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# *An Industry Perspective*

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Biotechnology is coming of age, after many years of work on the regulatory process and policies, as well as public awareness, educational issues, and intellectual property. We are now recognizing that we need to assess every new tool we use or product we develop to ensure human survival. Sustainability, food security, health, and safety have become our goals for tomorrow.

This paper considers challenged environments from a variety of perspectives of which the industry must always be cognizant — from the natural environment to the business environment. Three key messages should be kept in mind. First, biotechnology is a tool with which to develop new products — not an end in and of itself. It offers a range of products that can address some challenges, as well as offering novel options and value-added products not previously available to producers, the processing/manufacturing industry, and the consumer. The race to take advantage of this tool is on around the world, and Canada now enjoys a leadership position. The initial products are here, and whether we are users of this technology or not, we will be consumers of imported products using the technology. The choice is ours as to whether we will benefit.

The second important message is that partnerships are important to the industry and to other stakeholders. Industry is continually forming strategic alliances, either among companies or between the research community and companies, in ways that are mutually advantageous. Each offers a strength that the other lacks. The same is true for the community at large. We need to listen to each other and work together as a whole, rather than as divided factions on different missions. Forums such as this should be looked at as opportunities to accomplish this goal and to learn what others are doing.

The third message deals with recognition, learned the hard way, that no single magic bullet exists. All new technologies or approaches we try have to be used in the context of long-term sustainability. To accomplish this, we need to look at the entire system and understand the effects of technology while we trying to achieve our goals.

This paper deals with challenges from the industry point of view, recognizing that no perspective exists in isolation. Each perspective must include others when addressing these challenges. For this reason, while industry is a developer, manufacturer, and user of tools of biotechnology, it would never stay in business unless these products meet environmental, consumer, and community needs. Industry also has an opportunity to become more competitive via responsible use of biotechnology in traditional sectors. On the other side of the coin, Canadians would have fewer jobs if the biotechnology industry left Canada — but we would still be users of this technology because other countries would be exporting their products to Canada. We would fall behind competitively and economically. It is in this context that the challenges are a matter of perception. The reality is that everyone must deal with the same set of challenges.

We must ensure that sufficient, high-quality food can be produced while also enabling agricultural producers to make a living in a way that is environmentally sustainable over the long term. Consumers are concerned about food security, safety, nutrition, and quality. To ensure long-term survival, the industry must ensure that products developed will satisfy all these needs. Finally, all members of the community must listen to each other and develop ways to work together to help make these things happen.

I would like to address this technology from the standpoint of the opportunities as well as issues. In its most global perspective, biotechnology promises to meet challenges of several major sectors. In the health care sector, new drugs will cure chronic, intractable, and often fatal diseases such as cancer, AIDS, and osteoporosis. Compared to its world market share, Canada has a disproportionate percentage of biotechnology health-care products. The potential to develop more nutritious, healthier, high-quality foods and ways to produce those foods clearly benefit agriculture. Animals and fish also can benefit in many ways, such as improved health because of resistance to diseases and infections. Environmental applications include products used for bioremediation — cleaning up the environment using biological systems. In forestry, potential products will be trees with resistance to both disease and insects as well as the ability to grow faster. And finally, biotechnology shows promise for bio-leaching in the area of mining.

These benefits can also be realized throughout the value chain. The producer has access to more efficient, low-cost production methods that can also be more sustainable than those available in the past. Processors may be able to process more food products through the use of purer, lower-cost alternatives such as

transgenic chymosin to replace renin for cheese-making. Foods are becoming more nutritious, safer, and lower cost. What can this technology offer us as Canadians? We are leading in the development of these new products, and we can reap the benefits in terms of global competitiveness and its advantages for our economy. On an individual basis, this translates into a high standard of living, and more jobs from a healthy economy. This is where the developers of these products are important. These products will be useful not only to Canadians but to our export markets.

The biotechnology industry in Canada has developed over 20 years and is now enjoying a period of tremendous investment. Approximately 530 companies employing 23,000 Canadians use biotechnology as the main part or as a portion of their business. In 1996, \$1.7 billion was invested in research and development, and annual revenues now exceed \$3.5 billion. In addition, most of the companies are small and medium-sized, not multinational, as is the common perception. The industry is based on knowledge, innovation, and research.

