Policy Options For Reconciling Science-Based Considerations and Broader Socio-economic Issues in Regulating the Products of Biotechnology

An addendum to

International Approaches to Non-Science Issues in Regulating the Products of Biotechnology

Prepared For

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The Regulation of Genetically Modified Foods

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Purpose

In August 1998, the Federal Government announced the Canadian Biotechnology Strategy. The Strategy included a commitment to integrate social, ethical, health, economic, environmental and regulatory considerations. This reflected the fact that the biosciences are still evolving rapidly and scientific developments and social concerns are creating challenges for regulatory systems in numerous countries.

Subsequent to its inaugural meeting in the autumn of 1999, the Canadian Biotechnology Advisory Committee developed its plan of work for 2000-2001. This plan includes a Special Project on the Regulation of Genetically Modified Foods.

The present paper suggests policy options for dealing with broader socio-economic issues. Its purpose is to assist the CBAC to debate and consult on the challenges posed by the broader issues, and frame recommendations to Ministers. The paper should be read in conjunction with a report commissioned by the CBAC Secretariat, entitled *International Approaches to Non-Science Issues in Regulating The Products of Biotechnology (October 2000).* That report:

- identifies and analyzes the practices of selected foreign governments in addressing non-science and broader socio-economic issues when regulating the products of biotechnology; and

- compares and contrasts the approaches used in the various jurisdictions to consider and reconcile science and other socio-economic factors in the regulatory process.

Context For Considering Policy Options

Across the countries examined, the main socio-economic issues that currently have implications for the regulation of biotechnology are of three types.

Ethical in nature, for example:

- various issues raised by the human medical applications of the products and techniques of biotechnology;

- that it is unethical to treat nature in an industrial fashion; and

- that genetic modification is unnatural and an improper tampering with nature (e.g. creating combinations of genes not found in nature).

Social in nature, for example:

- concerns, fears, and anxieties of the public about the human safety of genetically modified foods, both in the near and longer-term;

- a demand to be allowed to have the choice to eat or avoid GM foods, as a matter of principle;

- concern by vegetarians, vegans, and religious groups that animal genes are being introduced into plants;

- concern that over time, the economic value of the environment will be damaged through GM crops and plants; and

- concern that biodiversity will be diminished in unexpected ways that will create problems down the road or are unacceptable in principle.

Legal in nature:

- these arise primarily from new ethical issues that emerge as a result of new applications made possible by continuing developments in science, and the lack of adequate legal policy frameworks to deal with these issues.

Some of the above issues have emerged because GM foods have not yet had obvious direct benefits for consumers. Consumers perceive potential risks or have other concerns. They therefore question the necessity of developing GM foods, on an ethical or purely practical basis, but don't have balancing considerations.

In general, non-government organizations internationally would like to see a wide range of expertise involved in the regulatory assessment of GMO-based agriculture, including experts in ecology, socio-economics, as well as public interest groups. This is intended to support the assessment of new biotechnologies within a framework of sustainable agriculture, encompassing both economic and resource sustainability.

The report of the Nuffield Council on Bioethics (May 1999) sets out proposed recommendations for the regulatory regimes in the UK that would, among other things:

- develop and maintain a public policy framework for regulations that would determine the ethical desirability of particular types of genetic modification and their cumulative impact on the environment and society at large;

- maximize consumer choice, so that consumers are informed when GM material is included in food products;

- require consultation with a broader base of stakeholders in the consideration of GM cases and the monitoring of impacts;

- require a broadening of the scope of risk assessments of GM plantings, to take account of effects on agricultural practice and the wider environment, and to bring potential benefits as well as risks into consideration;

- require more extensive monitoring over time of GM introductions; and

- require the introduction of environmental audit analysis on an ongoing basis, to ensure that any long-tem cumulative or indirect effects are being assessed.

No government regulatory system internationally incorporates this package of policy measures within its approval process. However, there is a growing recognition that policy decisions should be more transparent and inclusive.

While there is no consensus internationally on how social concerns should be reflected in the regulatory system, progress is being made in some countries in institutionalizing structures and processes to deal with such concerns.

Current government policies and practices internationally are summarized below.

- The regulatory approval process for the products of biotechnology is constructed exclusively on science-based considerations in almost every jurisdiction.

- With the exception of certain practices in Norway and the testing of medical products at the investigational stage, broader socio-economic issues are taken into account only if they are contained in the legislation or framework policy that governs the regulatory approval process. Therefore, ad hoc issues do not enter into the decision-making.

