizens and regulators to be comfortable about embracing such innovative technologies? We believe that it is necessary to look at these questions first and foremost, at scales relevant to the natural surroundings of communities, but also on more distant effects such as those related to climate change.

An ecosystem[49] is a basic natural unit in which living organisms and their physical environment exist in a dynamic relationship. It is an energy processing system whose components evolve together. The health, or functional integrity, of an ecosystem is determined by comparing an ecosystem against criteria such as those listed below:[50]

- ecosystem integrity and resilience;
- ecosystem productivity;
- ecological structure and biodiversity;

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[47] J. Wilson and M. Anielski, *Ecological Footprints of Canadian Municipalities and Regions*, Prepared for the Federation of Canadian Municipalities (2005): www.anielski.com.

[48] www.ec.gc.ca/ecosyst/backgrounder.html; www.eman-rese.ca/eman/reports/assessments; www.davidsuzuki.org; www.cec.org/soe; www.whc.org/climate_change.htm.

[49] Ecosystem is used in the sense of the major British and American scientific societies and based on the early work of A. Tansley, G.E. Hutchinson, Eugene Odum and others in the 1930s to 1950s.

[50] D. Rapport et al., *Ecosystem Health* (Malden, MA: Blackwell Science Inc., 1998): www.ec.gc.ca/ecosyst/backgrounder.html; D. Waltner-Toews, *Ecosystem Health and Sustainability* (Cambridge University Press, 2004).

- range of economically useful products and ecological services; and
- "special" characteristics and values (e.g., spiritual values, ecological corridors through landscapes permitting migrations, presence of specific creatures, plants).

In 2005, the global scientific community published the Millennium Ecosystem Assessment[51], a large-scale assessment of the earth's ecosystems based on criteria similar to those listed above. The Assessment expressed concern that communities and people everywhere are in danger of losing important ecological services that we take for granted, such as flood protection, natural air quality, the maintenance of soil fertility, and water purification. There is good reason for this concern, which can be traced in large part to a lack of effective stewardship of natural resources and ecosystems. Toxic substances leaking from old industrial sites (brownfields) and pesticides of various kinds are increasingly linked with human disease as well as air and water pollution. Persistent organic pollutants (POPs) and heavy metals discharged by industry are appearing in remote northern ecosystems where they affect biodiversity and human health. The lesson learned from the Millennium Ecosystem Assessment is that without adequate attention to long-term and cumulative effects based on careful and continuous monitoring, we will continue to see a loss in the basic functions of the ecosystems on which we depend.

There are also sociological reasons to be concerned about community health. Towns facing closure of primary industries such as pulp and paper, farmers living with crises year after year, and coastal communities struggling to survive the loss of productive fisheries all pin their hopes on discovering new economic opportunities. In the absence of such opportunities, the health of individuals and their community declines. It is not surprising therefore that governments around the world are rushing to biofuel opportunities, driven as much by the need for rural support as for other benefits. In summary, people, industry and communities must formulate better ways to obtain economically significant products and services, without compromising the integrity and functionality of ecosystems.

In this Chapter, we will consider how biotechnology may promote, or detract from, the stability of the relationship between human communities and natural ecosystems. We will identify some critical gaps in knowledge of the impacts of biotechnology on ecosystems, and point to the lack of an adequate process to build this knowledge. The Chapter also serves as an introduction to the next three, which provide more in-depth discussion of rural benefits, BSDE assessment, and deliberative dialogue.

A unifying theme of our focus on healthy ecosystems, healthy communities, is the recognition that for communities and their residents to fully profit from biotechnologies (or other major types of innovation), they must have access to and capacity to act on ecological and other information affecting their collective future.

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[51] www.millenniumassessment.org/en/index.aspx

Healthy Communities and Biotechnology

As the Federation of Canadian Municipalities (FCM) notes, "a sustainable community is a '*smart community*'." It achieves economic, environmental and social health by: making the most efficient use of resources, generating the least amount of waste, providing high quality service to its residents, [and] living within the carrying capacity of its natural resources—land, water and air." In other words, it operates in harmony with its ecosystem.

One of the principal ways in which communities may benefit is through building clusters of expertise and investment in technologies specific to particular sectors, for example in health or agrifood, the two most commonly developed clusters in both Canada and the US.[52] Certainly in a number of medium to large cities in Canada such biotechnology clusters have become important. While it may be possible for certain clusters to develop on a smaller scale, for example, in Maritime Canada for marine bioproducts, or in the Prairies for biofuels and other wastes, the future is less clear for environmental biotechnology, and for specialized industrial enzyme development. The dilemma is particularly difficult for smaller centres, including those in remote regions, typically with smaller, resource-dependent communities.

One way in which smaller rural communities may be able to benefit from biotechnology is by embracing those processes that can be adapted to small-scale operation. It should be possible to build biodiesel and bioethanol refineries on a scale that would serve a regional market, thus providing a local outlet for the raw material, reducing the transportation costs involved in distribution of the product, and reducing the heavy reliance on fossil fuel that characterizes modern agriculture. Similarly, it should be possible to install manure digesters in most medium- to large-scale hog operations to produce methane for heating and solve waste disposal problems. An interesting initiative is the Ottawa

Box 3-1. Federation of Canadian Municipalities (FCM) on SD technology

The FCM has noted the value of seeking new technology solutions for sustainable development, and actively pursues their application in a number of ways.

Bio-based Technology Clusters for Rural Development – In its 2005 policy statements, the FCM noted that, along with information technology and 'telehealth' clusters, the "revitalization and development of rural and northern communities would be greatly enhanced with a focus on bio-based technology clusters." These clusters could use "renewable bio-resources" and "eco-efficient bio-processes" to produce sustainable, environmentally-friendly bioproducts, while creating employment in both rural and urban communities. "Advances in the development and marketing of products derived from natural resources will enhance economies of rural and northern communities and will result in new networks, products and processes."

Remediation and Improvement of Community Environmental Quality – Through its Centre for Sustainable Community Development, FCM also provides financial services and resources to help municipalities improve environmental performance and reduce greenhouse gas emissions. In 2000, the Government of Canada endowed FCM with $125 million to launch the Green Municipal Fund. Established to spur investment in municipal projects aimed at improving air, water and soil quality, and reducing emissions, the fund was doubled in 2001 to $250 million, and increased again in 2005 by $300 million. Half of that amount has been earmarked for the remediation of brownfields.

Source: www.fcm.ca

[52] Government of Canada, *Biotechnology in Canada. A Regional View* (Industry Canada, Life Sciences Branch, March 2004): PowerPoint slides; J. Nioisi, "The Competencies of Regions. Canada's Clusters in Biotechnology," in G. Fuchs (ed), *Biotechnology in Comparative Perspective* (London: Routledge, 2003).

Valley-based eco-industrial Bioproducts Business Network, centred in part around byproduct synergy—optimizing waste and energy use.[53]

The FCM suggests that an appropriate way to catalyze action and value from environmentally-oriented biotechnologies may be through clusters of bio-industries (see Box 3-1). Such clusters exist in Saskatoon (agrifood and likely biofuels), Halifax (marine), and perhaps in Alberta (biorefineries in the future). The FCM suggests an approach that would bring benefits to rural areas and northern communities. The FCM also has played a significant role in brokering funding for the application of green technologies for municipal infrastructure. This is an area where there could be future biotechnology applications, even though most of the money now being spent involves quite conventional approaches.

These are still early days, however. Consider the list of already identified prospects from Chapter 2, summarized in Box 3-2. These currently make only a small contribution to Canada's overall economy, and their contribution to ecosystem health and healthy, sustainable communities is still very limited.

We conclude by noting that Canadian communities—rural and urban, large and small—have a very legitimate stake in the future of BSDE. Their interests are informed by perceived benefits—primarily the health of individuals and quality of life of the community, ongoing and new economic opportunities, and the health of ecosystems and the environment. Local stock-taking will also measure biotechnology benefits from the perspective of consumer choice, and access to and sharing of benefits from new initiatives. Major centres already feature "biobased" clusters, largely centred around medicine and food R&D. The challenge is to invest wisely in applications and potential scientific and development clusters focused on rural needs. We will take a more in-depth look at this challenge in Chapter 4.

Box 3-2. Potential applications of biotechnology to community and ecosystem health

- Sustainable livelihoods in rural communities through locally-based agricultural and natural resource processing including bio-fuel and bio-chemicals (e.g., expansion of bioethanol production from industrial grain in Minnedosa, Manitoba);
- Improved farm safety by reduction in biocides and fertilizers (canola production on no-till landscapes on Prairies);
- Byproduct synergies for industrial ecology (e.g., cooperation among local industries in Ottawa Valley);
- Advanced energy production including biogas and off-grid electricity;
- Value-added municipal and food industry waste processing;
- Air pollution reduction through bio-energy sources including biodiesel and ethanol-gasoline fuel;
- Safer drinking water and cost-effective sewage treatment;
- Reduced livestock and human public health risk of pandemics via new vaccines (e.g., genetically engineered avian flu vaccine to protect chickens, and possibly more effective vaccines to protect humans); and
- Environmental restoration and remediation of polluted mine sites, waterways, etc.

Source: www.fcm.ca

[53] www.ontariobioproducts.com/regional-networks/eastern.aspx

Knowledge for Healthy Ecosystems

While there is a compelling need to do more for achieving sustainable development, it is also important that we understand the full range of effects, and act to mitigate or remove undesirable ones. In order to understand the extent to which biotechnology is contributing to a healthier environment, adequate monitoring systems must be put in place to measure its impacts. This is especially important because even well-intentioned interventions in natural systems can result in unanticipated consequences—for example, the elimination of native species by invasive alien ones, or the cumulative effects of synthetic chemicals such as those found to be endocrine disruptors. Biotechnology links molecular and genetic-level interventions in life processes to ecosystem-scale outcomes, certainly at a level of human intervention never before experienced. Therefore, if we hope to achieve *healthier* ecosystems through biotechnological innovations, we must build a better understanding of ecosystem dynamics and how these natural systems are influenced by the use of biotechnology. This is a difficult task, one that so far has not been fully implemented. Such information will be crucial to developing responsive, smart regulatory strategies.

Reliable, publicly available information about the impacts of biotechnological innovations on the environment will enable society to adopt a systematic adaptive management approach to these new technologies. The availability of credible impact assessments will reduce the need to apply the precautionary principle, with the result that the regulatory environment will be less cumbersome and the market for innovative products will be more open.

Assessing Ecosytem Impacts of Biotechnology Innovations

Biotechnology is not an isolated technology; it is usually deployed as part of a larger technological innovation to a new or ongoing activity. For example, herbicide tolerant canola (a biotechnology innovation) is grown in an agricultural system that, compared to conventional canola, reduces the number of herbicide applications, changes the nature of the herbicide applied, and may involve the use of different agronomic practices (no-till). Similarly, innovations in industrial practices, such as industrial enzymes that replace inorganic catalysts and fermentation processes that transform corn into ethanol, are expected to benefit ecosystems by reducing the demand for heavy metals and reducing the damage associated with petroleum products, respectively. It is these *associated practices*, whether facilitated by biotechnology or not, that may well have the greatest environmental impacts.

Our prescriptions for generating better knowledge about biotechnology's ecosystem impacts must be understood, then, in the context of their association with the full range of effects associated with natural resource or other industries, keeping in mind cumulative impacts. Especially in a country with the scale of land mass and extractive activity of Canada, the understanding of ecosystem effects must be grounded in an understanding of the significance of ecosystem scale (global, regional, local, "micro-ecosystems", ecotones) and ecological linkages between and within ecosystems. This is a challenge because the data can be expensive and difficult to obtain as consistent input, and the appropriate analytical models are still being developed. It is a necessary approach, however, if we are to adaptively manage ecosystems within larger landscapes or regions. Research and monitoring programs that would document the health of ecosystems should be referenced in a national system that monitors the effects of human activities on essential ecosystem services.

Certain types of ecosystems and ecotones will require special attention when it comes to monitoring and assessment efforts. Agricultural biotechnology innovations are often applied in ecosystems that are already highly modified. In these cases, special attention must be paid to the adjacent areas or ecotones. It is here that native species are most likely to be exposed to modified management practices and organisms or novel genes. Other key areas are coastal and freshwater aquatic ecosystems, plantation forests, constructed ecological wetlands, and ecosystems involving bioremediation. Natural forested ecosystems, too, are especially vulnerable because of the long-lived nature of many of the dominant species. Soil fungi, microbes and invertebrates that promote decomposition, nutrient cycling and pollination must also be monitored to ensure that ecosystem processes are sustained.

Box 3-3. Approaches to collecting baseline and general surveillance data

The collection of baseline and surveillance data on such essential topics as biodiversity, spatial distribution of vegetation, and soil quality can be expensive and scientifically demanding. Information on these topics for ecosystems in Canada is often incomplete, with large data gaps; also, older data may no longer provide an adequate assessment of the current status of ecosystems. Four potential sources of baseline and general surveillance data are described below

Museum and herbarium collections can provide information on the distribution of species through time and across space.

Taxon-specific biodiversity monitoring programs, such as the Breeding Bird Survey and Plant Watch, use volunteer observers to track the status of particular taxonomic groups over time.

Broad-scale biodiversity monitoring programs, such as NatureServe (formerly the Association for Biodiversity Information), a continent-wide network including NatureServe Canada, aim to provide an overall measure of the state of environment over time. The Alberta Biodiversity Monitoring Program, covering the entire province, is another such project in Canada.

Trained-observer networks consist of personnel (e.g., agricultural extension workers, fisheries officers) who have experience in a particular ecosystem, and a trained eye to note changes that may occur after a release. Expert advisory groups have endorsed this concept as relevant to the monitoring of biotechnology innovations, because it could be a cost-effective approach to gathering ecosystem data (ESA, 2005;NRC 2002).

Source: Canadian Food Inspection Agency. (2006). Discussion Document prepared for the Joint Workshop of the Baseline Data Node and Ecosystem Impact Node of the Ecosystem Effects of Novel Living Organisms (EENLO) Initiative. March 2 and 3, 2006. Ottawa.

The availability of comprehensive baseline data is an essential starting point for an effective monitoring system to determine the effects of any product or activity. Some potential data sources are indicated in Box 3-3, and a framework for dealing with effects is outlined in Box 3-4.

Box 3-4. Ecosystem impact monitoring: Framework and approaches

Three targets for post-market monitoring (PPM) can be distinguished: anticipated effects, interactive or cumulative effects that are difficult to predict, and entirely unanticipated effects (ACRE, 2004).

- *Anticipated effects* and some difficult-to-predict effects can be addressed through *case-specific monitoring* (CSM). CSM is hypothesis-driven research to test whether a possible environmental effect, identified during the initial pre-release risk assessment, actually occurs after commercial release of the novel living organism (NLO). An example of an anticipated effect is the development of insect pest resistance to a *Bacillus thuringiensis* (*Bt*) toxin produced in a plant with a novel trait (PNT).
- *Cumulative effects* that are difficult to predict can result from the release of an NLO over spatial scales and time spans far larger than those used in confined field trials. *Interactive effects* that are difficult to predict may result, for example, from the interaction of an NLO with other NLOs that are released in the future.
- *Unanticipated effects*, and some difficult-to-predict effects, cannot be addressed by the hypothesis-driven research of CSM. Cumulative and unanticipated effects must be addressed through *general surveillance of ecosystems* following the release of an NLO. If a change in an ecosystem is detected, then subsequent hypothesis-driven research may establish a causal relationship between the change and the NLO.

Source: Canadian Food Inspection Agency. (2006). Discussion Document prepared for the Joint Workshop of the Baseline Data Node and Ecosystem Impact Node of the Ecosystem Effects of Novel Living Organisms (EENLO) Initiative. March 2 and 3, 2006. Ottawa

There undoubtedly will be opportunities for links with other monitoring programs that already exist or will arise in response to future needs, such as emerging diseases, invasive species, and conservation studies. As molecular tests for species and sub-species become cheaper and cheaper, they will increasingly be used and there will be opportunities for leveraging information from these disparate programs in conjunction with other broader ecosystem monitoring programs.

Generating Knowledge: The Case of "Novel Living Organisms"

Many proposed biotechnology innovations have (or are expected to have) ecosystem impacts. The use of enzymes in pulp and paper production, the use of biological waste material as feedstocks for biorefineries, and DNA probes to determine water quality are examples of some of the innovations being considered whose positive ecosystem impacts are an important part of the drive to develop them. But no biotechnology innovation has captured the public's imagination like that of organisms whose genetic material has been modified through the tools of modern biotechnology, commonly known as "genetically modified organisms" or GMOs. In Canada, they are referred to as "novel" organisms, because our regulatory system recognizes new things, regardless of how they were derived. This section deals with the case of "novel living organisms" (NLOs) as an example of how we think a biotechnology innovation should be assessed in relation to ecological effects.

Box 3-5. Canadian assessment criteria for plants with novel traits (PNTs)

The environmental safety of plants with novel traits is assessed on five criteria affecting potential:

- for the PNT to become a weed of agriculture or be invasive of natural habitats;
- for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive;
- potential for the PNT to become a plant pest;
- potential impact of the PNT or its gene products on non-target species, including humans; and
- potential impact on biodiversity.

Source: www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml#ch6-1

Where are we now with assessing NLOs? The Federal Government has a science-based regulatory system in place to address potential science-based risks due to the environmental release of novel organisms (such as PNTs, "plants with novel traits", in Box 3-5), and this system has approved a number of organisms, mainly crops, for unconfined release.[54] Although regulators perform detailed analysis of the organism, its new trait, and the expected ecosystem effects prior to its unconfined release, there is little in the way of follow-up research or ecosystem monitoring performed by the government.

The need for effective monitoring of ecosystem impacts, especially cumulative ones, is critical because:

- Novel traits of increasing complexity, such as multiple pest-resistance, and relevance to natural ecosystems, such as drought or frost tolerance, are being developed;
- New organisms are being bred for use in an increasing range of uses, and in an increasing range of industries;
- The scale of environmental release of GMOs and other organisms with novel traits is increasing rapidly, especially in developing countries.

[54] Responsibilities relevant to BSDE are allocated among four federal bodies: Environment Canada, Department of Fisheries and Oceans, Health Canada, and the Canadian Food Inspection Agency.

This deficiency in long-term monitoring has been identified by numerous scientific advisory bodies both domestically and internationally (see Box 3-6). Our international trading partners are investing in ecosystem effects research: the United States has a multi-million dollar a year research program, the EU has one, and even China is investing in ecosystem effects research. Multiple public opinion surveys have shown consistently that Canadians expect the government to undertake ecosystem effects research, indeed, their support for continued innovation is dependent on it.

Box 3-6. Science advice received—*determine ecosystem effects!*

Numerous domestic and international scientific advisory bodies have advocated long-term research into the environmental effects of novel living organisms. Domestically, pre-market environmental risk assessment, monitoring of long term effects, transparency, and the adoption of a multidisciplinary research initiative have been promoted by such advisory bodies as the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001), and the Canadian Biotechnology Advisory Committee in its report on GM Foods (2002)

Internationally, the OECD expert technical bodies (1999, 2001, 2001), the European Union (2002), UK advisory bodies (1999), the National Research Council of the United States (2002) and the Ecological Society of America (2004) have all supported the necessity for environmental effects research on novel living organisms. Specifically, scientifically-based monitoring and management, and large-scale field research have been repeatedly advised.

Source: See Appendix 1, at the end of this chapter.

<u>What have we learned?</u>

Research currently underway is turning up some very interesting findings. Some of the dire predictions of possible negative environmental effects ascribed to GMOs have been allayed:

- The toxin expressed by *Bt* crops does in fact kill target insects in the field but does minimal harm to non-target species.[55]
- DNA ingested by humans and animals during feeding studies is digested in the gut and therefore transgenes in food products derived from GM plants do not pose a risk to subjects or ecosystems.[56]
- Pollen from *Bt* corn does not adversely affect monarch butterflies in the field as had been feared from laboratory feeding studies.[57]
- Developers of the 'Trojan gene' hypothesis, which predicted that escape of GM salmon might lead to the extinction of native salmon, have abandoned the hypothesis and revised their predictions.[58]

Some of the most important work on GM crops in ecosystems has looked beyond predictable effects. A large-scale study in the UK found that a consequence of the reduction in weed populations, due to planting herbicide-tolerant GM crops, was that far fewer weed seeds were available for wildlife. This could be highly detrimental to birds that rely on these seeds for

[55] J. Romeis et al., "Transgenic Crops Expressing *Bacillus Thuringiensis* Toxins and Biological Control," *Nature Biotechnology* 24 (1) (2006), pp. 63-71.
[56] T. Netherwood et al., "Assessing the Survival of Transgenic Plant DNA in the Human Gastrointestinal Tract," *Nature Biotechnology* 22 (2004), pp. 204-209.
[57] M.K. Sears et al., "Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment," *Proc. Natl. Acad. Sci.* USA 98 (2001), pp. 11937-11942.
[58] W. Muir, "The Threats and Benefits of GM Fish," *EMBO Reports* 5 (7) (2004), pp. 654-659.

survival.[59] In a similar Canadian study, herbicide-tolerant canola was found to support bee populations three-fold lower than those of canola grown under organic or conventional farming regimes. This was attributed to a shortage of food, normally provided by weeds that flower before or after the canola.[60] Studies of this kind have led to the unexpected conclusion that 'weeds' can have beneficial effects in agroecosystems by supporting pollinators and wildlife.

Research has alerted us to some potential new problems. An increase in the incidence of infections of grain crop on the Canadian prairies by pathogenic fungi of the genus *Fusarium* has led researchers to suggest that herbicide-tolerant agricultural systems may be responsible. The reasons for this are not yet clear, but two hypotheses are that the herbicide glyphosate may promote *Fusarium* growth, or that increased levels of organic matter from no-till agriculture, may help these fungi to overwinter successfully in the soil.[61] On the other hand, an unexpected side benefit of *Bt* maize is that the corn kernels have been found to have lower levels of carcinogenic fungal toxins (mycotoxins). The fungus normally infects corn kernels that have been damaged by pests; because *Bt* corn is less damaged by pests, there is a lower frequency of infection.[62] The mycotoxins are a particularly important health hazard in developing countries.

Such surprises, some with major consequences for crop and human health, are the best argument to develop a thorough research program. In the first example, farming practices that are facilitated by herbicide tolerant canola (and other crops) may unexpectedly promote the growth of an important pathogen, while a different biotechnology reduces the incidence of a different pathogen's growth. None of these results were predicted as the technology was developed and tested. Both surprising results depended on a large-scale application of the technology before the signal was strong enough to warrant further investigation. These results remind us of the vital importance of following-up environmental releases with monitoring.

Uncertainty: What We Still Need to Know

The body of work described above, though extensive, leaves many important questions unanswered. We provide two examples below to illustrate how basic the knowledge needs are.

A key argument for developing significant biofuel capacity is Canada's "natural advantage": the surplus of 'waste' biomass, and biomass that could be grown on underutilized lands. Biomass is generated by green plants that capture only about one percent of the incoming solar radiation, much of which is quickly recycled by the decomposers, invertebrates, fungi and bacteria, which release nutrients and condition the soil. Biomass, then, is not an unlimited resource.

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[59] L.G. Firbank et al., "An Introduction to the Farm Scale Evaluations of Genetically Modified Herbicide-tolerant Crops," *Journal of Applied Ecology* 40 (2003), pp. 2-16.

[60] L. Morandin and M. Winston, "Wild Bee Abundance and Seed Production in Conventional, Organic and GM Canola," *Ecol. Applns* 15 (3) (2005), pp. 871-881.

[61] M.R. Fernandez et al., "Crop Production Factors Associated with Fusarium Head Blight in Spring Wheat in Eastern Saskatchewan," *Crop Science* 45 (2005), pp. 1908-16.

[62] P.F. Dowd, "Biotic and Abiotic Factors Limiting Efficacy of *Bt* Corn in Indirectly Reducing Mycotoxin Levels in Commercial Fields," *Journal of Economic Entomology* 94 (5) (2003), pp. 1067-1074.

When typical agricultural or forest products are removed, some of this biomass is lost from the ecosystem. In agriculture, the nutrients are generally replaced by fertilizers that require a substantial input of fossil fuels but, if straw is also removed, what is the long-term effect on the water-holding capacity of light soils or the workability of heavy ones? Forest products in the form of lumber, if harvested at appropriate times in the season, drain fewer nutrients from the system. However, coarse woody debris plays an important role in maintaining the health of the forest. It is broken down by fungi into humus, which helps to retain moisture, condition the soil, and provide an ideal substrate for germination and growth of tree seedlings. Removing too much of this biomass from the immature (<10,000 year-old) soils of the boreal forest may render them incapable of supporting the species that represent the primary forest resource. Insufficient work has been done to determine how much of this so-called waste can safely be removed on a continuing basis without detriment to ecosystem functioning.

Another illustrative lesson that is arising from the studies of genetically engineered (faster growing) salmon, is that, despite many studies that show behavioural and physiological differences between growth-enhanced and conventional salmon, there is very little information on whether these differences play out in "real" environments. Fish raised on bountiful food in tanks are physically and behaviourally different creatures from those grown under "nutrient limited" conditions in the wild, and predictions of their behaviour are limited by this fact. These challenges show that our ability to know an organism as an entity independent of its environment is limited, and that when conducting research to inform risk assessment, researchers must take the effects of an organism's environment on its ontological status into account.[63]

These examples illustrate the benefits of continuing, increasing and systematizing ecosystem-based research, especially when it applies to unanticipated or cumulative effects. The research must be designed to capture effects of scale and provide the appropriate statistical power to support decision-making. Such research can also address important concerns raised by preliminary results. It is important, especially when working in a field as new as biotechnology, to continue to follow-up worrisome leads. As these examples show, some of the dramatic early concerns were artifacts of the way the problem was approached. In these cases, precaution, which would have been triggered by the initial results, would not be necessary, based on the more recent, in-depth studies.

Important as it is, more scientific information alone is not enough. Knowledge must be integrated into communication and decision-making channels for it to help move society toward sustainability. A sustainable society must be able to learn from its knowledge gathering, and it must be able to adapt, based on that new information. We finish this section with some thoughts on this theme.

Determining Significance

Biotechnology products will often be substitutes for, or allow the substitution of, different previous processes or means of production. Early ecosystem studies are showing that the introduction of GM products and their associated practices do have effects on ecosystems, but that these effects are far from catastrophic, nor even, as illustrated in the case of the research

[63] R. Devlin et al., "Interface of Biotechnology and Ecology for Environmental Risk Assessments of Transgenic Fish," *TRENDS in Biotechnology* 24, 2 (2006).

done on *Bt* corn, arguably negative at all. The main shift in *Bt* corn field ecosystems, aside from absence of the target pest, seems to come from the absence of wounded corn plants, and the pests and pest predators that are attracted by the volatile signaling chemicals released by the plants in response to insect damage.[64] This absence of signaling compounds means different species and different mixtures of species inhabit the corn fields. Frequently, insect population changes in *Bt* crops are much smaller than those found in crops using conventional pesticide applications.

The big question that studies like this raise is one of significance. Are changes like this significant? Are they desirable? Who should determine this? Scientists realize that the answers to these questions go well beyond their scientific research, and require input from other stakeholders. These conversations, and the decisions that must be taken at their conclusion, will encourage scientists and others to develop deeper and more nuanced understandings of ecosystems and ecosystem health, as well as governance. Ecosystem effects research, dependent on monitoring, is vital to informing public debate, and fostering a "learn as we go" approach, which is a pillar of adaptive management. The establishment of communication systems that allow the dissemination, synthesis and integration of scientific results into public attitudes, into regulatory decisions, company strategies, and policy initiatives will be central to this need.

Canadian Government Efforts

As we see through the examples presented, there is much to be learned from ecosystem research on the effects of biotechnology innovations. What is the Federal Government doing to help promote and support this research?

