GROWING SAFELY?

CONCERNS ABOUT BIOTECHNOLOGY AND THE REGULATORY PROCESS

A Report to Agriculture Canada.

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1. Introduction

We appreciated the opportunity to participate in the November workshop on regulating products of agricultural biotechnology. This report begins by defining some basic goals for the regulation of biotechnology.* These goals provide the basis for all subsequent analysis. The report then provides some critical comments on the broad biotechnology policy, which the federal government uses as a basis to regulate agricultural biotechnology. The report continues with observations, questions, and recommendations for each of the four working sessions held during the consultation (i.e. risk-assessment, genetically engineered plants, animal health, and food safety). The final section of this report outlines some of our views on how Agriculture Canada should proceed in developing a regulatory framework for biotechnology products.

We should mention that our participation in the workshop and the production of this report was limited by the lack of full funding. This deficiency did not allow for a full analysis of all the issues and it did not allow for in-depth research. Future consultations must provide adequate funding to allow CEN Biotechnology Caucus to participate meaningfully.

2. Goals

The following goals should provide the basis for the development and establishment of a regulatory framework for agricultural biotechnology products:

SUSTAINABILITY

The regulation of biotechnology must favour sustainable and ecologically-sound agricultural practices. The integrity of organisms and ecosystems should not be diminished by applications of agricultural biotechnology.

BIODIVERSITY

The application of biotechnology must not destroy or endanger biodiversity.

GLOBAL SOCIO-ECONOMIC EQUITY

The regulation of biotechnology should not favour one party at the expense of another. The regulation of biotechnology should encourage global equity among all

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* For the purposes of this paper, we define biotechnology as including those techniques generally classified as genetic engineering.

countries. Biotechnology should not increase the technological dependency of southern nations, nor undermine their existing sustainable agricultural systems.

ANIMAL PROTECTION AND WELFARE

Animal welfare and well-being must not be compromised by biotechnology applications and research.

3. Broad Policy Issues

The broad policy underlying the discussions and principles of the workshop was announced by the federal government on January 11, 1993. This so-called "New Regulatory Framework for Biotechnology" really contains few new initiatives. While some parts of the framework are useful, others cause concerns for environmentalists. These concerns are summarized in the following pages.

3.1. Using Existing Legislation

The Framework specifies that existing legislation will be used to regulate biotechnology. This existing legislation, with the exception of the Canadian Environmental Protection Act, which specifically includes biotechnology products, was not drafted for the purposes of assessing biotechnology applications. Consequently, we have raised a number of concerns regarding the use of existing legislation to regulate biotechnology applications, including:

- The narrow scope of agricultural legislation which was developed for particular, non-environmental purposes, such as seeds classification in the Seeds Act. Consequently, the legislation does not provide a clear statutory basis for the conduct of environmental assessments of biotechnology products.

- The definitions provided in the legislation are often not clear enough to include biotechnology products or processes, or their environmental release, creating uncertainty regarding which piece of legislation applies in a given circumstance.

- The divisions made between the plant and animal worlds within agricultural legislation, and the resulting divisions between different administrative agencies, ignores the importance of ecosystem-level interactions.

- None of the existing agricultural legislation makes provision for the assignment of liability for damage caused by products tested or authorized under their authority.

- The existing framework regulates only products of biotechnology, ignoring the importance of the process which was used to develop the products.

- Existing legislation fails to incorporate the precautionary principle into decisions regarding environmental releases of biotechnology products.

- Existing agricultural legislation makes inadequate, or rather non-existent, provision for public participation in decision-making.

RECOMMENDATION 1:

The previous federal government's decision to use existing legislation to regulate biotechnology products should be reviewed, and a new comprehensive legislative structure for biotechnology applications should be developed.

3.2. Institutional Arrangements

As a result of the decision to use existing legislation, the regulatory system for biotechnology products in Canada appears to be evolving incrementally, with different approval processes and requirements for biotechnology products being developed by individual agencies, including the Departments of Health and Welfare, Environment, Agriculture, Fisheries and Oceans, and Forestry.

The approach of these departments in developing their biotechnology approval processes have varied widely. Environment Canada and Health and Welfare Canada have been relatively open in dealing with biotechnology issues. Other agencies have been, until recently, less than forthcoming. In addition, the ability of the government to regulate biotechnology in the public interest may be seriously compromised as various government agencies also act as promoters of the technology. As a result, the regulation of biotechnology, particularly in regard to food which affects the entire population, must be accompanied by open access to all relevant information, the relevance being decided not by the regulators or business interests, but by the public.