- The introduction of ad hoc socio-economic issues into the established regulatory decision-making process would lead to uncertainty and considerable financial risk for applicants. This would deter investments in biotechnology R&D and reduce the flow of benefits that the public obtains through the applications of biotechnology. The European Union recognized the existence of this problem in 1991, when the European Commission issued a Policy Statement on the subject.

- The broader socio-economic issues are considered to be important in all jurisdictions. Their role in the regulatory approval process can be illustrated by the situation with respect to GM foods. The OECD reports (May 2000) that certain Member countries face the challenge of reconciling social, economic, environmental and ethical aspects of the products of biotechnology, with

science-based regulatory frameworks. The view as to the extent to which socio-economic concerns should influence risk decisions varies across OECD countries. Many consider economic cost, technical feasibility, and risk perception, to be legitimate factors in risk management decisions. Nevertheless, socio-economic impact studies are not carried out as a routine part of the regulatory approval process for the products of biotechnology.

- The question of whether socio-economic concerns such as animal welfare, the environment, and biodiversity should be addressed within, or separate from, the food safety regulatory system is more controversial. Some countries emphasize the importance of taking account of such factors in their food safety regulations. Others stress that the integrity and credibility of their science-based food regulatory systems could be undermined by the introduction of other factors. There is as yet no agreement on the detailed process of assessing consumer concerns about GM foods and crops. Moreover, there is still uncertainty over the long-term environmental effects, potential complex ecological interactions, and impacts on biodiversity.

- Internationally, the consideration of broader socio-economic issues has been institutionalized primarily through the following structures and mechanisms:

    - Ethics bodies have been established by governments, typically to provide opinions on ethical issues that arise from developments in science and the application of biotechnology, provide advice to government on framework legislation that will codify ethical principles and practices to govern the regulatory process, and play a public consultation and education role.

    - Consumers have been provided with a voice through mechanisms such as the participation of a consumer representative on scientific advisory committees that are part of the regulatory process, the creation of consumer committees to provide a forum for consumer associations, and the provision of opportunities for consumers and groups to comment on proposed legislation.

    - Policy decisions about GM food and other biotechnology products, as well as the assessment of their safety and impact, is becoming more inclusive and open than has been the case in the past. The recent changes to the regulatory systems in Australia and Britain are illustrative. There are mechanisms for a range of stakeholders, including the public, to provide advice to Ministers on the regulatory policy frameworks.

    - In Australia, the objective of the Gene Technology Act (2000) is to regulate GMOs. GM products, including foods and therapeutics, continue to be regulated under existing legislation. Under the new Act,

the independent regulator has the ability to obtain ethics and other advice from two new committees. The Gene Technology Consultative Group will have representatives from a range of sectors, including the environment, public health, primary industry, local government and consumers. Its function is to provide advice on matters of general concern regarding GMOs. The Group may be consulted regarding the need for, and content of, policy guidelines and technical or other specific guidelines relating to GMOs and GM products. The Gene Technology Ethics Committee is composed of persons with expertise in ethics, religion, and law. It will provide advice on ethical issues related to gene technology. Neither body will be involved directly in providing advice on GMO licences and other applications.

- In Britain, the main concerns that emerged from the Ministerial review of biotechnology (1998-99) related to the treatment of broader socio-economic and environmental issues, and the challenge of anticipating developments in biotechnology. One concern was that the regulatory and advisory arrangements did not properly reflect the broader ethical and environmental questions and views of potential stakeholders. Two new biotechnology-specific bodies were established in 1999 – the Human Genetics Commission to advise on genetic technologies and their impact on humans, and the Agriculture and Environment Biotechnology Commission, to advise on all other aspects of biotechnology (except food). Their mandates include broader socio-economic issues. The members of the commissions act in a personal capacity, but are drawn from a wide range of interests and expert disciplines. They will consult the public and stakeholders in carrying out their work. Both commissions report to the Ministerial level. They will not control the work of the individual committees involved in regulation.

- Across jurisdictions, legislation governing the regulation of biotechnology incorporates ethical and social considerations that reflect, to varying degrees, the formal opinions and advice provided by ethics advisory bodies. This is particularly the case in the European Union, where the Group of Advisors on the Ethical Implications of Biotechnology has had an important influence on the legislation that governs the Member States.

- The ethics bodies in most countries have not articulated a set of core ethical principles per se, to guide the development of their opinions on issues. Rather, one can infer what the guiding principles are, by reviewing their published opinions (e.g. respect for human dignity; respect for consumer choice). The Danish Council of Ethics has concluded that such core principles can only serve as a starting point to guide deliberations on specific issues.

There are a number of conclusions that can be drawn from the study:

- The regulatory approval process for individual products and techniques should be based upon scientific assessments, in order to avoid uncertainty that would stifle investments in research, and have a negative impact on the flow of new developments that benefit the public.