There are a number of small-scale research programs underway in most of the natural resource-based departments and agencies, but as yet, there is no systematic effort to generate and communicate the kind of ecosystem knowledge we describe in this paper. We do acknowledge, however, three initiatives that we think, if implemented intelligently and resourced appropriately, would go a long way to incorporating sustainable development ideals into government action.

They are:

> (1) the *Ecosystem Effects of Novel Living Organisms* (EENLO), a proposed research strategy (see Box 3-7) that integrates the efforts of a number of departments to address the challenge of determining the ecosystem effects of novel living organisms (NLOs).

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[64] G.P. Dively, "Impact of Transgenic VIP3A x Cry1Ab Lepidopteran-resistant Field Corn on the Nontarget Arthropod Community," *Environmental Entomology* 34 (5) (2005), pp. 1267-1291.

Box 3-7. The ecosystem effects of novel living organisms (EENLO)

A federal interdepartmental committee, led by Environment Canada, has been developing a research strategy to generate knowledge, through an effective and integrated approach, on long-term ecosystem effects of novel living organisms (EENLO), in order to strengthen the sound scientific basis for policies, decisions and management of NLOs.

EENLO would take the form of a networked group of government and academic scientists. They will be supported by information technology tools that will allow:

- information sharing among researchers, facilitating project development,
- identification of experts, facilitating knowledge transfer to regulators,
- reporting and cataloguing of EENLO research, facilitating common access, and
- communication with the public, facilitating tnsparency.

Proposed Areas of Research:

1. Baseline data — accessing, generating, and maintaining baseline data on key ecosystems in order to be able to determine changes associated with the introduction of NLOs.
2. Detection and monitoring - testing and developing new tools for detection of NLOs, genes, and gene products of concern.
3. Ecosystem impacts of novel living organisms — determining impacts of NLOs and associated production systems on biodiversity, nutrient cycling, water quality, etc.
4. Gene flow and its consequences — determining likelihood of, extent of, and consequences of gene flow of novel traits into other species and varieties.
5. Risk assessment method development — developing and implementing better techniques and approaches to predict risks associated with NLOs.
6. Containment and mitigation — testing and developing biological and physical containment mechanisms to restrict unwanted migration of NLOs or genes.
7. Stewardship of released products — advancing research to manage the long term environmental impact of released products.

Source: www.ec.gc.ca/scitech/default.asp?lang=En&n=18BE230D-1#doc

(2) the *Stewardship Framework for Biotechnology* (see Box 3-8), an outline of a systematic approach toward the stewardship of biotechnology products, in a life-cycle manner that provides for regulatory and non-regulatory measures to ensure that biotechnology is being developed in a responsible manner in Canada.

(3) *Responsible Introduction of New Agricultural Products* (RIONAP) – a program being developed by Agriculture and Agri-Food Canada whose purpose is to integrate socio-economic concerns into the assessment process for new agricultural products. This program is still in its very early stages.

Box 3-8. Stewardship framework for products of biotechnology

To maintain and improve its leadership position in biotechnology, the Government of Canada (under the lead of Health Canada) is developing a *Stewardship Framework* that provides the foundation for an integrated approach to address biotechnology issues. The framework will set out principles allowing novel and appropriate mechanisms to effectively promote health and sustainability, and contribute to innovation and socio-economic growth.

Source: Text from *Action Plan of the Government of Canada in Response to the Royal Society of Canada Expert Panel Report on the Future of Food Biotechnology* www.hc-sc.gc.ca/sr-sr/alt_formats/hpfb-dgpsa/pdf/pubs/prog-rep-rap_06_2005_e.pdf

Conclusions

Biotechnology offers what appear to be genuine longer-term opportunities for: protecting, restoring and monitoring Canada's ecosystems; reducing material and energy flow through new industrial processes; creating local community opportunities to use Canada's agriculture and forest wastes; creating new cropping systems for industrial use, with both local and national "biorefineries"; and providing other possibilities for reducing air, water and hazardous wastes. These opportunities need to be seen through the lens of innovation systems, public and political acceptability, environment, and economic feasibility. Broadly these may be considered as commitments to R&D investment leading to commercialization generally over a 10-20 year period, addressing public interest and governance concerns, and producing knowledge for management and monitoring of transformative changes.

Definitions and objective measures of health and sustainability in communities and ecosystems are required in order to determine how biotechnology contributions might be considered in relation to community and ecosystem needs. These measures are far from being perfect or widely adopted, but they need to be in place over the same time period as innovative technologies for sustainable development emerge.

Sustainability indicators of community health are emerging and challenge existing social and economic measures. The National Round Table on the Environment and Economy (NRTEE) sustainability indicators, Forest Stewardship Council and Model Forest Network Indicators of Sustainable Forestry, Genuine Progress Indicators, and Ecological Footprint index of cities and towns are some well-recognized examples.

The links between healthy communities and ecosystems must develop along an adaptive planning and assessment approach, in order to build reasonable, on-going dialogue on the role of biotechnology in meeting sustainable development needs. A great deal of learning should take place, some of which is learning by doing. Methods must be developed for clarifying whether or not specific innovative technologies will actually lead to improvements, by comparison to existing pathways to sustainability or other alternative pathways. This is by no means an easy task since innovative technologies rarely show their full potential in the early stages, and, conversely, some early commitments may also lead to dead-ends.

The commitment to EENLO is still tenuous and has not resulted in any major new commitment to ecosystem research to build the needed understanding of and monitoring for potential impacts on ecosystems and ecological processes. There is no funded program for such research.

No strategic research network has been established on the subject of healthy communities and healthy ecosystems in Canada. Various Canada Chair appointments at various universities have provided some basis, but a focus on healthy communities and ecosystems remains remarkably unconsolidated at this point. While EENLO has made an effort to begin building relationships among researchers on the ecosystems side, no knowledge network or Centre of Excellence on communities and biotechnology, or ecosystems and biotechnology, currently exists within Canada.

CHAPTER 3, Appendix 1
Sources of Scientific Advice Regarding Ecosystems Effects Research

Canada

Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (2001), recommendations 5.7, 6.1, 6.2, 6.3, 6.4, 6.9, 6.12, 6.15, 6.16, 7.4: www.rsc.ca/index.php?page=expert_panels_food&lang_id=1&page_id=119. (Accessed June 15, 2006)

Canadian Biotechnology Advisory Committee, *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada* (2002), recommendations 5.1, 5.2, 5.3: http:www.cbac.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/Improving_Regulation_GMFoodAug02.pdf/$FILE/Improving_Regulation_GMFoodAug02.pdf. (Accessed August 30, 2006)

European Union

European Union, Document 301L0018, "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EECCommission Declaration", (April 17, 2001): europa.eu.int/eur/lex/en/lif/dat/2001/en_301L0018.html. (Accessed June 15, 2005)

European Commission, *Life Sciences and Biotechnology – A Strategy for Europe,* especially Action 23 (Brussels, Belgium: January 21, 2002).

OECD

OECD, *GM Food Safety: Facts, Uncertainties, and Assessment*, Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods, OECD Report C(2000)86/ADD3 (2000): www.oecd.org/dataoecd/34/30/2097312.pdf. (Accessed June 15, 2005)

OECD, "New Biotechnology Foods and Crops: Science, Safety and Society", Reports and summaries of OECD Bangkok Conference (Bangkok, Thailand: July 10-12, 2001): www.oecd.org/dataoecd/18/31/1829717.pdf. (Accessed June 15, 2005)

OECD. "LMOs and the Environment: An International Conference", Rapporteurs' report on OECD Conference (Raleigh Durham, North Carolina: November 27-30, 2001): www.oecd.org/dataoecd/21/55/2509367.pdf. (Accessed June 15, 2005)

United Kingdom

United Kingdom Government, "Genetically Modified Organisms and the Environment: Coordination of Government Policy", The UK Government's Response to the Fifth Select Committee on Environmental Audit (1999): www.defra.gov.uk/environment/response/gmo99/index.htm. (Accessed June 15, 2005)

United States of America

U.S. National Research Council Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, Board on Agriculture and Natural Resources, Division on Earth and Life Studies, *Environmental Effects of Transgenic Plants—The Scope and Adequacy of Regulation* (Washington, DC: National Academy Press, 2002).

U.S. National Research Council Committee on Defining Science Based Concerns Associated with Products of Animal Biotechnology, Committee on Agricultural Biotechnology, Health, and the Environment, Board on Life Sciences, Division on Earth and Life Studies, *Animal Biotechnology: Science Based Concerns* (Washington, DC: National Academy Press, 2002).

A.A. Snow et al., "Genetically Engineered Organisms and the Environment: Current Status and Recommendations" in *Ecological Applications*, 15(2) (2005), pp. 3774-04.

CHAPTER 4. Biotechnology for Sustainable Rural Development

Why Rural?

Technology innovation conjures an image of university research parks, technology clusters and industrial complexes, largely an urban and suburban dominated endeavour—a model well-suited for information and communications technology, or biotechnology medical research. When it comes to biotechnology for agriculture, forestry, aquaculture and other aspects of natural resource use, and for at least some environmental concerns, rural environments and communities become much more significant. "Canada's natural advantage" for biotechnology development is presumed to be our vast land and water base, as well as our well-established economic base of rural activities. But it also ties the rural biotechnology agenda to the urgent and on-going need for rural economic development and renewal. In the US and Europe, this same imperative has led to substantial new producer and processor incentives, including tax breaks and subsidies, especially for stimulating biofuel production. Canada appears to be heading down the same pathway. Many choices lie ahead—for producers, industry and governments. These choices will influence the future of rural development, perhaps more so than their contribution to an expanded Canadian economy.

At the moment there is only one federally-mandated bioproduct commitment for rural areas, and that is still at an early stage—a 5% ethanol content for gasoline and diesel by 2010. But the funding commitment to R&D, and to various pre-commercialization efforts, is extensive. Provincial interest levels are high, including mandated efforts in biofuels by Saskatchewan, Manitoba and Ontario, promotion of biorefineries (Alberta), and filling niches such as fish disease biotechnology diagnostics and treatments (Prince Edward Island).

Our Report's focus on sustainable rural development is itself a strategic choice. Rural areas have been on the front lines for the debate about GM crops and foods. They will be the centre of attention as Canada and other countries implement new commitments to expanding the production of biofuels such as ethanol and biodiesel. And by 2015, when truly transformative applications of biotechnology become more feasible, including "biopharming" and production of many chemicals and products such as plastics from biologically-based feedstocks, some believe that rural areas will experience a new era of economic growth and prosperity. Farmers will develop new income sources beyond food commodities, and new employment opportunities will exist for people living in smaller towns. In Chapter 2 we introduced a timeline from 1995 to 2020 for the roll-out of various biotechnology innovations at significant commercial and economic levels in Canada. Most elements in the timeline would involve rural areas.

Our premise is that along with rural economic and social well-being, biotechnology applications should bring substantial contributions to environmental sustainability. Examples include land use favouring higher levels of harvest from some areas, while relieving pressures on areas of special ecological and biodiversity interest; improvements to fish stock management, water quality and aquaculture through various bio-diagnostic applications; new forms of forest pest management; systems put in place to preserve genetic resources and the traditional and local knowledge that cares for them; and extreme reduction in water pollution through new methods of sewage and industrial redesign.

The following statements guide our examination of biotechnology and rural sustainable development:

1. Although there are many predictions of substantial economic rural renewal impacts arising from biotechnology applications beyond those of GE crops, a highly persuasive, economically feasible case has not been made for them, and perhaps cannot be made until there is more pilot experience;

2. The capture of benefits within rural areas is not assured, and could become a limiting factor if producers do not feel they are adequately rewarded, or if they suffer net losses;

3. Technology innovation is very familiar to farmers and the agricultural processing industry, forest industry, and in coastal communities, but the changes required for most bio-based products and for bio-refineries are demanding financially and operationally—to the point where it is not clear that they can be adequately orchestrated without integrated management efforts; and

4. The question of incentives will be front and centre for years—who should pay and how much? This issue is made more difficult by factors such as possible large-scale fluctuations in fossil fuel prices, and competition, both interprovincially and internationally.

We also consider who is likely to benefit from biotechnology innovations for rural areas. This is a complex question since benefits may be economic, social or environmental, and some will be national or global, perhaps justifying compensation to local producers. The relationship between an innovation and benefits may depend on the acknowledgement of local jurisdiction over knowledge about biodiversity, whether producers are early or late adopters of innovations, whether the innovation is available to their competition, or if it is an innovation that is peculiarly beneficial to Canadian producers, and not to others. A locality may benefit through knowledge and scientific skills shared with them by researchers exploring the potential of their local biological resources. The environment may benefit if less toxic methods are used in production or manufacturing. Consumers may benefit if the new product can be sold for a lower price. If the innovation is a process, such as a biorefinery, the community in which it locates may benefit from increased employment, so identifying the natural location for the process is crucial for assessing rural benefits. We recognize that increasing rural incomes may raise prices for all Canadians. If biorefineries are successful in selling, for example, ethanol made from grain crops, and the demand is substantial, this will drive up the price of grain for all grain consumers, not just for ethanol refineries. It is a reason why proponents of biorefineries place major emphasis on security of feedstock supply.

This Chapter is weighted towards economic potential and benefit/costs, and we therefore turned to the Conference Board of Canada, which has some experience with the biotechnology sector. We asked the Conference Board to determine the magnitude of opportunity for sustainable rural development based on biotechnology applications. The Board examined three sectors where biotechnology applications related to natural resource use are likely to increase in the coming 5 to 15 years—agriculture, forestry (including pulp and paper) and aquaculture. This turned out to be a very tough assignment for the Conference Board. The "hype" concerning new opportunities needed to be examined in relation to demanding realities, and possibly competing priorities, in the rural economy. Statistical data collection in this field is still rudimentary (the Board relied upon

Statistics Canada information, considered one of the world's best data sources for this sector). Some information, for example concerning forests, is aggregated into broader natural resource sectors. Reliable indicators for the biotechnology and sustainable development relationship are poorly developed. Therefore it is difficult to express this relationship as precisely or clearly as might be desired.

We have built upon the Conference Board analysis through our own broader examination of current studies, policies and state-of-the-art biotechnology initiatives in order to draw conclusions and recommendations on what it might take for biotechnology initiatives to play a major role in the future of Canada's rural areas.

Overall, the Conference Board findings, based on the application of their innovation framework[65], suggest that biotechnology applications for rural resource use are far from being an economic panacea. Their analysis suggests that biorefineries have the potential to be anchor facilities in rural communities. Biorefineries could bring some new, high-value jobs to rural communities, including support operations such as transportation and logistics. Moreover, biorefineries will produce many different outputs that can in turn be transformed into products and services. However, the economic viability of rural biorefineries remains speculative.

Conference Board of Canada's *Innovation Framework* Analysis

In previous work assessing Canada's biotechnology performance and potential, the Conference Board has successfully employed their *Innovation Framework* (see Figure 4-1) as an effective analytical approach. It looks at the steps necessary to move from an idea to a valuable contribution to the economy. The analysis covers the *supply chain for a product*, from the source of the raw material to the final market, asking what is necessary for this chain to function smoothly for the biotechnology innovation. The analysis is flexible and adaptable, captures the activities of a wide range of actors, and focuses on how knowledge is turned into economic and social value.

The six elements of the framework interact with one another in a dynamic manner:

- *Environment*—the overarching conditions that influence innovation (e.g., policy, regulations, leadership, not necessarily the biophysical environment);
- *Creation*—generating new knowledge or significantly improving existing knowledge (e.g., research);
- *Diffusion*—sharing knowledge (e.g., publishing, collaboration, teaching);
- *Transformation*—adopting or adapting knowledge for a specific purpose (e.g., creating new products);
- *Use*—delivering or implementing new or significantly improved goods, processes, programs or services (e.g., selling new products, using a new process); and
- *Value*—social, economic or environmental value from transformed knowledge (e.g., revenue, profit, social cohesion, reduced environmental impact).

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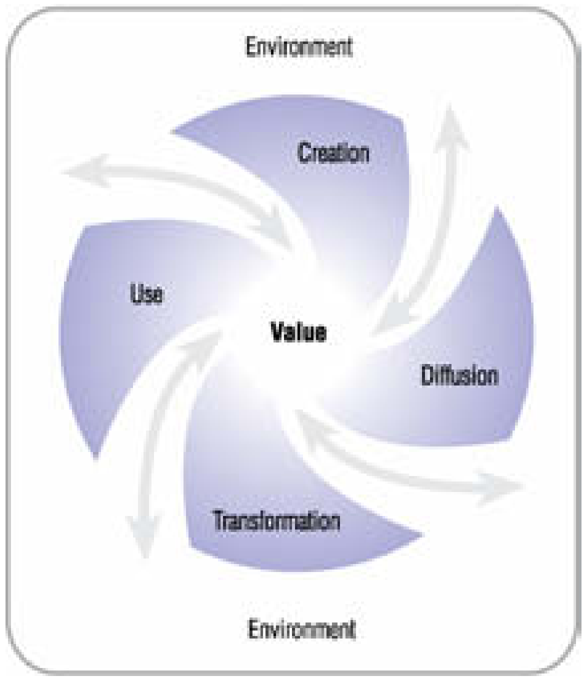
[65] The Conference Board of Canada's report, *Assessing Biotechnology as a 21st Century Technology Platform for Canada* (2005), provides a description of their innovation framework. The study on rural implications of BSDE will be published by the Conference Board.

The Conference Board analysis is rooted, where possible, in sectoral statistical data, including the trends and status of current biotechnology applications in relevant sectors and markets. We are looking to sketch out future outcomes, based on the best evidence and today's baseline situation. The goal is to create preliminary profiles of how significant biotechnology might be to Canada's rural sectors between now and 2020.

In this Chapter only a summary of key points from the analysis is provided. The complete analysis will be published by the Conference Board of Canada.[66]

Figure 4-1. Conference Board of Canada innovation framework



Key Findings

Key cases or features of the Conference Board study are provided in a highly summarized form below, combined with observations and analysis from the CBAC Expert Working Party.

Productivity, Efficiency and Competitiveness

Rise and fall of commodity biomass-based and fossil fuel prices: Long-term agricultural, pulp and paper, aquaculture and other price declines, when matched with rising fossil fuel prices, suggest opportunity for bioproducts. The reality is, however, that prices of both will fluctuate. Oil prices above US$75 per barrel are needed to drive biofuel development without significant

[66] www.conferenceboard.ca/

producer and processing incentives over the longer term. Even with prices just above this level, producer associations in Canada are lobbying for substantial incentives, as noted in Chapter 2. Creating instant demand through mandated targets for bioproducts may drive up renewable commodity prices (see Walburger et al.,[67] for soybean, sugar and grain examples). As efficiencies improve and prices fall, the competitiveness of biofuels can be expected to improve, perhaps dramatically. This has happened in Brazil, but only after a very bumpy 30-year learning experience, including the decade of the 1990s when low oil prices decimated ethanol fuel markets[68]. For the foreseeable future, novel biorefineries will have to compete on price with entrenched, highly efficient oil refineries.

Energy supply security: Bio-energy is now part of the United States' approach to fuel security, and other countries such as China and Brazil also hold this position. It is less clear that bio-energy needs to be a major component of an energy supply security policy for Canada, other than in the context of a North American energy approach.

Export trade: Canada's continuing dependence on natural resource exports makes its rural economy highly vulnerable to changing consumer preferences, environmental activism, disease factors (BSE, "stowaway" forest pests that become invasive species), fluctuating currency and other factors affecting competitiveness. The case of fast-growing tropical crops versus Canada's, which are constrained by the shorter growing season for biomass, is instructive. Super-sized mills, fast growing eucalyptus forests, and low-cost labour in Brazil means its pulp-and-paper production costs are only 60% of Canada's. These same types of advantages would work in Brazil's favour for bioethanol. Sugar cane and palm oil (produced mainly in Southeast Asia) have conversion efficiencies to biofuels that far surpass those of Canadian crops such as grain, corn and canola. Brazil seeks entry into US and European markets, and would likely out-compete any Canadian effort to become a biofuel commodity exporter. Indonesia and Malaysia, and possibly African tropical countries, are also likely to seek export markets.

Shifts in rural economics to larger producers: This trend may make it more feasible to justify investment in biorefineries since raw materials may be easier to source because larger producers have the economic and legal resources to make strong agreements with their suppliers. In the US, larger bioethanol companies have become very profitable, and have generated rising share prices. This dynamic may not bring as many benefits to local communities, though, because the plant owners will be located in far-off urban areas and seeking to get as much value for as little cost from their rural suppliers.

Biomass supply and utilization: Initial analyses indicate that there are large amounts of residual or waste biomass associated with existing natural resource sectors—for example, in the case of agriculture and forestry, of the more than 66 million tonnes (Mt) of carbon (C) per year (yr) in the residual or waste biomass stream, about 60 Mt/yr may be considered an available stock. This represents about 42% of the entire forestry and agricultural harvest. The energy content of these biomass resources (2.2×10^{18} J) is equivalent to about 27% of Canada's energy demand, currently

[67] A. Walburger et al., *Policies to Stimulate Biofuel Production in Canada: Lessons from Europe and the United States* (2006): www.biocap.ca/rif/report/Walburger_A.pdf.

[68] D. Sandilow, "Ethanol: Lessons from Brazil", in *A High Growth Strategy for Ethanol* (Aspen Institute: 2006); Brookings Institute: www.brookings.edu/views/articles/fellows/sandalow_20060522.htm.

met by fossil fuels."[69] These rough estimates cannot be used for detailed planning purposes. Canada is probably at least five years away from having accurate information on what would be considered an ecologically sustainable residue-harvest from forest and agricultural lands. This estimate is likely to be further reduced once deductions that take into account the requirements of ecosystems, and the economics of the energy required for harvesting and transportation, are considered.

Additional cautions must also be kept in mind. Biomass supply is generally seasonal, creating needs for storage and perhaps preliminary processing. This is an important constraint in the design, location and costing of biorefinery operations. Biomass inputs are subject to the effects of weather, pestilence and fires, which are difficult to predict and control. Climate change will also add an element of uncertainty by changing local ecosystems and the kinds of organisms that flourish within them (see Box 4-1).

Retooling and inventing supply chains: Transforming relationships between the web of producers, biorefinery operators, intermediate distribution and processing plants, and end-users is likely to be decades-long. For those who envision radical change from a fossil fuel-based energy and feedstock situation to the carbohydrate economy of bioproducts, perhaps the most significant barriers relate to supply chain problems. The relatively simple problem encountered in the US of re-tooling parts of the gasoline supply chain to accommodate the use of bioethanol as a gasoline additive is illustrative. Because of ethanol's chemical properties, the additive must now be mixed closer to the end-user rather than at the petroleum refinery, as the previous additive had been. This in turn creates the need for separate truck and rail transportation and new storage facilities. The extra demand for corn to ferment into ethanol is raising corn prices, which will be passed onto the food-buying public, as well as motorists. These problems undoubtedly can be solved, although there may be some short-term shortages of gasoline in some parts of the US until all the parts are in place

Box 4-1. Utilizing biomass from dead forests

Mountain pine beetles survive BC's increasingly warm winters in great numbers, causing rapid death of pine forests—the largest pest outbreak in recorded North American forest history. In 2005, 90 million cubic metres of forest in BC were affected. This is an alarming amount considering that the normal total allowable cut for the Province is 100 million cubic metres. There are estimates that by the year 2016, affected wood could increase to as much as 200-500 million cubic metres. The dead wood is potential biomass feedstock that must be removed quickly for it to be of even limited commercial value. Some of this biomass could be used as wood pellets for stoves, or could be processed in biorefineries for other products such as ethanol and lignin.

A similar situation involving different bark beetles and tree species has destroyed Alaskan and Yukon forests. It is possible over the coming 20 years that with warmer winters becoming the norm, massive damage could be inflicted by various bark beetles and other insects, feeding on weakened, mature forests in other parts of Canada as well.

Biotechnology solutions might include producing disease-resistant stock, finding more effective pest control treatments, and developing better ways to process vast quantities of dead wood, including energy-efficient conversion to biofuels and chemical products. These are urgent tasks.

[69] S.M. Wood and D. B. Lyzell. *A Canadian Biomass Inventory: Feedstocks for a Bio-based Economy* (BIOCAP Canada Foundation: 2003).

to allow the system to function smoothly. In Canada, cooperation is developing between the refineries and renewable-fuel representatives to address problems of implementing biofuel supply chains.

The problems of biorefinery supply chains in the future are likely to be much more complex and difficult to manage. These include diverse feedstock from various sources, perhaps erratically supplied; smaller rural biorefineries producing intermediate products utilized as biofuels or advanced large-scale facilities turning out a wide range of chemicals and synthetic materials, with each chemical requiring its own marketing and pricing strategies; and cradle-to-cradle re-processing after its initial use.

Canada may not have a comparative advantage over advanced biorefineries in Europe or the US, and it is also possible that technology developed in Canada could find its way into other regions offering better incentives or markets. A really gloomy outlook would be for limited multinational investment in advanced processing facilities in Canada, reducing our role to production for domestic use. Some biofuels and intermediate feedstocks would be exported , placing Canadian industry once again in yet another low-price commodity market, while a range of higher value products are produced from Canadian raw materials in large industrial operations elsewhere.

Regulation

Product regulation: There are gaps in the regulations governing biotechnology, and strains on the regulatory capacity to address the increasing levels of technological sophistication characteristic of modern biotechnology. These gaps create uncertainty among the innovators, as the "rules of the game" are unknown or ambiguous. The impact on rural producers is that rules governing innovative production systems, biosafety and waste disposal procedures and so on (e.g., procedures for transgenic "pharma" plant crops or animals) are unclear. This lack of clarity generates the risk of crop or product loss due to a change in the rules domestically or internationally, which in turn reduces the potential for uptake of innovative products. It also may inhibit participation and investment, and therefore a healthy level of experimentation in new institutional models.

There is little to suggest that the challenge to balance market forces with public safety will grow easier. Indeed, it is expected that the requirements to ensure traceability and containment of genetically modified crops—and the oversight required to ensure this happens—will only grow over time. This is a major challenge, considering that evidence indicates the Federal Government is struggling to achieve the regulatory approval timelines it has established for itself.[70]

Consistent policies: Many policies exist for rural renewal, sustainability and innovation. These policies, if leveraged appropriately, could support the development of sustainable bio-based economies. Canada's Agricultural Policy Framework (APF) covers several necessary elements, but is likely to be insufficient for the new challenges of rural biotechnology development. It is not particularly focused on non-food production on agricultural lands, or forest initiatives, and has no direct relevance to marine activities such as aquaculture. At present there is no overarching Canadian framework for biotechnology and sustainable rural development.

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[70] External Advisory Committee for Smart Regulations, *Smart Regulation for Canada—Draft Final Report* (Ottawa: August 2004).

Preserving and protecting our genetic resources and associated knowledge: Genetic resources are the building blocks of many biotechnology innovations—without genetic material, no new strains of animals or plants are possible. Canada has both domestic and "wild" genetic resources that could well become valuable once our knowledge of genetics is more advanced. It is important for Canada to develop the appropriate policies to ensure that these "public goods" are protected from exploitation by those who would extract value from them by developing new strains, varieties or other genetic inventions, but not share the benefits. Also, local and First Nations people often have knowledge about the medicinal and other value of the biodiversity in their locality that can be used to prompt scientific discoveries. Policies should be put into place to facilitate, when culturally appropriate, a fair and equitable sharing of information and benefits derived from the resulting innovations.

Biophysical Environmental Concerns

A number of biophysical environmental challenges are creating pressures both on and for biotechnology, many of which have been mentioned in earlier sections of this report. In this section, we will focus on those that may have the most relevance to rural sustainability.

Water: Increased demands on existing—and in many instances dwindling—water supplies is creating opportunities for biotechnology solutions that, for example, reduce the crop requirements for water. This already makes these crops attractive for regions that face droughts. The availability of enough water to supply the increased crops and processing facilities necessary for the large-scale production of bioproducts is a serious risk factor in the development of the bio-based economy.

