Author - Bio-Industries Branch

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Building the Canadian Biotechnology Strategy

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Although wide-spread interest in biotechnology

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- Canadian Food Inspection Agency
- Environment Canada
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Although wide-spread interest in biotechnology issues is a recent phenomenon, the Government of Canada first identified biotechnology as an important economic sector and a key enabling technology to support economic growth and international competitiveness in the 1970s.

The Government of Canada adopted the first National Biotechnology Strategy in 1983. It refocused its policies in 1993, with a revised Federal Regulatory Framework for Biotechnology. Now the Government's approach has been redefined once more to address a much broader range of emerging issues in a new Canadian Biotechnology Strategy (CBS).

Biotechnology is an umbrella term that covers a broad spectrum of scientific tools and techniques, ranging from traditional uses of living organisms such as yeast in bread or bacteria in yoghurt to more advanced techniques such as genetic engineering. Biotechnology uses living organisms, or parts of living organisms, to make new products or provide new methods of production.

Like many countries that began investing in biotechnology research in the 1980s, Canada can now build on its strengths. But worldwide investment in biotechnology is growing rapidly and the pace of development is accelerating. The faster pace of change has also brought many ethical, social and environmental issues to the forefront. Canadians want to realise the potential benefits from biotechnology, especially in the areas of personal health, quality of life, and the promotion of a sustainable environment. The Government of Canada wants to ensure that this new strategy reflects Canadian values and Canadian standards.

In addition to the promise of advances in the areas of health care and the environment, biotechnology offers economic opportunities. The Canadian biotechnology industry today generates almost $2 billion a year in revenues, including $750 million in exports. With over 500 firms, most of which are small companies, Canada has generated more biotechnology companies per capita than any other country. Every region of Canada shares in the growth of the biotechnology industry, which employs 25,000 people, typically in high-quality jobs. About 60 percent of Canadian firms are in the area of healthcare with most of the remaining activity in agriculture.

Canada ranks third in the world after the United States and the United Kingdom in a $20 billion industry that is expected to grow to $50 billion by

2005. The Government of Canada has consistently made biotechnology a priority, in the Science and Technology Strategy, the Jobs and Growth Strategy, and, most recently, in the 1997 Speech from the Throne.

Developing the New Strategy

The federal government consulted extensively and on several different tracks to involve stakeholders, the provinces and territories, and the general public in the development of this new strategy. Common to all these consultations was the main CBS Roundtable Consultation Document, which was used to initiate discussion with the various stakeholders.

At the same time the government was seeking advice through roundtables, R&D consultations, and sectoral consultations, it also consulted with the general public. Over 5,000 individuals and organizations participated in these processes, either by responding to the CBS World Wide Web Site, participating in the public opinion research, or writing directly to the CBS Task Force Secretariat. This input is also reflected in the development of the strategy.

This section provides a brief description of the main consultation streams.

Consultations on Research & Development

One set of consultations looked at issues relating to research and development. In addition to discussing common issues, such as the critical human resource needs in this area, this stream reached a consensus on Canada's strategic priorities for biotechnology research and development which included an important sub-set of biotechnology genomics and post genomics that warranted priority treatment.

Given that our resources are limited, especially in comparison with some of our major competitors, strategic decisions must be made about where Canada's R&D investment would have the best results. There was confidence that Canada can maintain and even accelerate progress with true world class excellence in certain specific areas of biotechnology, if public resources are invested wisely.

This consultation stream made some initial progress in developing the key criteria to be used in making these choices. In essence, we should seek out and support research and development initiatives that:

- Support public policy goals, such as economic growth, safeguarding the safety,health and environment of Canadians, and the wide distribution of the benefits of biotechnology;
- Advance our current knowledge base and capacity in the area of biotechnology;
- Strengthen our long-term research and innovation system; and,
- Retain the economic and social benefits of this research and innovation in Canada.

Sectoral Consultations

Another stream consulted industry sectors. The federal government departments and agencies that are involved in each sector led this process. Since many of the issues affecting specific sectors often fall under the responsibility of several departments and agencies, working groups were established to develop a common approach to the consultation process. For example, consultations with the agriculture and agri-food sectors were directed by a working group composed of representatives from Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Industry Canada, Health Canada, Natural Resources Canada, Environment Canada, the Foreign Affairs and International Trade, and the National Research Council.

