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Biotechnology, the Consumer and the Canadian Marketplace
Integration Document

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Preface

This paper, and the September 1997 Symposim on "Biotechnology, the Consumer and the Canadian Marketplace" are the result of the input of many individuals and organisations. The Acknowledgements page lists the members of the External and Internal Policy Advisory Committees whose input helped to shape this project.

Introduction

1. Background

What do we mean by biotechnology?

The term biotechnology is used in a variety of contexts and reflects a range of activities, processes and applications. Biotechnology is widely applied in the agricultural, environmental, fisheries, forestry, health and mining industries to develop products or applications with special characteristics. The *Canadian Environmental Protection Act* (CEPA) defines biotechnology as:

The application of science and engineering in the direct use of living organisms or parts or products of living organisms in their natural or modified forms.

This definition is sufficiently broad to encompass both traditional biotechnology and new techniques of genetic manipulation to develop novel varieties and traits.

Traditional biotechnology involves, for example, using yeast to make beer or selectively breeding dogs to create new varieties of breeds. New techniques, such as those provided through recombinant-DNA technology or genetic engineering, allow researchers to more precisely enhance desired traits in plants or animals and to develop new varieties of micro-organisms, plants and, to some extent, animals.

The term "biotechnology," used throughout this paper, refers to a wide variety of applications, many of which have little in common other than their reliance on an expanding body of basic knowledge of science at the molecular level [In fact one participant at the September Symposium argued that the term "product of biotechnology " has little or no meaning. It was noted that one restaurant chain in the U.S. is now advertising that their restaurants use no "products of biotechnology ". The participant asked how this term is being defined. " Does this term cover cattle and chicken which are fed 'Roundup Read " Soybean and BT Corn? Are these products of biotechnology? The cooking oil for the french fries comes from soybean or canola which is "herbicide tolerant ". Are these fries a product of biotechnology? The fructose in the Coca Cola syrup comes from pooled corn which could include BT corn. Is the coke a product of biotechnology?] .

Use of biotechnology in food production and in medicine has generated heated debate among industry, government, the scientific community, and consumer and environmental groups.

What is the background to the current debate on biotechnology?

Over the past few years, governments, the private sector and consumer groups haveconducted surveys and focus groups to gauge public awareness, views and concerns about biotechnology. The findings reveal some appreciation of the potential benefits of biotechnology, as well as information gaps and concerns about potential risks and the ability of government and industry to manage these risks in the public interest.

For instance, a 1994 consumer survey indicated that about 60 percent of Canadians were uncertain or undecided about genetic engineering, while the remainder were almost equally divided between "true believers" and "avid opponents". Previous research [Some of the surveys and focus groups are somewhat dated. For example, the Decima survey was done in 1993, the Optima survey was conducted in 1994, and the two focus group studies on agricultural applications and environmental applications were done in 1996. However, more recent surveys indicate that consumer concerns have not changed greatly over the past few years. See for example, Einseidel (full list of Research Papers in Appendix B). Her results show that Canadians are increasingly aware of biotechnological applications but their images of what biotechnology is all about remain nebulous. There also continues to be concerns about the adequacy of the regulatory system. Her research also suggests that Canadian attitudes are less p ositive than those in the US but more positive than those in Europe. however, views in Canada are more polarized than in

Europe and vary more depending on the application.] also underlined that consumers react differently to various applications depending on how they perceive the application will benefit them and society generally and on how the benefits and longer-term risks will be shared between consumers and industry [Much of the recent controversy has focused on ag-biotechnology applications. See, however, Caulfield who states that: "there are those who believe recent rapid increases in our genetic knowledge coupled with subtle social pressure, including commercial forces, could result in a consumer led "new eugenics " movement.] . Subsequent focus group studies supported these findings and inferred that people react this way for a number of reasons:

- because they lack information and understanding of biotechnology,
- because some biotechnology industries perhaps do not fully understand the needs, preferences and concerns of the final consumer, and/or
- because some consumers do not fully trust the ability of government and industry to manage this complex technology in the public interest.

2. Purpose of the OCA Research Program

In 1995, the Office of Consumer Affairs (OCA) assumed responsibility under the federal government's National Biotechnology Strategy to conduct surveys, focus groups and other research to better understand consumer attitudes toward biotechnology.

After an in-depth review of existing surveys, and following focus groups and consultations with partners inside and outside government, the Office decided that the next step should involve the development of an improved analytical framework to guide future work on consumer attitudes and public confidence regarding biotechnology.

The approach of using anaiytical research to encourage discussion amongstakeholders (consumers, government and industry) stems from the view that good public policy research and subsequent policy development may be able to promote understanding and consensus across stakeholders. Policy discussions should start from a solid understanding of the underlying issues. For the OCA work on biotechnology and the consumer, these issues might include the following: how consumers influence the economy and societal values by participating in policy making and by bringing to their purchasing decisions ethical, social and environmental concerns; how consumers and other market participants behave and interact with one another in the marketplace; how companies compete and are structured; and, how science-based industries with complex market transactions use consumer and other information.

This integration paper attempts to bring together the major findings of eighteen expert papers (see Annex B for a full listing) and to draw from them the most important policy and strategic implications for government, industry, consumers and others. The document consists of three main chapters on the roles and responsibilities of consumers, producers and government regarding consumer information, awareness and confidence. A short concluding chapter summarizes the major findings from the research and the September 1997 Symposium.

Annex A provides further information on the OCA research program, and Annex B lists the OCA research papers and other studies used to develop this paper.

This is the second version of the Integration Paper to be distributed. The first was completed early in September 1997 and distributed to all participants who attended the September Symposium on *Biotechnology and the Consumer* hosted by the Office of Consumer Affairs. (Other interested people who were not able to attend the Symposium also received the earlier version.) The first draft served as a reference point and central discussion paper at the two day Symposium held in Ottawa on September 24 and 25. The Symposium was attended by 150 people representing industry, consumer and environmental groups and other non-governmental organizations (NGOs), provincial governments and various federal government departments and agencies.

This second version incorporates major points from the Symposium discussions and comments received from participants and others in the six weeks following the Symposium. The Office of Consumer Affairs would like to thank all of our colleagues who attended the Symposium, commented on the first draft and contributed to our work in other ways.

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Consumer Approaches and Perspectives

1. Introduction to the Consumer Challenge

The consumer brings many roles, responsibilities and perspectives to a new technology such as biotechnology. In her paper, Edna Einsiedel highlights the challenge for proponents of biotechnology as follows:

In the past, public reactions to products generally took place in the postmarketing phase of development. Increasingly, however, the products of innovative technologies are undergoing scrutiny by publics in earlier stages of the technological development cycle. This appears to be the case with biotechnology. The coalescing of the impacts of various social changes and movements over the last several decades, including conusmerism, environmentalism, health activism and the visibility of public interest campaigns relating to a variety of technologies . . . have pushed forward the ime lines for consideration of market reactions to technologica products. [Einsiedel]

Consumer perspectives of biotechnology are being shaped by the rapid development of another enabling technology – information technologies, including the information highway and publishing technologies. These advances have significantly reduced the costs of producing and disseminating information [And misinformation. Many proponents of biotechnology have raised concerns about the misinformation on biotechnology now appearing on the Internet.] and made information about competing products and technologies more accessible to the busy consumer. They have contributed to an era of informed consumerism, wnere individuals increasingly have the tools, information and time to pursue their own interests in the marketplace. These factors, in turn, change the manner in which firms compete to satisfy consumer preferences.

Today's consumer is more educated, better informed and increasingly able to determine and express individual preferences and choice, and to challenge existing practices and arrangements. This is reflected in surveys of Canadians regarding the consumer interest in biotechnology and its many applications:

They...expect government to communicate balanced and understandableinformation on biotechnology. Through this, the Canadian public may achieve a higher level of comfort and self-confidence to make intelligent choices. [Optima Consultants, Understanding the Consumer Interest In the New Biotechnology Industry , Ottawa, November 1994.]

However, a better informed and educated consumer does not guarantee a broad acceptance of the products. The 1994 Optima survey indicated that only 51 percent agree that a high-technology society is important to improving Canada's quality of life.

Similarly, the 1995 CROP Environics survey of Canadian consumers shows the following consumer response to purchasing high-technology goods and services:

- less than 10% are eager to embrace the new goods and services
- 50% bring varying degrees of enthusiasm
- bring varying degrees of reluctance
- about 10% resist and distrust technology. [CROP Environics, 3SC Monitor 1995: Canada 's Monitor of Social Change , Montreal, 1996, as quoted in Derek Ireland, Consumer Perspectives on Competition Policy, Intellectual Property and Innovation in an Information-Based Economy , Ottawa, August 1996.]

Finally, while past surveys and focus groups suggest that attitudes towards science and technology may be positively correlated with the respondent's level of education [See for example, Sheehy] , more recent surveys (including one in July 1997 by the Environics Research Group) suggest there is little evidence that support for biotechnology and the current regulatory framework for this technology increases with education and income.

2. Interactions between Consumers and Biotechnology

Consumers may have concerns about whether certain technologies are needed or acceptable. They may base their opinions on their perception of factors such as

- the technology's ethical ramifications
- its impacts on the environment
- potential health risks
- its effect on the structure of the agricultural industry and other sectors in Canada and developing countries [Crampes & Hollander describe biotechnology 's tendency to reinforce industry concentration, and discuss some of the implications for agricultural employment as well as impacts on international trade. They find that it is not likely that biotechnology will strongly influence the evolution of agricultural employment . It may result in a redistribution and redefinition of employment.]
- its role in reinforcing and accelerating other trends in society [Jennifer Espey explains that many of the social and ethical concerns raised in the biotechnology debate are associated with processes and structures that are not specific to biotechnology. See: Envision Research, Socioethical Implications of Biotechnology Western Economic Diversification, Ottawa, March 1997]
- how it may affect future generations
- the extent to which the technology and its management by government and industry are trusted by concerned consumers

Apparent Consumer Preferences for Biotech Applications (Highest to Lowest Acceptance)

1. Applications which meet clearly identified social and personal needs (for example, new drug therapies for major disease such as cancer and AIDS)

2. Applications which meet a high social need but where consumer benefits are less evident (for example, bioremediation and other environmental applications to clean up pollution and oil spills, or the DNA testing which recently freed two innocent men)

3. Applications which meet a social need but offer no value to the consumer (for example, the beetle-resistant potato or other fruits and vegetables that have been genetically altered to be more resistant to insects)

4. Applications which offer some benefits to the consumer but have no apparent social value (for example, the FlavrSavr tomato which has been altered for longer shelf life and better taste, or pork that has been given hormone supplements to produce a leaner meat)

5. Applications which are perceived to offer no benefits to society or consumers, and where the benefits apparently go only to the producer -- with the consumer carrying most of the risk (for example, rBST in milk)

6. Applications which involve transferring genes between animals and plants (for example, the controversy that arose from reports that a fish gene had been transported into a tomato and that this application was being commercialized - these media reports were not correct)

7. Any application involving the transfer of human genes.

The listing underlines that consumers in surveys placed more weight on benefits to society than to themselves as consumers, and that socio-ethical concerns weighed heavily in their responses. This suggests that the applications in the lower categories would have to generate significant benefits to society to achieve market acceptance.