A number of proposals have been made to address these problems of institutional overlap, inconsistencies and inter-agency conflicts. The possibility of the creation of a National Biotechnology Commission has been put forward on a number of occasions.[1] This would consolidate and standardize the regulatory process for biotechnology products. Such a body would also provide a point of access for public interest intervenors in terms of both information and decision-making. Thus, we recommend that:

RECOMMENDATION 2:

Flowing from Recommendation 1, the Government of Canada should consider the creation of a National Biotechnology Commission to consolidate and oversee biotechnology regulation in Canada. In the meantime, there should be a clear demarcation between agencies acting as regulators and those acting as promoters of the technology.

3.3. Policy Decisions for New Technologies

Underlying the issue of regulating biotechnology is the wider question of how democratic societies make decisions regarding new technologies and their application. To date the establishment of policy contexts for the development and regulation of biotechnology products has been undertaken with little public debate or input. This must change if the regulatory system is to be credible and have public legitimacy.

A public debate about biotechnology and its applications would be timely at this point for a number of reasons. The expectations of biotechnology and the development of applications have surpassed the predictions of only ten years ago. In addition, genetically engineered products currently being developed or contemplated for a wide range of applications give rise to a spectrum of economic, environmental and ethical issues. Thus, we recommend that:

RECOMMENDATION 3:

The federal government should facilitate a full public debate regarding biotechnology applications. A Royal Commission, a series of regional conferences, or hearings by the Standing Committee of the House of Commons on the Environment could provide fora to address the wide range of issues raised by the application of biotechnologies.

4. Working Session 1:

The Risk-Based Approach to Regulation

4.1. Limits of the Traditional Risk-Assessment Approach

Environmental concerns related to the use of "risk-based" approaches to standard setting arise from a number of sources. Traditional risk-based environmental standard setting processes occur through two distinct phases:[2]

(a) the technical question of determining or assessing the threats posed to environmental quality, and to human health and safety, by particular events, activities or situations; and

(b) the determination of the acceptability of those risks to the affected parties, including the general public.

Traditionally, the first phase is understood to involve a calculation of the potential risk through the multiplication of the degree of intrinsic hazard in a given event, by the likelihood of the event happening (exposure). There are a number of well-developed critiques of this approach, which argue that the methodology appears to be designed to minimize the perceived level of risk associated with a given activity.[3] The model is particularly problematic when applied to biotechnology products, as the products of biotechnology are often living organisms themselves. They are consequently capable of movement and reproduction. This makes an accurate prediction of the likely level of exposure extremely difficult.[4]

The hazard assessment stage of risk-assessment processes is further complicated by the consideration that scientists are often asked to make determinations of risk or hazard on the basis of incomplete information. This will be especially true in the case of the environmental effects of biotechnology products, due to the very limited body of existing research regarding their potential environmental effects.[5] As a consequence, scientists will be frequently required to employ their judgement in making such decisions. In the result, the values, interests or beliefs of the researchers may be, consciously or unconsciously, reflected in their conclusions.[6]

The second component of the standard setting process is even more complex, as the issue of what constitutes an acceptable level of risk relates to the appropriate distribution of risk, costs, and benefits in society. Traditional risk-assessment models attempt to address this question through risk-benefit analysis. However, this approach suffers from a number of serious limitations. Indeed, it fails to acknowledge the political and moral character of these decisions at all, attempting to deal with them

as technical questions amenable to scientific resolution. This is a fundamental flaw which fails to recognize the epistemological distinction between values and facts. In other words, the risk-benefit model attempts to use science to resolve political and moral questions, something which science itself insists it cannot do. Furthermore, traditional risk-benefit models tend to ignore or underplay the significance of negative environmental and social externalities, and have failed to address the question of the fairness of the distribution of a given set of risks and benefits within society altogether.[7]

4.2. An Alternative, Precautionary and Participative Model of Regulation

4.2.1. The Precautionary Principle

For the reasons outlined above we reject the traditional "risk-based" approach to the management of environmental hazards related to biotechnology products. Rather, in a manner consistent with Principle 15 of the June 1992 Rio Declaration, to which Canada is a signatory, we believe that a precautionary approach should be taken in the design and implementation of a regulatory system for biotechnology products.