Climate change: As global warming affects the length of seasons, adaptations to changing growing periods becomes necessary. There may be opportunities for biotechnology to help with crop and domestic animal adaptation to different climates, or to facilitate the adaptation of exotic species into areas where the native ones can no longer survive.

Waste biomass: Deriving valuable products from waste streams is an attractive idea, not only because a higher value product is being created from a lower value one, but also because the environmental burden associated with waste disposal could be reduced or eliminated. It also allows the production of new bio-based products without any extra harvesting of natural resources, and reduces associated environmental impacts. Though bioproducts can use "waste" biomass as a feedstock, as noted in Chapter 2, it is still not known how much plant residue should be left behind to ensure healthy ecosystem function. When considering waste product utilization, the whole ecosystem must be taken into account.

Soil health: New types of crops that facilitate lower-impact farming practices (such as no-till farming) may help to increase soil health. However, increases in agricultural and agro-forestry that might accompany an expanded biobased economy could have a negative effect on soil health.

Infestations and disease: Biocontrol agents and traits for increased disease resistance can reduce the impact of diseases and pests in many natural resource sectors.

Toxic chemicals: Canada has about 2,500 federal contaminated sites and approximately 20 million kilograms of pesticides are applied to crops on the Canadian prairies every year. Many biotechnology innovations replace the use of toxic substances, reduce the need for them, detect their presence, or digest them.

Capital

Financial Capital: According to a recent study by Price Waterhouse Coopers,[71] the most pressing challenge facing the Life Sciences industry (an industry dependent on biotechnology) is stronger access to capital for seed and early stage companies. Thus far, this funding is most commonly sought through 'angel' investors or venture capitalists. The problem of finding venture capital funding may not be a stumbling block for rural industries that are supported by mandated activities such as conventional ethanol production. Indeed there has been a rush to invest in these government-supported initiatives. However, the dilemma for rural areas is that generally farmers, local enterprises and sometimes communities have to work together as financial partners. But local ability to participate financially is highly constrained by the string of misfortunes afflicting many parts of rural Canada.

Alternative funding models for rural areas have been proposed, and have been tested successfully in the US. The proposed solutions are "new style" cooperatives and limited liability corporations. These models encourage a high degree of local ownership in a distributive model of small or medium-sized biorefineries close to the origin of the wet biomass materials. But it is also possible that large, well-funded initiatives might dominate. In the US, Archer Daniels Midland has surged into a leadership role for ethanol, and the same type of relatively integrated large-scale industrial operation exists in Brazil.

The financial capital problem becomes more complex with either novel processes (e.g., cellulosic ethanol, where Iogen has developed partnerships with large companies such as Shell and financial investor Goldman Sachs), or with the large-scale integrated biorefineries of the future, where intermediate products are purchased and refined into a range of fuels, chemicals and final products such as degradable plastics. The most significant effort in the world is the $200 million Cargill facility in Minnesota designed around production of PLA, a source for many plastic products.[72] A key question is which financiers will be in a position to contribute at this level to facilities in Canada. Multinational corporations may well choose to locate near larger markets, in areas where they can negotiate the best possible arrangements concerning price and continuous supply of feedstock, or where the largest financial incentives are available. They also are more likely to be attracted to situations where national, provincial and local decision-making processes are well-defined, coordinated and timely, and where the regulatory situation is predictable and stable.

The transformation needed in the pulp and paper industry is yet another category. Here the opportunity depends largely on industrial re-tooling, probably through plant owners. This is, of course, not unusual. The pulp and paper business has already invested billions in major process, environmental and energy refits. But this next step towards transforming mills into biorefineries

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[71] BIOTECanada and PricewaterhouseCoopers, *Canadian Life Sciences Industry Forecast 2006: A Vision for the Future*: www.biotech.ca/PDFs/LifeScienceForecast2006.pdf.
[72] NatureWorks®: www.natureworksllc.com/corporate/nw_pack_home.asp.

is coming at a very difficult time. The pulp and paper biorefinery models highlighted in Chapter 2 are perhaps at least 7 to 15 years away from widespread adoption for both technical and financial reasons.

When all of these considerations are taken into account, it is clear that challenges for locating and financing novel industrial biotechnology activities in Canadian rural areas will be great. The spectre of interprovincial competition and barriers also needs to be addressed. There is already evidence for such competition developing, for example, incentives to stimulate ethanol in gasoline have been provincially funded, with provisions that the fuel be used within the province where subsidies have been provided.[73]

Knowledge and human capital: If rural areas are to be successful in attracting novel bioproduct industry, they must be able to compete with existing centres of expertise, often located in mid- to large-sized cities. We are not pessimistic about the ability of rural centres to compete, for several reasons. One is the level of federal and provincial commitment for improving access in rural areas to knowledge, through various mechanisms such as distant learning and broadband connectivity. Another is the strengthened science and management programs of universities and colleges within reasonable proximity to rural areas. It is significant that smaller cities, such as Saskatoon, Brandon, Guelph, Quebec City, Prince George and Charlottetown host relevant university programs for value-added activities in the agricultural, forestry or aquaculture sectors. A third reason is the strong interest of farmer associations and institutions such as the Prairie Farm Rehabilitation Administration in finding new strategies for rural economic development.

But there appears to be a deeper concern, expressed by some leaders in bioproduct sectors. The problem is the substantial set of issues required to fundamentally transform not only industrial processes, but also supply chains that feature more complex sourcing of feedstocks and end-products. The industrial processing side requires people who must deal with new fields beyond traditional chemical engineering, while the supply chains require new management skills. It has been suggested that new university programs producing graduates capable of bioproduct processing and management are needed. Such programs do not currently appear to be available, although it is quite possible for interested undergraduate and graduate students to orient their efforts toward this end by making choices within existing programs.

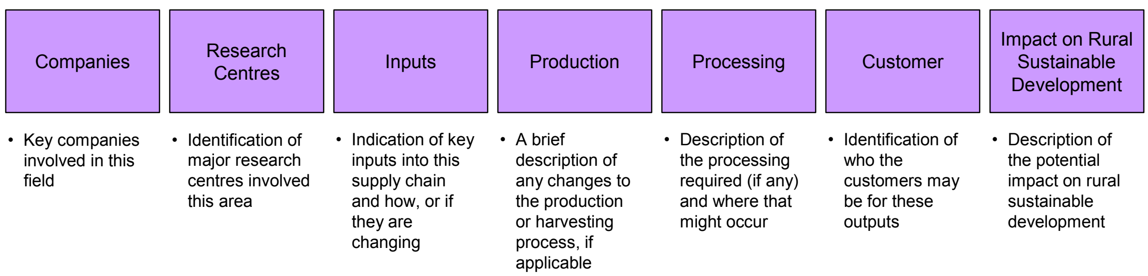
Building a solid base of bioproduct practitioners, researchers and others is essential for benefits to flow to rural areas. This should include local agricultural station researchers linking with local universities and colleges; the formation of public-private innovation consortia; and the building of new skills at the level of rural resource institutions and individual farmers, rural plant managers, and so on. The key point is that this will be an on-going issue for at least the coming 10 to 15 years, and will require considerable vision for effective action.

[73] Manitoba-based incentives for bioethanol are applied only to fuel to be used in Manitoba; Alberta bioethanol producers sell their product to US border states rather than to Saskatchewan due to inter-provincial trade barriers.

Sectoral Analysis – Looking at Supply Chains

Supply chain assessment: In order to analyse the role of biotechnology in each of the three sectors, a supply chain model was used (Figure 4-2). This model follows the product from the original source (farm, forest, etc.) through the necessary steps to make a product for the end consumer. There can, of course, be intermediate products. Looking at each step, some of the main elements necessary for the success of a new innovation can be identified. The model focuses on identifying the key players and customers, the required changes to both production and processing systems, and the potential impact on rural sustainable development.

Figure 4-2. Model for assessing supply chain changes resulting from biotechnology.



Source: The Conference Board of Canada.

Very tentatively, we have tried to identify characteristics of supply chains for bioproducts in 2020. It is difficult to cover the first two categories—the dynamics of companies will no doubt involve many surprises, and the research base will have matured but in hard to predict ways. The other five steps are somewhat more amenable to examine in this sectoral outlook. Table 4-1 identifies what might be some key pressure points regarding the development of rural biotechnology capacity for the three natural resource sectors described in this Chapter.

Beneficiaries along the supply chain: Who will reap the economic benefits? Rural producers may see a range of potential revenue increases from the sale of their feedstock. The magnitude of this increase could be from no increase (in cases where they are simply selling their commodity feedstock to a different customer), to marginal improvements (which may be sufficient to keep operations that are on the brink of bankruptcy in business) to major revenue growth (if high-value applications of their biomass can be developed).

Biomass and other crop producers are only one component of supply chains. There are potential benefits to a range of players throughout supply chains. Some will be located in rural areas, others in urban *and* rural settings in Canada, or possibly in other countries trading with us. The reality is that all will be trying to maximize their value-added from the supply chain. These players include:

- Input producers: Companies that sell the seeds, brood stock or seedlings for use by the producers (farmers, aquaculturists, etc.).
- Transportation companies: There will be significant opportunities for shipping and logistics companies to ship biomass, or intermediate and end products. These will be to new customers at new destinations.

- Processing companies: Biomass often needs to be processed prior to shipping and it may make sense for biomass to be processed locally in rural communities (particularly when the biomass is either too light or too heavy for economic transportation).
- Transformation companies: These are companies that will purchase these new biomass inputs for transformation into products and services. Moreover, they may be able to develop new products and services from unconventional biomass sources (there are significant possibilities for gasification using everything from turkey innards to old tires in an advanced biorefinery). These are less likely to locate in rural communities.

The needs of these and other potential beneficiaries should be identified and addressed as part of any effort to stimulate biotechnology applications for rural sustainable development.

The presence of biorefineries in rural communities is a key indicator of whether the benefits of biotechnology will stay in the community. Biorefineries have the potential to bring with them high-value jobs, which may attract new people to rural communities, and attract a series of business activities related to transportation and logistics. On the other hand, if they drive up rural wages they will increase costs of wage labour for farm operators.

Finally, we must consider the role of consumers. As Dow Chemical noted when leaving its NatureWorks® partnership with Cargill, customers are not always prepared to pay extra for environmental benefits such as those associated with biodegradable clear plastic food containers.

In fact, consumers may not be inclined favourably towards those products that do not demonstrate direct and immediate personal benefits. This point was made repeatedly in the early years of debate over the introduction of GM crops. Will it also emerge with bioproducts such as biofuels, or with new synthetic fabrics made from corn rather than petroleum? The best answer we can give is that it will depend upon price, quality, dependability of supply, durability, and so on. The contribution to a cleaner environment, better life for rural residents in Canada, and even whether it is “Made in Canada”, are secondary benefits in the actual decision-making of most people.

Clearly the biggest and most immediate impacts of the three sectors we have examined will be on agriculture, especially given the developing interest in biofuels, the likelihood of major advances related to carbohydrate-based chemicals and other feedstocks, and the possibility of biopharmaceuticals becoming important in the longer-term future. But we also believe innovation in the forest industry is important. Pulp and paper mills are significant biorefineries at present, even if some operators do not see them in this light. But there is much greater potential if research now underway can be applied. The end result could become new income steams and less waste for both older and newer plants, which are significant to maintaining to the health of some resource-based towns. Aquaculture is the most enigmatic of the three sectors. At a minimum, Canadian science will produce valuable solutions for aquaculturists world-wide through development of new biotech-based solutions to fish diseases. But whether biotechnology will have a major influence on aquaculture crops and products in Canada, and therefore on incomes in coastal communities, is hard to assess at this time.

Table 4-1.
Supply chain analysis of biotechnology in three natural resource sectors

	Agriculture	Forestry	Marine Aquaculture
Inputs	A range of crops including corn, wheat and others such as biopharmaceuticals, possibly some agroforestry; Crop residues, wastes from food processing, slaughterhouses; Solid and liquid manure from livestock.	Biotechnology applications assist in the bleaching of wood pulp; Residues and wastes from mill operations transformed into more valuable uses.	Biotechnology applications applied to improve reproduction, reduce spread of disease and improve feed conversion; Fish-processing plant waste.
Production	Some crops will need heightened containment procedures; Mix of non-GE and GE crops; More efficient use of water, better crop rotations and cultivation, reduced use of biocides.	Major supply likely to be wood waste; Pulp and pulp mill waste effluent; Little or no use of GE tree crops but fast-growing poplar plantations likely.	Greater range of organisms produced including unicellular organisms, algae and seaweeds, finfish and shellfish; Transgenic organisms, if approved, need containment, perhaps land-based facilities; Improved feed conversion, pest and disease control; High-value health and well-being products.

	Agriculture	Forestry	Marine Aquaculture
Processing	Variety of biorefinery types in use including smaller, intermediate and large refineries, with much greater efficiency than now; Cellulosic and thermal processes permit much greater use of wastes; Location competitively determined by transportation costs, processing type, local organizational factors, but with significant incentives or other factors still in play.	Existing and new pulp mills become biorefinery sites; Biorefineries extract lignin used for production of ethanol, and refine and collect valuable resins and other molecules; Self-fueled, with energy surplus.	Production and by-products are processed into biofuels, animal feed, chemicals and health products through biorefineries and other forms of processing.
Customers	New customers in new supply chains, but price competitiveness with fossil fuels and chemicals still a problem; International marketplace for commodity and specialized products is major concern for Canadian producers.	Companies requiring chemicals and feedstocks such as resins for glues, foods and health products; Companies seeking biofuel sources.	Customers include agricultural farmers, health and beauty product companies, beer manufacturers, others; Aquaculturists seeking vaccines, medicines, biodiagnostics; Fish vendors, consumers.

	Agriculture	Forestry	Marine Aquaculture
Impact	Increased farmer and rural community income through higher overall return from crops and sale of residues, high-value pharmaceutical or other specialized crops; Reduced environmental impact (e.g., reduced pesticides, animal waste disposal); Moderate reduction in GHG (carbon dioxide and methane); Concerns may develop over competition for land use, biodiversity, soil quality and water use.	Added income streams for pulp and paper mills, making them more competitive and preserving rural jobs in resource towns; Reduced environmental impact from pulp and paper operations and ecologically sustainable use of residues; Moderate reduction in GHG (carbon dioxide); Value-added to wood residues, including from forests damaged by climate change.	Improved incremental revenues for producers and economic improvements for rural locations with biorefineries or other processing; Improved predictability of revenue resulting from effective management of fish reproduction and disease; Better environmental control and reduction in wastes; Ongoing concerns over containment and other issues related to genetic mixing, species introduction, spread of disease to wild stock, allocation of space for aquaculture.

Conclusions

Searching for Canada's elusive "natural advantage" in biotechnology and sustainable rural development has proved to be more difficult than we anticipated. There is a presumption in Canada that vast amounts of waste material could be harvested, and that significant land areas and water resources could be given over to dedicated bioproduct crops. This may be true, but the evidence will emerge only over a prolonged period of time, 10 to 15 years at minimum. At the moment, there are no convincing figures for how much land and water is surplus, or could be sustainably used for bioproducts in Canada. Actual levels of use will be determined by price considerations and incentives, consumer acceptance, and, of course, on the choices made in various decision processes in rural cooperatives and communities, government agencies and industry. Summary observations on each of these important categories are noted below. In addition, we provide conclusions about the three key components of sustainable development: economic/financial, environmental and social.

Price and incentives

In many biotechnology gatherings, the juxtaposition of two curves is used to set the stage: a long-term curve of declining prices for renewable resource commodities, and a rising curve of hydrocarbon prices. This is a disturbing juxtaposition since, taken at face value, it would appear to trap rural producers in a long-term downward price spiral, especially if much of the value-added processing and other revenue-generating activities take place away from the areas of primary production. And it is conceivable that Canadian producers could become engaged in a new round of price slashing, but subsidy-supported commodity trade with countries like Brazil and possibly the US.

We believe that it is sensible to presume that dramatic fluctuations will occur for both oil and renewable resource prices at various times over the coming 15 years, and this factor needs to be considered as we embrace new technologies. Otherwise we may become trapped into price support structures that will be difficult to change.

Everywhere there is a fear that inflated feedstock prices will occur as a result of particular circumstances, for example as shortages of ethanol occur in response to mandated levels in gasoline, or where farmers hold back supply to major biorefineries in the hopes of higher prices, or where alternative uses of the crop are more profitable, or where drought or other problems reduce yield. These problems will be exacerbated if trade regimes are restrictive.

Another major concern we have is about the level of subsidies or other incentives that will be sought for stimulating production of bioproducts, such as conventionally-produced biofuels. While it is reasonable enough to fund research, as well as pre-commercialization and pilot commercialization efforts, what appears to be happening is a rush towards substantial subsidies and possibly major tax breaks. The comparison is made to other energy, transportation, and food incentives, in particular for unconventional oil (tar sands) and various agricultural payments, especially those in the US and Europe.

We fear that the development of a whole new set of trade-restrictive (interprovincial and international), environmentally perverse fiscal measures could be put in place. Once in place, they may be hard to remove. We advocate minimizing these incentives in Canada, whether in relation to innovation for biotechnology, or for other technologies. Clearly this may put us on a different path than some other countries, such as the US or countries in the EU, but it will also place emphasis on developing technology and industrial processes that fulfill the conditions we set out in Chapter 1.

Consumer Choice

While we might presume that new bioproducts may not encounter the same level of controversy as generated during the introduction of GE food products, many of the same issues will arise. And there will be new issues, including deciding what criteria should be applied to determine whether new supply chains such as those to supply biofuels are environmentally sustainable. These debates will come back to rural areas, since they must respond concerning their land and water practices, species and habitat concerns, and so on. Likely, international and possibly Canadian certification pressures will emerge (see Chapter 7). These could become costly, credibility-stretching efforts for which neither the biotechnology industry, governments or rural producers appear to be particularly well prepared.

Decision Processes

We suggest a simple hierarchy to guide decisions over the coming years, until there is much more experience with various supply and demand situations affecting biofuels, in addressing urgent matters such as the dead forests created by bark beetles, and in fulfilling Canada's role (possibly expanding in coming years) as an food exporter. Rule one: Strive to use bioproducts produced from wastes wherever possible. Rule two: Biomass for food, fibre, and biofuel, in that order of priority. Rule three: Favour processes that make full use of all byproducts and that minimize pollution or waste.

We seek a decision mode that focuses on adaptive planning and management, where we can learn as we go, anticipate surprises, fully involve rural stakeholders, and avoid becoming locked into new, unsustainable pathways of industrial and rural development. We should be capable of implementing pilot efforts to enhance efficiency of new processes and to achieve breakthroughs that may be commercially viable and provide optimum sustainable development benefits to society.

Triple Bottom Line Sustainable Development Analysis

Economy

It is hard to determine whether biotechnology development, and specifically bioproducts, will make a substantial economic impact on rural communities. Some types of biotechnology may provide transitory benefits to the first adopters, but limited long-term benefits once all competitors have adopted the technology. Some economic benefits such as creation of new jobs may drive up rural wages, thus raising costs for some farmers. On the other hand, if competing farmers embrace new biotechnology that raises their revenues or lowers their costs, farmers that do not adopt the same technology risk real reductions in their profitability, so not going along may not be an option.

One could argue that any augmentation of rural incomes has the potential to maintain an operation that might otherwise go out of business. That said, it is worth asking whether the objective of economic sustainable development is survivability or "thrivability". If the goal is to help operations that might currently be limping along to continue limping along, then it is possible that biotechnology may provide just enough benefit to see this happen. If, however, the goal is to see rural operations and communities grow and thrive, then the potential impact of biotechnology is much more questionable.

Our analysis suggests that the key factor will be the location of biorefineries. These facilities have the potential to bring new, high-value jobs to rural communities. The biorefineries will require support operations—particularly related to transportation and logistics—that may also bring greater employment. Moreover, biorefineries will have many different outputs that can also be transformed into products and services. Biorefineries have the potential to be anchor facilities in rural communities. However, the economic viability of rural biorefineries, including whether or not workable financial and institutional arrangements can be developed, remains quite speculative. Many more pilot efforts are needed over the coming five years.

Environment

As discussed at length in other sections of this report, the environmental prospects of biotechnology applications related to sustainable development are mixed. The proposed benefits, such as reduced pollution from feedlots, reduced pesticide application, and reduced energy use, are tempered in some cases with concerns about unintended effects due to the novel organisms themselves, and knowledge gaps around the effect of removing increased amount of biomass from the various natural resource systems. Environmental effects depend very much on the specific biotechnology innovation under consideration. We believe that greenhouse gas benefits arising from rural biotechnology applications will be modest for the foreseeable future, and will need to be compared with alternative action in terms of their cost-effectiveness.

Social

Biotechnology's major anticipated social impacts would result from higher levels of education and stronger information sharing networks in communities. Renewed or increased economic activity could bring collateral re-investment in rural social infrastructure, and successful cooperative ventures could increase the level of trust and cohesion within communities.

These positive outcomes must be balanced against identified potential negative outcomes[74]. such as:

- Increased secrecy and surveillance due to the intellectual property agreements that erode the culture of sharing and mutual support in rural areas,
- Loss of local control of land as farms become larger and possibly owned by absentee landlords,
- De-skilling of workers as new technologies enable producers to pay less attention to their local climate and land, and
- Increased conflicts between producers due to challenges of containing high-value products whose identity is key to their market value (e.g., GM contamination of organic crops; mixing of wild and aquacultured species).
- We expect that the impact of biotechnology on rural social sustainability will fall somewhere in an uneasy equilibrium containing all of these issues, depending on the community in consideration.

[74] M. Mehta, *The Impact of Agricultural Biotechnology on Social Cohesion* (Vancouver: UBC Press, 2005): www.genomecanada.ca/ge3ls2005/proceedings/06_03.asp.

Biotechnology in 2020 – Many factors; Difficult to Align

The supply chain analysis makes plain the complexity of the transformation to a bioeconomy. It will not just be about new technologies that can do things more cheaply or cleanly, but will depend on a suite of transformations that include new relationships, knowledge and infrastructure across many sectors. Imperative transformations include the following:

- Biorefinery technologies evolve quickly;
- The economic viability of these businesses improve rapidly;
- The price of oil continues to be maintained at levels above USD $75 per barrel;
- Producers embrace new production and processing practices;
- New relationships form quickly and deeply across supply chains;
- Regulatory processes achieve their established intents and targets;
- International trade remain open to biotechnology products and services; and
- Public attitudes toward biotechnology become more nuanced and open.

Having all these factors happen in the coming years is a tall order.

It is clear that in the near to mid-term future, biotechnology poses a "mixed bag" of opportunities for sustainable development in rural Canada. Although many of the innovations that are being considered or developed today could improve environmental or economic conditions, these innovations are being developed in a very complex international milieu, will require the re-tooling of supply chains, large amounts of social learning and not insignificant investments. There must be a strong will and a coordinated response from a number of different sources in order to make the transition successful.

CHAPTER 5. Sustainable Development Assessment Framework

Rationale for a Framework Approach[75]

If Canada, through its innovation policy objectives, wishes to develop biotechnology in support of sustainable development, an appropriate assessment framework should be developed. Without such a framework, it will prove difficult to assess either risk or opportunity accurately, and thereby make it more difficult to make solid policy decisions. In the absence of reliable assessment tools, decisions tend to be held up or avoided. This stalling can cause problems for private sector investors in new technologies and delay the development of potentially useful innovations to meet urgent SD needs. And public trust can evaporate, as exemplified by the controversies surrounding GE crop and food introductions in Europe.

As noted in other chapters, Canada has not fully considered the ecological, social and economic implications of tomorrow's wave of biotechnology applications, nor has it instituted mechanisms for gaining public understanding and acceptance. We would argue that this holds true across a range of today's initiatives, including GE crops and biofuels. Ideally, these implications should be addressed in an integrated fashion, examining interactions among the various categories of impact. Such an approach would cover the "triple bottom line" (TBL) of social, economic, and environmental facets of sustainability.[76] It would introduce a more balanced look at how to assess and regulate, for example, through the application of economic analysis and instruments on issues linked to environmental biotechnology and to biodiversity conservation.

A sustainable development assessment framework should be available for biotechnology policies, R&D initiatives, pre-commercialization development strategies, and the full implementation stage. A framework approach should make full use of existing assessment methods and tools, and would not displace existing regulatory federal frameworks, such as those mentioned in Chapter 3. Instead, the framework should help to address questions that generally go unanswered under current reviews. For example, proponents of biotechnology use sustainable development as a rationale for moving ahead, yet the question of whether sustainability is truly being advanced often is not examined rigorously, or with necessary indicators or assessment standards.

We must underline the provisional nature of a sustainable development assessment (SDA) approach, as there are no formal procedures in place in Canada. Fortunately, entry points to SDA exist at both the strategic and project levels, drawing upon Canadian and international

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[75] This Chapter is based in part on a Background Paper prepared for this Report by Barry Sadler, *Towards a Framework for Sustainable Development Assessment (SDA) of Biotechnology.* The topics discussed here are discussed in much more detail in this background paper. Available upon request from info@cbac-cccb.ca

[76] Development of biofuels is a prime example of such a need. There are about as many opinions of the economic, social and environmental benefits and costs as there are analysts. Examples of efforts to provide an overview concerning all three aspects include: K. Parris, *Lessons from the OECD Workshop on Biomass and Agriculture* (2004); W. Maybee, *Economic, Environmental and Social Benefits of 2nd-Generation Biofuels in Canada,* BIOCAP Research Integration Program Synthesis Paper (2006); A widely debated paper is T.W. Patzek and D. Pimentel, "Thermodynamics of Energy Production from Biomass," *Critical Reviews in Plant Sciences* (24) (2005), pp. 327-364.

experience.[77] In this Chapter, we lay out a proposed approach, and examine how the framework might be used in conjunction with existing assessment tools. At the end of the Chapter, we review some helpful methods developed for longer-term integrated assessments of biotechnology applications, including technology roadmaps, foresight analysis, and scenario development.

Today's Regulatory Situation

We do not wish to be alarmist concerning biotechnology regulation. Procedures exist to ensure that some level of environmental safety assessment is carried out before any new, (or "novel") biotechnology-derived product can be released into the environment in Canada. We believe a considerable element of precaution is currently in place under Canada's environmental regulatory scheme. Canada relies on several key regulatory processes to assess biotechnology. For example, aspects of forest biotechnology might be regulated under the *Seeds Act* for GM trees, the *Plant Protection Act* for imports, the *Fertilizers Act* for biofertilizers and mycorrhizae, and the *Pest Control Products Act* for biopesticides. The *Canadian Environmental Protection Act (CEPA)* comes into force when developers attempt the introduction of novel traits. It is conceivable that environmental assessments on some large projects or certain kinds of introductions would be carried out under the federal *Environmental Assessment Act* or provincial assessment acts. While Canada has not ratified some international protocols, notably the Cartagena Protocol that governs the trans-boundary movement of "living modified organisms", it is active in the development of this Protocol and other aspects of the Global Framework Convention on Biological Diversity.[78] This array of domestic and international law and regulations is imposing, even daunting.

What we seek is a means for streamlining regulatory processes so that priority initiatives move ahead quickly and effectively, while ensuring that we avoid being led into biotechnology directions that are unlikely to achieve better sustainability results, or situations that would end up creating ecological, social and economic problems that could be costly to address.

Biotechnology introductions in years ahead may suffer from the legacy of GE crop introductions, where the technology development surged ahead of society's understanding and willingness to accept assertions about benefits,[79] especially when such benefits were not seen to be of much direct value by consumers. The resulting controversies have provoked limitations on European research, holdbacks on proceeding with introduction of some GE crops (e.g., GE wheat in Canada), great caution about field trials for GE tree crops such as poplar, risk aversive trade action by countries such as China and the EU nations, and a rejection of GE food aid by some African countries. It has taken a decade after initial crop introductions for scientific assessment

[77] An up-to-date summary of innovative assessment approaches is provided in B. Dalal-Clayton and B. Sadler, *Strategic Environmental Assessment: A Sourcebook and Reference Guide to International Experience.* (London: Earthscan, OECD, UNEP, IIED, 2004): www.iied.org/Gov/spa/docs.html.