Support for biotechnology may be based on individual consumers' perceptions of the role of the technology in

- providing new products, health treatments and diagnostic techniques (see the box on this page which provides our interpretation of the ranking of consumer preferences based on previous surveys and other research)
- providing existing products at lower prices and/or better quality
- providing new jobs
- facilitating economic growth and diversification for certain industries and geographical regions
- increasing food production and improving the environment and health care

In broad terms, consumers influence the biotechnology industry in two ways. As members of the public, consumers can participate in the processes which provide for public input on these matters. They also attempt to influence the industry through market mechanisms by bringing their concerns about a productinto their purchasing decisions.

I. Consumers as Citizens of a Nation State

Before delving more deeply into the marketplace role of consumers, it is worth commenting on the existing mechanisms that facilitate the more "public" role of consumers -- as e.g. citizens, voters and participants in public interest groups. The degree of effectiveness of the public roles of consumers and their representatives can affect consumers' marketplace decisions. A public feeling of powerlessness, for example, may create frustration that manifests itself in a consumer backlash against certain technologies and products.

What may be the government's motivation for seeking public input in the area of biotechnology? Clearly, policy making should reflect public concerns, and citizen activism is a crucial part of any democratic process. Also, since consumers will be affected directly by many aspects of biotechnology, they are obvious sources of advice regarding consumer protection. By representing their own interests, for example through consumer groups, they can provide a balance to industry input in the policy-making process.

Another motivation behind consumer involvement is that it increases consumer awareness which, in turn, leads to better informed consumers. [Leroux et al in fact point out that "the majority of bodies studied pursue public educational and information dissemination objectives "] Also, having consumers and their representatives participate in the policy-making process legitimizes the policy outcome in the eyes of the public and increases the overall acceptance of biotechnology.

Consultation Approaches

Leroux et al examine the strengths and weaknesses of several consultation mechanisms that have been used to involve citizens and groups who wish to take part in the decision-making processes relating to the social and ethical issues raised by biotechnology. They present the strengths and weaknesses of the mechanisms from various standpoints. Their findings are summarized in the following table:

Consultation Approach	Representativeness of the public	Quality of information	Feasibility	Advantages	Disadvantages
Distribution of discussion paper and request for comments	+++	++	+++	Simple methodology Detailed oral or written comments	Participation of an informed public; Fragmentary, incomplete information
Opinion poll	++++	+	++++	Accessible Wide range of respondents	Static picture of public opinion Limited, one-way information
Focus groups	+	++	++	Process conducive to discussion and exchange Emergence of new, original opinions	Limited representativeness Factors of time and place
Sequential consultation	+++	+++	++	Circulation of information good; Verification of positions at different stages of policy development	Greater participation by interest groups Management of information gathered more complex
Consensus conference	++	++	++	Active participation by interested persons Consensus on a given subject	Limited number of participants in a single event Logistics
The Internet	?	?	+	Technology offering a variety of tools Investment according to organization's resources	Limited accessibility for public at large Lack of control of participants' identity
Legend: +poor / ++++very good / ?unknown					

The study findings indicate that when selecting a public consultation mechanism, it is necessary to take into account not only the country's social, economic, political and technological realities, but also, the characteristics of the target public and the accessibility of the mechanism under consideration.

International Comparisons

In comparing the Canadian experience regarding public participation with that of other countries, Einsiedel finds the Canadian experience inadequate. She describes the result of participation of social groups in the policy formation process in the Netherlands as a "broad consensus...over the policy adopted, accompanied by a commitment to share responsibilities for outcomes". [Einsiedel] In her view, public involvement and participation have not reached this stage in Canada, and "public and consumer representation on biotechnology remains inadequate" [ibid] .

As for providing information to the public, every organization cited by Einsiedel asbeing involved in such activities is either expressly industry promotional or is connected with the biotechnology industry through funding arrangements. Whether justified or not, any perception of undue industry influence could hamper the development of a more integrated industry/consumer approach. It will also discourage acceptance of biotechnology by more cautious consumers.

Commentators have suggested that the limited public representation on biotechnology issues in Canada is related to the relatively low degree of public debate here, as compared with the U.S. and Europe. [These commentators include Einsiedel] Protests in Europe about genetically engineered crops demonstrate the potentially explosive nature of the biotechnology issue, and MacIntosh and Cummings document the ability of such controversies to cause industry setbacks. The European protests highlight the necessity to structure consultations which garner broad support among stakeholders before consumer and other public-interest controversies reach their peak.

The research suggests that improved public representation on biotechnology issues in Canada may help to validate and legitimize public policies. Canada can learn from the experiences of other countries, as well as our own recent efforts (e.g. by AgWest Biotech, the Consumers Association of Canada and the Food Biotechnology Centre) to inform the public and build public confidence, and can apply these lessons to the next stage of the Canadian Biotechnology Strategy.

2. Consumers as Citizens in a Global Economy

Globalization of the world economy may limit public input on Canadian policies. Harmonization pressures at the national and international levels are one reason for this. The internationalization of most areas of public policy means that regulators are increasingly constrained by international agencies, other countries' national regulatory bodies, international interest groups, and the international rule-based dispute settlement processes. Pressures to harmonize to reduce costs and/or increase the speed of regulation can arise as large international firms "shop" globally for regulatory approval. [Doern & Sheehy]

Canada's difficulty in pursuing independent policies is exacerbated by trade pressures from foreign governments. For example, as a major exporter of agricultural products, Canada is sensitive to trade irritants with trading partners such as the United States, which recently demonstrated its willingness to take biotechnology trade disputes to the WTO and other multilateral fora [See e.g. various news article on the American WTO challenge with respect to bovine growth hormone in cattle and genetically modified soybeans.] . This phenomenon extends beyond biotechnologyand is consistent with the kinds of limitations that globalization can impose on domestic policy discretion.

Chen & McDermott examine the policies of some of Canada's significant trading partners (U.S., Japan and the European Union) and note that all these countries actively promote biotechnology. They find the regulatory approaches similar, with regulatory oversight being more or less science- and risk-based (more on this in the Government section). However in contrast to Canadian policies, European health and safety policies are concerned with the *process* by which foods are produced: there are separate regulations for genetically engineered foods, including the mandatory labelling of genetically modified foods. The Canadian approach which looks at the *final product*, matches the American approach. Labelling of genetically modified products and the patentability of transgenic animals remain controversial issues that divide the US and the EU.

Chen & McDermott conclude that, from an industrial-development perspective, Canada should consider harmonizing its regulatory system, to the greatest degree possible, with those of its trading partners. For example, new biotechnology firms need a large market to successfully commercialize and harmonization with trading partners can help to give Canadian firms the large market required for successful commercialization. [Chen and McDermott. It should be noted however that with the differences in regulatory approaches □) between for example, the US and the EU □) harmonization is more difficult and smaller countries such as Canada must decide the jurisdiction with which it will harmonize. The answer to this question is not obvious at this time.] However until we see greater convergence in the regulatory approaches of the U.S. and EU, regulatory harmonization on a broader scale will be difficult.

Although globalization may be seen as taking power away from citizens by reducing effective public input, it can also give people greater sovereignty in their roles as consumers by offering them more product choices, often with higher quality and lower prices. With greater international competition, the quality and performance of products are being set in the marketplace by the people who buy the products – not only by national companies and regulatory agencies.

Thus, global forces provide two challenges for consumer citizens and their representatives. First, consumer groups must become more knowledgeable about international developments, transmit this information to their members and the public in general, and develop alliances and partnerships with consumer and other associations in different countries. [This would include working with multi-country groups, such as Consumers International, which are actively pursuing an international agenda, including improved representation at the OECD and other international venues.] This will help to ensure that the consumer voice is clearly heard in multilateral trade negotiations and other international fora.

Second, the limitations of the consumers' role in domestic policy formulation meansthat the consumers' role in the marketplace must be enhanced. In the case of biotechnology, this means consumers must be well-informed. This subject is addressed in the remaining sections of this chapter.

3. Consumers in the Marketplace

Two Consumer Roles in the Marketplace

Strategic consumer activities seek to invoke consumer power as a method of influence, often as part of a coordinated action undertaken together with other consumers, such as a boycott or a campaign to support certain products.

The more traditional consumer role is strictly **consumption oriented**, focusing on obtaining and evaluating information about different products,

and using this information to select and consume products which will be of greatest benefit to them. Such choices may be based on factors related to the productions process, in addition to product attributes, and may be motivated by broad societal concerns as well as concerns of health, safety and consumption enjoyment.

A free market functions to provide choice to consumers and allows them to signal their preferences back to researchers, producers and marketers. Economic literature [See, for example, a recent article by two American competition and consumer policy experts □) Neil W. Averitt, an Attorney with the Office of Policy and Evaluation, Bureau of Competition, Federal Trade Commission, and Robert H. Lande, Professor of Law, University of Baltimore School of Law. The paper is entitled: "Consumer Sovereignty: A Unified Theory of Antitrust and Consumer Protection Law, " Volume 65, Antitrust Law Journal, page 713, Spring 1997.] suggests that two kinds of market failures can place these functions at risk. The first, which operates on the supply side of the market, limits the range and quality of products available to the consumer. This type of market failure is not seen to be a significant problem in biotechnology which is intended to improve the quality of existing products and add many new product choices to the m arketplace.