The lack of full certainty should not be used as a reason for not taking action to address the potential for environmental degradation. Rather, we recommend that

RECOMMENDATION 4:

Where uncertainty regarding the likely environmental effects of a genetically engineered organism or other biotechnology product exists, field-trials and other environmental releases should not be approved; and

RECOMMENDATION 5:

The onus of proof should be upon proponents of biotechnology products to prove that their products are safe and will not cause environmental damage, rather than on regulators to demonstrate the existence of potential environmental harm.

The value of proposed products should only be considered in terms of the establishment of a threshold test for proposed products to qualify for consideration for approval. Products which cannot demonstrate significant value or need should not be considered for approval. The establishment of need, and availability of less environmentally harmful alternatives should be components of this value assessment.

However, the value or benefit of a product should not be considered in determining the acceptability of the level of risk associated with the product. Rather, in a manner consistent with the "toxicity" test established under the Canadian Environmental Protection Act, the determination of acceptable risk should be focused on the level of risk posed by the product, and the degree to which that risk can be addressed through risk-management measures. The determination of the acceptability of the risk posed by a product should not rest on the "balance" between the risks and "benefits" offered by the product.

4.2.2. Public Participation in Biotechnology Regulation

The role of members of the public in the process of the characterization of "risk" and the determination of "acceptable risk" must also be addressed. Principle 10 of the Rio Declaration requires that the regulatory processes provide for public access to information concerning the development, testing and use of products, and provide meaningful opportunities to participate in decision-making processes. Information regarding the testing of products should be made widely available, and effective access to judicial and administrative proceedings, including redress and remedy, should be provided.

RECOMMENDATION 6:

Principle 10 of the Rio Declaration must be reflected in Agriculture Canada's approach to the regulation of the products of biotechnology. This could be achieved through the development of a decision-making process with the following components:

(1) Public notice of proposed field-tests and environmental releases. Notice should be provided through the local media in the area of the test (e.g. newspaper advertisements), directly to adjacent landowners and tenants, in the Canada Gazette, and to members of the public who request to be informed of proposed releases on a regular basis. The latter might be achieved inexpensively through on-line electronic networks such as the WEB. The initial notice should include the location of the proposed test or release, a general description of the material to be released and its purpose, and where to obtain further information regarding the release.

(2) A period for public comment of not less than 120 days should be established following the public notice of the proposed test or release. Copies of the data package supporting the release, including environmental impact statements, should be provided promptly to members of the public upon request. Notwithstanding confidential business information claims, members of the public must be provided with adequate information to provide the basis for meaningful

comment on the proposed approval. The establishment of a system to provide participant funding to assist members of the public in making comments should be considered.

(3) Formal notice of Agriculture Canada's decision regarding the application should be provided directly to adjacent landowners and tenants, in the Canada Gazette, to members of the public who request to be informed of proposed releases on a regular basis, and in response to requests from other members of the public, following the public comment period. The notice of decision should include a justification for the decision and responses to the comments received by Agriculture Canada. Agriculture Canada should include consideration of the availability of alternatives which pose less environmental or health risks than the proposed application in its decision. Risk and environmental assessment documentation supporting the decision should be promptly made available to members of the public upon request.

(4) An appeal period of not less than 60 days following the publication of Agriculture Canada's decision should be provided. During this period members of the public will have the opportunity to file a Notice of Objection with the Minister of Agriculture. This would parallel the process for objections regarding decisions made under the Canadian Environmental Protection Act. Grounds for appeal should include no value, unacceptable or undetermined environmental or health risk, or contrary to the public interest. Proponents should also have a right to appeal decisions not to permit field-trials or unconfined releases of their products.

(5) Following the receipt of a notice of objection, a Board of Review should be established to review the decision in question. Approvals for field-tests or releases should be stayed until the completion of the appeal process. The Board of Review should consist of individuals with appropriate environmental, agricultural or other expertise, who are not employees of the Government of Canada. The proponent and other parties should be granted the option of mediation rather than a formal hearing if this is acceptable to all parties.

(6) The Board of Review will conduct hearings, open to the public, to accept submissions from the proponent, objector and other legitimate intervenors. The Board's proceedings and evidence submitted should be matters of public record. Provision for the granting of intervenor funding to participants with a direct interest in the decision, or who are bona fide public interest intervenors, should be made to assist in the development and presentation of submissions from the public.