In many cases, sectoral working groups created and widely distributed a discussion document to initiate the dialogue with sectoral stakeholders. The responsible federal government department or agency circulated discussion documents prior to the sectoral consultations. For example, the Environment and Environmental Industries Sector Working Group created a discussion document that was distributed to over 750 individuals and organizations in this diverse constituency. This document was also posted on Environment Canada's Green Lane and on the CBS World Wide Web sites.

The sectoral consultations provided an opportunity for stakeholders to raise industry-specific concerns about the future of biotechnology. We were advised in the agriculture and agri-food sector consultations, for example, that Canada's capacity as a global leader in agricultural biotechnology may be compromised as resources begin to be stretched to their limits.

However, as with the other consultation streams, the sectoral consultations revealed a B consensus on a number of elements that are important to the

development of the overall strategy. Possibly the most striking example is the request for clarity, certainty, transparency and predictability in the regulatory process; industry players, academics and environmental advocacy groups alike supported this request. As well, increased public awareness of the regulatory process was seen to build public trust and confidence, two essential factors in the promotion of a biotechnology strategy for Canada.

Further, there was a strong belief that an overall "information vacuum" exists with regard to public awareness of biotechnology. This vacuum should be filled by information that is balanced, credible and easily accessible, both in terms of content and methods of distribution. The Saskatchewan Agricultural Biotechnology Information Centre (SABIC) was cited as a successful model where government, industry and consumer groups work together to provide information to the general public.

In general, a need for collaboration, information sharing, co-ordination and partnerships were clearly viewed by participants in the sectoral consultations as key to ensuring Canadian competitiveness in biotechnology and for overall success in this area. Government should continue to involve stakeholders through the consultation process and seek broadly-based advice to address the ethical and social concerns related to biotechnology.

As with the consultations on research and development issues, the sectoral consultations revealed concerns related to human resource issues. Currently, there is a critical shortage of skilled personnel in Canada, including scientists, managers, policy analysts, and intellectual property specialists. A number of short-term initiatives to address this deficiency were presented, but there was a consensus that action is needed to ensure the long-term supply of qualified personnel for the variety of activities involved in biotechnology.

Internationally, there was recognition that Canada needs to work multilaterally to develop common standards and approaches to biotechnology. There is also a requirement for bilateral action, not only to establish common protocols with those countries that currently have regulatory systems in place but also to work with those nations that are beginning to develop their regulatory systems in this area.

Other recommendations from this consultation stream ranged from the need for business investment in basic research, to making greater use of the perceived advantage in the export market

presented by Canada's global reputation for safety and quality standards.

Multi-stakeholder Consultations

In addition to the other consultation streams, a series of five multi-stakeholder roundtables across Canada considered such issues as the mandate for a new advisory body, public awareness issues, and the policy framework of a new biotechnology strategy.

As with the sectoral consultations, the most striking feature of the consultative process was the consistency of the input from across the stakeholder groups. As the consultations progressed, it was evident that a set of common themes was emerging that would inform the development of the renewed strategy and provide a basis for building an actionable work plan for the government and its partners with respect to biotechnology. This consensus was further validated and reinforced by the public opinion research work that was undertaken as part of the consultation process.

There was a remarkable consensus that, if biotechnology is to be a central part of Canadian life in the coming decades, enhancing quality of life should be the *raison d'être* of any strategy, with economic and scientific development and appropriate regulation as the means to this end.

Although some concern was expressed about the four-month time frame in which the consultation took place, there was also recognition that events, especially in the international sphere, are driving our need to move quickly on these issues. By strengthening the stewardship role and addressing ethical and social issues, it was felt that Canada could take a leadership role on biotechnology issues. It was also explained that these consultations were only a first step in developing a framework for the strategy. Further consultations would be required on implementing the strategy's goals.

A strong message was received from the overall consultation process that the federal government cannot and should not act unilaterally on biotechnology issues. Not only is a partnership approach seen to be a more effective way to utilize limited resources, it 's also thought that a broadly-based working consensus is necessary for us to achieve our mutual goals and objectives.