The second type of market failure operates on the demand side and results from misleading, incomplete or imperfect [Imperfect information is generally linked in the literature to risk and uncertainty, particularly when knowledge of a new technology is insufficient to permit a full assessment of its risks and benefits.] information which reduces the consumer's ability to choose rationally among the products in the marketplace. The OCA and other research suggests there is strong potential for consumer information problems with respect to many biotechnology applications and the technology more generally.

Consumer acceptance of biotechnology depends, among other things, on the type of information that is available. Accordingly, information – its *usefulness, quality, accuracy, timeliness* and *credibility* – is expected to play a pivotal role in consumer behaviour, influencing both public advocacy and the ability of consumers to make informed choices in the marketplace. Policy makers and producers have an interest in promoting information that supports these purposes. Yet, according to our findings,Canadian consumers remain largely uninformed [Sheehy] , and current information activities do not appear to be remedying the situation.

3. Information Factors that Complicate the Consumer's Role in the Marketplace

Links Between The Credibility of the Information and the Credibility of the Source

The Creative Research Focus Group participants suggested that an ideal information source would:

1. not be afraid to tell the truth
2. be neutral
3. have experience
4. not have a vested interest, and
5. not have a profit motive.

Based on these criteria and the research of others, the various sources could be ranked as follows from highest to lowest credibility:

1. University scientists, nutritionists, and physicians
2. Independent laboratories
3. Consumer and other public-interest groups
4. Government
5. Industry

These rankings are subject to interpretation and can change based on media reports. For example, government credibility may have been hurt by recent downsizing and perceived failures to protect the public interest (for example, in the cases of Canada's blood supply, Ontario Hydro's nuclear facilities, asbestos, thalidomide and breast implants). Despite this, almost all of the reports supported some kind of government role regarding biotechnology and consumer information.

Furthermore, there are concerns that university scientists could be losing their impartiality due to growing linkages between universities and industry.

These results suggest that public education campaigns should use a variety of sources for information, rather than relying on one source.

The following sections examine the potential for information problems associated with the nature of biotechnology products and the technology more generally.

The "Credence Nature" of Most Biotechnology Applications

Biotechnology applications and biotechnology products have qualities that are not necessarily obvious to the consumer. For example, a genetically altered vegetable can be indistinguishable from a regular vegetable. This, as well as the complexity of the technology, makes consumers dependent on specialists to learn about the benefits and/or risks of the products. When consumers rely on outside information, the information source must be one that they find credible.

Einsiedel finds that the credibility of the source depends on its perceived *expertise* as well as a feelingof *trust*. The accompanying box on this page examines the perceived credibility of different information sources and concludes that public information campaigns should include a variety of information sources.

Information Asymmetries Resulting from the Technology's Complexity

Biotechnology involving genetic engineering is relatively new and complex. This creates a large gap between what the specialist knows and what the non-specialized consumer knows. This asymmetry creates two kinds of problems:

1. It opens the possibility that the information could mislead the consumer, which is why the credibility of the source is important.•470
2. Because the technology is complex, it is expensive (in terms of time, money and effort) to communicate the information because it must be brought to a level that consumers can understand. This involves either reducing technical scientific data to information that can be used easily by consumers to make informed choices in the marketplace, or ir easing the public's understanding of the technology. •470
3. Traditionally government has the responsibility for increasing education levels with respect to science and technology. Government is also responsible for assessing risk and ensuring public safety. Producers can also provide information about product benefits and risks, through advertising and other forms of promotion, with the government implementing laws and regulations on misleading advertising, misrepresentations, labelling, and, where required, appropriate warning information. These roles are further explored in the sections on Producer and Government Roles.

Consumer Incentives to Seek Out Information

Hadfield & Thomson analyse how information is acquired. Consumers assess the value of information and compare it with the "cost" of acquiring it. The cost of information can involve the time to process and learn from it and/or the search costs associated with retrieving it. Whether a consumer will actually seek out and acquire this information is determined by the cost relative to the perceived or expected value. As a result, consumers will acquire high-cost information only when they perceive it will yield high benefit. The scientific nature and complexity of biotechnology information makes it expensive for consumers to acquire and absorb.

Efforts by the government and industry to reduce the cost of the information and increase its accessibility are well documented [For example, the Canadian Institute of Biotechnology (CIB), under contract to the Office of Consumer Affairs and the Canadian Food Inspection Agency, prepared the report "About Biotechnology: The Communication Experience in Canada ". The main findings were presented by CIB at the September 1997 Symposium on Biotechnology and the Consumer.] . Thus, the costs of acquiring information have been subsidized by government and industry; however, consumersremain relatively uninformed about biotechnology. These two developments when combined together may suggest that consumers do not perceive information about biotechnology as particularly valuable to their purchasing decisions in the marketplace. Accordingly, given current consumer beliefs and the biotech applications now available for purchase, it can be questioned whether additional efforts by government and industry to reduce in formation costs or increase its accessibility will succeed in addressing consumers' basic valuations of the usefulness of biotechnology information and thereby succeed in altering consumer behaviour and increasing consumer acceptance of biotechnology.

One reason why some consumers may not value new information is that they may already have strong beliefs that a product or technology is risky. If consumers already believe a product is high risk, they will require substantial contrary information in order to adjust beliefs sufficiently to change their behaviour. This is perceived to be costly, and as a result learning is not likely to occur. [Hadfield & Thomson]

Limitations to Acquiring Information

The research on risk evaluation supports the view that, up to a certain point, providing consumers with additional information can increase consumer well-being. That is, when individuals are given additional information, they tend to respond in a rational manner, by taking more or fewer precautionary actions depending on the risks involved. However, as they become increasingly informed, the additional increments of information have less impact on behaviour. This suggests that a person's ability to process risk information is limited and diminishes with the amount of additional information.

Similarly, research on the psychological assessment of risks is consistent with arguments on the limitations of consumers' ability to employ risk information usefully. If the information is too complex for people to absorb, they will resort to heuristics (such as buying time-proven products or those with well-known brands, or consuming only "naturally produced" foods) and other simple rules to facilitate decision making.

As a result, information policies should distinguish between the *processability* and *availability* of information.

Any solution to the consumer information problems posed by biotechnology, therefore, should build on what we know about the source of consumer information problems (not an absence of information per se but rather a limited and costly capacity to absorb and apply information) and the ways in which consumers can exploit less costly and cognitively manageable ways of obtaining and applyinginformation. [Hadfield & Thomson. Similar comments were made during the Symposium, where participants noted that most of the information that consumers need is known and available. The bigger issue is how to best provide that information.]

The Role of the Media as a Source of Consumer Information

Proponents and critics of biotechnology either praise or criticize the role of the media –often depending on the content or impact of an article or

news item. It is important therefore to understand the media's role, strengths and limitations.

On the one hand, some argue that the media is one of the most important sources of consumer information because people tend to regard it as impartial and therefore credible. However, the print and other media may not be the best source of biotechnology information for consumers.

Strauss describes some of the challenges the print media face in addressing a subject such as biotechnology. First, the media are always rushing toward a deadline and this can compromise a story's accuracy and clarity. Also, the definition of news being "about conflict, or progress, or disaster, or novelty, or human interest", where "things are made more newsworthy by their timeliness, their proximity to readers, and the prominence of those involved", dictates that news about "process, slow change, of the kind which clearly takes place in biotechnology, doesn't get reported until something happens". Reporters face an additional "dramatic imperative", so that information "may sit around for ages as it awaits a dramatic framework" [Strauss] . The push for stories of dramatic appeal may tend to create an anti-biotechnology bias, as potential risks are highlighted more than the benefits or may cause the stories to under-emphasize the real and useful information which the public can actually employ to understand biotechnology.

Finally, the media may suffer pressures from interest groups, particularly in small markets where a few large firms dominate advertising revenues. In all markets pressures exist to design the information so that it "makes a good story". In addition, although reporters are able to separate hype from facts, like consumers, they also depend to a great extent on specialists and their reporting may ultimately reflect the particular bias of sources. A predilection among science writers to consult experts can in itself create biases, so that journalists may tend to "become defenders and champions of what they legitimately should only report upon" [Strauss] .

4. Conclusion

This chapter has only touched the surface of the more detailed discussions on consumer information needs, found in the research papers. Public scrutiny is starting early in the development of biotechnology. Different papers point to the need for better consumer involvement. Public involvement and participation in policy formulation are important and in the case of biotechnology in Canada must be increased for policies and the technology to be better accepted by consumers. As compared to the experience in other countries, the participation of the Canadian consumer is still seen as insufficient by many of the OCA authors and participants at the September 1997 Symposium on *Biotechnology and the Consumer.*

Factors such as globalization, which complicate consumer involvement, further underline the need to enhance the consumer's role in the marketplace. In the case of biotechnology, this means the consumer must be well-informed; and many papers indicate that better, more comprehensible, information to consumers is critical. The current situation is not seen as satisfactory by many concerned consumers, as well as by NGOs and many business representatives. The information provided must be accessible and credible to the consumer, and the information sources themselves must be seen as credible and trustworthy. This is important in biotechnology where information is complex. Finally, new information must be highly valued by consumers to have any influence on their behaviour.

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Producer Roles

From the consumer's perspective, producers conduct two essential roles with respect to biotechnolo

1. They conduct R&D, commercialize innovations, and compete with other companies – and traditional as well as other biotech products –for consumer dollars.
2. They provide information on specific applications and on biotechnology in general through advertising, point-of-sale information, general promotion and public-education endeavours and by participating in government bodies and multi-stakeholder initiatives.

The following sections briefly discuss these two roles from the perspective of consumer choice and information.