(7) The final report and recommendations of the Board of Review should be made public immediately upon their delivery to the Minister. The Minister should not make a final decision regarding the approval under appeal until the Board of Review has delivered its recommendations and they have been made public.

Notice of the Minister's final decision should be provided in the Canada Gazette, and directly to the participants in the review board process.

4.3. Additional Issues Raised During Consultation

4.3.1. Triggers for Detailed Study

A "risk-based" model for the screening of agricultural biotechnology products for detailed risk-assessment was considered by one of the working sessions in the consultation.[8] The document proposed to employ the concepts of "familiarity" and "substantive equivalence" for this purpose. The model suffers from a number of significant problems and cannot be endorsed in principle.

The screening process is intended to provide a means for Agriculture Canada to focus its resources on biotechnology applications which potentially pose human health, animal health or environmental risks. The system should only provide for exemptions from assessment for activities which, on the basis of well-established past experience are widely accepted as safe from human health and environmental protection perspectives. It must be ensured that the system captures for detailed study and review activities which, on the basis of past experience, may pose risks to animals, human health or the environment, or for which, due to their novelty in terms of end products or processes used to create their end products, there is uncertainty regarding their likely effects.

Furthermore, the decision as to whether a detailed assessment by Agriculture Canada is required must not be left to proponents on the basis of their judgements regarding "familiarity" and "substantive equivalence." As was agreed during the workshop, recommendations on these categories should be developed by Committees which reflect a wide range of environmental and agricultural expertise.

With respect to the concept of "familiarity," it is important that it be remembered that "familiarity" is not synonymous with safety. The concept of "substantial equivalence" is even more problematic. During the workshop it was pointed out that little or no specific analysis has been done on the environmental effects of traditional agricultural products and practices. As a result, there are very limited benchmarks against which to measure the environmental "equivalence" of new products or practices. Consequently, the concept of "substantive equivalence" may be largely meaningless in an environmental context.

RECOMMENDATION 7:

Activities or products which are "familiar," and which are known to have hazards associated with them, should result in a refusal to authorize a proposed activity, or a requirement for detailed assessment.

RECOMMENDATION 8:

Given their novelty and the degree of uncertainty regarding their potential environmental impacts, genetically-engineered plants and other genetically-engineered organisms under Agriculture Canada's jurisdiction should <u>not</u> be exempted from review.

RECOMMENDATION 9:

Exemptions from detailed oversight and review by Agriculture Canada should only be granted for clearly defined, well-known and well-understood categories of activities which are widely accepted as safe, established through regulations made under the relevant legislation. Activities which fall outside of these clearly defined and delineated exempted categories should be subject to reporting requirements and be potentially subject to further review by Agriculture Canada.

RECOMMENDATION 10:

Agriculture Canada should consider the establishment of some reporting requirements for activities in exempted categories to ensure that the exemption provisions are not accidentally or deliberately abused.

4.3.2. Liability

The current legislation under which Agriculture Canada proposes to regulate biotechnology products makes little or no provision for the establishment of liability for damage which might occur as a result of the testing or use of products. This situation should be corrected at the earliest opportunity.

RECOMMENDATION 11:

Proponents of field-tests of agricultural biotechnology products should be <u>absolutely</u> liable for any environmental damage, or harm to persons or animals, resulting from

field-tests. Under such a liability regime proponents would be responsible for the costs of repairing any environmental damage caused by field-tests and the payment of damages to persons harmed by the tests regardless of any approvals granted by government agencies. Where the proponent is an artificial person (i.e. a corporation) the liability should extend to the officers and directors of the corporation. This approach is now widely accepted in Canadian federal and provincial environmental legislation.

5. Working Session 2:

Environmental Releases of Genetically Engineered Plants

5.1. Background

The workshop on genetically engineered plants represented a starting point for discussing environmental regulation of these products even though confined field-tests have been conducted in Canada since 1988. Perhaps most importantly, the workshop high-lighted the diversity of opinions on the environmental, socio-economic and ethical implications of agricultural biotechnology products. This presents a great challenge to the Department of Agriculture and Agri-Food to develop a regulatory regime through a process that is fair, open and credible to all stakeholders.

5.2. Legal Issues and Uncertainties

The workshop on genetically engineered plants pointed out critical areas where more information is required before a regulatory regime can even be considered. The legal questions that arose when the first field-test of transgenic plants was approved still exist, and the workshop did not assist in clarifying the situation. Specifically, there is a need to know the following:

QUESTION 1:

Do environmental regulations such as those proposed fit within the scope of the Seeds Act? The Seeds Act appears to deal only with evaluating the efficacy of new varieties of commercial crops.