[78] An important aspect for Canada is to have a solid strategy concerning genetic resources including access and benefit sharing and a clear understanding of what the implications are for the entire variety of such resources in Canada. See M.J. Middelkoop et al., *Strategies for Accessing and Using Biodiversity-based Genetic Resources for a Bio-based Economy Assessment of Approaches in Other Countries and Options for Canada* (Ottawa: Stratos, Inc., 2004).

[79] For a retrospective look see G. Brookes and P. Barfoot, *GM Crops: The Global Socioeconomic and Environmental Impact – The First Nine Years 1996-2004* (UK: PG Economics Ltd., 2005).

to catch up and to start providing useful evidence-based responses, [80] and even now there are still gaps according to many serious reviewers in the science community.

Issues arising from existing GE crop situations and from newer biotechnology applications such as bioproducts, for which only limited information is available, include:

1. A lack of comprehensive knowledge about basic ecological factors such as long-term effects on soil ecology and fertility[81], and on biodiversity[82]. As noted in Chapter 3, fundamental research on ecosystem impacts remains incomplete and a much-needed eco-region approach is absent;

2. A lack of credible results demonstrating actual environmental improvements;

3. Inadequate mechanisms to ensure flow of benefits to producers and end users;

4. Inconsistent application of the precautionary principle and limited value of risk assessment methods;

5. Potential unintended impacts such as contamination of adjacent farming areas, spread of modified genetic material into "wild" populations, possible toxic effects on non-target species, and selection for herbicide-tolerant pest species;

6. Limited commercial success of some bioproducts under current economic policies and established petrochemical dominance in markets;

7. Gaps and potential overlap in Canadian regulatory frameworks, and lengthy time period for approvals; and

8. Fragmented knowledge about the full range of impacts from integrated operations such as those associated with biorefinery value chains.

Identifying these issues does not imply that biotechnology innovations are bad. However, the lack of a good analytical framework and sound scientifically-based findings makes it difficult to develop a comprehensive, integrated overview that allows the determination of <u>which options are most beneficial</u>. We can expect that future examination of biotechnologies will be more difficult and as more becomes known, resulting questions will be tougher to answer. This has already become apparent, for example, in examining the long-term impact of removing an increasing fraction of plant residues from industrial croplands or from forested areas. The difficulty of assigning intellectual property rights and access to benefits associated with biodiversity, such as

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[80] U.S. Institute of Medicine and National Research Council, Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health, *Safety of Genetically Engineered Foods. Approaches to Assessing Unintended Health Effects. (*National Academy Press, 2005).

[81] P.P. Motavalli et al., *Impact of Genetically Modified Crops and Their Management on Soil Microbially Mediated Plant Nutrient Transformations. J. Environ. Qual.* (33) (2004), pp. 816-824.

[82] Government of Alberta, The Alberta Biodiversity Monitoring Program, Program Overview and Consultation Background (2005). This provincial initiative provides for a large number of biodiversity/ ecological monitoring sites, and periodic release of a State of Biodiversity Report, among other features.

bioprospecting of the ocean floor to create new industrial enzymes, is another type of concern requiring assessment.

The final note in this section is one of urgency. The challenges faced in the past decade, when the agricultural biotechnology 'cart' got in front of the policy and regulatory 'horses', could pale in comparison to those posed by what is now in the pipeline. This is especially the case for those aspects of biotechnology involved in the transformation from a fossil fuel-based economy to a bio-economy. These include:

- The economic, ecological and social benefits and costs of technology choices for biofuels;
- The integrated assessment of biorefineries and their products;
- Mechanisms for ensuring safe introduction of "bio-pharming"; and
- The difficult questions surrounding GE invasive species and deliberate introductions in forestry, aquaculture, agriculture and some forms of bioremediation.

In the near future, new fields such as bio-nanotechnology will open additional integrated assessment needs.

Sustainable Development Assessment (SDA) Essentials

The main purpose of this Chapter is to take a forward look at the potential of an SDA framework for biotechnology. Below we discuss procedures for identifying initiatives requiring further assessment. We will also examine the reliability of instruments and methods for evaluating the significance of potential cumulative, ecosystem-level impacts that may be associated with wide-scale biotechnology applications, particularly GE-based farming and industrial crops, use of residual materials and the operation of biorefineries, and impacts of bioremediation. Assessment should be comparative, examining proposed initiatives in comparison to status quo situations and also considering other alternatives, for example, the various means for producing bioethanol, in order to gain a clear sense of benefit/cost and feasibility.

We will contemplate how to bring together economic, environmental and social considerations when making decisions on future investments, or weighing the pros and cons of particular proposals. This last concern points toward the need to undertake assessments at various levels and stages of decision-making, such as policy development in support of innovation, new technology research and development, raw materials and industrial production processes and products, and end-of-life disposal and re-use ("cradle-to-cradle").

An accepted, made-in-Canada framework for sustainable development assessment (SDA) has yet to be developed, let alone pilot-tested for its application to biotechnology. However, the basic concepts, perspectives and principles of sustainable development are now well-known and different forms of impact assessment procedure and methodology have been in place at the federal level for some 30 years. Approaches to SDA or equivalent terms[83] have been rolled out in several countries including the UK and Australia. These trends represent the emergence of a 'third generation' process of impact assessment, one that builds on and extends project-level

[83] Equivalent and near-equivalent terms for SDA include: sustainability assessment or appraisal (UK), sustainability impact assessment and integrated assessment (European Commission), strategic impact analysis (OECD/DAC) and integrated assessment and planning for sustainable development (UNEP).

Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) of policy, plans and programs. By unpacking these developments, we can outline the building blocks of SDA, at least in provisional form.

Our proposed framework consists of a series of interlocking parts, leading from the general idea to specific application:

1. Fundamental perspectives of sustainable development for assessing general progress toward or away from sustainability;
2. Aims, principles and criteria that can support an integrated approach to SDA;
3. Examples of SDA systems and processes and their near equivalents considered in the context of biotechnology; and
4. Available tools.

Foundation

Three fundamentals of sustainable development provide the foundation for SDA. A biotechnology initiative should:

1. Meet the twin principles of intra-generational equity, or improving the welfare of all people, particularly the poor and disadvantaged, and inter-generational equity**,** or maintaining development options and opportunities for the generations that follow;
2. Maintain or preferably increase the stock of capital available (per capita) to meet current *and* future needs, with particular attention given to the maintenance of natural capital at a level that guarantees the unimpaired functioning of critical sources and sinks (i.e., "strong or moderate sustainability"); and
3. Not transgress key global environmental thresholds, but should observe the four system conditions for long-term or absolute sustainability (see Box 1-4).

Integration

SDA requires substantive integration of the economic, environmental and social pillars of sustainable development, and the procedural integration of assessment steps, methods, opportunities for stakeholder participation and inputs to decision-making on proposed strategies and actions. Current progress towards or away from sustainable development can be measured against objectives and principles (normative values to aim for) or bottom-line criteria (warning signs to avoid or safe minimums to stay within). These can be described generically, but they are context-dependent and need to be specified for application to different types of biotechnology initiatives.

For integrated decision-making, the key objectives must be addressed simultaneously and appropriately balanced to reflect the mix of environmental, social and economic gains that a society, sector or community wants to achieve *and* gains in one area cannot be made at the expense of losses that exceed the triple-bottom-line figure of another. Such an approach will have five elements (see Box 5-1).

The assessment should contribute to an integrated process of decision-making focused on the three columns of Box 5-1, as noted in more detail below:

A systematic process for analyzing the economic, environmental and social impacts and issues associated with proposed biotechnologies. A large body of experience exists for assessing all three forms of impact separately. EIA procedure, with certain modifications, could be applied to undertake SDA for biotechnology at the project level in two stages: preliminary assessment (screening and scoping); and impact analysis of major initiatives (e.g., a commercial-scale bioethanol plant). Similarly, SEA procedure (now enshrined in legislation in EU member states) could be adapted to biotechnology strategies and other higher-level proposals. In this model, impact assessments could either proceed as three parallel streams with full integration undertaken in final decision-making (see below) or utilize an integrated methodology. The former approach seems more practical based on current experience, although it is not without its own challenges.

A framework of sustainability aims, principles and criteria against which effects can be evaluated. This involves testing the significance of economic, environmental and social effects of a proposal against an explicit framework of sustainability criteria. Such a framework might have four sub-levels:

- **Economic, environmental and social aims and objectives** that sector-wide or specific biotechnology initiatives are intended to achieve, giving direction and focus to an SDA.
- **Process principles** that govern the conduct of assessment overall, including statutory requirements, formal guidance and widely accepted lessons of good practice, backed as necessary by SDA-specific rules of thumb (e.g., for determining net gains and losses associated with biotechnology initiatives).
- **Substantive principles** that guide the assessment of effects with regard to the determination of significance in a sustainability context. For strong sustainability assurance, this involves applying supply-side or capacity-based principles to maintain natural capital, and demand-side or precautionary principles to address scientific uncertainty inherent in supply-side principles.
- **Specific indicators** that translate general principles into concrete measures for assessing effects (and outcomes). These comprise two types: triple-bottom-line (TBL) or safe-minimum thresholds not to be exceeded, and target optima that indicate objectives or values to be reached.

A set of rules for integrating and weighing different objectives in evaluation and decision-making in support of sustainable development. Within an SDA framework, the most critical requirement is a process that relates and reconciles the economic, environmental and social considerations of a proposal. Borrowing from the CBAC *Dialogue Tool* (see Chapter 6 for a description), these could be as follows:

- Highest priority given to win-win-win options that maximize net gains with no serious adverse effects and then to options where gains significantly outweigh losses;
- When trade-offs must be made, preference given to the best practicable option for realizing gains that does not involve a potentially significant adverse impact;
- For trade-offs that assume potentially major or significant adverse impacts can be mitigated, the burden of proof or argument rests on the proponent and must be substantiated as reasonably prudent;

- Given the scope of potential changes from biotechnology alterations and releases, decision making needs to take account of the effects within extended time and space scales. In this context, particular emphasis should be given to the issue of cumulative, ecosystem-wide effects.

Box 5-1. Framework for integrated assessment in support of sustainablity

Elements of assessment	Environmental, social and economic impacts	Sustainability reference points and perspectives	Rules for decision-making and process governance
1. Preliminary assessment (screening and scoping)	Environmental, economic and social impact assessment	Selected goals, principles, indicators	Science, participation and transparency of trade-offs accountability, ownership
2. Impact analysis and mitigation			
3. Comparison of alternatives for significant effects			
4. Trade-offs and choice			
5. Implementation and monitoring of decisions			

Source: Modified from United Nations Education Program, 2003.

Practical Application

The general approach to SDA described above represents what has been called "third generation" impact assessment. A small number of systems and processes are already in place, in Canada or elsewhere, which consider social, economic and environmental pillars and/or relate them to some form of sustainability framework. These operational examples of SDA and equivalent approaches deserve attention here, for their potential adaptation to a Canadian SD framework for biotechnology assessment.

EIA and SEA processes: When these processes include social, health and economic impacts, or have some reference to sustainability considerations, they provide a basis for undertaking an integrated approach. In Canada, the federal regimes for EIA and SEA both fall in this category, although neither really has been applied to biotechnology. Rather, health, food risk and environmental safety assessments are undertaken under different pieces of legislation. However, there is emerging recognition of the potential of EIA to provide a safety check on major ecological and socio-economic concerns related to the possible commercial introduction of GE crops and the potential of SEA[84] to integrate these considerations into the earlier, pre-commercial phases of biotechnology development[85]. A risk-based approach, using qualitative and quantitative analysis and opportunities for public participation, has been promoted.

Ecosystem-wide effects from the potential dispersion and cumulative changes associated with introduction of novel living organisms (NLOs) should be part of environmental assessment. Over the longer-term, EENLO could provide the baseline and assessment methods needed (see Chapter 3). Discretionary provision is made for regional assessment in recent amendments to the *Canadian Environmental Assessment Act*. At the provincial level, consideration of cumulative effects is a component of integrated resource management systems (e.g., Alberta and BC). Key elements of this approach include baseline analysis, identification of resource potentials and use capability, and evaluation of possible changes against ecological principles and indicators. So far, however, these aspects are very weakly applied, or not at all, in the context of biotechnology assessment in Canada.

Full coverage systems. A number of countries have established impact assessment systems that address economic, environmental and social considerations. These include:

Regulatory Impact Assessment (RIA) that, in traditional form, is a benefit-cost analysis of regulatory proposals that determines if they represent the best alternative when they address health, social, economic or environmental risks. Extended forms of this approach include the *European Commission Integrated Impact Assessment*, and the *UK RIA* process, which has incorporated a flexible, integrated policy-appraisal framework in an attempt to assess the full range of effects (e.g., on health, rural areas and multi-cultural impacts). Both EC and UK experience suggests that RIA, in practice, might best be seen as a partial integration model that emphasizes cost-benefit analysis with little explicit reference to sustainability.

Comprehensive Regional Assessment (CRA), as applied to Australian forest policy and plans, is undertaken through two parallel streams of environmental and heritage assessment: one relating to forest values and options for ecologically sustainable management, the other to economic and social assessment of resource use and development opportunities, and consequences of exploiting them. It is conducted as an open, public process consistent with EIA procedure and leads to the conclusion of federal-state agreements on the balance of forest protection and use. The CRA

[84] N.A. Linacre et al., *Strategic Environmental Assessment. Assessing the Environmental Impact of Biotechnology* (summary of longer article) (IFPRI, 2005): www.ifpri.org/pubs/ib/ib41.pdf.

[85] An interesting Canadian effort is SAFT (Sustainability Assessment Framework and Toolkit) being developed as an integrated means of examining R&D initiatives and possibly other pre-commercialization stages of biotechnology development. See D. Minns, *A Prototype Sustainability Assessment Framework and Toolkit (SAFT) for application to Technology and Innovation Roadmapping* (Industry Canada, 2003).

approach offers insight on how to assess biotechnology strategies that provide for the introduction of GM-trees or crops on a regional or ecosystem-wide basis.

Biotechnology-specific assessments: Examples of assessment systems that apply specifically to biotechnology fall into two main categories:

- **Technology assessment (TA)** has been used in the US since the mid-1960s to address the benefits and potentially harmful, social, economic and environmental consequences of new or modified technologies. It is more broadly construed and less well-defined than EIA, although there is considerable overlap in their process and approach. TA has become more fragmented (demand-driven) and narrower in focus recently. Biotechnology and nanotechnologies are seen as warranting a return to bigger-picture TA, which establishes the basis for systems redesign or promotes constructive investments.

- **Risk assessment (RA)** is widely used to determine the possibility or likelihood of health or environmental harm occurring as a result of a range of activities, including the introduction of biotechnologies. It is a formalized process to address uncertainty, typically through quantification of effects. In many situations of high uncertainty, public perceptions of risk need to be taken into account, and incorporated into risk communication. A risk-based approach is also used in EIA and SEA, particularly to deal with cumulative effects and ecosystem level changes. In this context, the qualitative use of comparative risk assessment can be helpful in prioritizing the biotechnology issues to be addressed in Canadian policy discourse.

  Two examples of institutionalized risk-based approaches to biotechnology are the Australian *Gene Technology Act* (2000), which provides for assessment and regulation of certain 'dealings' in relation to genetically modified organisms (GMO), including research, manufacture, production, propagation, commercial release and import; and the New Zealand *Hazardous Substances and New Organisms Act* (1996), which established the Environmental Risk Management Authority. The Authority undertakes a risk analysis of the benefits and risks associated with new organisms, including their relationship to Maori values and societal ethics (through advice from a specially constituted panel).

Tools for Analysis

A large tool kit is available for use in SDA. Some of these are integrative or have specific application to biotechnology application, such as life cycle analysis (LCA). However, there is no single 'best' methodology for conducting such an analysis and use can be made of traditional tools such as cost benefit analysis, or trend analysis for assessing economic, environmental and social impacts and risks. In Box 5-2, examples of tools are given for four key analytical steps (which broadly correspond to elements in Box 5-1).

A number of general rules of analysis apply when employing these or other tools in SDA of biotechnology proposals. First and foremost, they will need to be adapted to the geo-political context and circumstances of the application. Second, an interdisciplinary process should be followed to ensure that economic, environmental and social information and inputs are integrated or interrelated at key stages in the process. Third, the simplest tool consistent with the task should be used in SDA, although in the case of biotechnology applications more advanced methods often will be appropriate. Fourth, the tools should be adjusted to the temporal and spatial dimensions of likely effects and to uncertainties, which may arise due to limited knowledge of cause-effect relations, insufficient data, etc. Finally, information should be structured to help clarify the trade-offs at stake and to substantiate the relationship of gains and losses.

Box 5-2. Application of tools in SDA

Analytical steps	Tasks and tools for examining biotechnology strategies
SDA application	Determine legal or policy triggers Technology roadmaps Use formal/informal sustainability checklists
Background and baseline analysis	Environmental scan to look at the total picture Trend analysis and extrapolation Policy compatibility matrix Scoping the issues and approach
Impact analysis	• Decision 'trees' and effects networks • Scenarios • Systems modeling • Comparative risk assessment (CRA) • Life cycle analysis (LCA)
Comparison of alternatives and clarification of trade-offs	Expert judgments Multi-criteria analysis Cost-benefit analysis Sensitivity analysis

Detailed comments are provided in the SDA Background Paper by Barry Sadler on each step and the various tools.[86] Here we will restrict ourselves to several observations of particular significance.

Use of Checklists

There are no institutional arrangements in force in Canada that would trigger an SDA of biotechnologies. A checklist approach could be done on an informal basis as an entry point for more detailed SDA work. Checklists can vary in complexity and purpose, from a simple set of questions to a structured methodology or system that also assigns significance by scaling and weighting impacts. They may include goal statements, as the example noted in Box 5-3 represents. The example, from a recent examination of mining and sustainable development, might be particularly helpful for some bioproduct value chain assessments.

[86] To request this paper, please contact info@cbac-cccb.ca.

Box 5-3. Questions for a Sustainable Development Checklist

The following questions were developed as part of the North American component of the Mining, Minerals and Sustainable Development (MMSD) process commissioned by the World Business Council for Sustainable Development (WBCSD) and IISD:[87]

1. **Engagement:** Are processes of engagement in place or committed to that ensure all affected communities of interest (including vulnerable or disadvantaged sub-populations by reason of, for example, minority status, gender, ethnicity or poverty) have the opportunity to participate in the decisions that influence their own future; and are these consistent with the legal, institutional and cultural characteristics of the community?

2. **People:** Will the project/operation lead directly or indirectly to maintenance of people's well-being (preferably an improvement) (a) during the life of the proposal and (b) following closure?

3. **Environment:** Will the project or operation lead directly or indirectly to the maintenance and strengthening of the integrity of biophysical systems so that they will continue post-closure to support the well-being of people and other life forms?

4. **Economy:** Is the financial health of the proponent assured and will the proposal contribute to the long-term viability of the local, regional and global economy in ways that will help ensure sufficiency for all and provide specific opportunities for the less advantaged?

5. **Traditional and non-market activities:** Will the proposal contribute to the long-term viability of traditional and non-market activities in the community and region?

6. **Institutional arrangements and governance:** Are appropriate institutional arrangements in place and do they provide certainty and confidence that the likely effects of the proposal will be properly addressed and managed throughout the full life-cycle?

Life Cycle Analysis (LCA)

LCA has been identified as one of the most promising methods for assessing the impacts of biotechnology proposals.[88] However LCA also has been one of the most difficult to come to grips with, since there are many assumptions made in any LCA and data are generally limited. It analyzes the full environmental impact of a strategic or specific action over its entire life cycle (whether cradle-to-grave, or cradle-to-cradle). LCA tends to focus on material and energy flow, and pays scant attention to ecologically significant features or biological diversity impacts.[89] In reality, the value and practicality of LCA is subject to questioning and this is particularly so at the strategic level (given that this tool was developed largely for specific products).

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[87] www.iisd.org

[88] An example application is G. Zhi Fu et al., "Life Cycle Assessment of Bio-ethanol Derived from Cellulose" *Int. J. LCA* 8(3) (2003).

[89] An example of this problem is the very useful, but still limited approach to LCA described in B. Dale, *Environmental Impacts of the Biobased Economy,* Presented to the OECD Workshop on "Managing the Transition to a Biobased Economy" (Ghent, Belgium: December 1-2, 2005).

From a biotechnology perspective, the OECD (2001) has described three levels at which LCA can be conducted:

1. **Conceptual LCA**, provides a framework or *aide memoir* to think through the issues, which may be useful to scope biotechnology issues and, perhaps, structure an SDA;

2. **Streamlined or simplified LCA**, covers the whole life-cycle of a proposal, but only superficially or strategically, where specific impacts are difficult to determine or where the concern is to gain a qualitative but informed overview of issues and effects; and a

3. **Complete or detailed LCA**, which follows the standard methodology to calculate the full effects of a proposal in accordance with the approach outlined in ISO 14040-43.

Clearly LCA can be a useful adjunct to SDA, but it does not replace the need for such a framework, or even the need for broader environmental assessment. And the assumptions, quality of databases and transparency of calculations all must be considered.

Looking at the Long-term: Technology Roadmaps, Scenarios and Other Means for Adaptive Planning and Assessment

Building a vision for a sustainable future permits the examination of the assumptions on what is possible and then the necessary backcasting for how to get there. Such an approach can use a variety of models, mechanisms for drawing out expert and public opinion, and formal approaches such as foresight exercises. Generally these efforts are one-off, yielding insights about sustainable development potential outcomes that become fixed around technologies and assumptions of the time. One favoured approach is the development of technology roadmaps that provide a comprehensive overview of possibilities and sources of innovation. A number of these have been prepared in Canada and elsewhere[90] and are pertinent to BSDE.

In our Executive Report we describe *Just Imagine … 2020 …* as a positive scenario concerning biotechnology and sustainable development. Of course it is only one of many possible scenarios that could be considered. Some might be much more pessimistic about possibilities and timelines. Others might emphasize the competitive advantages of other nations in relation to levels of investment, size of markets, etc. And, it would be possible to construct a "muddling through" scenario, where Canada fails to adopt new technologies due to various barriers and an inability to foster key drivers such as strengthened calls for a clean environment. Some might be bolder, speaking to Canada's "natural advantage" of a large land and biomass potential.

Biotechnology scenarios feature prominently in several international initiatives. The OECD has examined the role of biotechnology in agriculture, medical, environmental and industrial applications, leading the OECD Secretary General in 2002 to prepare an article [91]entitled *Biotechnology: The Next Wave of Innovation Technologies for Sustainable Development.* The OECD has now embarked on a new project: *The Bioeconomy to 2030: Designing a Policy*

[90] An example of a privately prepared effort in the US is *The Technology Roadmap For Plant/Crop-based Renewable Resources 2020,* Renewables Vision 2020 Executive Steering Group (a group comprised of representatives from the corn industry, chemical producers and others).

[91] I. Serageldin and G.J. Persley (eds.), *Biotechnology and Sustainable Development: Voices of the South and the North*.

Agenda. The core of this project[92] is to develop a "no-regrets" form of policy-making for the biosciences, so decisions can be made without foreclosing on future opportunities and options. The OECD study will rely on scenario development rather than forecasting, since technology futures are "inherently unpredictable."

In 2000, the World Business Council for Sustainable Development[93] introduced three biotechnology scenarios at a global level, each dealing with a different driver: fear of innovation, consumer choice, and opportunity to shape outcomes. The third, called *Biotrust*, is based on building trust among stakeholders while taking into account eight areas of concern: transparency, ongoing stakeholder involvement, ground rules for risk-benefit analysis, a global system of safety standards, inclusion of developing nations in the benefits of biotechnology, data protection, guidelines for patenting and licensing, and responsibility for external costs and other liability issues.

The most comprehensive Canadian effort to look ahead is through several foresight exercises initiated through the National Research Council and the Office of the Science Advisor[94]. This effort is intended to influence policy in a number of ways based on five forms of "innovation capital" ("education, environmental protection, R&D supported risk sharing, and social institutions and network efficiencies created by public infrastructure investments"). The methodology is aligned with strategic policies, but is viewed as complementary to, rather than actual policy-setting.

Most scenario work and foresight related to biotechnology, including the examples cited above, might be described as still at the 'mile-high' stage—first-time examinations of the subject. In the context of a sustainable development framework, the tools need to be sharpened to the point where they will become more useful in detailed examinations of specific applications (e.g., what options exist for the farm economy of western Manitoba to invest in bioenergy and biorefinery development; how might this compare with massive investment in wind farms over the coming 20 to 40 years; and what might be the impact of climate change on the economic scenario?). Scenarios should be regularly developed and incorporated into adaptive planning and management, leading to decisions that reflect not only the availability of updated information, but also take into account the results of changing attitudes and implementation results.

We reflect on these hypothetical examinations because they lend insight into the kinds of issues we must consider now if we are to understand and shape science and technology applications for future use. Throughout this report, we will place emphasis on adaptive planning and management, which requires both public dialogue and trust-building. We live in an age where change is constant and surprises are common. An adaptive approach encourages mutual learning processes, where all parties openly acknowledge that innovations are indeed experimental, with implications and impacts being revealed only gradually.

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92 OECD, *Scoping Paper*, International Futures Programme (2006): www.oecd.org.

93 WBCSD, *Biotechnology Scenarios: 2000-2050. Using the Future to Explore the Present* (Geneva: 2000): www.wbcsd.org.

94 For a description of recent examples, including Bio-Systematics, Bio-Products Industrial Economy, and APEC Future Fuels Foresight, see J. Smith, *S&T Foresight: Provocateur for Innovation Policy* (2006): www.proact2006.fi/chapter_images/267_Ref_A10_Jack_Smith.pdf.

Throughout our BSDE Report we emphasize the need for an adaptive planning and management approach. We consider the sustainable development assessment approaches described in this Chapter as a way of introducing adaptive assessment, since SDA looks into the future, and likely will be done in an iterative fashion as major initiatives mature. Canadians invented the concept of adaptive environmental assessment, and its use is becoming more generally recognized in decision-making in Canada. The methods of adaptive assessment are intended to guide resource management (e.g., "learning by doing" in the Department of Fisheries and Oceans; wildlife management in the Canadian Wildlife Service; Climate Change Adaptation Country Study and initiatives). However these methods are not being systematically applied in the case of biotechnology. We believe this should become a more active area of exploration by adaptive assessment researchers.

Conclusion

The lack of legislation or directives specific to either biotechnology and sustainable development assessment and management in Canada can be seen as both a problem and an opportunity. It is a problem because there is currently no legislated commitment and therefore applications are spotty at best. On the other hand, an opportunity exists to engage in the design of a robust framework that could serve Canada well during the period of intensive innovation and transformation that we expect over the coming 15 years and beyond. We believe the time to act is now.

The starting point could be piloting of efforts, especially for the rapidly evolving bioproducts sector. These are the initiatives most clearly identified for their potential in achieving sustainable development objectives. And they present the full range of assessment issues and methodological problems. We consider the current approaches, including EIA, LCA, economic and risk analysis, and application of foresight inadequate to move this sector into the mainstream of Canadian rural and industrial development. The many assertions and fragmented analyses do not add up to a convincing whole in terms of policy needs, especially for the major transition away from existing fossil-fuel dominated approaches. Further, in the absence of an approach designed around adaptive planning and management, and based on extensive dialogue, learning, and actual achievement of benefits (especially with rural communities) this new sector could well run into the developmental roadblocks faced by GM agriculture.