1. Biotechnology and Commercialization

Commercialization Is Now Taking Place

Potential Applications and Benefits

1. Genetically engineered plants that yield bigger crops at lower cost
2. Trees genetically engineered to grow faster or to exhibit greater resistance to pests
3. Replacement of pesticides with genetically engineered bacteria that are less harmful to the environment
4. Significantly enhanced milk production from cows, providing savings in land and other agricultural inputs to produce the same amount of milk
5. Gene therapies for a variety of diseases, such as heart disease, cancer and diabetes
6. Mapping of genetic similarities between racial and ethnic groups to determine historical patterns of human migrations
7. Production of synthetic drugs (for example, insulin), making many such products available at lower cost
8. Specially designed bacteria and other agents to clean up environmental pollution

Source: MacIntosh and Cummings

As is the case with most "technological revolutions", the development of the first biotechnology products was more the result of scientific discovery and feasibility than of economic cost or demand considerations. This situation is rapidly changing, with the focus shifting to market demands and opportunities for profit. Biotechnology is now at the stage of commercializing a wide variety of products. These commercialization activities may well increase consumer welfare, as new products serve the different needs, preferences and tastes of consumers. and potentially reduce prices. The box on this page illustrates some of the potential applications and benefits from biotechnology.

However, the successful development ofbiotechnology applications still depends on their technical feasibility; profitability; environmental safety; and public health benefits; and their acceptance by both producers and consumers [Crampesand Hollander] . Commercialization of biotechnology still has had few successes relative to other new technologies, up to the time of writing [although participants at the Symposium stressed that the number of biotechnology applications entering the market could increase dramatically over the next few years.] : Only one in 10 pharmaceutical products entering clinical trials is ultimately commercialized and, of those, only 30 percent generate sufficient revenues to cover the R&D costs [Ernst and Young, 1991, as reported in Crampes and Hollander] .

Regulation is a key factor in a biotechnology firm's success [Caulfield] and many countries recognize the potential of biotechnology and support its development and diffusion.

Investment in Biotechnology

In Canada the biotech industry is growing more rapidly than in other countries. Ernst & Young report that spending on research and development by biotech companies has grown from $250 million (CDN) in 1993 to $402.7 million in 1996 -- a 161% increase. (Health Protection Branch)

The U.S. is the leader in biotech investment. Ernst & Young report that in 1994, American biotechnology firms invested $US 7.7 billion in R&D, a 28% increase from 1992, and a 10.5 percent increase from 1993. For the same year, U.S. government investment in biotechnology research was $US 4.3 billion. This investment was mainly in medical research. (Crampes & Hollander)Although industrial development is not the primary focus of this paper, the following sections, drawing from research by Crampes & Hollander and Green, will briefly review the determinants of successful commercialization with a view to identifying whether this stage raises any issues [As noted earlier in the text, the exercise of consumer sovereignty can be impeded by either failures on the supply side of the market which limit the product choices available to the consumer; or by information and related failures on the demand side which impair the consumer 's ability to make informed choices among the product choices whic h are available. This part of the text focuses on market failures on the supply side.] related to competition policy and other marketplace, public interest and regulatory concerns. These sections will include an examination of the scientific and commercial advances, the economic regulation of these industries and the producer's roles with regard to information.

Commercial Advances in the United States

Activities in the United States, the international leader with respect to developments in biotechnology, show that commercial advances are being made and new applications are coming to market. The U.S. experience provides a good example of how the biotechnologyindustry can develop.

Whereas the U.S. federal government has been active in supporting basic scientific research, with particular emphasis on medical applications, it has done much less in terms of direct promotion to stimulate the development of the biotechnology industry as a whole and the commercialization of biotechnology applications. The American lead has much more to do with the dynamism of small private firms and their linkages with large organizations as well as the increasing linkages to university research and to venture capital financing [Crampes and Hollander] . These linkages between firms result mainly from the difficulties of bringing together, under one roof, various activities such as research, development, production, commercialization and regulatory approval. In order to understand these linkages it is useful to examine the biotechnology "industry."

Vertical Integration

A firm which engages in many activities, from R&D to production to distribution, for example, is "vertically integrated."

Biotechnology firms, which generally do only R&D, often need to create linkages with other firms. When is a firm willing to engage in such alliances? That depends on its perceptions of:

1. whether its technology is protected by intellectual property rights
2. the relative cost of transferring know-how to production personnel within the firm, as compared to outside companies
3. how feasible it will be to manage contracts with outsiders compared to managing in-house resources
4. if there is access through alliances to complementary assets at lower cost than through outright purchase.

Crampes & Hollander What is the Biotechnology "Industry"?

As noted earlier, biotechnology more represents a specific technology than a specific industry. Biotechnology applications are used as an enabling technology to improve products and processes in many different industries. This makes it difficult from an industrial organization perspective to characterize and examine its static and dynamic economic elements in terms of industrial structure, firm behaviour and performance [Green]

Most current biotechnology companies are focused almost exclusively on research and development (R&D). For example, in the U.S., in 1991, the biotechnology industry invested 47 percent of its sales in R&D (compared to a figure of only 14 percent for the traditional pharmaceutical industry). Biotech companies often are small firms, with relatively little vertical integration. This is in contrast to the pharmaceutical industry which is dominated by large firms in which R&D is only one activity which isvertically integrated with other activities, such as production, marketing and distribution. [Green.] Successful commercialization of biotechnology applications therefore depends on formal or informal linkages often involving vertical integration with other firms for production, marketing, and distribution. See the accompanying box on the previous page for more information on vertical integration.

How Biotechnology Companies Compete in the Marketplace

In general, biotechnology companies compete through high R&D expenditures, forming alliances and other linkages with larger companies, and being first to market new innovations [although one implication from the Green and Crampes & Hollander studies is the dangers of being a "first mover " in biotechnology. A preferable strategy might be to be a follower and thus allow the first mover to absorb all of the public controversy.]

Given the narrow definition of biotechnology firms as being producers first and foremost of R&D, the most important form of economic regulation with respect to biotechnology relates to the protection of intellectual property rights. [Chen & McDermott; Crampes & Hollander] The importance of property rights is to ensure that these firms have sufficient incentives to engage in R&D activity, as well as to attract venture capital and to encourage foreign companies to invest.

Usually, protection of intellectual property rights is in the form of patents. However, many biotechnology products are unpatentable because they do not meet the requirements of novelty or utility. In the U.S., inventors have the alternative of patenting the *process*, rather than the product, or of obtaining the special status of an orphan drug [This type of intellectual property protection is not available in Canada.] .

How does competition and competitiveness among biotechnology firms impact consumer welfare? On the one hand, intellectual property protection stimulates innovation in products, processes and applications, which benefits consumers by providing greater product choice and lower prices in the marketplace. However patent protection can also result in monopoly behaviour leading to higher prices and less product diversity for the consumer. In addition, strategic alliances and vertical integration across firms can lead at least theoretically to anti-competitive behaviour [However, in general, informal and formal strategic alliances raise fewer competition issues than mergers and takeovers, and vertical integration raises fewer competition concerns than horizontal integration.].

Among biotechnology firms, however, the danger of such behaviour does not appear to be high at the present time. First, the small size of most new biotechnology firms indicates that the concentration levels of firms within any industry are low, reducing theopportunity for monopoly pricing and other forms of anti-competitive behaviour.

Second, vertical integration among biotech firms through merger is slow to develop, and still depends on the benefits of full integration relative to establishing contractual relationships with distributors as is currently the case. These latter activities do not appear to present any negative impacts on competition.

Third, biotechnology often leads to greater product and process diversity. As mentioned earlier, product diversity is desirable for a market comprised of many different consumer needs and preferences. Process diversity provides producers who use the technology with more assurance against economic and technical risks by providing them with ways to respond to unexpected input price hikes, regulatory changes and predatory agents who control certain essential inputs.

Commercialization in Human Genetics

Commercialization in human genetics (and some other medial care fields) raise quite different market and public interest issues than other areas of biotechnology [The OCA research has largely focused on the role of the final consumer. However, one of the commentators on the first draft of this paper, Ted Schrecker, noted there are at least two different categories of consumers for the purposes of medical applications of biotechnology: patients; and health care professionals; and to this list could be added third party payers, whether provincial health insurance plans or private insurers He noted as well that the information needs of each will be quite distinct, and important debates arise about (for instance) whether or not new treatments should be promoted directly to patients and prospective patients.]. Accordingly, Timothy Caulfield was commissioned by OCA to examine the importance and effects of the ethical, social and legal ramifications of genetic services in the health care system. There is concern that commercial pressures will result in premature entrance of genetic services into the marketplace. For example, the building of an expensive laboratory infrastructure creates a need for a market. What is the effect of industry creating for itself a market by determining the criteria regarding who will be offered a genetic test?

Decisions about who should be considered an "at risk" individual, and therefore within the criteria to be offered a genetic test, should be based on sound scientific, psychological and social information and not a desire to increase the potential market. [Caulfield]

The most controversial fear associated with the commercialization of human genetics is that it could result in a consumer-led eugenics movement. "Will biotech companies, through their efforts to create a robust market for the emerging genetic services, affect our perception of normalcy?" [Caulfield] For example, if a producer creates a hormone that successfully treats dwarfism, it can decide to increase its potential market by promotingthe perception that normal shortness is a disease

Caulfield raises questions relating to potential costs to the health care system as well as liability:

- will commercial pressures create artificially high expectations among patients?
- will there be over-use of genetic services?
- will health fears lead to inappropriate use of diagnostic tests?

Caulfield recommends further research into the benefits and possible negative ramifications of commercialization, with a view to "regulate the potentially adverse impact of market forces while still allowing the rapid dissemination of genetic innovations."

2. Producers as Providers of Information on Biotechnology

Producer Incentives to Provide Quality Information to Consumers

The incentives for biotechnology producers to provide information to consumers about the benefits of their products, can depend on whether they are engaged in *product* innovations or *process* innovations. [Crampes and Hollander]

Product innovations include new products with particular characteristics (e.g. nutriceuticals), substitutes for existing products (e.g. unicellular proteins), and alternative uses of existing products (e.g. bio-ethanol developed from corn).

In this case the characteristics of the products are beneficial to consumers. Producers have incentives to provide information about the products so that the consumer can identify them and differentiate them from other products. Information can be provided through marketing and advertising programs.