By acting as a catalyst rather than the sole agent, the federal government can play a positive role in facilitating advances in biotechnology. This approach means that the government should show

leadership by setting the example on developing a responsible and progressive biotechnology policy. The federal government would maintain its current regulatory responsibilities to ensure the health, safety and environment of Canadians, but would seek the cooperation of industry, advocacy groups, the general public and other levels of government to promote the appropriate development of biotechnology. As well, this approach would ensure that the economic and social benefits derived from this enabling technology are widely shared by Canadians.

Participants in the consultation process, whether it was in the roundtable consultations or in the focus group sessions, also felt that this approach would be effective on the international scene. A positive, cooperative role focussed on building capacity in the developing world and developing common world standards would dovetail with many of our current foreign policy objectives. Although there was recognition that a highly competitive world market might, in the short-term, favour other nations that had highly focussed strategies and investments, there was confidence that a renewed strategy that focussed on strategic investments, high standards, and high quality would best position Canada to compete over the long-term.

Finally, there was B universal support for the development of a new body to advise the government and Canadians in general on biotechnology issues and policy. This advisory committee, composed of a small central body with the ability to draw on wider resources and expertise through the use of working groups, would facilitate an open, ongoing discussion with Canadians on biotechnology issues. Members of this body would be experts, but not advocates. Representatives of the general public would also be asked to participate in the advisory committee.

Activities associated with the operation of the advisory committee included:

- Expert advice on emerging issues;
- Facilitating, and being open to, public input;
- Ensuring that information is widely shared between all major stakeholders (the provinces, non-government organizations, existing advisory bodies, industry, and academia) and the general public;
- Mutual co-operation and discussion to identify issues;

- Feedback mechanisms to ensure that the results of consultations, studies and research are disseminated to stakeholders and the public; and,

In addition to the activities outlined above, the roundtable consultations also determined a basic model for the operation of the advisory committee. Since the success of this strategy relies on input and interaction with stakeholders, the general public, and the various levels of government, the benefits of this basic model would contain, but are not limited to, the following:

- **Inclusiveness** in ensuring that advisory body receives input from stakeholdersand from the public
- **Transparency** in operations and reports
- **Integrating** social and ethical concerns and considerations
- Providing **continuity** with regulatory agencies and existing departmental lines of authority
- **Facilitating dialogue** among stakeholders and other participants, for example, in the consultative conferences.

Components of the Canadian Biotechnology Strategy as announced on August 6, 1998

A number of important elements of the Canadian Biotechnology Strategy emerged from this very broad and far-reaching consultation process. These include:

Internal co-ordinating machinery

The consultation process revealed that there is a need for better internal co-ordination within government to address the issues affecting biotechnology. Although government agencies and departments may approach the same issue from different perspectives, they share a common responsibility to Canadians. To ensure that issues affecting multiple departments and agencies are dealt with effectively and without unnecessary duplication or delay, Ber internal co-ordination on these "horizontal" issues is required.

To meet this challenge, a committee of ministers has been appointed by the Prime Minister to oversee the development and implementation of the broad policy issues associated with biotechnology. The

Minister of Industry co-ordinates a team of ministers responsible for Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade.

The ministerial committee is supported by a committee at the Deputy Minister level that will meet as required to provide guidance and to resolve internal matters, while a team of Assistant Deputy Ministers will oversee day-to-day co-ordination and implementation. All of these groups are supported by a single secretariat.

An external advisory body

Canadians, whether they were industry stakeholders, representatives of various non-governmental organizations, or members of the general public, wanted an advisory body that will operate at arm's length from government. In addition to considering the science and research priorities within biotechnology, they wanted this body to consider the broad range of ethical, social, environmental, and economic issues that are affected by new discoveries and techniques in this field. Since many of these issues are inter-related, they want the new advisory body to take an integrated approach.

As well, Canadians wanted the new advisory body to facilitate an ongoing public discussion about biotechnology. Although the new advisory body will not have a regulatory role, it must have an influential voice in advising on broad policy directions for biotechnology. The new advisory committee will have an important mandate to give Canadians a forum to voice their views and concerns. CBAC will act as the catalyst, engaging Canadians in an ongoing, open and transparent dialogue on biotechnology issues, including ethical and social issues. These views will be taken into account in its advice to government. As part of the need to demonstrate openness and transparency, the advisory committee will make all of its reports and studies available to the public.

