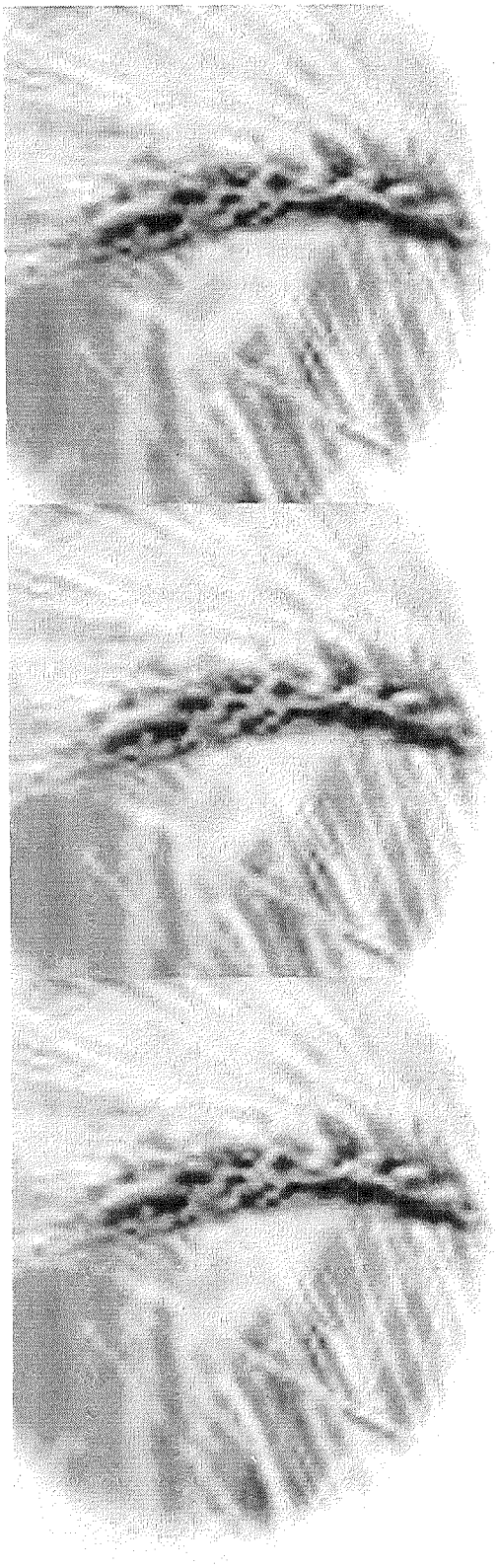

Principles for the Regulation of the Safety of Foods Derived from Agricultural Biotechnology

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CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY

INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT

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Introduction

As products of agricultural biotechnology proliferate across the landscape and on grocery store shelves, public unease regarding their effects on human health and the environment continues unabated, both in Canada and globally. The debates extend from church meetings in small communities to national capitals to the halls of the World Trade Organization in Geneva.

The Canadian Institute for Environmental Law and Policy (CIELAP) has been involved in these debates, in consultations with governments and industry and in making policy recommendations both nationally and internationally, for nearly 20 years. CIELAP's work in food biotechnology has included conferences, publication of a number of research documents, two editions of a *Citizens' Guide to Biotechnology* and a multi-year project on sustainable agriculture and food biotechnology with an environmental law centre in Costa Rica.

Recommendations and rule-making regarding these products multiply from the Organization of Economic Cooperation and Development (OECD) and its member countries, the little-known Codex Alimentarius of the UN, and the *Cartagena Protocol on Biosafety.* Model laws have been drafted by Southern countries that differ markedly from current Northern regimes. All proposals for regulation of agricultural biotechnology are purportedly based on "sound science" as the foundational principle.

However, scientists, environmentalists and health advocates continue to express doubts about the environmental and health risks of genetically-modified (GM) foods and the reliability of the Canadian regulatory regime. To assist in responding to these public concerns, the government of Canada appointed the Royal Society Expert Panel on the Future of Food Biotechnology which reported in 2001[1]. The Panel made extensive recommendations regarding the regulatory regime. Ottawa has responded to its recommendations[2] and also continues to consult with international regulatory bodies including the FAO/WHO Codex Alimentarius.

To assist in further reform of Canadian and other regulatory regimes, CIELAP has commissioned these Principles for a Model Law on the Safety of Products of Agricultural Biotechnology.

CIELAP has never said it is opposed to biotechnology, but we believe that the current applications and the system that regulates them are inappropriate. In our *Citizens' Guide to Biotechnology published in 2002*, CIELAP calls for a moratorium on GE technology until a rigorous regulatory system is put in place. CIELAP repeats this call at this time.

Canada needs to consider how to incorporate the precautionary principle into our regulatory system. We need to create a space for a societal debate on what applications of biotechnology are consistent with the public good that we as a society wish to pursue. We need to decide how that decision is made. We need to acknowledge that GM crops are uncontainable. We need to understand the risk to the environment, possibly human health and to the economics of agriculture, in the long term. It is CIELAP's view, that if we were

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[1] *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada, (Ottawa: January, 2001).

[2] Action Plan of the Government of Canada in Response to the Royal Society of Canada Expert Panel Report, (Ottawa 2001), www.hc-sc.gc.ca/english/protection/royalsociety/intro.htm.

in a position to carry out a scientific review in accordance with the Royal Society Expert Panel recommendations, especially taking into account the GM weed problem, GM food crops would not be approved on environmental grounds. Therefore, the proposals that CIELAP is putting forward for principles for the regulation of food biotechnology are protective of the environment and human health and founded on governmental and corporate responsibility within the Canadian legal system.