QUESTION 2:

How does the proposed regulatory scheme relate to the Canadian Environmental Protection Act?

QUESTION 3:

How do the environmental assessment requirements of the Canadian Environmental Assessment Act apply to the proposed scheme?

QUESTION 4:

What are the legal ramifications of embodying the requirement for notification and assessment in guidelines or in regulations?

It should not be forgotten that the regulatory regime for genetically engineered plants is environmental in nature and, therefore, other environmental statutes and regulations can provide important information on relevant provisions. For example, one might examine the Canadian Environmental Protection Act to determine how that legislation makes provision for the establishment of boards of review and agreements with the provinces.

Overall, the participants in the workshop were ill-equipped to discuss such issues since information on the legal status of the proposed regulations was not provided in advance of the workshop. All stakeholders should be told clearly what the consequences might be if the courts are called upon to determine the legal status of environmental regulations for genetically engineered plants under existing agricultural legislation.

5.3. Evaluating the Need of Biotechnology Applications

As mentioned in Section 4.2.1 above, the value or need of proposed biotechnology products must be evaluated. Discussion on this issue was limited during the workshop, even though such an evaluation is consistent with environmental assessment principles:

(a) An evaluation of need will allow an examination of the proposed benefits, as claimed by the proponents of a product. Often, the biotechnology product is supposed to address a particular societal or environmental problem. An assessment of need or purpose could determine whether the proposed benefit will address the cause of the societal or environmental problem, rather than just its symptoms.

(b) An evaluation of need will allow for an examination of alternatives which may be less intrusive, less costly, and more ecologically sound.

(c) Since biotechnology products will affect many societal sectors (industry, farmers, workers, consumers and others), an evaluation of need will identify the effects or consequences on particular sectors.

(d) Finally, an evaluation of need is necessary because the use of a technology which is based on the domination of nature must be limited in its application.

Therefore we recommend that:

RECOMMENDATION 12:

The federal government use a screening or criteria system to evaluate the need for biotechnology products. Such a screening system should be based on clearly defined sustainability principles, and be developed through open and fair consultative processes.

5.4. Decision-making Processes

As mentioned in section 4.2.2. above, decisions about biotechnology products need to occur in an open, democratic and fair manner consistent with the Rio Declaration. Unfortunately, the lack of time during the workshop session did not allow for a substantive discussion on public participation. Thus, Section 4.2.2. outlines a general model to enhance public participation and at its core is an independent "Board of Review." The primary function of this Board is to decide on public objections to the application of a biotechnology product or its environmental release. Again, such a Board is consistent with environmental assessment principles, since:

(a) A Board of Review will allow for a transparent process where decisions are made openly.

(b) A Board of Review will allow for equal access by all members of the public to the decision-making processes, provided intervenor funding is available. This is a fundamental democratic principle.

(c) A Board of Review will assist in identifying additional scientific and cultural information and may help to resolve, or identify, questions of need or scientific uncertainties which had not been previously considered.

(d) A Board of Review will clarify whether the identification and allocation of risk is appropriate or not.

Therefore we recommend that:

RECOMMENDATION 13:

The Government of Canada should provide for the establishment of an independent body, or bodies, to investigate objections to the need for a biotechnology product or objections to its environmental release.

5.5. Data Requirements for Assessing Environmental Safety

The working sessions on plants discussed a document on the assessment criteria for determining environmental safety.[9] The following recommendations will improve the assessment criteria. Since the data requirements are crucial in applying the precautionary principle, we do not claim to have identified all data requirements. Instead, the determination of the data requirements require further time and resources. Nonetheless, the following preliminary comments can be made:

RECOMMENDATION 14:

The data requirements should include the following:

- *a determination of the effects on biogeochemical cycles; and*
- *some measure of ecosystem effects, based on principles of system analysis (e.g.: ecosystem changes in energy or material flow, diversity of species and species' relationships, and others).*

These requirements should also be included for confined field-trials.

In addition to this recommendation, we have a number of questions with regard to the assessment criteria:

QUESTION 5:

How will Agriculture Canada deal with information gaps in assessing biotechnology products?

QUESTION 6:

With reference to Table 4 of the document, how will Agriculture Canada differentiate between risk-assessment and risk-management? Furthermore, how will decisions for the risk-management aspect be made, and who will make them?