Process innovations include medical processes (for instance, diagnostic kits, vaccines), production enhancing applications (for example,

hormones to speed growth of plants or animals), and cost-reducing innovations due to resistance to disease and pestilence. Process innovations have beneficial effects on producer productivity either through increased production and/or decreased costs of production. These may benefit consumers indirectly, depending on the extent to which the productivity gains are translated into lower market prices. Such gains will only reduce prices if the marketplace is a competitive one. Here producers have few incentives to provide information about the biotechnology processes used.

The Positive Aspects Of Producer Information

Producers typically convey information to consumers through marketing and advertising efforts. The economic literature distinguishes two polar views on advertising: the *positive* view, explored here, and the *adverse* view, explored in the next section.

The positive view sees advertising as providing information which enables consumers to make rational choices. Under this view, advertising announces the existence of a product and describes its qualities, characteristics and use. It reduces consumers' learning costs and helps them choose between brands of products. Advertising can also reduce product differentiation associated with a lack of information about some products and has been identified as encouraging the production of high-quality goods. Seen in this context, producers of biotechnology applications have incentives to develop and communicate information about the beneficial aspects of products to consumers. "If these potential . onsumers could be informed about these product features at low enough cost, demand for the product would increase enough to create profit opportunities for producers" [Mathios] .

When product attributes are too complicated to convey through advertising, or if the attributes cannot be determined on purchase (what economists like to call "credence goods"), firms can use advertising as a "performance bond." Klein shows how pharmaceutical firms invest heavily in their brand names, promoting recognition and demonstrating to consumers a willingness to stand behind their products. "If firms renege on their implicit promise of quality, consumers punish them by refusing to buy their products" [Klein] . As a result, clear and strong links between information on products and company names creates reputation effects which allay consumer misgivings about product safety and quality.

However even scientific information can be effectively provided by producers in a way that consumers can understand, as is examined in Mathios' paper. Mathios [Mathios] shows how producers in the U.S. were effective in providing information on the links between diet and disease to promote healthier food products. Producers were able to educate the public using a variety of media to target specific markets and seemingly alter consumer behaviour to bring about dietary improvements. Government advertising, on the other hand, which was not product specific and tended to be print media oriented, failed to reach all sectors of the public. This example serves to show that producers can provide useful and accessible scientific information and increase consumer welfare. If consumer demand for information increases, there will be an incentive for producers to satisfy this demand.

Limitations to Producer Information

The adverse view perceives advertising as a means to mislead consumers, and as an instrument to "create" product differentiations which are not real and thus offer no real benefit to consumers. Seen from this perspective, advertising reduces product competition and introduces barriers to the entry of new products and companies. These potential disadvantages relate to the more conventional role for consumer protection – that is, the monitoring of truth in producer representations of their products. Since consumers cannot verify science-based claims directly, there exists a potential for deception, reducing the credibility of producer information:

Unless the market or government has the mechanisms to punish firms that lie, or consumers can verify information in some way, consumers would be expected to be sceptical of producer-provided information, limiting food producers' incentive to make claims. [Mathios]

Research of advertising practices in the U.S. pharmaceutical industry is consistent with both the positive and adverse views of advertisements. That is, advertising is used to provide information to consumers about new products but it can also generate barriers to the entry of new firms and products in order to protect market share [Klein] .

In the case of biotechnological advances in health care, Caulfield warns that if producers market their new products or genetic tests directly to the consumer, there is potential for abuse. For example, women fear breast cancer. Marketing campaigns can prey on this fear by first increasing their anxiety and then offering testing as a solution. [Caulfield] Caulfield recommends continued regulation of advertising distributed by pharmaceutical companies in the field of genetics, allowing only direct-to-physician advertising as is now permitted under existing laws and regulations.

3. Conclusion

Commercialization of biotechnology products is now taking place, with limited success up to the present time (but with more success expected in the near future). Economic regulation is seen as a key factor in a biotechnology firm's success. Biotechnology firms largely conduct only R&D and thus the most important form of economic regulation for biotech companies is the protection of intellectual property rights.

In the commercialization of human genetics, there are still ethical, social and legal issues that must be assessed. Further research into the benefits and possible negative ramifications is recommended.

Producers also have a role as providers of information. There are both positive and adverse views to producer advertising, and both are relevant to biotechnology. Past experience has shown that producers can sometimes provide superior information than government.

Whether or not advertising is used to misinform consumers and/or enhance consumers' market power will depend in part on competition in product markets and on government monitoring and enforcement of relevant statutes in the areas of misrepresentation and misleading advertising. Research and experience to date suggest that markets and industries involving biotech applications could be characterized by fairly healthy company rivalry, suggesting that advertising may play more a positive than negative role in informing consumers about biotechnology applications.

However, even with strong company rivalry, producers will tend to accentuate the positive attributes of their products in their advertisements. This underlines the need for other information sources – such as government and consumer groups – to complement the efforts of industry and to ensure the entire story is told.

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Government Roles

1. Public Perceptions of the Government's Roles and Responsibilities

With respect to biotechnology in general and consumer interests more specifically, the government has taken on various roles, including:

- law maker and regulator;
- ensuring public safety;
- supporter of the basic science and R&D to provide consumers with new innovative products;
- information provider;
- organizer and manager of non-market mechanisms (for example, advisory bodies) to promote public understanding and the public interest;
- representative of Canadian consumer, industry, socio-ethical, environmental and other public interests at various international fora (OECD, WTO, NAFTA, various UN initiatives on Biodiversity and the Human Genome project).

The table below summarizes the 1994 Optima Consultants survey of Canadian views about the role of government in biotechnology. Of the 10 listed potential roles that governments could play, the survey found that the top six deal with issues of safety, ethics and consumer information. In line with market economics, the public survey indicated comparatively little support for direct government involvement in financing and commercialization of biotechnology activities.

Table 1: Level of Agreement with Statements Regarding Government's Role in Biotechnology

	Agree (percent)	Neutral (percent)	Disagree (percent)
Protect the safety of workers in biotechnology industries	87	8	5
Determine the safety of biotechnology products	87	8	4
Enforce regulations on activities of biotechnology	84	10	5
Consult the public on regulating biotechnology products and uses	81	13	5
Conduct a public information campaign about biotechnology	77	14	9
Assess the benefits of biotechnology	76	16	7
Be involved in the ethical aspects of biotechnology	75	16	8
Educate the public by offering seminars on biotechnology	74	16	9
Financially support biotechnology research in companies	37	33	29
Develop biotechnology products for commercial purposes	33	28	37

The federal government has responded to the need for safety of product and process innovations by developing a Canadian framework for regulating biotechnology. The survey also identified government roles for conducting a public information campaign, assessing benefits and risks and educating the public about biotechnology - all of which relate to the informational roles of government.

The following sections focus on the information and regulatory/stewardship roles of government in relation to biotechnology and the consumer.

2. Information Role

In general, when governments are faced with consumer concerns and perceptions about risks, their role is to:

1. provide impartial and balanced information about the risks to consumers
2. ensure consumer involvement in risk assessment processes.

Also, as examined in the second chapter on the consumer role, biotechnology is subject to market failures on the demand side, resulting from incomplete or inadequate information. The government as well has a role to work with other stakeholders to facilitate the market acceptance of appropriate biotechnology innovations. Accurate, up-to-date information in plain language is important to that success.

On the other side of potential benefits to consumers, there are downside risks. There are risks to our health and safety. And, perhaps even more importantly, many see risks to our values and beliefs. In this latter respect we can easily see, for example, the threat to our society from human cloning. But there are potential applications where there will be differing perspectives; and we were reminded that we often have no "standard of proof" by which to evaluate arguments about potential threats to our social fabric.

Bryne Purchase, *Rapporteur's Remarks* Government as a Provider of Information on New Technologies

Two rationales exist for the government to provide information to the public. The first relates to the fact that it is not in the producer's interest to discuss the cost and risk aspects of their products. Second, government regulators may have informational advantages over consumers and producers in communicating risk information because of their regulatory functions in collecting and examining risk data.

Providing consumers with risk information holds the potential to yield superior market outcomes compared to direct regulation. This is because consumers are a diverse group, and amongst themselves, they will display different preferences for risks. A single regulatory rule cannot fully reflect this diversity.

Information Role when Risks are Unclear

Although there are strategies for increasing consumer understanding of measurable risk, it is less clear what an appropriate policy response would be when dealing with the risk uncertainty that arises when scientists cannot fully understand or anticipate the secondary effects of genetic engineering. Even when risks are not identifiable or measurable, the government still has a role in providing information.

In light of the scientific uncertainty, the fact that there are no known scientific risks is not a basis for concluding that there is no need to inform consumers about potential risks. [Hadfield & Thomson]

An unknown or unmeasurable risk should not be treated as no risk at all.

Consumers' Complete Information Needs

Consumers benefit by acquiring information that corrects their mistakes about product safety. But even when risks are known and measurable, their information needs go beyond science-based risk assessment. Consumers also have ethical beliefs, or, in the case of food products, they may have special dietary preferences. Thus, although consumers benefit from acquiring information about risks, that information can still be incomplete. Consumers' idiosyncrasies and different information needs must be taken into account.

Allergic response is one form of idiosyncrasy. Another is individualized approaches to nutrition and diet, such as combining diets which recommend eating foods from one group -- such as vegetables -- only in combination with foods from specified other groups, such as grains. Yet another is represented by the array of ethical preferences with respect to food. [Hadfield & Thomson]

Potential Limitations to the Government's Role as Information Provider

There are also potential limitations to government provision of information to the public, particularly when it is the major source of information. When technologies and markets change rapidly, it is difficult for government officials to stay *au courant*, resulting in incomplete or incorrect information. There is also concern that government agencies can be influenced by special interest groups, affecting the information that is provided to the consumer. One solution to this problem is an increased role for markets in providing information.

Towards a Marketplace Solution to Information about Biotechnology

Labelling is one way to address consumers' various information needs whileharnessing the incentives offered by producer-provided information described in the previous chapter. There is already a movement towards this in Europe, where some countries are looking at mandatory labelling of products derived through genetic engineering. The notion of government encouraging the labelling of biotechnology products, or mandating it by law, has received support in Canadian public opinion surveys. It is argued that labelling serves the goal of consumer protection from a consumer-centred perspective and allows consumers to match their transactions with their intentions.