- Governments need ongoing structures to deal with broader socio-economic issues that are separate from, but complementary to, the regulatory approval process.

- Broader socio-economic considerations, to the extent they are relevant in the regulatory process, should be incorporated into the framework legislation or policies that govern that process, to the maximum extent possible.

- How broader socio-economic issues are dealt with by government has an important impact on the public acceptance of the products and techniques of biotechnology. This is a responsibility of government.

- To the extent feasible, it is preferable that governments anticipate broader socio-economic issues and address them early on, to avoid having them become publicly controversial.

- It does not appear to be possible to develop a set of guiding ethical principles that would be sufficient for resolving all ethical issues that will arise. Nevertheless, it would appear to be useful to develop such principles, both as a way of developing a consensus on what is permissible and not permissible in a society, and guiding the evolution of the policy framework for the regulatory system

Policy Options

It is becoming increasingly clear, as experience internationally accumulates, that in framing public policies for the regulation of biotechnology, scientific, ethical, economic, and social issues cannot be completely separated. There are two reasons. One reason is that society sets certain values on the use of scientific information. Moreover, these values vary between countries. The second reason is that some social concerns can only be addressed through science, but the regulatory approval processes internationally cannot (due to a lack of adequate methodologies) or don't (as a matter of policy) take them into account.

This finding leads to the conclusion that the definition of policy options for dealing with broader socio-economic issues should be considered by the CBAC together with the findings of the analyses of Canada's science-based regulatory system.

The policy options below have therefore been framed with this perspective in mind.

Option 1: The regulatory approval process would integrate and consider all science and non-science Issues.

This integrated approach would draw together and consider, in a single regulatory decision-making process:

- scientific assessment;
- the public perception of risks; and
- ethical/social issues.

As part of this process, the government would develop and adopt a set of ethical principles to guide decision-making with respect to ethical and social issues. Otherwise, the scope for intervention by the public would be unlimited (e.g. the claim that any genetic modification is an improper tampering with nature and, per se, is not acceptable). These principles would be developed in consultation with the public and may also articulate what is acceptable and unacceptable.

Implementing this option, de facto, implies that in addition to the ethical issues, the public would likely expect the regulatory decision-making process to consider such things as:

- the need for a socio-economic assessment on a case-by-case basis, that weighs all the risks against all the benefits, for example:
  - impacts on biodiversity, including non-target species
  - the direct and indirect risks and benefits to human health and well-being and the environment (e.g. potential for loss of genetic diversity)
  - the balance of rights of, and benefits that would be obtained by, biotechnology companies, farmers, food processing companies, distributors, and the public
- the cumulative environmental impacts over time of introducing many GM crops (not only the individual application under consideration).

In terms of structure, the public would have input into the regulatory process on a case-by-case basis. This implies the appointment of an advisory panel to the regulator. The members would be the representatives of the various stakeholders, but would not be the official representatives of stakeholder groups. The panel would provide views and advice, but would not participate in the final

decision-making for regulatory approval and would not have veto power over individual applications.

Pros

1. Superficially, this option would be very attractive from the public's perspective, since:

   - ethical desirability would become a criterion that the regulator has to take into account explicitly;
   - the public, through the panel, would have input on broader socio-economic issues as part of the regulatory decision-making process; and
   - the regulator would deal with the entire range of science and non-science issues of potential interest to the public, as part of the regulatory approval process, constrained only by the nature and scope of the ethical principles that are government policy.

Cons

1. The experience internationally is that there is no comprehensive set of ethical principles that could guide regulatory decision-making for all situations that might arise. For example, the Danish Council of Ethics has concluded that a set of core ethical principles are useful, but they can serve only as a starting point to guide deliberations on specific ethical issues that arise.

2. The potential for the introduction of ad hoc broader socio-economic issues into the established regulatory decision-making process would lead to uncertainty about what the regulator will examine, potential delays in approval, and financial risk for applicants. This would deter investments in biotechnology research and industrial innovation in Canada.

3. Implementation of this option would raise expectations on the part of the public that the regulatory system will be unable to satisfy. The public would have the expectation that all of its social concerns would be taken into account by the regulator. Yet the capability to assess some of the social concerns that will likely arise is not in place. For example, at an early stage of a technology, it is difficult or impossible to weigh all of its risks and benefits explicitly.

4. This option would be out of step with other OECD countries. Canada would have perhaps the most stringent regulatory approval process. This could result in a shift of biotechnology research and related investments to other countries, notably the US.

5. The potential for trade disputes would increase when economic, social, and ethical considerations are superimposed on the science-based regulatory approach.