As was emphasized at the various roundtables held across the country, the process of consultation does not end with the creation of the Canadian Biotechnology Advisory Committee (CBAC). The Government needs ongoing advice from Canadians on how to turn the goals and objectives of the strategy into reality. As well, CBAC needs public input to ensure that the priorities and concerns of Canadians are addressed.

It was also evident from the various consultation streams that encouraging public participation,

education and awareness strengthens public confidence in the development of a biotechnology strategy. Canadians want accurate, understandable information on biotechnology, how it is applied, and how it is regulated. An emphasis on public participation is central to the operation of the advisory committee.

Policy framework

The Canadian Biotechnology Strategy policy framework defines a vision, a set of guiding principles, and specific goals. As will be discussed in the next section, ten themes have been identified that will form the basis of federal government action to be taken in concert with its partners in the coming years.

The vision is:

To enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology.

The vision receives further elaboration in the strategy's guiding principles, which emphasize:

- Canadian values;
- An open, ongoing transparent, dialogue;
- Sustainable development, competitiveness, and an innovative economy;
- Responsible action and co-operation - ir Canada and internationally;
- Public health, and
- Scientific excellence.

The level at which concerted action will take place in implementing the new strategy is described in the nine goals that emerged from the consultation process. These goals are to:

- Ensure that Canadians have access to, confidence in, and benefit from safe and effective biotechnology-based products and services;
- Ensure an effective scientific base and make strategic investments in research and development to support biotechnology innovation, the regulatory framework, and economic development;

- Position Canada as an ethically and socially responsible world leader in the development, commercialization, sale and use of biotechnology products and services;
- Be sensitive to the needs of developing countries to build indigenous capacity to assess and manage the risks of biotechnology;
- Improve public awareness and understanding of biotechnology through open and transparent communications and dialogue,
- Solicit broadly based advice to the government on biotechnology;
- Promote awareness of, and maintain excellence in, Canada's regulatory system, based on the Federal Regulatory Framework for Biotechnology (1993), to ensure Canada's continued high standards for protection of health, safety and the environment;
- Support the development of a Canadian biotechnology human resources strategy to ensure an adequate supply of highly qualified personnel; and,
- To develop action plans with other stakeholders, including provincial and territorial governments, business, academia, consumer and other advocacy groups.

Themes for action

Finally, the Canadian Biotechnology Strategy identifies ten themes for concerted action over the coming months on implementing the strategy's goals in partnership with provincial and territorial governments, industry, academia, consumers, environmental groups and other interested parties. As with the goals outlined previously, these themes were determined through the overall consultation process. These themes are:

- Public confidence, communication and awareness;
- Research and development;
- Regulation to protect health and the environment;
- Biotechnology for public health;
- Intellectual property;

- Technology commercialization;
- International issues;
- Human resources;
- Policy relevant data collection and analysis; and,
- Sector strategies.

The Canadian Biotechnology Strategy identifies these as priority areas of activity to be taken in conjunction with partners. Within each of these themes, there are a series of possible initiatives that could be undertaken.(1) In the research and development theme, for example, initiatives include an examination of such issues as:

- The strategic choices to be made on investments in basic science, public good, and regulatory research;
- The adequacy of federal funding for R&D;
- The R&D tax credit policy; and,
- How to form and sustain effective biotechnology clusters.

Conclusion

The renewed Canadian Biotechnology Strategy will position Canada as a nation that takes a sound, integrated approach to the development of its biotechnology industry. In addition to promoting our quality of life and economic growth, this strategy will address the social, ethical and environmental issues of concern to Canadians.

This "made in Canada" approach builds on the values of public consultation, awareness and participation. As well, it is evident that Canadians want their government to work in the spirit of partnership and collaboration with the other stakeholders. No single group can do it alone - biotechnology issues are too complex for any one group to have all the answers.

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1. The document *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process* outlines possible initiatives in each of the ten thematic areas.

Canada
http://strategis.ic.gc.ca