A sustainable development framework has the advantage of providing for the examination of environmental, social and economic benefits and costs – together. It needs to be designed so that these factors are not simply lumped together, but so that each can be distinguished by those who use assessment results. Over time it should be possible to provide integrative measures and indicators that are widely accepted, but this level of sophistication is not likely to be achieved soon. In one sense this is good, because it means the framework can be implemented by relying on methods and tools that people are already familiar with.

We see three practical starting points based on existing processes: (1) risk-based safety assessments, (2) the existing federal environmental impact assessment process, which are sometimes starting to become more like sustainable development assessments[95]; and (3) perhaps a strategic environmental assessment process for biotechnology and sustainable development.

[95] See R. Gibson, Canadian Environmental Assessment Agency R&D Monograph on moving from environmental assessment towards a sustainable development approach.

For the longer-term, a specifically designed SD framework for biotechnology should cover:

- Screening procedures that may be applied in order to separate out those initiatives requiring extensive review.
- Integrated impact assessment methods appropriate for biotechnology, including new value chains, such as those involving bioproducts and their raw materials, biorefineries, disposal and transformation of final products.
- An approach that provides for assessment at various stages in development—from early R&D through to pre-commercialization, full production and end-of-life disposal and/or re-use and recycling.
- Reliable benefit/cost and benefit/risk calculations tailored to specific circumstances.
- In-depth research, especially at the ecosystem level, to set baselines and establish effects using standardized methodologies.
- Application of dialogue tools and scenarios designed for their learning value, and for inputs to adaptive planning and management.

This approach should become a mandatory part of all major biotechnology initiatives intended to meet sustainable development goals, and applied at various points in the development cycle.

Finally, we note that a biotechnology and sustainable development assessment framework is likely to be of the greatest value when applied in the context of a national sustainable development strategy (or at least a clear, forward-looking federal strategy) that presents overarching objectives, principles, specific mechanisms and timelines for achieving SD goals, along with indicators of progress. A Canadian sustainable development strategy ought to follow 'good practices' that have been identified by the OECD (2005).

CHAPTER 6. Public Learning and Dialogue

Continuous Learning and Dialogue

Our purpose in this Chapter is to set out the case for, and propose some means to implement, a continuous dialogue on biotechnology and sustainable development in Canada. This dialogue needs to take place for a substantial number of years, seeking points of convergence and action. Without it, we believe that the case for innovation applications that could support sustainable development will be weakened or ignored, and possibly rejected by many Canadians.

A suitable approach to dialogue will:

- Enable citizens to discover, link and synthesize the rich lode of information produced domestically and internationally on biotechnology and SD;
- Open new opportunity for seeking convergence on views about this theme, and to clearly identify major points of divergence;
- Provide a broader information base from which to understand and test policy and operational directions; and
- Provide important inputs to the innovation system by helping researchers and developers understand Canadians' needs and preferences.

Dialogue should be cost-effective in its application, and broadly accessible. It will be supportive of adaptive planning and management, recognize the need for experimentation, and address innovation as a unique process.

Effective dialogue will require up-to-date, reliable information made available in a timely fashion, and be helpful in building trust between diverse stakeholders and agents involved in decision processes. At the present time it is not clear whether there is even a common vocabulary bridging these interests. Much of the initial dialogue is likely to focus on values (Box 6-1).

Our secondary goal is a strategic one. While literacy on innovative technology introductions is required for people of all backgrounds and ages, it is youth and people in early stages of careers that hold the key to future acceptance and

Box 6-1. Values in public dialogue

Understanding and respecting values is an important component of decision-making and policy formulation. This is clearly true for biotechnology, and especially for new products not yet in the public eye (e.g., transgenic animals, bioremediation). The desire for consumer choice, the use of "science-based", decision-making regulatory protocols, concern for food "purity" and for introduction of novel life forms into the environment are all examples of value-driven concerns. More fundamental is the concern about interfering with the 'building blocks of life'.

These debates are sometimes well informed and sometimes not. What can be done to ensure full respect is paid to the diversity of views likely to be expressed? How can the debate be based on a reasonable understanding of the science and technology as well as values? And how can precaution and risk be factored into the dialogue in a responsible fashion? Finally, how can the dialogue take place in a fashion that arrives at good policy decisions, rather than default positions taken in the absence of proper dialogue? It is unlikely that these goals will be met through a centrally-guided approach operating on its own. Increased awareness of the appropriate role of the public at different stages of decision-making, along with supporting policies and tools for information exchange, will be the likely route to bring about a satisfactory biotechnology and SD relationship.

guidance. Therefore, we focus on tools and on communication strategies likely to connect with younger people. We believe it is worthwhile at present to focus on Internet-based approaches to a considerable extent, although that may change as communication technologies evolve.

There is an increasing knowledge base on various aspects of biotechnology and elements of sustainable development. Some Canadian sources, such as the federal BioPortal, are acclaimed as information sources.[96] In terms of public participation in decision making, Europe is leading the way internationally, through the "ordre public" aspect of patent law, via new provisions in the Aarhus Convention[97], and with on-going, very transparent EU debate on its comprehensive approaches to biotechnology promotion and regulation.

Public Engagement Strategies

The biotech-SD landscape is complex. Federal officials set R&D budgets, tax policy and regulations, university researchers develop innovative products within international networks, municipal governments encourage high tech business parks, corporate managers decide on product, marketing and financing strategies, and provincial governments support biotechnology innovation in their natural resource sectors. All this activity should be in service of the citizen or consumer who will support or reject the technology in the marketplace or in political arenas. It makes for confusion, and this factor alone can be a serious obstacle to both learning and consent.

Robust public engagement will be vital to a number of the key process principles we advocated in Chapter 1: "justice", the recognition of "wider community interests beyond the interests of the individual", "respect for the law and system of government", and "fostering public participation and transparency in decision making". Most important, however, is the need for reliable ideas and information from researchers, developers and promoters honestly presented to stakeholders and citizens, along with governance processes that promote social learning.

In short, we hope for conditions where all involved parties become more familiar with, and literate in, addressing possibilities and conditions related to biotechnology innovation, in the context of sustainable development goals and action.

To be successful, dialogue must involve reciprocal listening. This takes it beyond the conveyor belt of information flow (and, often, overload) associated with many government, industry and NGO websites—not only those intended for promotional purposes, but also many of the well-meaning but crowded clearinghouses and other knowledge-brokering sources. Dialogue also differs from polling efforts, although the information from polls may fit into dialogue processes.

[96] www.bioportal.gc.ca
[97] UNECE Aarhus Clearinghouse for Environmental Democracy: http://aarhusclearinghouse.unece.org/.

There are many ways for governments or organizations to engage. We break them down into three main groupings: information exchange, structured consultation and deliberative dialogue. Box 6-2 describes each use and its context. All approaches have their place in different situations, but we presume that information and structured discussion should support dialogue processes.

Box 6-2. Types of public engagement processes

Information Provision

Education, Marketing: One-way flow of information to citizens via intermediaries, e.g., media, web, published materials

Informing: Direct contact, but largely expert monologue

Structured Discussions

Consultation: Dialogue without diffusion of power

Placation: Sharing of power by citizen appointment onto committees

Partnership: Stakeholder decision-making involving multiple interests

Dialogue

Adversarial: Use of formal channels such as legal, regulatory or scientific, or mass media and public relations "campaigns"

Deliberative: General dialogue that may be informal—dialogue space and materials provided to the general public, inviting broad participation (e.g., farm forums) or formal – dialogue space and materials provided to select group of representative or key individuals.

Source: Based on: James Tansey. 2003. *The Prospects for Governing Biotechnology in Canada.* www.ethics.ubc.ca/workingpapers/deg/index.htm

Information Provision

Good information is the "foundation" of constructive dialogue; it is an important contributor towards creating a common vocabulary and a basic set of understandings amongst those involved. A key problem is that sustainable development assertions flow freely in biotechnology debate, for example, in current discussions on biofuels. Box 6-3 shows a range of important environmental topics for which definitive information is not currently available.

In Canada, thus far, there have been varied means for information provision. These include: polls; media reports; workshops and conferences; academic publications; clearinghouse web sites (e.g., Canadian node to Biosafety Clearing-house of Cartagena Protocol); websites (Government of Canada BioPortal and Green Lane); private sector information; research organization and NGO publications by Pollution Probe, Canadian Institute for Environmental Law And Policy and others; environmental assessment analysis and hearings; foresight and other 'expert' sampling; *Notice of Submission* (when new products involving biotech are submitted for regulatory review); court cases; Commissioner on Environment and Sustainable Development Petition Process; and Commission on Environmental Cooperation petitions. Expert views are available through CBAC and Royal Society reports, and other organizations such as BIOCAP Canada.

The question is, what more can or should be done? Certainly, there is a need for on-going efforts to maintain accessible national-level information. For example, in the case of bioethanol, it is not easy to determine the overall levels of subsidy for this introduction, in either Canada or elsewhere. Another example is bioremediation, a topic that should be of great concern for those interested in the environment and SD technologies in Canada. Yet the information base is scattered among various organizations, and it is necessary to seek out sources advisory to the UK government in order to get a reasonable overview of the state of maturity of this complex topic.

Long-term environmental and cumulative impact information is another area of some difficulty. The Conference Board of Canada, in its analysis presented in Chapter 4, noted that statistical indicators linking biotechnology and sustainable development were lacking, and that there were many gaps in basic biotech statistics. These are only some of the information problems that need to be addressed.

Box 6-3. Sample environmental information needs for transportation biofuel and sustainable development

- Sustainability of energy crop production;
- Ecologically and economically available biomass from various sources;
- Potential displacement of food crops and/or of conservation lands for biofuel crops;
- Impacts on biodiversity of increased biomass use for biofuels;
- Net energy balance likely to be realized from commercially produced biofuels;
- Cost-effectiveness of biofuels in reducing air pollution and greenhouse gas emissions;
- Societal value of bioethanol for fuel produced from grains, sugar beets and corn;
- Information for a reliable sustainable certification process, especially for international trade of biofuels.

Structured Discussions

This function requires leadership with respect to issue definition, but with input from and response by many actors in society. CBAC could at least partially fulfill this role, and there have been various efforts for it to do so. However, it has not always been possible to bring all key actors into discussions. For example, the Canadian Environmental Network did not participate in the structured discussions on GM food and food labelling. Other public consultative organizations such as the NRTEE and the Policy Research Initiative have not examined innovation technologies for sustainable development in depth. It is fair to say that the relationship of biotechnology and sustainable development has not had the same level of public and policy attention as medical or food biotechnology, either in Canada or elsewhere.

Instead, there has been an emphasis in Canada on expert advice, some tied to stakeholders, but often not. Such consultations include recent foresight exercises (e.g., on bioproducts), and many meetings arranged in conjunction with industry associations. These have been valuable sources of input for Canadian policy-makers as they grapple with the often-complex scientific, social and economic issues presented by biotechnology. Expert advisors help government officials to mediate between the legislation and regulations developed in a pre-biotechnology era, and the constraints and opportunities afforded by recent developments in the science.

But in carrying out these discussions, limited effort has been made to reach out to general civil society. Examples of such discussions might include more emphasis on public inquiries, workshops on specific topics, roundtables, consultations, and citizens' advisory committees. This relative lack of engagement on the part of government has led to some criticism by NGOs, particularly environmental NGOs. They contend that because most of those who provide advice to the government are already committed to biotechnology, dissenting, or more cautious voices are excluded from the conversation. Thus, they argue, the discussions on the government's policy approach may not end up being a balanced one.

Among international efforts, the UK's "GM Nation" debate stands as the largest public consultation exercise sponsored by a government (see Box 6-4). This one-off attempt at public engagement can be viewed, at best, as a modest, but flawed success. Many of the more cautious recommendations made in the final report have not, it seems, had much influence on subsequent UK government decision-making.

While we believe much more fine-tuning could be done around discussion processes, we would like to see more energy and attention given to seeking methods that genuinely create dialogue and active learning.

Dialogue

Adversarial Dialogue

We do not dismiss the usefulness of adversarial dialogue in order to arrive at new understandings and for testing values, performance or other aspects of the relationship between biotechnology and sustainable development. It is a legitimate part of scientific, legal and regulatory practice. Disagreements ideally should be settled through better research, new information or more convincing argumentation. Frequently, adversarial dialogue increases clarity around the problem, or generates new creative solutions.

Especially important are those kinds of adversarial dialogue that are part of government's transparency and accountability obligations. Because they present opportunities through which citizens can formally engage decision-makers, we consider these mechanisms central to a democratic governance system attuned to meeting societal goals while recognizing the legitimacy of different views. It has been a fundamental way to achieve environmental action over the past 35 years. Yet there are still major hurdles relevant to BSDE that need to be addressed, including the examples noted below.

Box 6-4. Public consultation on a grand scale: The UK's "*GM Nation?*" debates

A six-week period over June and July 2003 marked a period of public debate about future policy relating to the possible commercialized growth of genetically modified (GM) crops within the UK. The public debate involved six major 'regional' debates, designed to be the stimulus for a cascade of 'second and third tier' open access meetings. Estimates of the number of such meetings range from 400-700 throughout the UK. 'Stimulus material' was provided to initiate debate at such meetings, plus what was generally regarded as an uninspiring (and hence largely ignored) videotape. Feedback forms, allowing recipients to record their views on GM crops, were provided within the booklets, and in an electronic form on the *GM Nation?* website. Overall, 37,000 feedback forms were submitted, with almost three million 'hits' recorded for the website.

The process received a number of serious criticisms, however. Among those presented by the official evaluation team of social scientists, were that:

- the debates were insufficiently resourced in terms of money, time and expertise;
- there was a failure to engage with the broad mass of hitherto disengaged members of the lay public;
- the preparation of the Steering Board's final report on the debate was over-hasty and under-resourced, and featured a methodologically worrying analysis of the findings.

Source: Jeffery N. Thomas. Science Faculty, The Open University, United Kingdom. *GM Nation?* www.vuw.ac.nz/talking-biotechnology/session_abstractW2%20Deconstructing%20Dialogue.pdf

Dialogue and Governance: Regulatory Transparency

Disclosure of information that has been, or will be germane to important regulatory decisions made by governments is an important issue. Although the provision of information is in itself a measure of transparency, it is only half the story. For the communication to support adaptive management goals, there must be the possibility of dialogue.

Currently in Canada, the public's ability to intervene in regulatory decision-making is limited by, among other things, provisions in trade agreements such as those of the World Trade Organization (WTO) that limit the justification for decisions about new biotechnology products to science-based arguments. Canada has no legally mandated provisions to disclose information about product environmental assessments, or an obligation to consider the public's queries. There is no requirement for the government or the developer to advise the public even that a product is being assessed. This is a policy decision made to streamline development of innovative products.

According to the Federal Government, transparency in Canada's regulatory decision-making is provided by the *Access to Information Act* (ATIA), whose structure "balances Canadians' right to access information regarding the environmental assessments of novel products of biotechnology (including the studies on which regulatory decisions are based), while protecting the rights of third parties who have provided information to the Government of Canada."[98] However, data supporting product assessments can be classified as confidential business information (CBI), based on the discretion of the developer. This limits the public's ability to obtain information regarding new biotechnology innovations through the ATIA because CBI is exempt, and can be withheld from the Canadian public. Although we grant that CBI concerns are valid, we note that in the European Union, no environmental safety and health data can be considered CBI[99] (see Boxes 6-5 and 6-6). This arrangement is much more supportive of adaptive management goals.

Box 6-5. GMOs, environmental release, and the public's right to know: Europe

In Europe, the public has the right to see the data that substantiates, and the rationale that supports, the environmental release of genetically modified organisms (GMOs). Under the EC policy directive that guides all member states' laws on the matter, "in no case" should the information related to "environmental risk assessment" or "methods and plans for monitoring" the GMOs be kept confidential (see Art. 25 (4)) europa.eu.int/comm/environment/biotechnology/pdf/dir2001_18.pdf).

In 2005, Greenpeace took advantage of this provision, among others, to force the German authorities to release the data submitted by Monsanto for an environmental/health risk assessment for a strain of *Bt* corn. Upon examination, they found statistically significant differences between rats fed the *Bt* corn and those fed conventional corn. Amid controversy, the European Commission approved the product.

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98 www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/D44FA5A66A01C9638525714E007B4554

99 The courts have ruled in the Monsanto vs. Greenpeace case that the importance of health and safety testing data to the public good outweighs the protection of a company's declared CBI. See www.eu.greenpeace.org/downloads/gmo/MON863briefing0601.pdf.

One step forward is a transparency and pilot notification project in Canada undertaken by Health Canada (HC), the Canadian Food Inspection Agency (CFIA), and CropLife (an industry consortium of agricultural biotechnology firms). Together they are working on a voluntary information-sharing project that provides Canadians with summaries of the information provided to the regulators[100] during the assessment period. During a 60-day comment period, anyone can provide comments to the assessors. Science-based questions will be forwarded to the assessors, and non-science based questions to other officials. After approval, it is CFIA policy to post synopses of the rationale upon which the regulatory decision was made. While we support this initiative, it does not go far enough in providing the level of transparency and dialogue that would support truly adaptive management of new biotechnology products.

Box 6-6. From transparency to influence: amending the Aarhus Convention to include GMOs

In May of 2005, European states took the notion of transparency in regulatory decision-making a step further. They already had the Aarhus Convention, established by states of the UN Economic Commission for Europe, considered by Kofi Anan to be "the most ambitious venture in environmental democracy so far undertaken under the United Nations." The Convention consists of three pillars: informed citizens on environmental decision-making; improved participation in environmental decisions within a transparent and fair framework; and access to justice, including challenging decisions concerning access to information. Initially, decisions regarding the environmental release of GMOs were exempt from the Convention.

Parties have now agreed to extend the public's legal right to participate in environmental decision-making to the release and placing on the market of GMOs. Under the amendment, the public would have the right to submit comments and the public authorities would be expected to take these into account in the decision-making process. Once made, the assessor's decision should be publicly available together with the information, reasons and considerations upon which it is based (excepting information protected by commercial confidentiality). This amendment extends the original directive's provisions for disclosure to include influence in the decision-making process.

Source: www.ictsd.org/biores/05-06-10/inbrief.htm#1

Dialogue in the "Marketplace"

We also must consider the dialogue carried out in the tempestuous space of public discourse enacted through the media, and open sources such as the Internet. Although important for a functioning democracy, and often extremely valuable in content, it can be very damaging for issues that have complex scientific bases, and that lack scientific consensus. The main distinction between "dialogue" that happens in this space, by comparison to the dialogue mentioned above, is that it is not a structured or bounded discourse. The goal of the conversation is not necessarily to increase understanding, and may contain messages that are deceptive, manipulative or erroneous. Indeed, socio-scientific issues in general are vulnerable to misleading oversimplifications, poor metaphors and inappropriate claims of benefits or risk.

The dialogue is often asynchronous and parties do not address each other, directly rebutting or refining their arguments. Due to the heterogeneity of the discourse, few of the participants have common understandings or vocabularies, and frequently participants fall into polarized camps, simply "for" or "against" whatever is at stake. Under these circumstances, it is difficult to creatively transform understanding or make progress towards the resolution of an issue.

[100] www.inspection.gc.ca/english/plaveg/bio/subs/subnote.shtml#intro

The danger of these types of dialogues is that they often do have impact on policy, and when they do, the impact is rarely a positive or balanced one. They can erode trust in institutions, and create a sceptical, confused public; this lack of a public consensus on the way forward often results in political gridlock. The development of biotechnology, a technology that has matured in the information age, has been affected by the machinations of media-savvy public-relations firms, NGOs, and the sometimes hard to understand response of governments.

Deliberative Dialogue

The second broad category of dialogue we term "deliberative dialogue". We define deliberative dialogue as that which facilitates productive information exchange, articulation and dissemination of knowledge through diverse, ongoing forums, in order to increase civic literacy on complex, critical public policy issues.[101] This dialogue is designed to enable people from diverse sectors, academic disciplines, and civil society to engage in trans-disciplinary discussion, which we believe is fundamental to faster up-take and adoption of innovative sustainable community development solutions. Sometimes, deliberative dialogue involves conversational interactions among parties, that is, where different parties respond to one another's claims and critiques, as well as put forth their own perspectives and arguments. This process is unique and based on earlier Canadian experiences with multi-stakeholder and open-ended deliberative processes.

This type of dialogue is just emerging in Canada. Tools have recently been developed that will facilitate its development. We feel such dialogue is the missing link that will enable productive public engagement in adaptive management of biotechnology innovation for

Box 6-7. "Terminator Genes."

An example of how adversarial dialogue can distort a nd negatively affect a nascent biotechnology is the case of the development of "genetic use restriction technologies" (GURTS), dubbed "terminator technology" by opponents (www.inspection.gc.ca/english/plaveg/bio/gurtse.shtml). An NGO pressed the case that "despite widespread opposition, in February 2005, the Canadian government attempted to overturn the Convention on Biological Diversity's (CBD) international *de facto* moratorium on terminator technology" (www.banterminator.org/the_campaign). This statement was the vanguard for a global NGO-led campaign culminating at the CBD Conference of the Parties in Curitiba, Brazil, in March 2006.

In short, many (though not all) messages by the NGO community distorted the nature of the "moratorium", misrepresented Canada's position, incorrectly described the technology, and generated much discussion around issues that were secondary to the technology. Acknowledging that certain uses of GURTS, especially in concert with restrictive IPR regimes, are undesirable, this dialogue did not advance the development of a technology that could prove very powerful, and mobilized tremendous energy for an issue that did not hit its target. The Canadian government did not engage in any kind of meaningful dialogue with its critics, leaving the issue to develop along increasingly hyperbole-laden storylines, all of which were highly critical of Canada.

What is lost in this sort of debacle is: the creative flexibility in exploring the potential of a new technology, and its associated basic science knowledge, the ability of a country to intervene in a positive way by introducing innovations for the public good on a global scale, and the chance for a co-creative relationship between civil society and governments on this and other biotechnology-related issues.

[101] A. Dale, "A Perspective on the Evolution of e-Dialogues Concerning Interdisciplinary Research on Sustainable Development in Canada," *Ecology and Society* 10 (1) (2005): www.ecologyandsociety.org/vol10/iss1/art37/.

sustainable development in Canada. The dialogues are loosely structured, and the discussion is allowed to evolve in response to input from the participants. The structure of the dialogue will provide a means for participants to engage with the products of the other two forms of public engagement, essentially linking them, and providing an opportunity for new, emergent ideas to arise from the other, isolated pieces of information.

Deliberative dialogues are dependent on strong support from a sponsoring organization, government, public broadcaster, university, etc., to establish and maintain a prolonged, exploratory discussion. The organization that provides the educational setting is crucial to the success of this endeavour. It must be seen as providing a neutral, safe space, and accurate, clear background information. If the dialogue space or information provided is perceived as biased, incomplete or poorly done, participants may become suspicious. The resulting lack of trust is likely to cloud the discussion, as the participants quibble over the existence of hidden agendas, definitional debates or the factuality of the information provided.

Within Canada, some of the pieces for a healthy dialogue on biotechnology and SD are definitely present. Not only the government but also a wide range of organizations are researching, discussing and distributing opinions. This abundance of well-researched information and engaged organizations can provide a strong foundation of information and people for productive dialogue.

Dialogue Tools – "Made in Canada"

New information technology tools and research will undoubtedly make broad-ranging public dialogue more achievable. In Canada, there are some tools already developed, and ongoing process research is underway that will help us understand how to design and integrate dialogue processes for maximum impact.

Providing a Space and a Structure

Royal Roads' e-Dialogues™ Royal Roads University has developed a tool that supports dialogue through the use of deliberately designed synchronous on-line spaces that can bring together anyone with the appropriate computer software and Internet connection.[102] E-Dialogues™ happen through a website that offers a description of the issue under discussion, and an illustrative list of resources that includes links to informative websites and "blogs". The supporting websites are developed by e-Dialogue™ researchers. During the dialogue, participants can append reference material directly, which enriches the available store of information for the discussion.

The dialogue model that has been used thus far features leading-edge researchers and practitioners with diverse perspectives engaged in on-line "chat." They are moderated by a well-recognized researcher, who ensures that underlying tensions and differing perspectives are revealed in a respectful manner. The e-Dialogues™ occur in real time and on-line expert panel members dynamically converse with one another. The on-line audiences listen in. Each dialogue is archived for further access by the public, younger scholars, the media and public policy decision-makers. Thus each e-Dialogue™, with its background material, expert opinion, emergent ideas and spur of the moment appended information, adds a new layer of synthesis and insight upon which further dialogues can build.

[102] http://e-dialogues.royalroads.ca/

Box 6-8. Excerpt from BSDE e-Dialogue™ on bioethanol fuels, held on June 6, 2006 with 15 participants

Dialogue Question: ***What criteria would you want to apply in order to be satisfied that Canada is on a sustainable track for its biofuels policy?***

Three scenarios prepared as background: "*Conventional and Incremental", "Be a Free Trader", "Lead the Way".*

What happens when there is no longer enough excessive waste product to make the bioethanol infrastructure economically viable? Will we be faced with the tough decision of plant material for food or fuel?

Scale:
What is our notion of scale? I see ethanol production and use as a pilot project which should be encouraged but we have to keep in mind that it can only make a small contribution to the overall challenges of our lifestyle dependence on personal vehicles.

Yes, scale seems to be a critical question. How could we produce enough biofuels for a 5% blend? Enough to replace our use of conventional fuels? To export a percentage of the production?

Do we, or should we, facilitate a shift in energy supply, focusing only on supply side dynamics? Is this right to facilitate the shift and ignore the fact that we are facilitating a culture that is consuming at an increasing rate?

Benefits:
Buy local? Burn local?

What are co-benefits, for example, protection of watersheds, and habitats, if areas are planted to biofuel crops?

Incentives
Subsidies will be a necessary evil, as oil, coal and tar sands are so heavily subsidized. If subsidies are too narrow, they might encourage a technology that is not in the long run the best option.

Life cycle analysis:
Do we have reliable life cycle analysis of environmental and social impacts for the various bioethanol production scenarios? This seems to me important if we are interested in it primarily for sustainable development.

Broader prospects:
Maybe biofuels will prove to be most valuable as a transition fuel, as they are compatible with our current fuel system.

The forest industry role is unclear due to the hardship created by the softwood dispute. The impacts on biotech fuel production of the pulp and paper sector will be much like that of sugar in Brazil, switching to whichever is most profitable.

Place greater emphasis on multi-product biorefineries, green chemistry and green production, not just biofuels.

E-Dialogues™ have a number of features to recommend them as tools for enabling informative and ongoing dialogue on complex topics such as biotechnology and sustainable development. First, because they allow people in different spaces to interact on-line, they drastically reduce the cost and personal time investment required to bring interdisciplinary experts together from around the globe. Second, they appear to facilitate more integrated thinking about broader, complex social issues resulting from the linearity of the medium. Third, they can reach a diverse cross-section of Canadians, particularly, they communicate public policy issues where younger people are communicating—the Internet. Fourth, they create new e-communities of practice and hence consensus between the on-line experts themselves and between them and certain members of the e-audience. Fifth, they increase the speed of connectivity and dissemination of knowledge and research between policy-makers, researchers and community decision-makers. Sixth, they offer a unique window for government decision-makers into the points of convergence and, more critically, divergence in emerging and existing public policy issues.

Over the period of the BSDE study, we conducted two experimental e-dialogues organized by Royal Roads University. The participants included members of the Expert Working Party, graduate students and young professionals with some expertise in the subject matter. The method was to define a central question and background document distributed in advance, and have a focused two-hour effort during which there was intensive on-line discussion concerning the topic and questions. The sessions were open only to a limited number of invited participants. We were impressed with the quality of the exchange and the promise of the approach. In Box 6-8, excerpts from the June 2006 e-dialogue on biofuels are provided.[103]

Government of Canada "*Dialogue Tool*": Several years ago, CBAC, in concert with NGO and stakeholder partners, developed a "*Dialogue Tool*[104]," which is a structured way to discuss biotechnology issues. The *Dialogue Tool* is not intended to produce consensus among dialogue participants. Instead, it facilitates a dialogue to increase the literacy of the participants and encourages the development of new policy solutions by:

- breaking down a complex issue into its component parts;
- characterizing the attributes that make a product of biotechnology more or less desirable/ acceptable/beneficial to Canadian society;
- considering the health, environmental, social, ethical and "broader" (e.g., international implications) aspects of an issue;
- identifying the conditions required to make a biotechnological innovation more acceptable to certain stakeholder groups; and
- exploring solutions (i.e., identifying the promising directions or options for policy).