6. This option runs counter to the statement in the G-8 Summit Communiqué (2000) on biotechnology/food safety that "The commitment to a science-based, rule-based approach remains a key principle…".

Option 2: Expand the current regulatory approval process to include broader socio-economic concerns, under condition that:

- the capability exists to deal with a given socio-economic concern through scientific methodology and the government has made a policy decision that the regulatory process will include its consideration in all cases;

- ethical concerns that are not science-based are embedded in the regulatory decision-making process only through a change in government framework policy; and

- as a matter of principle, the nature of the issues to be examined during the regulatory approval process are all defined and known to applicants in advance (i.e. all applications to the regulator would be dealt with on a consistent basis).

The implementation of this option would require a program of supporting research that is launched by the Government of Canada. This research program would be a collaborative initiative between federal science-based departments and agencies. It would not be part of the regulatory approval process. The CBAC would provide advice on the specific issues that should be examined, and maintain oversight of the research work and its findings. Where appropriate, the Committee would integrate the findings and make recommendations to the Government.

The research program would have three components, as follows.

Component 1

The research agenda would consist of scientific and policy research studies on the broader socio-economic issues, in order to determine the scientific feasibility and policy desirability of making them part of the regulatory approval process. This work would be carried out within government and by external experts for government. Issues to be examined would include longer-term ecosystem impacts of genetically modified plants, the feasibility of carrying out cost-benefit studies on GM foods and plants, ways and means of carrying out post-market

monitoring of the impacts of GM foods, and reassessments of the impacts of released GM organisms.

The Government of Canada would propose to the OECD that Member Countries launch a joint study to identify all of the broader socio-economic concerns related to the regulation of biotechnology products and the extent to which they would be amenable to a scientific response, as well as the issues that should be the subject of scientific and/or policy research in Member Countries.

Component 2

This component is designed to systematically identify the scientific capabilities that Canadian biotechnology regulators will require in the future, as new developments and products in areas such as nutraceuticals and functional foods enter the regulatory approval pipeline. As with Component 1, this is a subject where Canada would benefit if it were to be studied at the OECD.

Component 3

This component consists of studies on current and anticipated broader non-science issues, that are currently outside of the considerations during the regulatory approval process for the products of biotechnology. The objective would be to determine whether and to what extent a given issue should be reflected in the framework policies that govern the regulatory approval process. These issues include social justice, religious concerns about the introduction of animal genes into plants, and the ethical desirability of creating transgenic animals.

Pros

1. The public would appreciate that this is a farsighted course of action that goes well beyond the status quo and provides mechanisms to respond to social and ethical concerns.

2. Broader socio-economic and ethical issues would be institutionalized and dealt with systematically and in a realistic way.

3. New science-based issues and socio-economic issues would be incorporated into the regulatory decision-making process only through a government policy decision. This would avoid the possibility that ad hoc issues would be added to the regulatory process that an applicant did not anticipate, or that it is not equipped to deal with.

4. By taking a leadership role and engaging other OECD countries in collaborative work, Canada would accelerate its own deliberations and

create a basis for encouraging the international harmonization of approaches to addressing broader socio-economic issues.

Cons

1. This option would require a significant scientific and policy research budget.

2. If, through unilateral actions, Canada's regulatory system were, over time, to become significantly more stringent than those in other OECD countries, this could be perceived negatively by investors if the climate for research, innovation, and commercialization is less attractive than in other countries.

Option 3: Maintain the status quo in the Canadian regulatory system for now. Introduce changes to reflect broader science-based issues, social concerns, and ethical issues, as approaches to deal with them are developed internationally.

Canada would consider taking action to change its policies and regulatory process when consensus is reached internationally (e.g. through the OECD) on:

- the methodologies to permit the consideration of science-based issues that are currently not generally part of the regulatory approval process in OECD countries; and
- the types of non-science issues that should be considered in the regulatory approval process and the approaches for addressing them.

Pros

1. This is a cautious approach that would ensure that Canada's regulatory system is not out of step with the approaches in the major OECD countries.

2. In the short-run, this would be the least cost option.

Cons

1. The responses to many broader socio-economic issues raised by developments in biotechnology are conditioned by the social environment and values in a country. Moreover, these types of issues tend to be politically sensitive. It would therefore be very difficult to reach a consensus internationally on how to deal with broader issues in a harmonized way. Therefore, Canada should not rely on the expectation that the appropriate solutions will emerge internationally in a timely way.

2. By not institutionalizing its own processes to reconcile scientific with social concerns and ethical issues in the regulatory system, Canada would be inviting frequent crises that would have to be dealt with on an ad hoc basis.

3. Public confidence in the regulatory system could erode further.