The benefits are seen to be threefold. First, a label guarantees the identification of biotechnology applications in the market, increasing consumer awareness. This, in turn, provides incentives for consumers to seek out and learn about biotechnology, according to their personal needs, preferences for risks and benefits, and value systems. This creates an increased demand for information that the marketplace can satisfy [The effectiveness of producer provided information is examined in Mathios study (see previous chapter)] , leading to better informed consumers.

Second, labels give producers strong incentives to meet this demand for information, particularly when consumers are inclined to perceive high risks.

Intuitively, if producers are faced with the prospects that consumers will, through lack of information, avoid biotechnology products, they will devote resources to providing information. More importantly, they will devote resources to understanding the complex nature of consumer beliefs, information-processing capacities and so on, and devising effective methods for achieving the goal of conveying useful information that consumers can understand and apply. [Hadfield & Thomson]

Third, labels would better ensure that purchasing decisions are based on informed consent -- which through time would have the effect of turning involuntary into voluntary risks. Research suggests that consumers prefer voluntary risks over involuntary risks, even when objectively the actual degree of risk is about the same. Therefore, in this manner, labelling through time could enhance consumer confidence and acceptance of biotechnology.

However, no studies have yet been done on the compliance, administrative and other costs, the possible international implications, and if similar benefits could be obtained through voluntary means that are less costly than mandatory labelling. As well, whether voluntary or mandatory, this approach may be more relevant to some types of biotechnology applications such as processed foods which contain a large biotech component, than to others where there may be only a trace of a genetically modifiedsubstance. [As noted by one symposium participant, it will become rare to find any processed food that has does not, at some stage, include ingredients that are are produced with biotechnology applications, with the result that almost all foods would require a label. A more efficient solution could be to label those foods that are completely free of biotechnology applications.]

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3. Regulatory Role: Ensuring Safety

As stressed at the beginning of the chapter, consumers and the general public place priority on the regulatory or stewardship role of government with respect to health, safety, and protecting the environment. This section explores the consumer interest within the context of the principles underlying the federal regulatory framework for biotechnology. More specifically, it will attempt to describe consumer perspectives and approaches to risks and how these compare with the approaches used within the Canadian regulatory framework for biotechnology.

The Federal Government Framework to Regulate Biotechnology

The federal government framework to regulate biotechnology emerged from the Canadian Biotechnology Strategy (formerly the National Biotechnology Strategy), which has promoted the development of biotechnology in Canada since 1983. The framework was designed to satisfy a set of six principles.

The Six Principles

1. Maintain Canada's high standards for the protection of human health and the environment.
2. Build upon existing legislation and institutions, clarifying jurisdictional responsibilities and avoiding duplication.
3. Develop guidelines, standards, codes of practice and monitoring capabilities for pre-release assessment of the risks associated with release to the environment.
4. Develop a sound scientific database, upon which risk assessments and evaluations of products can be made.
5. Promote development and enforcement of Canadian regulations in an open and consultative manner, in harmony with national priorities and international approaches.
6. Foster a favourable climate for development, accelerating innovation and adoption of sustainable Canadian biotechnology products and processes.

Consumer perspectives on the regulatory system tend to support the broad objectives of maintaining the same level of human health and environmental standards that Canada currently enjoys. For instance, the 1994 poll by Optima consultants indicated that consumers were anxious about the safety of the environment with 81 percent agreeing that land, air and water are more contaminated than ever before, and thatgovernment should increase its regulation of the environment (62 percent) [Optima Consultants,] . Although consumers support regulation of biotechnology to promote health and environmental safety, some question its capacity to address long-term risks and hidden hazards [Ekos Research Associates Inc., Focus Groups on Agri-food Applications of Biotechnology - Final Report , Ottawa, March 1996.] :

Even with pure motives and strict controls, participants felt that no one really knows what will happen. They point to things that have gone wrong in the past - citing Thalidomide, radiation and DDT. [Creative Research International, Environmental Applications of Biotechnology: Focus Groups , Ottawa, March 1996. None of the things cited above involved biotechnology, but because biotechnology uses the same regulatory structures as other products and technologies, participants were quite justified in citing problems outside biotechnology. This issues is further explored later in this section.]

An analysis of the regulatory structure should therefore examine how adequately the design captures the advantages and limitations of scientific knowledge in order to promote a high level of human health and environmental safety.

Doern & Sheehy analyse the strengths and weaknesses of the regulatory framework. He finds it is nested within the existing statutes, laws and departmental authorities of Health Canada, Environment Canada, Fisheries & Oceans, and the Canadian Food Inspection Agency.

The biotechnology regulatory framework was deliberately based on a decision not to create a separate new regulatory agency, and hence in a very real sense, its creators knew that it was embedding the biotechnology framework in a set of existing regulators. [Doern & Sheehy .]

Doern notes that, as a result, the regulatory framework for biotechnology maintains both the strengths and weaknesses of the existing regulatory frameworks and preserves the political-economic and organizational cultures of each departmental authority [Doern & Sheehy] .

Thus, while building on what is already in place is efficient, the regulation of biotechnology is as a consequence influenced by factors which have

contributed to a decline in ublic trust in existing regulatory agencies:

First, regulatory agencies have been perceived to have been overly influenced by industry; second, agencies are seen to be inappropriately biased in favour of promoting particular technologies; third, agencies have been known to mismanage particular health or environmental activities; fourth, government officials and experts have been known to disagree amongst themselves. [Einsiedel]

These factors do not relate solely to the framework for regulating biotechnology. However, given that the framework is based on existing regulato y bodies, these broader concerns do influence how the public perceives the regulatory processes associated with this technology, and thus can heighten public anxiety about certain biotechnology applications.

All federal legislation must comply with the "equivalency" clause as stated in the *Canadian Environmental Protection Act* (CEPA) regarding environmental assessment standards. Thus CEPA can be seen as the ultimate back-up legislation which ensures a minimal environmental and notification standard across government. [Doern & Sheehy] However, the CEPA basis for regulation is "substances" while the other departments regulate on the basis of "products."

Regulating produc s different than regulating substances and both are different than regulating biotech processes as enabling technologies covering clusters of products. [Doern & Sheehy]

To further complicate the matter, the *Standing Committee on Environment and Sustainable Development* states that,

- *the concept of equivalence or harmonization [between federal regulatory departments], does not mean that the same precautionary tests and data are required for all products, but that appropriately comprehensive and stringent standards shall apply to all products, whichever legislation those products fall under.* [Standing Committee on Environment and Sustainable Development, Third Report , Ottawa, November 1996, Chapter 5, Recommendation 1, as quoted in Doern & Sheehy]

This complexity of the statutory base for regulating biotechnology can cause two problems. First, with respect to the differentiation between "product" and "substance," it may become increasingly difficult to reconcile these differences once the caseload of biotechnology substances or products increases. It is generally assumed thatconsumer acceptance of biotechnology will increase as more products move through the regulatory process and are marketed, thus increasing the consumer's direct experience with such applications.

However, as the caseload increases, conflicts and tensions within the regulatory system could tend to undermine consumer confidence in both the technology and the regulatory framework. Particularly given recent government cutbacks and regulatory controversies, questions could arise about how and whether government can cope with this new complex technology.

Doern & Sheehy find the complexity of the statutory base for regulating biotechnology can cause problems. Any conflicts or tensions within the regulatory system could undermine consumer confidence in both the technology and the regulatory framework. Furthermore, to gain consumer support, the regulatory system must be able to communicate its processes to the public.

Because it is so central to their commercial or research interests, biotech producers know first-hand what the regulatory road map looks like . . . In real terms, however, the case handling road map is not objectively very clear or self-evident for those other interests which may be more occasional participants in the regulatory process or whose own incentive structures make it difficult for them to know the system as wall as business interests. [Doern & Sheehy]

To prevent further erosion of trust in the government's capacity to make science-based decisions, it is important that regulatory decisions be clear. All affected parties must be able to find out how a particular regulatory decision was reached, and be comfortable with -- if not necessarily in agreement with -- both the process and the decision.

Several authors, including Doern & Sheehy, note that the government's dual mandates, to both regulate and promote (principle 6) the technology, have given rise to public concerns that this may compromise its ability to protect human health and environmental safety [Creative Research International, Case Study Analysis of a Marketplace Application of Biotechnology "Roundup Ready Soybeans " , Ottawa, June 1996;] · [Wohl] · [Hadfield & Thomson] . One concern is that these dual mandates appear to compromise the government's ability to provide accurate and credible information on the true costs and risks of this technology. Doern & Sheehy note that the government -led biotechnology strategies are seen by environmentalists as "lobby from within,"giving insufficient weight to environmental and human health issues. [CIELAP 's comments on the research include that "Given the evidence of a lack of social consensus within Canadian society it seems profoundly innappropriat e that the government of Canada focus its efforts on the development of means to facilitate the acceptance of biotechnology products by Canadian consumers. This is especially true in the context of the review of the [Canadian] Biotechnology Strategy, which is one of the government's primary vehicles through which public funds are committed to support the biotechnology industry.]

Evaluating Risk

The fourth principle of the federal biotechnology regulatory framework acknowledges the limitations of scientific understandings of biotechnology. It proposes to develop a sound scientific basis for the assessment of risks, with explicit mention of developing the capacity to pre-assess risks associated with release into the environment.

Some product risks can be measured by a quantitative assessment of the degree of harm and frequency of occurrence. But there is also "risk uncertainty" which encompasses risks not known to science or which are difficult to assess accurately.

Biotechnology, at the forefront of scientific development, presents the scientists who work in the field and the regulators who must determine appropriate policy in the field with extraordinary information needs of their own. Those who produce and those who must regulate the science involved are themselves at places uncertain about the match between what they expect or intend and what they will realize...just as consumers must figure out how to take account of and act in spite of uncertainty, so must the regulators. [Hadfield & Thomson.]

When regulators are faced with risk uncertainty, they approach the limitations of scientific understandings by sponsoring additional scientific inquiry by independent researchers.

Regarding measurable or *quantitative* risks, the current "risk-based" approach to regulation allows for some degree of risk and seeks to manage or confine it to "acceptable levels". However consumer assessments of risk often diverge from scientific assessments. Canada's existing regulatory approach is "science-based", which means that objective scientific standards, rather than consumer perceptions of risk, are the basis of regulatory decisions.