Using the *Dialogue Tool*, participants are guided through a dialogue process to see how a complex case can be deconstructed into more understandable components.

The policy issue is examined from the perspectives of health, environment, socioeconomic, ethical and other broader considerations (e.g., international). Participants consider the risks, impacts, benefits, implications and possible trade-offs under each consideration theme.

[103] The full exchange for both e-Dialogues is archived on the website http://e-dialogues.royalroads.ca/.
[104] *Dialogue Tool* - http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/h_ah00350e.html.

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.

This tool could become very important in helping groups of citizens and stakeholders who hold polarized positions on certain biotechnology issues move into dialogue that helps to guide productive policy.

Research Supporting Dialogue Process Design

The best-designed processes and spaces can still founder if their input and output are not properly targeted. It is important that the support for dialogue not be designed on naïve social or cognitive principles. There will be an on-going need for research on effective processes. Below, we highlight two relevant research projects at Canadian universities funded by Genome Canada through its GE^3LS initiative (ethical, environmental, economic, legal and social issues of genomics).

Providing the appropriate information, from the right sources: How do Canadians use different sources and types of information to navigate their way through issues when there are competing claims about health, economic, social and/or environmental effects, such as with biotechnology and sustainable development? This UBC research should enable sponsoring organizations to more effectively support dialogue participants by providing the right kind of information, from the appropriate sources.[105]

Enhancing dialogue's impact: One of the key goals of deliberative dialogue is to support adaptive management. This research will provide crucial advice regarding the institutional structures for making dialogue an effective tool in enabling change and democratic decision-making. By assessing past practices by governments and social science research (including social experiments), the researchers at the University of Calgary will provide suggestions to strengthen the role of public participation and dialogue in governance and regulation of biotechnology innovations.[106]

Conclusions

Through the Canadian Biotechnology Secretariat, Canada has some of the best public opinion research data in the world, and through Statistics Canada some of the best available information on the biotechnology sector. Some of Canada's top scholars are developing powerful analytic tools that will help us understand, from an institutional/policy and public knowledge-gathering perspective, the most effective means for engaging publics in effective decision-making. The e-Dialogue approach provides us with an easily accessible forum for debating and discussing issues with experts, and we have found it an invigorating way to discuss biotechnology issues

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[105] M. Burgess and P. Danielson, UBC, *Building a GE^3LS Architecture:* www.genomebc.ca/research_tech/research_projects/ethics/building_ge3ls.htm.

[106] E. Einsiedel, University of Calgary, *How is Genomics translated in Health Systems?* (Genome Canada), and *Public Participation, Institutionalization and Technology Assessment* (SSHRC): www.ucalgary.ca/%7Eeinsiede/current.htm#gels.

with concerned audiences. Further, the CBAC-sponsored *Dialogue Tool* could serve as a valuable process guide that brings together opposed views on the topic. These tools for discourse and analytic approaches are all either in the pilot stage or still under research.

Looking to the years ahead, we recommend a continuous, respectful engagement process between citizens, stakeholders and government. Such engagement should be well supported, with excellent up-to-date knowledge and information. It should also enhance social learning that integrates a truly adaptive approach for BSDE. The strategy of continuous dialogue and social learning allows issues to evolve over time and in response to participants' inputs. These dialogues, though supported with resources from government, are led through strategic partnerships with other sectors of Canadian society—dynamic, multi-stakeholder practitioner networks of support. These networks will legitimize and add to the outreach and impacts of the dialogues. By constructively engaging civil society leaders, early adopters, marketers, and researchers, biotechnology innovations are developed in such a way as to promote important ecological, social and economic imperatives.

In order to reach this stage, Canada should:

- Commit to a continuous dialogue with Canadians - build upon existing tools and methods being developed by Canadians such as the e-Dialogue™, the new CBAC *Dialogue Tool*, and leading-edge research;
- Optimize these approaches to develop a comprehensive "tool kit" that allows for effective, long term engagement;
- Commit to the need to increase civic literacy and continuous social learning by strengthening strategic partnerships with industry stakeholders, academic institutions, environmental organizations and church groups; and
- Ensure that mechanisms exist to allow the input received to have an effect on the outcomes, and that there exist tracking measures to allow the impacts to be noticed and reported.

These new approaches could be reinforced by several existing, useful mechanisms for building an understanding of biotechnology perceptions and interests:

- Public polling carried out through the Canadian Biotechnology Secretariat in order to examine knowledge and public views about new biotechnology approaches of the types described in this report;
- Use of findings from scenarios, foresight and other futures studies to determine public reaction to choices our society may face;
- Statistics Canada data gathering, which should be redesigned to provide better information on biotechnology and sustainable development relationships;
- Cooperative efforts with others in the international community (e.g., via the OECD, UN bodies such as FAO, scientific unions, and groups within other nations) on studies and dialogue that will provide a broader international understanding of public concern and lessons learned from dialogue on new technologies.

CHAPTER 7. International Cooperation

Canada and the World[107]

Internationally, biotechnology is recognized as an emerging driver of economic, social and environmental development. A number of multilateral organizations, along with the EU and other nations, are launching programs to address how biotechnology can help to achieve national and international sustainable development priorities. Canada's past policy statements identify the pursuit of sustainable development as a priority for the Government of Canada.[108] There has also been a strong emphasis on the role of science and technology in Canada's international relations.

International cooperation has a significant role to play in achieving a sustainable future. No country working alone can successfully tackle issues such as global climate change or the sustainable use of ocean resources. Trade and investment funding know no borders, R&D increasingly depends on an international flow of knowledge, and other effects of globalization such as pandemics or invasive species depend on internationally negotiated and recognized rules of conduct. Perhaps most importantly, our own long-term security and well-being are linked to success in reducing poverty everywhere, especially in developing nations.

Three themes form the substance of this chapter:

1. Canada's international competitiveness in new industrial approaches involving biotechnology, especially bioproducts;

2. Canada's international connections to build necessary knowledge, attract investment, and create action for the sustainable use of biotechnology in our own land and to address issues of global significance; and

3. Canada's international development cooperation to address poverty.

We need to pay particular attention to how Canada can meet globally agreed targets, such as the UN's Millennium Development Goals (MDGs). The eight MDGs aim, by 2015, to:

- eradicate extreme poverty and hunger;
- achieve universal primary education;
- promote gender equality and empower women;
- reduce child mortality;
- improve maternal health;
- combat HIV and AIDS, malaria and other diseases;
- ensure environmental sustainability; and
- develop a global partnership for development.

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[107] This Chapter in part draws on material from a more detailed Background Paper prepared for this Report: M.A. McLean, *International Cooperation for Biotechnology and Sustainable Development* (Ottawa: Agbios, 2006). Available upon request from info@cbac-cccb.ca.

[108] Government of Canada, *A Role of Pride and Influence in the World.* (Ottawa: 2005): www.dfait-maeci.gc.ca/cip-pic/ips/overview-en.asp.

These critical targets are in danger of not being met, and it has been acknowledged that biotechnology could play a role in meeting some of them. In fact, the UN Secretary General has noted that "Biotechnology … has the potential to become a powerful tool in meeting the challenges posed by food insecurity, industrial underdevelopment, environmental degradation and disease."[109]

This Chapter identifies specific paths for enhancing our contribution to global sustainable development through biotechnology applications. We focus on partnerships and Canadian efforts to meet the needs of poorer nations. Perhaps more speculatively, we examine how international cooperation on biotechnology and sustainable development can benefit Canada directly. Such benefits could be social and environmental, and certainly economic, in terms of increased productivity and competitiveness.

Competitiveness and Sustainability

Canada's competitiveness depends upon international cooperation. While relatively abundant natural resources can work to our advantage in agriculture, forestry and mining, Canadian producers realize they must strive for new levels of environmental sustainability in these and other markets, especially EU countries. A case in point is the growing movement by the Canadian forest industry towards internationally-defined Forest Stewardship Council (FSC) certification.[110] The working hypothesis that our comparative advantage in land and water will allow us to supply new bioproducts to these markets may be put to a severe test in the future. It could turn out that European countries have the advantage because of their subsidy structures and long-standing expertise in refining and chemical processing. Perhaps it will be Canada's ability to demonstrate being a good steward of the environment as well as a good producer of bioproducts that will make the difference.

Canadian businesses are already competing against other nations to supply 'raw products'. Canola producers are selling their products to Europe for conversion to biodiesel. In the future they may face stiff competition from tropical producers eager to enter European or other markets. Indonesia has announced plans for a US$22 billion investment to convert six million hectares into palm oil plantations for biodiesel – there is potential for some of this conversion to impact undeveloped rainforest. Brazil, India and China are the world's largest ethanol producers, while Canada currently ranks 14th. Brazil, already the leading exporter, would like to expand this role. There are active plans to encourage exports of biofuel from Africa to Europe, even describing some countries as "biofuel superpowers."[111] It is hard to imagine Canada developing a robust market abroad for bioethanol produced from grain or corn. But it is possible to envision a time 5 to 10 years from now when Canada's leadership in cellulosic ethanol production could be a

[109] United Nations, *Impact of New Biotechnologies, with Particular Attention to Sustainable Development, including Food Security, Health and Economic Productivity*, Report of the Secretary General, United Nations General Assembly (A/58/76) (2003); A. Rath. *Biotechnology, Millennium Development Goals, and Canada* (Canadian Biotechnology Secretariat, 2004).

[110] Canada has the world's largest area of FSC-certified forest lands, 17 million hectares (ha) as of June 2006, and has the largest volume of FSC certified paper production: www.fsccanada.org.

[111] In late July 2006, the Pan-African Non-Petroleum Producers Association (PANPP) was formed to promote biofuel production. This effort is being fostered through a body called 'Biopact' that seeks a "green energy" pact between Africa and Europe: www.biopact.com.

major advantage. It is also possible that innovative, made-in-Canada industrial processes could be commercialized in Europe. A case in point is Iogen Corporation's recent partnership with Volkswagen and Shell to investigate the feasibility of producing ethanol in Germany.

A pertinent question then, is: how should Canada develop investment patterns and R&D cooperation in ways that improve, rather than reduce, Canada's competitiveness in a globalized world, while also enhancing domestic and global environmental and social sustainability? For example, could international cooperation to develop biofuel sustainability certification leverage Canada's ability to sell biofuels in developed country markets? Organizations within the EU are already starting to examine certification needs—for both carbon and sustainability reasons.[112]

Through Canada's participation in many international negotiations in areas such as environment, development, trade and health, Canada has been viewed as an international leader for sustainable development. And there has been some Canadian leadership on biotechnology issues in international fora, as exemplified by Canadian participation in OECD's biotechnology programs. How much more should Canada be doing? What might be the longer-term impact of these international activities on our national sustainable development policies and practices?

Canada's International Advantages

Various reviews of Canada's biotechnology advantages exist.[113] None have directly addressed the joint subject of biotechnology and sustainable development. However, we can make some informed choices about which Canadian biotechnology strengths might apply to sustainable development in an international context. (see Box 7-1: Note that this Box does not address the full range of medical applications). While it may seem surprising that agriculture and some bioproduct categories are not rated more highly, the reality is that Canada carries out much of its biotechnology activities in the R&D and investment shadow of the US . Compared to Canada, the US has invested more in R&D, and has established favourable laws and subsidies in order to mainstream certain types of biotechnologies. In Canada, although R&D investments can be substantial, strength is frequently in niches, for example fish vaccines and bioremediation. Ultimately, Canada's strengths in all areas of biotechnology could be valuable to the country's work with developing nations and international knowledge networks.

In fact, Canada's commitment to various knowledge networks and centres of excellence could prove quite significant for international cooperation. Canadian scientists and other 'communities of interest' in this country are accustomed to collaborative relationships, and funding patterns now reinforce this approach. These collaborations frequently spill over into international efforts. This has worked to Canada's advantage, as typified by the Canadian presence in many international bodies related to environment and development, such as the World Conservation Union and United Nations Environment Programme (UNEP).

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[112] The EU consulted widely in mid-2006 on six topics concerning its Biofuels Directive review. Many organizations noted the need for sustainability certification, for example, see the submission of the European Environmental Citizens Organisation for Standardisation (ECOS) brief: www.ecostandard.org.

[113] D. Campbell et al., *Scan of Canadian Strengths in Biotechnology* (Montreal: Science-Metrix, 2005); Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth* (2005).

Box 7-1. Areas of Canadian biotechnology strengths with potential sustainable development applications

International Leadership Role	Potential to be Among Leaders	Potential Strength but Generally not a Leader
▪ Vaccines (human and animals) ▪ Animal sciences ▪ Aquatic sciences ▪ Environmental technology	▪ Forest products ▪ Crop residue utilization ▪ Agricultural crops ▪ Biofuels, cellulosic ethanol	▪ Industrial ecology ▪ Byproduct synergy ▪ Biorefineries for chemicals and bioplastics

The same also holds true for the industrial sector. Canadian branches of major corporations have played significant roles in pioneering more environmentally responsible development. David Buzzelli of Dow Canada piloted "Responsible Care™" for drastically reducing pollution in the chemical industry. This program has spread throughout the world and into a number of industrial sectors. Industry Canada staff have taken leadership roles in helping to develop OECD's ground-breaking work on industrial biotechnology and on bioproducts. And Canadians have been very active in the International Organization for Standardization, including helping to steer the development of ISO 14000—a global standard for managing organizations for optimal environmental impact.

But there is much room for additional cooperative effort, including the development of an international knowledge network on biotechnology and sustainable development, perhaps with leadership by Canadian academics and research organizations. At present no such network exists, although OECD's efforts (described later in this Chapter) are helpful.

International Agreements Affecting Environment and Economy

Canada's role in international agreements is complex. Over the past 35 years, Canada has shown leadership by helping knit together sustainable development frameworks, such as the Convention on Biological Diversity. Our national weakness, probed deeply in reports by the federal Commissioner on Environment and Sustainable Development, lies in failing to take definitive and effective action on commitments made. In some other cases, such as the Cartagena Protocol on Biosafety, Canada has so far not ratified its signed commitments. It is remarkable how many international agreements to which Canada is signatory have major implications for biotechnology and sustainable development. Those examined in this report are noted in Box 7-2, but they represent only a small portion. Others include the *Law of the Sea*, which has provisions that might need revising to cover future bioprospecting of the ocean bottom,[114] the UN Convention to Combat Desertification, and various World Health Organization agreements.

Both the UNFCC and Kyoto Protocol provide numerous entry points for Canadian action on biotechnology and sustainable development. These include industrial ecology applications that reduce greenhouse gas emissions through new processing methods such as low temperature enzymes and power plants that burn bio-based fuels derived from the thermal conversion of various wastes. Credits for carbon sinks could be provided for reforestation and afforestation, and some forms of cropland and grazing land conservation and management.

Box 7-2. Examples of global agreements and protocols with BSDE implications for Canada

- UN Framework Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety
- UN Framework Convention on Climate Change (UNFCC) and Kyoto Protocol
- WTO, including the Preamble to the Marrakesh Agreement, Trade Dispute Resolution Panels; Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Kyoto Protocol also includes three market-based mechanisms designed to help Annex I Parties such as Canada cut the cost of meeting their emissions targets, by allowing them to earn or buy credits outside their borders. The Clean Development Mechanism (CDM) allows countries to earn credits by investing in emission reduction projects in developing countries. Under the Joint Implementation (JI), countries can earn credits by investing in emission reduction projects in developed countries that have taken on a Kyoto target. And International Emissions Trading (IET) permits developed countries that have taken on a Kyoto target to buy and sell credits among themselves.

Technological measures, both to reduce emissions and increase sinks, could help Annex I Parties meet their obligations. Replacement of fossil fuels with biofuels, increased energy efficiency in food production, re-growth or increased areas of forests (as sinks for carbon) are all areas where biotechnology may contribute to meeting the requirements for reduced greenhouse gas emissions. Transferring these technologies to other countries could potentially help reduce emissions on a global basis and fulfill other commitments in the UNFCC. Some of these actions may prove quite controversial, because they involve further spread of biotechnology products on the landscape, including forests and croplands. Others may be less controversial, such as use of enzymes in industrial processes.

An ongoing problem in which Canada has a large stake is the compatibility of measures proposed among these various agreements, especially between multilateral environmental agreements such as the CBD, and trade agreements. The WTO oversees some 30 agreements including SPS and TRIPS (see Box 7-2). The relationship between the TRIPS Agreement, specifically Article 27,

[114] United Nations University-IAS, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects* (Tokyo: 2005).

and the CBD has become a source of considerable controversy, particularly in the context of access and benefit sharing and transfer of technology under Article 16 of the CBD[115].

Box 7-3. Global Alliance for Vaccines and Immunization (GAVI)

GAVI leverages the strengths and experience of all the major stakeholders in global immunization, governments of developing and developed nations, UN organizations, the Bill and Melinda Gates Foundation, NGOs, vaccine manufacturers, public health and research organizations. GAVI partners created the Vaccine Fund which makes low cost immunization possible. GAVI is mandated to accelerate the development of priority new vaccines.

Canada's relationships with the US, Europe, emerging biotechnology powers such as China and India, and developing nations, present potential advantages for the usual reasons: Canada is perceived to be reasonably trustworthy, moderate in approach, and to possess ample expertise and experience. How Canada can build on such advantages depends upon having some clear objectives and able partners. Obvious examples include the GAVI-led development of recombinant vaccines (see Box 7-3) and other biotechnology measures for meeting MDG health objectives. In fact, Canada's Minister of International Cooperation has served as a GAVI board member.

However, this application of biotechnology to international sustainable development is the exception rather than the rule. Aside from support for selected human and animal health goals, the international development community has made relatively few biotechnology commitments regarding food or the development of bioproduct technologies, a fact that we will explore in more detail later in this Chapter.

Conclusion

Much more could be said about the complex set of relationships that will be needed in the coming years to foster competitiveness and sustainability relationships. We have provided a number of examples that demonstrate linkages, and relate them to current issues of biotechnology development and commercialization. The most important point is to recognize that rapid change is occurring, for example in biofuels. This is likely only the first round of such changes, and more profound alterations will occur as biorefinery technologies mature.

These smaller changes will create more opportunities for transformative change towards sustainable development, and highlight the need for Canada to act rapidly in developing highly competitive international positioning. It may appear anomalous, but this competitive positioning will depend on our ability to cooperate internationally. Such cooperation will allow Canada to: establish rules and voluntary measures compatible with our strengths; attract international investment and businesses that provide access to new methods, technologies and markets; and work in partnerships to solve 'big problems', such as those addressed by GAVI, while drawing on Canadian strengths, such as our ability to develop and produce vaccines.

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115 S.K. Verma, *Fitting Plant Variety Protection and Biotechnological Inventions in Agriculture Within the Intellectual Property Framework: Challenges for Developing Countries,* Proceedings of Intellectual Property Rights (IPRs), Innovation and Sustainable Development (2004): www.iprsonline.org/unctadictsd/dialogue/docs/Verma_2004-11-08.pdf.

International Development Cooperation

Canada's two main federally-supported international development bodies, the Canadian International Development Agency (CIDA) and the International Development Research Centre (IDRC), have a strong commitment to sustainable development, but possess less experience and investment in biotechnology initiatives

International Development Research Centre (IDRC)

In 2002, the International Development Research Centre (IDRC) established a Task Force on Biotechnology and Emerging Technologies. The Task Force adopted three objectives[116]:

1. To clarify the biotechnology debate in the developing regions of the world;
2. To identify key sets of research questions around the more significant debates in biotechnology and emerging technologies; and
3. To further identify priority or niche areas in which IDRC can strengthen Southern capacity to assess the technology, develop appropriate policy and identify needs.

Outcomes of this review included a dozen regional consultations to address the links, issues and concerns about biotechnology and development, particularly agricultural biotechnology[117], and a useful primer. The primer states that "IDRC's mandate and history would emphasize objectivity and evidence, Southern capacity development, multi-stakeholder decision-making, and building of an applied research and knowledge base"[118] as the philosophy that will inform IDRC's activities in this field.

In 2005, IDRC established a new program area, Innovation Policy and Science (IPS), which will support the development of science, technology and innovation policies to alleviate poverty in developing countries[119]. IPS is responsible for IDRC activities related to Research on Knowledge Systems,[120] the Task Force on Biotechnology and Emerging Technologies[121], and a Challenge Fund Designed to support global health issues. IPS will also serve as a forum to strengthen IDRC's role in the Canadian science policy community, so that international cooperation and development are promoted as important priorities for Canadian research and development, and to encourage research partnerships between Canadian universities and developing country researchers. IPS will support research on questions of governance, public understanding, and access and benefits associated with emerging technologies like biotechnology and nanotechnology[122].

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[116] www.idrc.ca/uploads/user-S/10968192161External_IDRC_TFoB_About_Us_Sept04.doc
[117] www.idrc.ca/en/ev-60505-201-1-DO_TOPIC.html
[118] www.idrc.ca/uploads/user-S/108484101314_Chapter_3_Agriculture.doc
[119] www.idrc.ca/en/ev-90465-201-1-DO_TOPIC.html
[120] www.idrc.ca/en/ev-10380-201-1-DO_TOPIC.html
[121] www.idrc.ca/en/ev-58019-201-1-DO_TOPIC.html
[122] www.idrc.ca/uploads/user-S/11398486831IPS_Newsletter_Issue_1.pdf

What is notable about the IDRC effort is its breadth of consultation, its link to science policy in Canada, and its ability to draw upon Canadian research capacity to develop new partnerships with institutions in developing areas. Overall, this program appears to have good potential for future growth and development that is directly relevant to biotechnology and sustainable development.

Canadian International Development Agency (CIDA)

CIDA's mandate is to support sustainable development in developing countries in order to reduce poverty and to contribute to a more secure, equitable and prosperous world[123]. CIDA does not have either a specific policy or program dedicated to address biotechnology and sustainable development needs. Biotechnology certainly could contribute directly to CIDA's work on the MDGs and its program priorities, for example in:

- CIDA's social development priorities,[124] especially in the provision of recombinant vaccines for infectious diseases.
- CIDA's agriculture priorities,[125] particularly building the capacity to respond to the opportunities and risks of biotechnology; assisting developing countries to negotiate and respond to multilateral conventions and agreements that directly impact agriculture; strengthening national, regional, and international agricultural research and transfer capabilities; improving crop and livestock stress-adaptation and enhancing the efficiency of natural resources use; increasing the food and feed value of staple crops of the poor; and reducing post-harvest losses.

CIDA also makes contributions to multilateral agencies such as the Consultative Group on International Agricultural Research (CGIAR) and the Global Environment Facility (GEF). Such channels provide indirect support for activities related to biotechnology. The CGIAR-sponsored International Food Policy Research Institute (IFPRI) examines biotechnology policy needs for international agriculture. Biosafety and Cartagena Protocol implementation by developing countries is aided through a GEF-funded initiative administered by the United Nations Environment Programme (UNEP).

CIDA has recently funded several biotechnology-related projects through the Canada Fund for Africa[126]. These include:

- International AIDS Vaccine Initiative[127]: $45 million to fund work in mobilizing support through advocacy and education, encouraging private sector companies to participate in AIDS vaccine development, and ensuring global access to new vaccines. There are currently 30 test vaccines in clinical trials worldwide.

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123 http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/NIC-5493749-HZK

124 CIDA's policy priorities are outlined on the following website: http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/JUD-826145832-Q9M.

125 www.acdi-cida.gc.ca/INET/IMAGES.NSF/vLUImages/agriculture/$file/Agriculture-e.pdf

126 The $500-million Canada Fund for Africa was launched at the G8 Summit in June 2002. It supports the G8's Africa Action Plan, developed in response to the priorities set out in the New Partnership for Africa's Development (NEPAD). The NEPAD is the first made-in-Africa plan intended to put the continent on a path of sustainable growth and development, and into the mainstream of development in the 21st century: www.acdi-cida.gc.ca/canadafundforafrica.

127 www.iavi.org/

- Biosciences Eastern and Central Africa[128] (BecA): $30 million to fund a new centre of excellence in biosciences for agriculture, based in Nairobi, Kenya. BecA will focus on priority areas such as production of stress-tolerant, disease-resistant, and nutritionally enhanced strains of crops, and development of vaccines, diagnostic tests, and genetic resistance to disease among livestock. Its ultimate aim is to help poor farmers keep their land, improve their productivity and income, and increase their market opportunities. Future assistance will support fellowships and education and training activities, especially for young scientists, female scientists, and scientists from post-conflict countries.
- CGIAR: $40 million to fund research on agricultural productivity, including biotechnological research, to reduce hunger and poverty, improve nutrition and health, and protect the environment in Africa.

It is striking how limited the contribution of CIDA has been to an innovation approach that has been billed by some as perhaps the most significant technology of the new century. This reluctance is not limited to bilateral aid agencies such as CIDA. It is also reflected in the limited attention given to biotechnology by the World Bank (except through the CGIAR) and regional development banks. Also, there is little exchange between the influential OECD Development Cooperation Directorate and OECD groups examining the potential of industrial biotechnology and bioproducts.

Various explanations can be offered, for example, the influence of some NGOs and others not in favour of agricultural biotechnology introductions; the stronger role of private sector companies such as Monsanto in GE crop introductions to developing countries; the lower priority accorded biotechnology by some countries; and the untested or unfavourable economics of some aspects such as industrial-scale biorefineries. Perhaps these reasons account for the current antipathy towards a comprehensive approach to biotechnology and sustainable development by CIDA and some other international development organizations.

We believe that CIDA should re-examine its policies and practices regarding the relationship between biotechnology and sustainable development. Some biotechnology applications in human health, agriculture and environment are unlikely to be highly controversial, and may be beneficial, for example those that involve solutions like cheaper, better diagnostic tools that can be used by local people for health or environmental testing. Others include improved pest and disease control in agriculture and aquaculture, clean water biotechnology, and vaccines for use in animal husbandry or for addressing MDG-targeted diseases.

Canada can also help build capacity to improve the implementation of international agreements relevant to biotechnology and sustainable development. Gaining full benefits regionally and locally from any of the agreements noted in Box 5-2 remains very difficult for most developing countries, especially smaller ones. Canada has made an important start with its climate change initiatives, but has done far less on those related to biodiversity, and the sustainable development aspects of trade, including intellectual property, and access and benefit sharing. These topics involve inherent issues of global and intergenerational equity.

[128] www.biosciencesafrica.org

One policy front that seeks to link these three issues is "Access and Benefit Sharing" (ABS). Best characterized as a broad approach to biotechnology development, ABS is based on the so-called "third pillar" of the Convention on Biological Diversity (CBD)[129]. The premise is that because some biotechnological innovations arise from the modification of genetic material found in organisms in the environment, those nations who harbour, and/or those people who steward the organisms or genetic material, deserve to also benefit from the innovations. Benefits needn't be monetary. They can include research training, sharing of data, public acknowledgement, and so on.[130] A related issue is the appropriate compensation of indigenous peoples, who are often the holders of knowledge about the biodiversity and its uses, based on their own traditional knowledge. There are a few anecdotal instances of this traditional knowledge being misappropriated by transnational corporations, and now negotiations are underway, both at the CBD and on a case-by-case basis, to work out ways that benefit both the providers and developers of genetic resources.

This is a far from simple task. Valuable genetic resources reside in public gene banks, museum collections, with individual farmers, and on lands under different levels of government jurisdiction, including those considered the "global commons." Canada needs to articulate its own position on this complex issue and continue to contribute constructively to the international debate. It is a challenging but important task to ensure that alongside the market-based approach to biotechnology innovation, there are mechanisms to ensure that the common good is also supported.