QUESTION 7:

Again with reference to Table 4 of the document, how does Agriculture Canada define the criteria of "sustainability" and "resource conservation"?

5.6. Establishment of a Database

Given the living nature of the products, releases of biotechnology products need to be monitored and catalogued for longer-term scrutiny. Thus we recommend that :

Recommendation 15:

The Government of Canada establish a public data-base on all environmental releases of biotechnology products. The data-base should include summaries of proponents, provinces, traits, environmental assessment data, records of decisions, and other information.

6. Working Session 3:

Animal Health

6.1. Regulations Based on Ethics

Ethical and moral concerns in regulating agricultural products of biotechnology cannot be ignored. Ethics and morality play a large part in formulating other governmental regulations, i.e. laws against murder and theft, freedom of speech, or human rights. While we agree that one cannot legislate morality or ethics directly, these considerations, nonetheless, are fundamental when developing the laws and safeguards which govern civilized societies. Biotechnology and genetic manipulation of living animals raises serious ethical and moral questions. Animals are more than a collection of cells or chemical sequences. They feel pain, fear, stimulation and loss. Humans have often used animals solely to serve their own ends, and biotechnology, with its reductionist approach, offers ever greater potential for their exploitation.

The transgenic engineering of animals as disease models for use in medical research, such as the thousands of genetically engineered mice which have suffered and died from various forms of cancer and other genetically created diseases, is problematic.

The production of human proteins in animals for use in the pharmaceutics industry, known in the industry as "pharming", transforms the animals into "bioreactors". These processes can produce painful malformations, such as the 1986 USDA transgenic pigs with human growth hormones. There are many other genetic engineering examples in which basic ethical/moral questions should be raised. The basic ethical/moral question of whether humans have the right to interfere with the genetic integrity of any species must be recognized and debated.

There are non-animal alternatives available or being developed which would relieve the burden on creatures being subjected to genetic engineering. Instead of financing usage of transgenic laboratory mice, we should support companies which are developing non-animal methods of disease research. Bacteria and even plants can be engineered to produce certain pharmaceuticals.

RECOMMENDATION 16:

Agriculture Canada should ensure that individual animals used in genetic experimentation are treated humanely while decreasing the number of animals required for all these procedures.

6.2. Animal Protection and Welfare Concerns

In our view, animal welfare and well-being must not be compromised by biotechnology applications and research. There are many protection problems in relation to animals which are used only for research, where they are less visible and neither productivity nor length of life matter. Biotechnology creates the potential for more animal pain and suffering than we have previously tried to deal with. Therefore, our concerns for animals used in these procedures include the following areas.

GAP IN REGULATIONS

Regulations should be created to protect the well-being and welfare of animals used in biotechnology, particularly in the early research and development stages and in product testing. Examples include genetically altered mice with predispositions to produce cancer or other diseases and the Beltsville pigs with developmental abnormalities and numerous crippling disease predispositions. The Canadian Council on Animal Care Guidelines are insufficient, and they are not enforceable.

RECOMMENDATION 17:

Agriculture Canada should develop stringent and enforceable regulations protecting laboratory and other experimental animals.

NUMBERS OF ANIMALS USED

Vast numbers of animals have been tested and used for research and development of biotechnological products, pharmaceuticals, and proteins. Many of these procedures, such as the ones mentioned above, generate pain and suffering in the animal subject.

RECOMMENDATION 18:

Agriculture Canada should fund or encourage companies researching and developing non-animal alternatives. An example is Merck Frosst, which has ..."developed a drug screening assay using recombinant DNA cell cultures instead of lab animals, a measure that cuts costs, saves time and eliminates animal deaths. It has also worked on selecting specific molecular targets for new drugs, such as key enzymes, and has developed techniques that use insects as test subjects for new forest products instead of animals."[10]

MODIFYING ANIMALS

Modifying animals to serve as "protein factories" or "bioreactors" (for "molecular pharming" purposes), raises a series of moral and ethical questions. Moreover, many of these procedures place added stress on an animal's system, and cause pain or discomfort.

RECOMMENDATION 19:

This use of animals should be allowed only on the condition that no known alternatives are available and that the animals are kept under humane conditions which fully satisfy their behavioral and social needs.