The industry still faces scientific challenges. This is a challenging technology, and the science is still in its infancy in terms of understanding what genes code for which traits, locating and transferring genetic material from one organism to another, and finally expressing the genetic material in the intended organism. The industry still needs to ensure that its new products meet a variety of needs, including those of the business sector, the stakeholders, and the environment — not an easy task. In addition, there are cultural differences between scientists at universities and in industry and between the different sectors. As an example, the culture is very different in the pharmaceutical industry than in the agricultural industry. Public awareness issues and education are everyone's responsibility and industry is no exception. The industry is also faced with a shortage of highly skilled people needed to meet the growing demand for in the near term for scientists and managers. Regulations and policy will always be a challenge. Wherever possible, countries should strive to harmonize their regulatory requirements and approaches. Canada must provide a competitive regulatory environment and ensure these issues are addressed in both national and international ways.

I will highlight two of these issues — human resources and regulations policy. A report entitled *Building Long Term Capability Now* projected 8,000 new biotechnology jobs by the year 2000. Canada does not have the skills base to meet this demand. The experience or skills gap is in the following areas:

- Basic and applied research
- Technology development
- Product/process development
- Marketing and sales
- Management

The Biotechnology Human Resources Council (BHRC) has been established, with support from the Human Resources Department of Canada, to help develop people with the necessary expertise. The International Biotechnology Association of Canada (IBAC) will manage the day-to-day operations of this council, and an executive director will implement directions set by the BHRC Board of Directors. Meeting these needs will require partnerships with academia, government, and other organizations to develop training programs and consider immigration policies.

Industry is working to establish policies regarding food labeling, intellectual property protection, and biosafety. IBAC released a position paper at the international CODEX Alimentarius meetings, held last month, that looked at the various options available and their relative impacts. Small and medium-sized businesses depend on outside financing, and the high costs of this new area include that of intellectual property. Protecting assets through patents also provides the opportunity to exchange scientific information. In the area of biosafety, an international protocol for living modified organisms is under development that will mean that products cannot be imported or exported without prior notification and approval. It is anticipated that this protocol will be in effect by January 1999.

The community has taken key steps to start meeting today's challenges in biotechnology. National and regional biotechnology organizations have developed and agreed to the Biotechnology Accord, which provides working principles for cooperation and partnerships throughout the community. We are in the initial stages of implementing this accord and still need to define how we can best use it to coordinate our activities. An issues/crisis management team approach is being established to respond to issues as they arise. This will allow various members of the community to share information and to provide similar messages when necessary. Finally, the Food Biotechnology Communications Network is leading the development of a national communications strategy that should help coordinate various activities.

We still have some challenges to address. There are a significant number of representative organizations to coordinate, and we need to become more efficient in dealing with issues without duplication. The national organizations are focusing on this problem. Specifically, IBAC and the Canadian Institute of Biotechnology may merge into a single organization over the next two years. In addition, there are numerous activities under development across Canada that might be adopted or augmented. We need to consider how we can work with organizations initiating new activities. The NABC should be looking for such partnerships.

Finally, what is IBAC? We are a not-for-profit organization that was established in 1987 to represent the biotechnology industry. We have dealt with regulatory and policy issues in an advocacy role. We are now undergoing an evolutionary process that embraces "reasoned advocacy." Although regulatory

and policy issues will always be a part of our mandate, we now embrace human resources, a much stronger communications role, support of research, and financial considerations. We are committed to facilitating a supportive environment for research and development as well as the commercialization of new products in Canada.

In conclusion, biotechnology has become an important tool that offers new alternatives to various sectors and stakeholder groups, from the producer to the consumer. It has helped place Canada in a strong competitive position internationally. As the use of this technology moves forward, we need to look for more ways to work together, for a variety of reasons, including the effective use of our resources to develop consistent messages. We need to tackle today's problems using a systems approach with sustainability and integration as our priorities.

Biotechnology is an important tool that can help develop alternatives in our move to more sustainable practices. To guarantee that Canadians have access to the responsible use of these alternatives, we need to work together to ensure that issues are dealt with and questions are answered. Finally, we need to ensure that biotechnology, like any new tool, is based on our understanding of whole systems rather than their parts. Challenges from different perspectives need to be addressed, ranging from what can be done scientifically in the development of new products for various users to what is needed. Other challenges include meeting human resource requirements, differences among the various use sectors, and, perhaps most important, public awareness.