We support the development of ABS regimes that adequately balance the benefits that are due to those who have maintained the relevant biodiversity and those who are working to transform it into something new.

Canada, through CIDA and other federal agencies and departments, should provide more capacity development for the environmental and health risk assessment of biotechnology products. Our thoughts on this subject are two-fold. First, Canada could take advantage of existing expertise and methods. Canada's regulatory framework for biotechnology is respected internationally, and government regulatory agencies such as Health Canada, Environment Canada and the Canadian Food Inspection Agency have considerable expertise in the risk assessment of biotechnology products. Second, over the longer-term we could transfer the experience gained with new approaches, such as the proposed sustainable development framework for assessing biotechnology described in Chapter 5.

Networks and Partnerships for Biotechnology and Sustainable Development

Our premise is that many of the sustainable development issues that Canada and other countries are addressing cannot be solved without considerable sharing in the development and dissemination of knowledge, and in coordinated efforts for developing new environmental and economic policies, rules, standards and domestic action. The roll-out of new technologies is particularly vulnerable to trade challenges and other action. Increasingly, barriers are arising related to intellectual property, perceptions of harm, and local acceptance. The bottom line is that it is better to build an approach to change that includes international dialogue, and is scientific and rules-based, rather than presume that (1) technology introduction will be quickly accepted

[129] www.biodiv.org/doc/publications/guide.shtml?id=web
[130] Bonn Guidelines: www.biodiv.org/programmes/socio-eco/benefit/bonn.aspx, paragraphs 45–50.

because it is better, (2) scientific and technology breakthroughs will be the province only of existing leading nations, and (3) international governance will be simply done, for example via the WTO. In fact, governance will likely be a mix of multilateral environmental agreements, trade arrangements, health and safety rules governed by several bodies, and voluntary measures developed in response to civil society lobbies.

We therefore emphasize the need for Canadians in government agencies, research organizations and universities, the private sector and civil society organizations to engage with others in the development of international partnerships, knowledge networks and action initiatives to address biotechnology and sustainable development. Of course, many linkages currently exist, but not to the extent needed. There are many topics of longer-term significance; we present some candidates for study and action below.

Example Topics

Aside from major medical matters such as stem cell research, the international debates on biotechnology 5 to 10 years ago focused narrowly on biosafety, especially impacts of GE food crop introductions, labeling issues, and several still largely unresolved matters related to access and benefits sharing. Today, although those debates continue, there is a widening and maturing of biotechnology discussions to include subjects such as the attainment of the MDGs, and the role of bioproducts and industrial biotechnology in the transition to a bio-based economy. This discussion features less intensity than the GE food crop and labeling debates. But that is not a reflection of the issues being less complex, or easier to address. Indeed, the opposite is the case.

Canada's role in a future of globalized research: What of the future? What concerns should be on the radar screen for 2010 and beyond? Clearly, the current focus on pandemics is one. Measures to address new forms of disease increasingly involve biotechnology. From where the solutions will come is speculative. But we can anticipate that new vaccines and control measures are perhaps as likely to come from Chinese or Indian laboratories as they are from North American or European ones. The point to be made, and perhaps generalized beyond disease control to some other forms of biotechnology, is that the balance of investment in biotechnology and other new technologies is rapidly shifting to China by comparison to countries like Canada. The implication is that Canada must choose its biotechnology and sustainable development niches very carefully, and also look more closely at how it can cooperate further with large, fast growing countries like China, India and Brazil, and with technologically advanced countries like Singapore.

Managing novel organisms: Another issue likely to gain strength is the significance of novel organisms being transported to Canada, either by choice or by chance. Since we do not have a full understanding of the ecological implications of biotechnology, the precautionary principle will likely be applied for a long time to come on such issues as GE fish releases. But GE fish will appear elsewhere, and tree varieties such as GE poplar will undoubtedly be used much more widely in some countries such as China. The practical means to monitor and regulate entry into Canada of 'undesirable' GE organisms will likely be a subject of growing concern.

Canada's place in a global market for biofuels: As discussed, the growing commitment in Europe, North America and elsewhere to use blended fuels containing biodiesel and bioethanol raises a number of questions about where the supply will come from, and whether it will be sustainable. Speculation has already arisen about whether rainforests in Latin America, Africa and Southeast Asia will be at risk for conversion to cheap sources of carbohydrate or palm oil to supply Europe, China or even North America. Will Canada compete in these same markets, will it participate as a customer and what are the implications of these choices?

What is 'appropriate' biotechnology for the poorest developing nations? In the context of applications in poor countries, this is a very relevant question to ask, especially in relation to matters such as the value chain of bioproducts. What would a biorefinery for rural areas of Ghana or Laos look like? Can claims that biotechnology could be an effective contributor to clean water in poor and isolated communities be verified and supported by economically sound propositions? How well will the biotechnologies for development in 2010 stack up against alternative energy sources such as wind and solar power?

Fair and equitable distribution of biotechnology's benefits: Will the promise of biotechnology providing benefits to traditional knowledge holders and keepers of biodiversity be realized? An international consortium, supported by Genome Canada, has begun the social science research to help address this problem, focussing on the potential of public-private partnerships to deliver benefits, especially in the health realm.[131] We support their continued work toward developing a framework for an international system that functions fairly and efficiently.

International Policy Cooperation

The continuing effort to find innovative solutions for pressing, global sustainable development needs, and to avoid undesirable effects of both new and old technologies, will produce an unending stream of new policy needs. To address these in a harmonized fashion—nationally and internationally—policy initiatives must be formulated in a broadly participative, highly credible fashion. Who should participate? What needs to be done in the way of improving the information base for biotechnology and sustainable development? How can existing cooperative efforts be improved? And how should Canada allocate its efforts, either regionally, within global bodies such as FAO that are associated with the UN, or in specific 'clubs' such as the OECD? What should be the role vis-à-vis biotechnology and sustainable development of an organization like the trilateral Commission on Environmental Cooperation (CEC), which is part of the NAFTA Side Agreement?

The answers to some of these questions are quite clear. Participation must be open and inclusive, and the processes of policy development quite transparent, anticipatory in nature, and comprehensive. For example, such policy development should help to reconcile economic and environmental international agreements. Some of these processes, such as developing access and benefits sharing agreements, will be long-term.

The issue of credible information is one where quick gains could be made, even where longer-term needs are certain. Statistics Canada is considered a world leader in compiling data on biotechnology innovation at a national level. Its collection and analysis of environment and sustainable development statistics is considered highly credible. But it has very limited experience with collecting information on biotechnology for sustainable development. At a regional and global level, the available data and information on this subject area is still very

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[131] www.genomealberta.ca/research/projects/ge3ls/translate/index.php

limited, which constrains the performance monitoring of new policies. Statistics Canada and like-minded organizations in other countries could make a major contribution to address this information gap, perhaps via either the OECD or the UN.

The OECD is the international body with the greatest experience in analyzing the relationship of biotechnology and sustainable development (see Box 7-4). In 2004, the OECD Committee for Scientific and Technological Policy (CSTP) released "Biotechnology for Sustainable Growth and Development", a report describing actions the OECD should take to strengthen its investigation of biotechnology as a driver for sustainable growth[132]. Three key areas for OECD attention were identified: scientific infrastructure and biological resource centres; industrial biotechnology and sustainability; and biotechnology, innovation and health. On-going work where the OECD has been influential includes industrial biotechnology and bioproducts. The OECD now proposes to examine policy needs of the bio-economy to 2030 through its International Futures Programme.

Canada should continue to support and build upon the initiatives in biotechnology at the OECD. They will provide the baseline information required to set our policies on biotechnology and sustainable development. In addition, Canada should seek the greater participation of a number of developing countries in OECD biotechnology efforts, especially China and India; and also try to bring about better linkages with the Development Cooperation Directorate and other elements of the OECD.

Box 7-4. OECD bodies active in biotechnology

- OECD Council
- Committee for Agriculture (COAG)
  - Seeds Scheme
  - Co-operative Research Programme
- Committee for Scientific and Technological Policy (CSTP)
  - Working Party on Biotechnology
  - Working Group on Human-Health-Related Biotechnologies
  - Task Force on Biological Resource Centres
  - Task Force on Biotechnology for Sustainable Industrial Development
- Environment Policy Committee (EPOC)
  - Working Group on Economic Aspects of Biodiversity
- Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (Joint Meeting)
  - Working Group for the Harmonisation of Regulatory Oversight in Biotechnology
  - Task Force for the Safety of Novel Foods and Feeds

Conclusions

We conclude that Canada should strengthen its participation in international cooperation for biotechnology and sustainable development—for Canada's own good, and to support global sustainable development objectives, including the Millennium Development Objectives. Some international development organizations have acted on the merits of biotechnology, primarily in

[132] OECD, *Biotechnology for Sustainable Growth and Development* (Paris, 2004): www.oecd.org/dataoecd/43/2/33784888.PDF.

relation to health and food issues, intellectual property rights, and access and benefits sharing.[133] Others, including a number of international ENGOs have fiercely debated subjects such as GE trees, rules for biosafety, and "terminator" genes, among many topics.

The subject area will become more complex as other natural resource, environmental and industrial biotechnologies are added. Meanwhile, biotechnology gaps are building between biotechnology-sophisticated countries like China and India, and most nations in Africa and poorer nations in other parts of the world. There is growing interest in the potential role of Africa as a supplier of biodiesel and other biofuels to Europe.[134] Undoubtedly, there will be debate about whether this can be done sustainably, producing local benefits while safeguarding soil fertility and biodiversity, and within limits of available water. And, as will be discussed below, there are major public health, clean water and food security issues where biotechnology is likely to play a more central role in Africa and other developing regions.

International Knowledge Networks

Canada and Canadian organizations should engage in various international knowledge networks and initiatives concerning key aspects of biotechnology and sustainable development. While this is already occurring through organizations such as the OECD and the FAO, our view is that strategic participation is needed on a broader basis with European and other North American research groups, and with emerging biotechnology leaders among developing countries such as China, India and Brazil.

To serve Canada's national interests adequately, Canada should take a leadership role and initiate a biotechnology and sustainable development knowledge network explicitly designed to address practical issues. such as trade certification and procedures for sustainable development assessment. The network should cover new areas, such as biofuels and other emerging environment and sustainable development technologies where biotechnology has a role. Canada has strong motives to do so, since BSDE matters will find a place in international trade and multilateral environmental agreement negotiations. We must also develop the necessary knowledge for BSDE in the most cost-effective and timely way. Often, this will be through joint efforts at an international level, involving public- and private-sector interests.

International Development Cooperation

The second major need is for Canada and Canadians to contribute towards a responsible approach for biotechnology and sustainable development applications in developing nations and at an international level. Such engagement is particularly important to meet the UN Millennium Development Goals, for future economic initiatives such as biofuel plantations and processing

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133 See the FAO Statement on Biotechnology (www.fao.org/biotech/stat.asp), extensive biosafety and other discussions related to the Framework Convention on Biological Diversity (www.jiwlp.com/contents/biosafety_resources_net.html and www.biodiv.org); UNCTAD, *The Biotechnology Promise* (2004): stdev.unctad.org/docs/biotech.pdf; International Food Policy Research Institute (IFPRI) Program for Biosafety Systems and other topics: www.ifpri.org/themes/biotech/biotech.htm; UNESCO Biotechnology Action Council: portal.unesco.org/sc_nat/ev.php?URL_ID=2494&URL_DO=DO_TOPIC&URL_SECTION=201&reload=1062152397.

134 www.biopact.com.

that could have major ecological implications, and for future international trade or multilateral environmental negotiations.

One new area for developing nations is ABS mechanisms to ensure the fair and equitable sharing of the benefits of biotechnology between the provider of the genetic "raw material" and those that develop such materials into useful innovations. Use of various policy instruments or approaches, such as private-public partnerships, reduction or elimination of tariffs, open-source IP agreements, patent pools, strategic licensing approaches, farmers' rights, research partnerships, and benefit-sharing agreements may balance some of the perceived local negative effects of intellectual property rights. This is an area where Canada has many shared interests with developing nations, and also a vested interest in having robust, globally acceptable arrangements in place.

While Canada has internalized sustainable development within its international development strategy, no comprehensive policy for biotechnology applications exists within the Canadian International Development Agency (CIDA). Only a limited understanding exists within CIDA for the roles innovation technologies could play in international development. Various pressures on CIDA make it cautious about engaging in this area, especially on food production.[135]

Canada's International Development Research Centre (IDRC) has initiated a promising new program on Innovation, Policy and Science that will link Canadian expertise on technologies with developing country researchers.[136] This program will be driven strongly by the interests and needs of developing nations for poverty alleviation. IDRC, taking on a role of non-partisan broker, has held a number of dialogue sessions in developing countries on the role of biotechnology and other emerging technologies.

Canada has some distinct advantages vis-à-vis biotechnology and sustainable development that could benefit developing nations. These include: our promotion of value-added agricultural innovation; our expertise in vaccines and disease prevention for humans, livestock and fish; our environmental technology capabilities; and our fledgling efforts to establish new lines of bioproducts. Also of considerable interest to some developing nations is our domestic regulatory system and domestically applied experience with international agreements. These are matters of interest for other countries wishing to build capacity in the regulatory arena. They will also influence how Canada approaches negotiation and subsequent implementation of international agreements.

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[135] See, for example, The Working Group on Canada's Policy with Regard to Agricultural Biotechnology and Developing Countries, which is made up of international development organizations, farmers groups, and other civil society organizations including: Canadian Organic Growers, ETC Group, Inter Pares, National Farmers Union, Social Justice Committee, The United Church of Canada, Union Paysanne, and USC Canada: www.interpares.ca/en/publications/pdf/no_more_silver_bullets.pdf.

[136] www.idrc.ca/en/ev-90465-201-1-DO_TOPIC.html

CHAPTER 8. Governance for Adaptive Management

Introduction

Governance is a theme throughout our Report. Canada is not unique in finding governance of biotechnology to be a challenge (see Box 8-1). Strengthening biotechnology governance requires cooperation, collaboration and alliances among governments, private sector stakeholders and civil society. Only an ongoing commitment to maintaining formal and informal strategic partnerships and relationships will allow us to achieve our objectives. The Federal Government is in a position to provide important leadership in this area. In particular, the Federal Government can lead by example—as a regulator, as a participant in international forums, and as a promoter of new technology and innovation—and should do so with skill and energy. It can encourage the achievement of sustainable development goals with biotechnology and the development of an effective governance regime by its own example and by enabling involvement of other stakeholders. This can be done by providing fora for discussion and cooperative decision-making and by creating opportunities for working together to meet the challenges created by this technology.

Box 8-1. Challenges faced by BSDE governance

- Developing a higher political profile;
- Developing flexible means of integrating new knowledge into decisions and actions;
- Applying adaptive management techniques to evolving technologies;
- International arrangements are evolving and untested;
- Biotechnology raises inter-generational concerns and, by definition, not all interests can be directly represented;
- Developing risk management approaches that in time and scope go beyond familiar techniques;
- Consistent leadership is needed not only for today but for the long term;
- Education, information and promotion will play key roles in BSDE governance;
- More effective use of existing institutions.

The scope of governance institutions and arrangements must be comprehensive, covering the full life cycle of biotechnology activities from cradle-to-cradle. Thus, a governance regime—or possibly, series of regimes—will encompass biotechnology research, commercialization of new technologies, regulatory approvals and oversight associated with manufacturing and introduction into the marketplace of products and services, disposal and reclamation. It will have local, national and global dimensions and it will recognize the need for continuous knowledge and adjustment through monitoring and additional research throughout the ongoing cycle. It will facilitate adaptive management, allowing for the exploration of alternative approaches and adjustment as our knowledge grows. And, it will recognize a unique feature of biotechnology—the creation of new living organisms—and the unprecedented concerns raised by this. The governance regime must be sustainable in the long term to accommodate the long time horizons demanded by biotechnology. Such a governance regime, however, will be dynamic and capable of reflecting changing demands and responding to new technology whose full potential is not yet known.

In this Chapter, we will examine the governance and management approaches that are necessary to optimize the benefits and minimize the risks of biotechnology over the long term. This requires active use of the full range of policy instruments (e.g., regulation, taxes, subsidies, information) that are available to governments and international organizations in order to credibly promote the development and use of biotechnology while protecting the public interest. The focus of improved governance must be on strengthening existing institutions and governance mechanisms rather than on inventing new ones in a field that is already extraordinary complex, with multiple players and interests. As new technologies both create gaps and place new demands on existing institutions and governance arrangements, however, adjustments will be required. This argues against developing a centralized or highly structured system of governance and suggests instead a flexible approach where partnerships and arrangements may be tailored to correspond to new knowledge and changing priorities.

This Chapter ends with our vision of what a successful and effective governance regime for biotechnology might achieve in ten or twenty years' time. This vision is not merely "wishful thinking," but implicitly identifies the results of a successful and vibrant BSDE governance regime. By establishing a vision of where we want to be in the future, we can make the necessary adjustments from time to time to reach our goals.

What is Good Governance?

When we speak of governance, we are referring to the processes by which organizations are directed, controlled, and held to account. Governance encompasses authority, accountability, stewardship, leadership, direction, and control. It can involve establishing the strategic direction for the organization, supervising the performance of key officers, risk management, control and allocation of resources, monitoring of results, and adjustment of direction according to information gained through monitoring and evaluation.

While good governance practices and institutions may have value for their own sake, they are successful when they are *enabling*—facilitating the achievement of objectives. In the context of biotechnology, an enabling governance regime promotes the optimization of benefits while reducing risks to public health, safety and the environment. A good governance regime for biotechnology will involve, directly or indirectly, all the interested sectors—governments, academic and research institutions, manufacturers, retailers, and the general public as consumers and citizens. It will have the characteristics described in Box 8-2, and will build on existing capacities and institutions. In particular, it will strengthen our ability to direct biotechnology toward sustainable development outcomes, while at the same time not adding to the complexity of the regulatory system or making more difficult the investment climate faced by biotechnology developers.

Box 8-2. Attributes of good governance

- It is *accountable*: there is the capacity to hold to account and change direction;
- Roles and responsibilities are *clear;*
- Results are *evaluated* and adjustments made, if necessary;
- It is *transparent*: what decisions are made, how they are made and what information is used;
- It is *efficient* and promotes efficiency;
- It is *inclusive*, engaging existing and new partners;
- It fosters an *integrated approach to decision-making*, taking into account environmental, economic and social imperatives;
- It is *flexible*, with the capacity to change, involve new partners, and focus on different priorities at different times;
- It is *simple* and *affordable,* recognizing constraints and available resources in both the public and private sectors;
- It is *effective*;
- It provides opportunities for *guidance* to stakeholders and reduces uncertainty.

Objectives of Renewed Governance: Evolving Relationships

There are three key objectives that a renewed governance regime should promote. These can be seen as three pillars supporting the primary objective of promoting biotechnology in sustainable development. First, the Federal Government must take a strong leadership role. Second, all sectors of society must be engaged. Third, we must promote informed and integrated decision-making drawing on a solid, accessible body of knowledge, including science-based information. This goes beyond government decisions and includes such matters as citizens' political, consumption and investment decisions.

Box 8-3. Existing governance institutions

- Smart Regulation Theme Tables
- Smart Regulation Sector Sustainability Tables
- Canadian Councils of Ministers of the Environment and Natural Resources
- Committee on Consumer-Related Measures and Standards
- OECD
- Canada-EU Regulatory Framework
- Standing Parliamentary Committees
- National Round Table on the Environment and the Economy

To do this, we should be building on existing institutions (such as those noted in Box 8-3) and governance arrangements: there is no shortage of organizations that are or could be used to promote BSDE. While there are institutions and arrangements to build on, this is not a prescription for the status quo. New practices are needed and a new sense of accountability to serve the country rather than the host organization is required. The Auditor General and others have provided detailed commentary on the causes and effects of inadequate collaboration and coordination of Departments and agencies of the Government of Canada[137]. In this Chapter, we offer some practical and useful steps that would improve the performance of the government as a whole and increase the understanding and engagement of other governments, institutions and civil society.

Leadership

The Government of Canada should be actively pursuing its crucial role of creating the conditions to enable Canadian society to adapt to and profit from a fundamentally new technology. There have been only a handful of such transforming technologies historically, and biotechnology has already started to extend into all areas of our lives—economy, health, food, security, climate, and environment. While the potential effects are profound, the full engagement of governments will only occur with political oversight and commitment. Only the Government of Canada has the ability to address these issues on behalf of the country. Indeed, we believe that it has an obligation to do so and that the nature and scope of this obligation can best be described as a trustee role. The essential characteristics of government as trustee are provided in Box 8-4 and include the importance of taking a long-range view of enhancing the well-being of all persons with a disinterested sense of the government's obligations to the public good. To do this, a form of leadership is needed that pulls the public and private sectors into appropriate roles in governance to promote biotechnology in sustainable development. A facilitating, enabling, and catalyzing form of leadership is needed.

[137] www.oag-bvg.gc.ca/domino/reports.nsf/html/20051104ce.html

In addition to this pivotal leadership role, the Federal Government has specific responsibilities for important aspects of the protection of health, environment and security. The public attaches great significance to the Federal Government's regulatory role and this underpins much of the confidence that the public has, and will continue to have, in the use of biotechnology and willingness to accept the benefits and the risks that new technology offers. The Federal Government also provides incentives for research and development, and technology commercialization through direct funding and tax expenditures. Fiscal policies aimed at supporting major industrial sectors such as energy, agriculture and forestry will often have unintended consequences—both positive and negative—to the prospects for a transformative technology such as biotechnology, particularly in its period of early adoption.

Box 8-4. The model of government as trustee

- The direct duty of government is to protect and enhance the wellbeing of all persons and nature.
- The legislator must discharge these obligations to the public good on the basis of impartial and disinterested deliberations.
- There is an obligation to respect human rights and provide and be accountable for the protection of those rights.
- Waste of entrusted resources is explicitly prohibited.
- Respects the virtues of commerce.
- Provides a framework for setting foreign policy.

Source: Brown, Peter G., *Restoring the Public Trust: A Fresh Vision for Progressive Government in America* (Boston: Beacon Press, 1994)

The Federal Government has the constitutional responsibility to take the lead in the international arena, promoting international cooperation, harmonizing regulatory approaches, and sharing the task of monitoring and assessing long-term data on cumulative effects. International agreements, standards and organizations will be playing an increasingly important role in biotechnology governance (see Box 8-5 for examples). Complex international agreements governing trade, environmental protection, and eco-labelling of goods, and non-statutory agreements involving global corporations will have to be reconciled in order to make progress on issues on the international agenda. These initiatives translate into domestic obligations and policies of both public and private sectors. Canada has so far generally taken cautious approaches, for example in not signing the Cartagena Protocol on Biosafety, and in not adopting compulsory labeling of GM foods.

Box 8-5. Examples of the international context

International treaties that bear on biotechnology innovations include:

- Codex Alimentarius (food safety standards);
- The Convention on Biological Diversity (protection of environment, equitable sharing of benefits);
- The International Treaty on Plant Genetic Resources (sharing agricultural biotechnology resources); and
- The Trade-Related Aspects of Intellectual Property Rights Treaty (intellectual property).

The OECD has been working on biotechnology issues for over 20 years. Governance studies include development of policy options for science and technology infrastructure; the implications of intellectual property rights and licensing; and consideration of human health and environmental safety.

International institutions will continue to be amongst the most influential players in determining the future of this technology. Canada has a long and encouraging history in this field. We must continue to participate actively and build on our current 'good' reputation. From time to time, we must be ready to play the leading international role when important issues or Canadian interests are at stake.

The foregoing describes some of the central decision-making roles that the Government of Canada plays in addressing issues arising from the confluence of biotechnology and sustainable development. All Canadians have reason to expect that not only will individual organizations perform according to their mandate, but that the system at large should be able to respond effectively to new challenges derived from the unique characteristics of the technology. This was certainly intended as the measure of success when the Canadian Biotechnology Strategy launched in 1998. Although progress has been mixed and frequently disappointing, we believe that the original goals and machinery are capable, by and large, of doing the job. However, political renewal or reinforcement of the mandate and a much higher level of public accountability is required.

A Renewed Canadian Biotechnology Strategy (CBS)

The purpose and proposed outcome of the CBS is "to ensure that biotechnology continues to enhance Canadians' quality of life in terms of health, safety, environment and social and economic development."[138] Further, the CBS should position Canada as a world leader in biotechnology. Thus, the aspirations of this Strategy are well in line with those we have identified. We therefore propose strengthening existing institutions and governance mechanisms, rather than inventing new ones in a field that is already extraordinarily complex and prone to polarized views.

Governance for biotechnology (and also for sustainable development) presents the classical need for horizontal initiatives. In addition, there is a need for integrated effort related both to policies and to outcomes. Overall, the CBS was set up to be catalytic, keep files moving, and provide funding for special initiatives. It is quite complex[139], reflecting the need for leadership, coordination and integration, for independent advice (via CBAC) to ministers and officials, and to have a communications role internally across government, with stakeholders, and with the public. There are several biotechnology coordinating committees to guide the overall process and provide strategic direction (Ministerial and Deputy Minister levels) and technical-level guidance (Directors General). In between is the BACC (Biotechnology Assistant Deputy Minister Coordinating Committee). BACC operates at a level with considerable accountability for outcomes and with a degree of both strategic/political and technical capacity, recognizing the dual role of ADMs in government. The small CBS Secretariat works in a coordinating, not directive role.

The Auditor General's 2005 review concluded that "Overall, the Canadian Biotechnology Strategy has not functioned as planned. It was designed for leadership from the top, which was not provided; however, management and working-levels did provide some co-ordination."

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[138] www.tbs-sct.gc.ca/rma/eppi-ibdrp/hrdb-rhbd/cbs-scb/description_e.asp and www.biostrategy.gc.ca.

[139] An overview of governance structure and performance of the CBS is provided in Chapter 4 of the November 2005 Report of the Auditor General of Canada: http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20051104ce.html

We believe that having a well-functioning coordinating and integrating body will be needed even more in the future. This body should have the capacity and operational ability to enable deliberative dialogue, to ensure that adequate statistical, monitoring and scientific knowledge is being produced and used in assessments, to draw integrative understandings relevant to policies and implementation performance from the plethora of studies and experimental initiatives funded through the CBS and other sources, and, of course, to be accorded a high level of visibility inside and outside of government.

The CBS should operate in an adaptive planning and management fashion. Through its existing structure and mandate, it has the elements necessary to commission necessary experimental and interdisciplinary analysis, to consider the results and recommend corrections through progressively higher bureaucratic, and, ultimately, political channels, and to initiate broadly based public and stakeholder dialogue. These are key ingredients for adaptive planning and management.

Ongoing adjustments will be required as new demands arise, especially late in the current decade when many new BSDE applications emerge. This argues against developing a centralized or highly structured system of governance. Instead, a flexible approach is desired—where partnerships and arrangements can be tailored to correspond to new knowledge and changing priorities. This also is consistent with the approach of adaptive planning and management that we advocate.

There may be a need to broaden membership within the CBS. For example, the interests related to international development are not well represented. The subject matters of bioterrorism and biosecurity are becoming key concerns within many countries, including Canada, and are related to stewardship matters in various ways. These are topics not currently covered, nor are some relevant agencies represented on the various committees.