From the point of view of scientists, consumers decisions may not seem rational, but their risk assessment includes other *qualititative* factors, that are not included in thescience-based assessment of risk. [In his presentation, the Symposium Rapporteur, Bryne Purchase summarized tneses difficult issues in the following manner: "In respect of risk, the public is heavily influenced by the "dread " factor in certain adverse outcomes. It matters to public attitudes, as well, whether or not the risk was entered into voluntarily and whether there are strategies that make the risk controllable. The public cares also about the distribution of the benefits from risk taking, as well as the distribution of the risk itself. And while there is no such thing as a zero risk, there is often a great deal of scientific and social uncertainty involved in biotechnologies. That is to say, we simply do not have enough information to make scientific statements about risks. That consumers must make choices anyway, perhap s makes them vulnerable to the risk of misinformation and the potential for irrationally forgoing benefits. This, as an example from another technology, may be the case with respect to the irradiation of food which appears simply unacceptable to the consuming public, notwithstanding its very great benefits. "] These qualitative factors (see box) can be **How do consumers perceive risk?**

From the consumer's perspective, there may be some limitations to the science-based approach of the current regulatory framework. There are several **qualitative** features of risk which influence consumers' acceptance of risk. These characteristics include:

- how much **dread** is associated with the outcome should it occur (cancer is dreaded more than emphysema, for example)
- whether the risk is taken **voluntarily** (voluntary risks are more acceptable than non-voluntary)
- how much **control** one has over the incidence of the risk
- how much is known about the **magnitude** of the risk
- how the benefits and risks are **shared** between producers and consumers, and
- whether this distribution is seen as fair by the affected parties.

Wohl considered an equally legitimate basis for regulatory decisions. Acknowledging and incorporating these factors in some manner into the government's management of th's technology may contribute to bringing consumer perspectives more into line with scientific assessments.

Consumers' risk assessment also depends on their trust in science and trust in the information source. The issue of trust and credibility of information sources is explored in the first section of this paper.

However, a single regulatory rule may be inadequate if consumers display a wide range of preferences for benefits and risks. Crampes & Hollander point out that if information is properly provided, and if public and professional organizations can identify products derived from biotechnology (with labels, point-of-sale information or some other means), then the marketplace may be the preferred place to achieve the appropriate balance between natural and genetically engineered products [Crampes and Hollander] .

The risks posed by biotechnology may be considered less acceptable than risks from other activities if people feel they do not have a choice, or if they feel that the distribution of risks and benefits between producers and consumers is not fair.

There are other considerations which increase the rationale for individual consumer choice. Wohl cites survey and focus group results which indicate that consumers are concerned about the moral and ethical implications of the use of biotechnology, and additional non-health implications, such as the distribution of benefits. [Wohl p. 2.]

Regulation and Ethical Concerns

Ethical concerns are not directly reflected in the six principles of the federal framework for the regulation of biotechnology. [Doern & Sheehy] It is not obvious from the literature and the Symposium discussions how such considerations can be directly incorporated into the current regulatory framework, without placing additional burdens on regulators and compromising the benefits of international trade in these products.

Ethicists and others have argued for parallel structures, such as:

- the development of ethical frameworks (to be embodied perhaps in voluntary codes of practise for industry and the scientific community), and

- the establishment of one or more advisory bodies,

to ensure that ethical values and social norms play an appropriate role in the development of this technology – from the basic science, R&D and product testing through patenting, commercialization and marketing [For example, a well designed ethical framework which is effectively applied to the basic science, research and product development would act as an early warning system which would perhaps prevent ethically questionable biotechnology applications from being brought to the stage of regulatory approval and commercialization. This would both serve the public interest and prevent industry from allocating scarce resources to ethically and commercially questionable products and processes.] .

As noted in the following textbox, these are some of the challenges to be addressed in the Renewal of the Canadian Biotechnology Strategy (CBS) to take place over the first half of 1998, and could be given priority in the terms of reference for a more broadly based national advisory body on biotechnology which could result from CBS Renewal.

The Important Links Between Trust And Meaningful Involvement

The questions of public trust, appropriate processes and meaningful involvement received considerable attention in the research and at the Symposium. To quote the Rapporteur, Bryne Purchase:

The Conference heard repeatedly about the desirability of designing institutions that were equitable in their accessibility, transparent in their proceedings, and independent from any special interest.

Rightly or wrongly, some NGOs indicated that they feel excluded from the policy-making process. There is a perception that biotechnology policy has been driven by industry, government and the scientific community working closely together, and by desired outcomes --jobs and growth, new products, a labelling policy -- at the expense of transparent and inclusive processes which allow all voices to be heard and thus build consensus. These same NGOs argued that compared to Europe there has been limited public debate in Canada on the broader public interest concerns and longer term benefits and risks raised by biotechnology.

The September 1997 OCA Symposium received grudging praise from NGOs as the "only game in town". Based on presentations at the Symposium and subsequent meetings, there are high expectations that the CBS consultations and the new advisory body expected to result from CBS Renewal represent important departures from the past -- and an important opportunity to addressed perceived problems directed towards past processes and build trust in biotechnology and the management of the technology by government and industry. Some direct quotes from the Symposium place these concerns in context:

"Ultimately, biotechnology will be judged by who is speaking for it, not on what the facts and data say about it "

"Societies are moving from blind to earned trust."

"Consumer fear is not due to lack of knowledge but lack of trust."

"Providing choices will go a long way in building trust."

Earning and keeping trust will be the major challenge facing government, industry and others in the Renewal of the Canadian Biotechnology Strategy over the first half of 1998.

3. Conclusion

This chapter reviews the information and regulatory roles of the government. Consumers have a wide range of needs and concerns, and therefore providing consumers with information may be preferable to more regulation, which cannotencompass differing consumers' needs. One approach being pursued by the EU and proposed by some NGOs in Canada is the labelling of certain biotechnology products, especially food products, thus allowing consumers to make choices according to their personal preference and risk tolerance. Labelling may also be an effective means to harness producer incentives to meet information needs. However, as noted above, a number of issues need to be further assessed in developing government policy and corporate strategies on labelling.

This chapter also reviews the federal regulatory framework for biotechnology. The fact that the regulation of biotechnology is currently divided among four departments makes case handling and compliance activities complex. Potential conflicts within the regulatory system, as well as lack of transparency of case handling procedures could serve to undermine consumer support for the regulatory system. However consumers also recognize the importance of the role of regulatory agencies in protecting them from harm and promoting a clean environment. Producers as well recognize the importance of product approvals from a sound and trusted regulatory framework for sending signals of quality to their customers and for marketing their products in Canada and other countries.

Governments will continue to devote significant energy and resources to ensuring that products marketed in Canada meet minimum thresholds for health, safety and the environment. However, in the absence of absolute guarantees of no-risk (a "state of grace" which is impossible to achieve without virtually infinite resources), governments may also need to explore how consumers:

- can be provided with better information and choice,
- can participate more fully in policy-making at every stage, and
- can be made more aware of the risks they may be having to accept in consuming certain products, so that they more fully understand

the implications of these product choices (thus turning involuntary into voluntary risks).

Concluding Remarks

Biotechnology is an enabling technology which can make existing industries more dynamic and competitive. It is also new, rapidly developing and complex, raising consumer concerns about the safety and ethics of its applications. As biotechnology continues to develop, the government has a role to play in working with industry, consumer groups and other NGOs to build consumer trust that will permit the market success of potentially beneficial new products or processes.

While important efforts have been made in the recent past, public input in policy making is still insufficient. Consumer concerns should be reflected in policy outcomes. Consumer input will also serve to legitimize policy decisions in the eyes of the public.

Greater information to the public remains a laudable means of promoting public confidence about this technology. Information must be credible in terms of content and source, accessible, and provided in a manner that the non-specialized consumer can understand. The research indicates that the industry has been active in preparing and disseminating positive information about biotechnology.

The low level of consumer awareness about biotechnology may relate more closely to the limited value consumers place on the usefulness of biotechnology information to increase their effectiveness in the marketplace and their quality of life.The lack of explicit consumer choice diminishes consumers' interest in this technology, since they are cannot distinguish products in the marketplace and hence see less need to learn about biotechnology.

Risk assessment needs to take into account consumer perspectives of risk, which include factors beyond science-based assessments. One suggested approach would be for the regulatory system for biotechnology to incorporate the consumer perspectives of risk. Another approach, which would better address diverse consumer needs, is the promotion of participation and choice, with improved risk and benefit information. This would provide consumers with the opportunity to assess products according to their risk, socio-ethical or other preferences and to choose products accordingly. This could then be supplemented by alternatives to regulation such as a broadly based advisory body and the establishment and use of ethical frameworks by industry, government and the scientific community.

In addition to the known, scientific assessments of risk, the notion of potential or unknown risks remains a challenge for consumers and regulators.

Regulatory responsibility for biotechnology is divided among four governmentdepartments. The way in which health and safety regulatory decisions are reached must be clear to all affected parties in order to maintain public trust in the government's ability to make science-based decisions. The government's dual mandate of both regulator and promoter of biotechnology, also affects public perceptions of trust.

More must be done to address social and ethical concerns. Government could minimize the potential negative impact on the industry and consumers by taking some direct responsibility for addressing these issues -- through, for example, an advisory body and other consultative groups. Government could also facilitate the establishment of ethical frameworks to be embodied in voluntary codes of practise implemented by industry and the scientific community.

Earning and keeping public trust will be a major challenge facing government, industry and consumer groups in the Renewal of the Canadian Biotechnology Strategy. Canadians have changed both as citizens and as consumers. We have become a "harder sell", and trust must now be earned, not taken for granted.

The OCA research and Symposium underline the complexity of biotechnology -- in terms of its various uses, the issues raised by different applications and how we as individual Canadian consumers and citizens respond to it.