PRODUCTIVITY

There may not always be a need to boost productivity in farm animals. A good example of this is bovine somatotropin or BST which increases milk production in dairy cattle. BST increases occurrences of mastitis or udder infection in treated cattle, adds stress to already high-yielding cows and, some scientists say, poses a potential human health risk. The increased milk production will also adversely affect many farmers. Thus, the need to boost productivity is questionable.

RECOMMENDATION 20:

Agriculture Canada should not license recombinant Bovine Growth Hormone (BGH or BST) for use in Canada.

DISEASE RESISTANCE

Biotechnology proponents argue that their products will benefit animals, increasing disease resistance. We agree that some new veterinary biologics, such as Vaccinia-Rabies Glycoprotein (VRG) may be very beneficial. Our concern is with diseases affecting intensively farmed animals. Many of these ailments are stress related, directly or indirectly caused or exacerbated by overcrowding and sanitary shortcomings.

RECOMMENDATION 21:

The first line of defense for animal diseases is prevention. Farmers can make changes in their farming systems with improved handling, transport, housing and husbandry practices to prevent diseases. Thus, using genetic engineering should only come only after prevention practices have been exhausted.

TRANSGENIC ANIMALS

The joint Animal Health and Food Safety session of the workshop was of limited use in part because the primary discussion document "Issues Relating to the use of transgenic animals: Research, Food and Pharmaceuticals" never materialized. It was therefore not possible to raise animal welfare concerns such as transgenic manipulations used for the marketing of human genes, or organ farms.

7. Working Session 4:

Food Safety

7.1. The Context of Food Safety

The underlying difficulty with using "food safety" as a criterion for the regulation of agricultural products of biotechnology is that it is based on a reductionist form of knowledge, and within that, of science. Quite simply, we consider the attempt to establish the safety on the basis of a reductionist evaluation of the product and its known characteristics, together with a very short term and limited assessment of its possible consequences, to be inadequate. Too little is known about the breadth and depth of possibilities of transformations and mutations in organisms in the short term, to say nothing of the long term. Yet the assumption of food safety evaluation is that we do know and can predict what might happen as organisms reproduce in different environments, or how alien genetic material will perform in a variety of environments over time. This is not sound science.

Because the final outcome of genetic manipulation remains so much in question, an evaluation of the product at one point in time is inadequate. For this reason, the process by which the product is created may be as important or even more important than the product itself. That is, the deliberate creation of novel organisms, or products of novel organic processes, because of the uncertainty in knowing the outcome when that novel organism is introduced into the environment unrestricted, requires great caution and restriction. In addition, there must be some clear demonstration of real public (as opposed to private) need.

7.2. Food Labelling

One of the many concerns around food production is the issue of labelling food which was derived by genetic engineering techniques. Labelling is a fundamental principle and thus we recommend that:

RECOMMENDATION 22:

The Government of Canada establish food-labelling legislation with at least the following components:

(1) Where a genetically engineered food or a food containing any genetically engineered ingredients is offered for sale as a prepackaged product, the principal display panel of the label applied to the package shall carry the symbol described

in subsection (5).

(2) Where a genetically engineered food or food containing any genetically engineered ingredients is not a prepackaged product and is offered for sale, a sign that carries the symbol described in subsection (5) shall be displayed immediately next to the food.

(3) The symbol required pursuant to subsection (1) or (2) shall appear in close proximity on the principal display panel referred to in subsection (1) or on the sign referred to in subsection (2) to one of the following statements:

(a) "genetically engineered";
(b) "contains genetically engineered ingredients".

(4) No person shall sell a food that has been genetically engineered or contains genetically engineered ingredients unless the requirements of subsections (1) to (3) are met.

(5) For the purposes of subsections (1) to (3), the symbol that indicates genetically engineered food shall:

(a) have an outer diameter:
(i) in the case referred to in subsection (1), equal to or greater than the height of the numerical quantity prescribed in section 14 of the Consumer Packaging and Labelling Regulations for the declaration of net quantity of the package; and
(ii) in the case referred to in subsection (2), not less than 5 cm; and (b) be in the following form:

LOGO

(6) Notwithstanding subsection (1), any genetically engineered food that is an ingredient or component of a prepackaged product shall be included in the list of ingredients and preceded by the statement "genetically engineered".

(7) Any advertising of genetically engineered food or food containing genetically engineered ingredients shall identify the food as having been genetically engineered.

(8) The statements referred to in subsections (3), (6) and (7) shall be in both official languages.