The CBS should function as a centrepiece of the federal effort for BSDE. But, of course, it is not the only element. In addition to the responsibilities of departments and agencies, the Federal Government also has a central coordination role, facilitating federal-provincial relationships. The provinces play important regulatory and enabling roles in their governance of innovation, environment and development. We see opportunities for federal-provincial cooperation to reduce interprovincial trade barriers concerning bioproducts, to harmonize standards on use of biomass and on environmental assessment of biotechnologies, to harmonize taxes and incentives, to develop a national ecosystem monitoring system and to develop biotechnologies related to sectors such as marine and forest products. We also hope for a high level of accountability for results, including the possibility of dedicated effort concerning BSDE by the Commissioner on Environment and Sustainability (CESD).[140]

A renewed governance regime should reinforce three pillars supporting the primary objective of promoting biotechnology in sustainable development. First, the Federal Government must take a strong, effective and ongoing leadership role. Second, all sectors of society must be engaged. Third, we must promote the development of knowledge, including sound science-based information, to support societal decision-making. This goes beyond government decisions,

[140] The CESD in her 2004 Annual Report responded to petitions received on biotechnology. This is only one of several roles that the CESD could play in examining biotechnology and sustainable development: www.oag-bvg.gc.ca/domino/reports.nsf/html/c20041006ce.html.

and includes such matters as Canadians' behaviour and views on sustainable consumption and investment decisions.

An effective BSDE governance regime can build on complementary private-sector initiatives. At some point, for example, segments of the biotechnology industry may be sufficiently cohesive and mature to develop a non-legislated performance system along the lines of chemical producers' "Responsible Care™" program. The "Stewardship*first*™" program run by Croplife represents one such starting point related to biotechnology.[141] Similarly, industry segments may be able to draw upon or develop quality management standards like ISO 14001, which not only improve credibility, but also enhance the public's trust in private-sector risk management. The biofuel area presents an important immediate opportunity, with both domestic and international trade implications.

The Government of Canada has the ability and the obligation to address biotechnology and sustainable development issues on behalf of the country. A facilitating, enabling, catalyzing form of leadership is needed, which pulls stakeholders together so they can play important governance roles and promote biotechnology for sustainable development.

Ministers and Deputy Ministers will continue to define the political goals, set strategic directions, establish priorities, allocate resources and create the context within which the government machinery will operate. We believe that the committee of Assistant Deputy Ministers, BACC, as well as the committee of directors general, is where the day-to-day governance emphasis at the Federal level must be placed.

There are three key roles that BACC should play in promoting biotechnology. The first is to align biotechnology to contribute to the Government's agenda and priorities, e.g., linking biotechnology with drives for improved productivity, competitiveness, climate change, better health for Canadians and so on. In doing so, it must be noted that there are numerous matters competing for prominence on the Government's policy agenda. It will be necessary for influential stakeholders in the private sector and civil society to raise a clear and strong voice demanding that the potential contribution of biotechnology to sustainable development be acknowledged in Government priorities and commitments.

The second role for BACC is to ensure that national leadership institutions, such as Parliamentary Standing Committees and Canadian Councils of Ministers, are provided with the information and analysis about biotechnology that they need make decisions and provide the leadership that is their mandate.

The third role is to ensure that the Federal Government delivers on its responsibility in an exemplary manner. For example, the Government must ensure that the actions of individual departments, be it regulation or research, are coherent and mutually reinforcing in terms of benefits. In order to do the work, capacity in the form of biotechnology and sustainable development literacy and working knowledge must be developed in both the public and private sectors. These abilities include the technical skills for research, knowledge and technology transfer and development and commercialization of new technologies, as well as the knowledge and literacy necessary for informed political debate and social awareness. In this country, the Government of Canada is the primary player in the generation and funding of "public good"

[141] www.croplife.ca/foodforthought/crop_protection_canada/crop_protection_canada_01.php

science and information. It must thus become the principal disseminator of this knowledge to other governments, sectors and interests in Canada and even abroad.

In order to deliver on this third goal, the role of the BACC and the Biotechnology Secretariat in coordinating issues should be strengthened. They currently perform a valuable role, but more would be expected in order to realize the ambitions enunciated in this report. The authorities and responsibilities of their member organizations cover all the essential functions of government, but the challenge they face is to collaborate across organizational lines to provide a whole-of-government approach. BACC should catalyze and facilitate this approach. This higher level of accountability and additional tasks proposed below would need much greater clarity in terms of mandate and increased resources to do the work. To emphasize and legitimize this role, BACC requires a renewed mandate from the Government. As well, the Commissioner for the Environment and Sustainable Development, the Auditor General, and advisory bodies can all assist in the task.

To provide a productive, accountable and transparent structure for Federal Government leadership, we recommend that BACC should prepare a series of reports, one annually, dealing with various facets of biotechnology.

- First year: a consolidated Biotechnology Research Plan, setting out the research initiatives directly or indirectly funded by Federal Departments or Agencies, the results achieved, comparable action in other countries, and approaches taken and results achieved with provinces, the private sector and other countries in both the natural and the human sciences. This would provide a useful context for reporting on the results of 'technology foresight' exercises. The current assessment of "public good science" issues, including those associated with the state of population and ecosystem health, should be provided.
- Second year: a consolidated description of the regulatory regimes applied to biotechnology, including new or proposed regulations; evaluation of existing regulations or regulatory programs; Parliamentary or other reviews of legislation or regulations, including state of compliance; and harmonization of standards within the Federal Government, as well as harmonization with provincial standards.
- Third year: a description of the state of development and commercialization of biotechnology applications, providing information on active players, financing arrangements (including public-private partnerships), number of companies and profile, number of employees, geographical distribution, etc.
- Fourth year: a description and forecast of the international public and private sector policy agenda; a description of how international agreements are integrated into the domestic policy agenda and vice versa; and an outline of current and projected international achievements and challenges.
- Fifth year: a description of the public attitude to biotechnology, together with an account of techniques and experience with engaging civil society. The number of people working in all aspects of the technology in both the public and private sectors should be documented and future demands and sources of supply for competent workers projected.

In the sixth and subsequent years, a renewed cycle should continue. Consideration should be given to laying these reports before Parliament and providing opportunities for comment and public debate. At the outset, these reports should concentrate on the activities of the Federal Government, but they should be made national in character as soon as possible. Special reports may be prepared outside the recommended schedule to meet particular needs or opportunities. For example, privacy and intellectual property rights raise important issues that would benefit from special reports. In addition, a particular scientific finding may generate public interest and the government of the day could welcome the opportunity to make a substantive response in a timely way.

BACC may also take a lead role in creating and stimulating regional and national dialogues on emerging biotechnology issues to contribute to building capacity, literacy, skills, and knowledge. Indirectly, these dialogues could foster strategic partnerships and alliances as well as providing information to feed into the continuous learning so critical for adaptive management.

Engaging all Sectors of Society

All levels of government—federal, provincial, territorial, and municipal—are involved in some or all aspects of BSDE. Together, they fund research and promote commercialization and the dissemination of novel technological applications. They support clusters of public and private institutions for mutual benefit (see example in Box 8-6). They have a statutory responsibility for the protection of the environment and public health. They deliver programs that have the potential for the use of biotechnology and for promoting biotechnology for sustainable development. There are a range of Ministerial Councils that provide strategic direction to fields of common interest. BACC should facilitate the discussion of applicable biotechnology issues through the appropriate lead department or agency. Priority should be given to getting on the agenda of environment, forestry, fisheries, energy and agriculture Councils within the next 24 months. A comprehensive report of these activities would provide a useful sense of which elements of society are most engaged and with what result.

Some of these governmental responsibilities are clear and understood; others are not. In some cases, more than one government has a legal authority to act regarding the same human activity. Pragmatism should be a major consideration in deciding which government is best suited to act or play a leading role. The capacity to do the job in terms of qualified people, equipment, proximity and acceptance of clear accountability should be determining factors.

Box 8-6. MaRS Discovery District in Toronto

Created in 2000 by business and the public sector to strengthen Canada's ability to commercialize academic research to benefit the health and economic future of Canadians.

Located in a unique urban setting that connects MaRS to other research and educational facilities in the area, the financial district and the multi-cultural, creative city core, it provides the following to companies and entrepreneurs:

- Expert resources
- Entrepreneur-in-Residence (EIR) Program
- Peer-to-Peer Mentoring Programs
- Information resources and business tools
- Specialized facilities and equipment
- Capital access to companies and entrepreneurs

A further challenge will be bringing in other players, some of whom may not yet realize the degree to which they should be interested or involved. These include such groups as ENGOs, Aboriginal groups, and various commercial interests, as well as citizens who are concerned about their health and environment and the future of their children. In addition, broad engagement means that the skills and knowledge of players outside of the more traditional research networks must be engaged. The potential of small- and medium-sized business (SMEs) to participate, particularly in the commercialization stage, in biotechnology must be recognized.

Engaging various sectors does not mean simply consultation by governments, although that will be important in adding to informed decision-making, discussed below, and building public trust. It also means that collaborative and cooperative arrangements are most likely to succeed in the areas where creativity and the synergy may be needed for success, particularly in integrating the benefits of biotechnology into sustainable development. Constructive engagement of the different sectors, which may include those not normally consulted by governments, may require exploration of different means of communication and exchange. Other new technologies, such as the Internet, can promote collaboration among colleagues and provide a forum for increasingly informed debate and discussion with citizens.

Promote Informed and Integrated Decision-making

To fully reap the benefits of the BSDE relationship, a number of conditions must be put in place. Canadians (and our international partners and neighbours) must be able to trust decisions made regarding biotechnology by both government and the private sector. In particular, they must be able to trust the regulatory structure established to protect and promote public health and safety and the mechanisms in place to monitor and assess information about immediate and long-term impacts of biotechnology applications. A credible, informed and active regulatory system is an important base for building public trust.

Clearly, sound science—both social and human sciences—must inform decisions so that benefits to society are optimized while risks are minimized. Promoting the development of the necessary knowledge base for decision-making will be critical. Indeed, it will be necessary in future years to stress the importance of ecosystem science that melds the natural and human sciences together so that we will develop a better understanding of the potential or actual impacts of new technologies in the broadest sense. We refer the reader to our recommendations made in Chapter 5, where we suggest mechanisms to integrate these different types of knowledge into decision-supporting frameworks.

Information and governance must be developed with the "long haul" in mind. It will be necessary to build databases, create networks of relationships and develop the capacity to explore and link the fruits of investigations and trials. These must be developed over time, with an eye to future generations and our obligations to mitigate long-term risks. The importance of identifying both short-term effects and longer-term cumulative impacts of new technologies and biotechnology applications means that the governance regime must emphasize the elements of *monitoring, assessing and adjusting to information.* We must have the capacity to track the consequences of cumulative decisions throughout their life cycle and provide the earliest possible warning of risks to the ecosystem and population health. This capacity does not currently exist at the required level. We offer an outline of an approach in Chapters 3 and 5.

In creating the systems and capacity for long-term data gathering and analysis of cumulative effects, we strengthen our skills to deal with our limited ability to predict the full consequences of both discrete and cumulative decisions. In biotechnology, as in any dynamic system, we are bound by the "law of unintended consequences"—the inter-related nature of actions will cause results, whether in the natural world or in human responses, that cannot be easily predicted. We must encourage the use of adaptive management to deal with the fact that the development of biotechnology will be neither predictable nor ordered. We must use pilot projects, or deliberately choose alternative approaches to a particular problem or alternative ways of applying a new technology so we can watch and learn from experience. It will be necessary to fund and explore several routes, adjust and even abandon unproductive avenues as experience is gained.

This adaptive management approach to a new technology gives us a means of dealing with issues that may otherwise be too complex, interwoven, and dynamic to assess with conventional predictive or risk averse approaches. It allows us to move forward while providing the information needed for risk identification and risk management. Specifically, adaptive management is an approach that will contribute to our objective of advancing sustainable development goals through the use of new technologies, while reducing the risks associated with uncertainty and complexity.

The need for informed and integrated decision-making is not just at the governmental level, however, but occurs in all sectors. We must consider extending partnerships into the education system to build broad capacity in future generations, as well as expand the range of information available for civil discourse. Ensuring that citizens are well informed in their own decision-making and informed about actions being taken by government (particularly with respect to risk management) will be key elements in ensuring that the decisions taken advance broadly held societal goals in a way consistent with Canadian values.

A Governance Vision

If we were to look forward 10 to 15 years, we would hope to see a culture in which sustainable development is accepted as a lode star of decision-making across all sectors of society. There will be a solid and growing store of information about techniques to create a sustainable environment and this information will be widely available. More particularly, innovations based on the emerging technology of biotechnology will be recognized as an important contributor to sustainable development in a host of ways. For example, biotechnology innovations could be a key factor in providing citizens and government decision-makers with the "breathing space" they may need to enhance well-being in a time where rapid adjustments to changing environmental and social pressures may be required.

Both ordinary citizens and government decision makers will be aware of and comfortable with the contributions being made by biotechnology and its continuing potential to benefit society. Biotech "success stories" will be well known and consumers will be able to identify desirable new products or technologies made possible by biotechnology. By this time, the potential of biotechnology to contribute to productivity and competitiveness will be recognized, and citizens will benefit from the transformations of biotechnology.

To facilitate this culture, a number of highly collaborative and cooperative relationships will be in place. National and international governments will have links and networks dealing with biotechnology. Governments will have the capacity to take information about new technologies and convert it into proposals for new investment strategies and support for research, development, stewardship, and commercialization. There will be strong arrangements within governments to deal with cross-cutting issues, and civil servants will be rewarded for their ability to recognize the need for and foster collaborative relationships.

Governments will also be working with non-governmental organizations, Aboriginal groups, research institutions, academia, and with other sectors of society exploring issues, establishing programs, and building trust. The store of knowledge on matters of cumulative impacts and longer-term effects of decisions made in the early years of the 21st Century will have enlarged. New analytical approaches will have been developed, including an improved capacity for dynamic risk assessment. Governments will actively use and explore the potential of the various instruments at their command to promote BSDE goals, and optimize benefits while reducing risks. Information will be available to allow for independent assessment of the effects of government action, and government evaluations will transparently examine cumulative effects of government decisions and examine the combined effects of multiple policy instruments.

The ability to be flexible and adaptive when dealing with new technologies will be seen as a strength, not as a sign of indecision. Greater value will be attached to benefits, both commercial and social, that will accrue years in the future. There will be dialogue, learning and increasing trust in societal institutions, and in the programs and decisions emerging from these institutions. Citizens will be more knowledgeable about sustainable development in general, and there will be mechanisms for civil discourse and discussion on means to achieve a world where future generations would have the resources and opportunities to explore their own potential, without having been constrained by the over-consumption of their forebears. There will be institutions in place, some real and some virtual, to allow information and discussion to flow among all sectors of society.

Biotechnology and sustainable development will have a "profile" in the discourse and institutions of government. For example, there will be references to biotechnology in Budgets and Speeches from the Throne. Parliamentary and legislative committees will from time to time examine issues relating to biotechnology and their activities will play a key role in promoting public awareness of issues and stimulating discussion. Government departments and agencies will consider issues of sustainable development routinely in the assessment of new policy proposals and will consider the implications of using a range of policy instruments to achieve objectives of sustainable development through biotechnology. The Federal Government will be active in international fora dealing with biotechnology issues and Canada will have the reputation and capacity to take the international lead on important issues, such as harmonized regulation.

Biotechnology industries will have come to recognize their common needs and will work together to build credibility with their customers and the general public, as well as build their reputation with regulators. Industry, possibly with the encouragement and cooperation of governments, will have developed self-regulatory approaches to raise their levels of compliance with regulation. There will be industry codes of conduct in place, and industry-driven co-regulation programs (along the lines of "Stewardship*first*™") will be maturing.

This Governance Vision might seem overly optimistic or demanding. We believe, however, that it is necessary to have a vision and a goal in order to know the paths to follow. While we may advocate flexibility and adaptation for specific approaches, the overall values and vision do not change. The governance regime must set out broad objectives and be clear about roles and responsibilities. We must not confuse our inability to predict the full range of uses of biotechnology or the contribution they will make to sustainable development with an unwillingness to take specific action to improve governance and foster accountability. There is still a tremendous untapped capacity within existing institutions to strengthen governance for BSDE and these opportunities for improvement should be explored further.

CHAPTER 9. Recommendations

The overarching message of our BSDE Report is that biotechnology could help Canada and the world attain sustainable development goals while enhancing Canada's overall economy. A strong sustainable development-oriented biotechnology sector can reduce humanity's ecological footprint, reduce toxic substances, support clean air and water goals, and perhaps play a role in mitigating the effects of climate change. Domestically, building a strong biotechnology sector could position Canada to take full advantage of new knowledge and skills coming available over the next several years.

Can Canada create a future where a national innovation system supports the invention, commercialization and market acceptance of new technologies for achieving sustainable development? Augmented by a regulatory system that ensures the safety and health of the environment and Canadian citizens? And supported by an excellent system of knowledge generation and communication that serves civil society, government and business? Where these three interlocked systems are guided by values, ethics and principles that steer their functioning towards environmental and human sustainable development outcomes? If these goals are achieved, there should be renewed confidence in this country's national ability to act for the public good—and to be seen, domestically and internationally, as doing so.

The nine recommendations presented below arose from the research we conducted, the conversations that we have had, and current events in this emerging set of endeavours we have labelled *Biotechnology, Sustainable Development and Canada's Future Economy*. The basis for and implications of these recommendations are described in our accompanying Executive Report.

We believe these recommendations, if acted on quickly, will be important steps towards creating a productive, safe and long-term relationship between Biotechnology and Sustainable Development.

Our first recommendation covers Canada's need to take a strategic approach to BSDE—not piecemeal. Our second recommendation is that Canada should focus on implementation of advanced technologies if we are to properly seize new bioproduct and biorefinery opportunities—that some call "Canada's natural advantage." The next three recommendations address the need to recognize the interlocked nature of environment and economy. Canada needs to get the market signals right for biofuels and other novel products by avoiding long-term distortions, and to effectively monitor ecological change. And, there should be a gradual move to an integrated sustainable development assessment approach which, if properly implemented, need not become burdensome. Our sixth recommendation is to engage citizens and stakeholders in deliberative dialogue in a manner that has not happened up to this point. We believe Canada should take a strong international cooperation role for BSDE. We need to participate more fully in international knowledge networks, and to strengthen biotechnology and sustainable development both internationally and with developing nations. These points are covered in recommendations seven and eight. Most importantly, Canada needs to strengthen governance for adaptive management of BSDE. We believe this can be done mainly through making existing governance mechanisms work better, the subject of our final recommendation.

Recommendation 1 – Develop and Implement a Strategic Policy Framework

The Government of Canada should develop a biotechnology strategy that contains explicit values and ethical principles driving the assessment and uptake of new opportunities, the implementation of adaptive management integrating ecology and the economy, and the development of a global outlook for meeting Canada's sustainable development goals.

Recommendation 2 – Support Advanced Biotechnologies

The Government of Canada, in order to give Canada a comparative advantage, should enable the establishment of advanced biorefineries capable of using either agricultural, forest, food or municipal wastes and residues. This should be done through arrangements with provincial governments and the private sector that do not impose ongoing costs on Canadian taxpayers.

Recommendations 3, 4 and 5 – Address Community Health, Economic and Ecological Needs

Recommendation 3 – Get the Market Signals Right

The Government of Canada should ensure that positive fiscal policies (R&D funding policy, tax structure, etc.) are linked to positive sustainable development outcomes. Direct government intervention should be recognized to be temporary funding only and involve careful monitoring. The Government of Canada should promote participation in the development of eco-labelling and sustainable development certification schemes for bioproducts, and remove import tariffs on sustainably produced biofuels and other bioproducts.

Recommendation 4 – Monitor Environmental Effects

The Government of Canada should implement an ecosystem monitoring and information program to provide sufficient and robust information on the ecosystem effects of new activities related to biotechnology. A dedicated effort is required that would integrate this program with existing ecosystem health initiatives and include the implementation of EENLO. The monitoring strategy should provide for transparent, timely and scientifically credible development of regulations, and for testing of important ecological hypotheses concerning innovative technologies.

Recommendation 5 – Develop an Integrated Assessment Framework

The Government of Canada should develop, by extending the use of existing tools and assessment processes, a sustainable development assessment framework to:

- guide the formation and implementation of policy towards sustainable development goals and principles,
- screen applications for new products and services, and
- assess products at all stages of their development and life cycle.

The assessment will support, not replace, existing health, safety and environmental reviews, and could be introduced in a progressive fashion.

Recommendation 6 – Foster Public Dialogue

The Government of Canada, working cooperatively with others, should initiate and maintain long-term deliberative dialogue with citizens and stakeholders on biotechnology and sustainable development. This dialogue should take place using cost-effective electronic exchanges, and should emphasize dialogue with younger people. Learning and dialogue efforts should be designed to yield measurable results linked to adaptive planning and management.

Recommendations 7 and 8 – Build a Role for BSDE in International Cooperation

Recommendation 7 – Establish Knowledge Networks

Establish one or more Canadian university centres of excellence on biotechnology and sustainable development, with a requirement of strong international research linkages. To ensure relevance, funding could be delivered by Canada's research agencies in cooperation with relevant federal and provincial government departments and private sector support.

Recommendation 8 – Focus on International Development

The Government of Canada should build policy and capacity in CIDA and other Canadian institutions to address biotechnology and sustainable development opportunities and needs for poorer nations. This should be done in a way that promotes equitable distribution of the benefits of biotechnology, especially in the international arena and for poorer developing nations.

Recommendation 9 – Establish Governance Mechanisms for BSDE

The following three objectives should be promoted by the Government of Canada for BSDE governance.

1. Provide strong federal leadership.

Ministers and deputy ministers will continue to define political goals, set strategic directions, establish priorities, allocate resources and create the context within which the government machinery will operate. The Biotechnology Assistant Deputy Ministers' Coordinating Committee (BACC) is the level at which important political and technical understanding can be integrated to shape policies and outcomes in an adaptive fashion. There are three key roles that BACC should play in promoting biotechnology:

- Align biotechnology policies, regulations and incentives so that biotechnology contributes to the government's agenda and priorities related to sustainable development.
- Ensure that national leadership institutions, such as parliamentary standing committees and Canadian councils of ministers, are provided with the information and analysis about biotechnology and SD that they need to make decisions.
- Make certain that the Federal Government delivers on its responsibilities in an exemplary manner.

2. Engage all sectors of society.

Within the next twenty-four months, priority should be given to getting BSDE on the agenda of environment, forestry, fisheries, energy and agriculture ministerial councils representing the different levels of government. As well, there must be a greater degree of engagement with sectoral interests, including the substantial number of large corporations, small- and medium-sized enterprises (SMEs), industry associations, environmental NGOs, aboriginal groups and others with a stake in BSDE.

3. Promote informed decision-making.

In support of environment, health and safety, the governance regime must emphasize monitoring, assessing and adjusting to information in order to identify both short-term effects and longer term cumulative impacts of new technologies and biotechnology applications. This information is essential for developing regulations, making robust assessments and evaluating the effectiveness of decisions.

In support of policy development, transparency and accountability, BACC or an independent third party should prepare a series of annual reports for public distribution. These should deal with a different facet of biotechnology and sustainable development each year: research, regulatory regimes, commercialization success and competitiveness, international and domestic policy agendas, and public attitudes towards the achievements of biotechnology in reaching sustainable development objectives.

BSDE GLOSSARY

Biobased: a short form of 'biologically based', meaning derived from organic matter.

Biodiesel: a processed fuel derived from biological sources that can be used in diesel-engined vehicles. Biodiesel is biodegradable and non-toxic, and releases fewer emissions when burned than petroleum-based diesel.

Biodiversity: the variety of the world's organisms, including their genetic diversity and the groupings they form. Reflects the interrelatedness of genes, species, and ecosystems.

Bioeconomy: an economy where the basic building blocks for production and the raw materials for energy are derived from renewable resources, such as plant- and crop-based sources.

Bioethanol: ethanol that has been produced through fermentation of sugars by microbes. It is being touted as the world's first major biofuel, and is currently derived from the fermented sugar or starch in crops such as corn and sugarcane. *Cellulosic* ethanol, which is not currently commercially available, is derived from the sugars present in woody and fibrous plant material such as straw and wood chips. Many analysts consider cellulosic ethanol to be a more sustainable biofuel alternative than grain ethanol.

Biofuel: a fuel that is produced using biological processes and/or feedstocks. It is a renewable energy source derived from biomass, such as plants, agricultural or forestry waste, or waste cooking oil. Commonly used biofuels include ethanol, methanol, and biodiesel.

Bio-IT: involves the use of techniques from applied mathematics, informatics, statistics, and computer science as well as chemistry to solve biological problems usually at the molecular level. Also referred to as 'bioinformatics' and 'computational biology'.

Biomass: refers to living and recently living biological material. Examples include plant matter grown for use as biofuel as well as plant or animal matter used to produce fibres, chemicals or heat.

Bioplastics: a form of plastic derived from plant sources such as hemp, canola or soy bean oil and corn starch, unlike traditional plastics, which are derived from petroleum. Bioplastics are being designed to be biodegradable, thus reducing the pollution problem associated with plastics.

Bioproduct: new products developed from biological materials. Bioproducts may replace or enhance products derived from non-renewable resources.

Bioprospecting: the collecting and testing of biological samples, such as plants, animals, and micro-organisms, and frequently leveraging indigenous knowledge, to help discover genetic or biochemical resources. An activity driven primarily by economic purposes, for example to produce new drugs, crops, and industrial products.

Biorefinery: an industrial plant that takes biological material as its input, transforms the material into mixtures of valuable chemicals and then separates and purifies them, yielding multiple valuable products and often a large amount of energy as a byproduct, with minimum waste and pollution.

Bioremediation: any process that uses living organisms, such as microorganisms, fungi and plants, to restore a contaminated environment. Some organisms being considered for use in bioremediation have been genetically engineered to consume or digest certain pollutants.

Biopesticide: a pesticide in which the active ingredient is either an organism, or a toxin produced by an organism. One such toxin in common use is the *Bacillus thurengiensis (Bt*) toxin.

Biosafety: prevention of large-scale loss of biological integrity, focusing both on ecology and human health.

Biota: the combined flora and fauna of a region.

Biotechnology: the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

Brownfields: former industrial and commercial lands that are contaminated with toxic substances.

Eco-efficiency: a term coined by the World Business Council for Sustainable Development that is based on the concept of creating more goods and services while using fewer resources and creating less waste and pollution.

Ecosystem: the complex interaction between plants, animals and micro-organisms and their environment.

Ecotone: a transition area between two neighbouring ecological communities or ecosystems.

Enzymes: biological agents that catalyze chemical reactions, usually requiring much milder, and therefore less energy intensive and toxic, conditions than traditional chemical catalysts.

Feedstock: a substance used as a raw material in an industrial process.

Gasification: a process that converts carbon-based materials, such as coal, petroleum, petroleum coke or biomass (i.e., wood waste), into gaseous products such as hydrogen and carbon monoxide that can be combusted or used as building blocks for further chemical syntheses.

Industrial ecology: the shifting of traditional waste-producing industrial processes to a closed-loop system where wastes become inputs for new processes. Involves redesigning manufacturing processes to use less energy, and non-polluting catalysts and enzymes.

Molecular farming: the growing of plants in agriculture to produce pharmaceutical or industrial compounds instead of food, feed, or fibre. Also referred to as "biopharming" or "molecular pharming".

Nanotechnology: An approach to the understanding and control of matter that operates at dimensions less than 100 nanometers. Nanotechnology enables novel applications, such as computer chips and other devices, that are thousands of times smaller than current technologies.

Persistent organic pollutants (POPs): organic compounds that are resistant to environmental degradation through chemical or biological processes.

Recombinant vaccines: vaccines produced using recombinant DNA processes.

Sustainable development: defines desirable, long-term outcomes for living within planetary ecological limits, with more equitable sharing of economic and social benefits among today's population and future generations.

Terminator Technology: the informal name given to controversial methods for restricting the use of genetically-modified plants through the insertion of an element that can, upon induction by a certain chemical, cause second generation seeds to be sterile. Also known as "genetic use restriction technologies" or "GURTS".

Transgenic animals: animals whose DNA has been altered through the introduction of genes from organisms of another species. Transgenic animals are used as models to test the effect of certain genes on health, to produce enhanced versions of animals, or to produce extra substances.