Shakespeare's Hamlet says, "There is nothing either good or bad but thinking makes it so". If this is true, then one is invited to reflect on where our thoughts come from . Why would we think the science or applications of biotechnology either good or bad? In this regard there is an old saying that, "What you see depends on where you sit". In all of this complex reality we tend to see what we focus on. And what we focus on is dictated very much by our prior knowledge and experience of the world. In short, our attitudes and perspectives will be shaped by our interests and our professional expertise.

Bryne Purchase, *Rapporteur's Remarks: Symposium on Biotechnology and the Consumer*

This complexity and diversity -- of uses, issues and consumer preferences and concerns -- makes it difficult to build understanding and consensus around government policies and corporate strategies regarding biotechnology. There was however one area of consensus among most if not all participants at the Symposium -- that it is time to move forward with this technology through:

1. multi-stakeholder consultations, involvement and partnerships
2. finalizing, vetting and publicizing key policies of interest to concerned consumers
3. preparing the information already available on this technology for broader distribution, and
4. sorting out the responsibilities of government, industry and public interest groups in providing consumer information.

Moving forward also means addressing and consulting on the new issues which are now emerging, such as:

1. genetic testing and mapping,
2. xenotransplantation (use of genetically engineered animals for organ production for human transplants eg "Dolly"),
3. biodiversity and biosafety,
4. international rules and disciplines to influence, extend or replace national rules,
5. access to foreign markets,

in addition to the broader socio-ethical agenda now being explored under CBS Renewal.

In short, many participants stated that this is not the time for more research and generation of new information. As noted by one Symposium attendee: "Biotechnology has been studied to death". Rather, it is time to capitalize on the information and mechanisms now in place – or expected to be established under CBS Renewal – in order to improve consumer access to information that they need, to make their own choices about biotechnology and its many applications. It is hoped that this report and the OCA research will make a modest contribution to moving the biotechnology agenda forward in the months and years to come.

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Biotechnology, the Consumer and the Canadian Marketplace
Integration Document

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- Canadian Federation of Agriculture
- Industrial Biotechnology Association of Canada
- National Biotechnology Advisory Committee (NBAC)
- Consumers' Association of Canada (CAC)
- Federation nationale des associations de consommateurs du Quebec (FNACQ)
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- Chemicals and Bio-Industries Branch, Industry Canada
- Federal Science & Technology, Industry Canada
- Competition Bureau, Industry Canada
- Intellectual Property Policy Directorate, Industry Canada
- Health Protection Branch, Health Canada
- Science Branch, Canadian Forest Service, Natural Resources Canada
- Science & Technology Section, Department of Foreign Affairs and International Trade
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ANNEX A

Background on the Preparation of the Research and the Integration Document

The research agenda was developed from information gathered over the course of the Optima, Decima and CROP surveys, follow-up focus groups and general discussions with stakeholders at various biotechnology events. As such, although it did not represent an exhaustive list of the wide variety of economic issues, nor the ethical and social aspects of biotechnology, the papers were intended to address an important subset of the main consumer and marketplace concerns on biotechnology.

To ensure that the analysis of the expert papers on which this document is based is rigorous and accessible to all biotechnology stakeholders, the Office of Consumer Affairs engaged a General Editor (Dr. Bartha Maria Knoppers who is Full Professor at the Faculty of Law, Université de Montréal) to oversee the preparation of papers; and established two Project Advisory Committees – one comprised of interdepartmental biotechnology stakeholders and the other comprised of non-governmental organizations with an interest in biotechnology issues

The General Editor served as an intellectual guide for the preparation of manuscripts. In this capacity, she:

- fleshed out in a detailed manner the themes to be addressed in each paper
- identified potential authors for the preparation of manuscripts
- oversaw the thoroughness and quality of papers
- added credibility to the process by ensuring that the ideas and notions developed and advanced in the expert papers are at arm's length from all stakeholders
- oversaw the preparation of the first draft and reviewed the second draft of this integration paper which draws on the findings of the expert papers and the results from the September 1997 Symposium on *Biotechnology and the Consumer*

As many of the consumer themes that are identified in the expert papers deal with issues related to the particular functions of government departments involved in biotechnology – be they regulatory, policy development, public awareness or industrial development – the Office deemed it essential to structure an internal Project Advisory Committee (IPAC) committee that would permit the variety of functional views and expertise to be reflected in the research effort.

The authors of the papers submitted detailed outlines of the methodology, scope and findings of their papers which went to all IPAC members for their review and commentary. Once comments were incorporated into revised outlines, the authorsstarted writing their manuscripts. All papers were then circulated to IPAC members for their review and commentary. Authors were required to consider all comments and views put forward by the IPAC.

To ensure that all biotechnology stakeholders, particularly the consumer and industry NGOs, had the opportunity to contribute their views and commentaries on the expert papers, the Office of Consumer Affairs also established an External Project Advisory Committee (EPAC). This committee ensured that the research ideas and potential policy recommendations were more broadly communicated to the NGOs and other groups. The activities of this group paralleled the activities of the internal committee with respect to the review of draft copies and commentaries.

Building on the discussion provided in the Introduction section in the main text, it is hoped that the research contained in this document and the individual papers will contribute to developing more appropriate structures, defining roles and activities, and promoting collaboration among non-governmental biotechnology stakeholders to address the varied views and concerns of consumers in order to support:

1.Future survey, focus group, policy analysis and other socio-economic research which is more policy oriented, deeper probing, better informed and better directed towards:

- addressing the fundamental risk/benefit/information issues and other concerns of consumers and other users; and,
- meeting the needs of government regulators and policy makers and of the private sector.

2.Future policy formulation and, where required, regulatory changes which have broad understanding and support among stakeholders within and outside government.

3.The establishment of a strong, sustainable consensus among government, the scientific and academic communities, industry, consumer groups, and other organizations concerning:

- the kinds of biotechnology information needed by consumers and their representatives to make informed decisions in the marketplace and to contribute knowledgeably and effectively to policy and regulatory development in the biotechnology field;
- the advantages and disadvantages of the various alternatives available to provide that information – for example, labelling, point of sale information, industry advertising and promotion. more general information campaigns on the part of government, industry and NGOs and,
- the respective roles and activities of different government, industry, consumer groups and other stakeholders in providing information whichaddresses consumer concerns on biotechnology.

4.The development of a greater understanding and consensus across stakeholder groups regarding the role of product markets – relative to other instruments and processes (public opinion monitoring, public and industry consultations, policy formulation, the marketplace for ideas) – in addressing the many questions and concerns raised by biotechnology and the consumer, including:

- information asymmetries (for example, regarding health and safety and other forms of traditional market failure)
- social, cultural and ethical issues
- the role of the consumer in supporting the development of biotechnology and related applications, services and industries, and
- mechanisms for consumer consultation and participation.

Many of the problems faced by biotechnology are shared by other science-based activities. It is hoped that the lessons learned from this research will assist in the development of government policy and corporate strategies in other industries and markets which are based on the commercial applications of advanced science.

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ANNEX B

Listing of OCA Research and Related Studies

The OCA Research Papers

- Canadian Institute of Biotechnology, *About Biotechnology: The Communications Experience in Canada*
- Caulfield, Timothy (University of Calgary), *The Commercialization of Human Genetics: A Discussion of Issues*
- Chen, Zhiqi (Carleton University) and Alison McDermot (Office of Consumer Affairs), *International Comparisons of Biotechnology Policies*
- Crampes, Claude (Université des sciences sociale de Toulouse) and Abraham Hollander (Université de Montréal), *Biotechnological Innovation and Industrial Performance*
- Creative Research International, *Case Study Analysis of a Marketplace Application of Biotechnology*
- Doern, Bruce (Carleton University) and Heather Sheehy (Office of Consumer Affairs), *The Federal Biotechnology Regulatory System: A Commentary on an Institutional Work in Progress*
- Einsiedel, Edna (University of Calgary), *The Market for Credible Information*
- Green, Christopher (McGill University), *The Industrial Economics of Biotechnology*
- Hadfield, Gillian and David Thomson (University of Toronto), *An Information-based Approach to Labelling Biotechnology*
- Kleit, Andrew (Louisiana State University), *Using Advertising to Generate Information and Signals for Product Quality*
- Leroux, Therese; Marie Hirtle and Louis-Nicholas Fortin (Université de Montréal), *Comparative Study of Mechanisms Developed for the Ethical and Social Issues*
- MacIntosh, Jeffrey and Douglas Cummings (University of Toronto), *Theoretical Perspectives on Consumer Controversy and the Funding of Biotechnology R&D*
- Mathios, Alan (Cornell University), *The Dissemination of Science-Based Information to Consumers*
- Purchase, Bryne (Queen's University), *Rapporteur's Remarks: Symposium on Biotechnology and the Consumer*
- Sheehy, Heather (Office of Consumer Affairs), *A Synopsis of Survey and Focus Group Research*
- Strauss, Stephen (The Globe & Mail), *Biotechnology and the Media*
- Weise, Christina (Industry Canada), *Biotechnology: Background on Regional Issues*
- Wohl, Jennifer (University of British Columbia), *The Economics of Application Risk*

Related Studies

The OCA work represents only one of many biotechnology-related initiatives currently being conducted by federal departments. Past, present and future work includes:

1. The reports of the House Standing Committee on the Environment, particularly the results from its Biotechnology Forum on October 8, 1996;
2. The Sector Competitiveness Framework being prepared by the Bio-Industries Branch of Industry Canada;
3. The research paper on socio-ethical issues managed by Western Economic Diversification, with a consulting report generated in Spring 1997;
4. The work of Corporate Governance/Industry and Science Policy, Industry Canada, on the patenting of higher life forms;
5. Papers on the ethical dimensions of biotechnology prepared for the federal inter-departmental working group on biotechnology and ethics;
6. The research and policy analysis of various government agencies and non-governmental organizations on the review of the Patent Act (Bill C-91);
7. The 1998 Report and Recommendations to the Minister of Industry by the National Biotechnology Advisory Committee; and,
8. Ongoing research and papers of various federal agencies on the regulatory, industrial and science aspects of biotechnology, as well as the research of academics, industry associations etc. which often is contracted by government departments.

Our work on biotechnology and the consumer is designed to complement these efforts and will feed into the renewal of the Canadian Biotechnology Strategy now being prepared for presentation to the Cabinet and Treasury Board in 1998.

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