(9) A primary producer, manufacturer, wholesaler or retailer who sells a food that has been genetically engineered or contains genetically engineered ingredients shall keep on his premises, for at least 5 years from the date of sale, a record containing the following information:

(a) the type, quantity and lot numbers of the genetically engineered food;
(b) the name and mailing address of the supplier of the genetically engineered food, ingredients or additives;
(c) the date of purchase; and
(d) a description of the nature of the genetic alteration.

(10) Every person who imports a genetically engineered food that is intended for sale in Canada shall keep on his premises a record of the information referred to in subsection (10) for at least 5 years.

(11) Every person who exports a genetically engineered food that is intended for sale outside of Canada shall keep on his premises a record of the information referred to in subsection (10) for at least 5 years.

8. Concluding Comments

Long-Term Effects

A major concern regarding Agriculture Canada's, and other agencies', including Environment Canada, approach to biotechnology regulation has been the narrow focus of their efforts on the direct, incremental environmental impacts of biotechnology products. There has been little apparent effort to consider the long-term environmental or economic consequences of the technologies in question.

For example, it is widely known that research and field-trials of genetically altered crops in Canada are overwhelmingly focused on the development of herbicide resistant strains. However, to date, there has apparently been little consideration within the government, and certainly no public discussion, of the long-term implications of this effort for sustainable agriculture in Canada. Will the development of herbicide resistant crops increase herbicide use in Canada? Will it leave farmers in a condition of greater economic and technological dependency than is currently the case? Critical questions of this nature have not been addressed, and the regulatory models proposed by Agriculture Canada, and Environment Canada provide no opportunity to do so.

Timelines for Development of Regulatory Regime

What is required now is an opportunity for a wider debate on these questions. Indeed, this should have occurred prior to the stage at which we now find ourselves, at the threshold of commercialization of some of these technologies. However, it is not too late to consider some of these broader issues, and to bring some basic principles of environmental impact assessment, including the establishment of need, the evaluation of alternatives, and the consideration of long-term and cumulative environmental effects, into the debate. We look forward to opportunities to do precisely this.

The multi-stakeholder consultation approach taken by the Department of Agriculture and Agri-Food in this workshop is an important step to developing a regulatory regime for genetically engineered plants and animals and the Department should be commended for taking such an approach. However, the Department's commitment to consultation will be measured by how it carries forth the consultative process in the future.

Clearly, there should be further discussion as to how a consultation should be structured to make it fair, open and credible for all stakeholders. It is recommended that in designing the ongoing consultation, the Department should examine closely the

process that Environment Canada has embarked upon for drafting regulations for microbial products pursuant to the Canadian Environmental Protection Act. A multi-stakeholder committee has also been used to draft regulations under the Canadian Environmental Assessment Act.

Since Agriculture Canada is considering several regulatory reform issues, more than one multi-stakeholder committee will likely be necessary. As a result, the timelines proposed by Agriculture Canada are clearly unrealistic. Getting the regulatory structure right, so that it protects and promotes the long-term public interest, is far more important than getting it done fast.

Endnotes

1. See M. Valiante and P. Muldoon, "Biotechnology and the Environment: A Regulatory Proposal," (1985), 23 Osgoode Hall Law Journal.

2. C.G. Brunk, L. Haworth, B. Lee, Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy (Waterloo: Wilfred Laurier University Press, 1991), p. 4.

3. See, for example, R. Ginsburg, "Quantitative Risk Assessment and the Illusion of Safety," New Solutions, Vol. 3, No. 2, Winter 1993.

4. See Generally M. Alexander, "Biotechnology Ecological Tier Testing," December 1992 (unpublished paper prepared for the United States Environmental Protection Agency).

5. Ibid.

6. See generally Brunk, Haworth and Lee, Value Assumptions in Risk Assessment.

7. See for example, W. Leiss, Risk Management Approaches: Concepts, Issues and Choices (Paper Presented to the Federal Pesticide Review Team) (Vancouver: William Leiss and Associates Ltd., 1989).

8. Agriculture and Agri-Food Canada, The Risk-Based Approach to Regulation of Agricultural Products. (Ottawa: AAFC, 1993).

9. W.D. Beversdorf, Proposed Assessment Criteria for Determining Environmental Safety of Genetically Modified Plants, (Ottawa: Agriculture Canada, 1993, pp. 15).

10. Sandu Goldstein, Director of Research and Planning with Merck Frosst Centre for Therapeutic Research, 1993 Biotechnology Public Awareness Workshop Summary of Proceedings, Ottawa.