The purpose of these principles is to ensure protection of the environment and human health by establishing a statutory regime which fully considers the entire range of risks and uncertainties associated with these products, on the basis of credible research and advice from scientists who are independent of producer companies and governments. Further, the principles require government regulators who are fair and independent from industry and are not promoters of these technologies.

1. Foundation of the Principles

These principles are based on the recommendations of the Royal Society on science and measures to enhance accountability of regulators, bolstered with pertinent additions from the European regime, the *Cartagena Protocol on Biosafety* and model biosafety laws from Africa and the Third World Network.

The guiding precepts for these Principles are the assertions of the Royal Society Expert Panel that:

The fundamental tenets of the Precautionary Principle should be respected in the management of the risks associated with food biotechnology[3]

and

The claim that the assessment of biotechnology risks is "science based" is only as valid as the independence, objectivity and quality of the science employed[4].

2. The Royal Society Expert Panel Report

Substantial equivalence and the Precautionary Principle

Supported by an exhaustive review of the scientific literature, the Royal Society made extensive recommendations for the regulatory regime for GM foods, and included a conservatively reasoned commentary on the application of the concept of "substantial equivalence" (SE) in the regime.

The Royal Society noted the origins of the concept of SE in the conventional breeding process, in which the development of new varieties from varieties with relative genetic uniformity usually do not result in harmful progeny. However, in Canada, when invoked regarding a new GM variety, the concept "essentially pre-empts any requirement...to assess further the new variety for unanticipated characteristics....If a plant or food is judged to be substantially equivalent to one present in the Canadian diet, passage of this step in the

[3] Op. Cit p.205

[4] Op. Cit p.212

openness since the scientific method requires transparency, peer review and independent corroboration of all aspects of research.[12]

The Royal Society recommends that:

- regulatory departments institutionally separate their role as promoter from the role as regulator;
- data on environmental and ecological consequences not be proprietary;
- regulatory officials maintain a neutral stance in the public debate;
- regulators provide increased transparency of scientific data and rationales for regulatory decisions; and
- regulators institute regular peer review of the Risk Assessments for approval by external, independent panels of experts, with access to data and rationales for decisions.

These recommendations of the Royal Society provide a basis for principles for regulation of GM agricultural products based on "sound science."

Labelling requirement

The Royal Society considered whether there is a scientific reason to require food labels on GM products when they are not required for novel or exotic foods produced by conventional processes, and concluded that "there was not at this time sufficient scientific justification for a general mandatory labelling requirement."[13] basing these recommendations on an expectation that the Panel's recommendations regarding regulation of GMOs are fully implemented. The Panel supports voluntary labelling.

However, the recommendations of the Royal Society regarding risk assessment have not been implemented and there is another basis for requiring mandatory labelling of these products, namely, widespread consumer support for such labels. For example, a Consumers' Association of Canada poll released December 3, 2003 records that 91% of those surveyed want labels listing GMO content and 88% believe such labels should be mandatory[14].

A regulatory approach founded on transparency is incompatible with a lack of transparency regarding the presence of GMOs in food, given broad public support for labelling. Mandatory labelling is therefore proposed in these principles.

3. Principles for the Regulation of Products Derived from Agricultural Biotechnology

1. Requirement for Approvals

[12] Op. Cit p.212-213

[13] Op. Cit p.225

[14] Globe and Mail, December 3, 2003

Regulatory approval shall be required for the introduction of genetically modified organisms of agricultural biotechnology and products derived from them for release in the environment and market or for contained use. Regulators may provide approval with or without conditions or deny approval.

2. Scope and definition

The law shall apply to agricultural products of modern biotechnology, as defined by the *Cartagena Protocol on Biosafety.* [15]

3. Consolidated agency and regulation

A consolidated regulatory agency, responsible for assessing the safety of these products for human and animal health and the environment shall be authorized by a consolidated law. The agency shall operate at arms-length and independently of government agencies promoting or funding biotechnology industries.

4. **Risk Assessment**

The agency shall assess the safety of all GMOs. It shall require proponents to provide a rigorous demonstration of the level of risk for human and animal health and the environment, based on appropriate scientific testing protocols and parameters in order to determine whether or not the potential risks associated with the product are substantially equivalent to those of the organism from which it was derived.[16]

5. Independent scientific advice and peer review

Testing protocols, data requirements, and review of test data shall be conducted with independent scientific advisors with full transparency. The protocols shall mandate research and data that satisfy standards for publication in peer-reviewed journals.

6. Application of the Precautionary Principle

Regulatory decisions shall be based on the application of the Precautionary Principle including:

- Testing of each GMO to establish if it is substantially equivalent in its health and environmental effects to its conventional predecessor;
- Shift of the burden of proof to the proponents of the technologies to test and demonstrate that they do not pose unacceptable risks;

[15] The Biosafety Protocol defines modern biotechnology in Article 3(i) as: "the application of: (a) In vitro nucleic acid techniques, including recombinant deoxribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[16] The Royal Society made extensive recommendations regarding the categories of data necessary for credible assessment of risks of various GMOs. Detailed lists of risk assessment requirements for living GMOs appear in Annex III to the *Cartagena Protocol on Biosafety*. Further proposals are included in the proposed model biosafety laws from Africa and from Gurdial Singh of the Third World Network. Some of these data are currently required in the Canadian regulatory system. With the advice of independent scientists and a commitment to peer review quality testing protocols and decision-making, risk assessment in Canada, depending on the product, may draw on data requirements from any of these sources of recommendations.

- If scientifically reasonable theory or evidence indicate the possibility of serious harm to the environment, human or animal health, but uncertainty exists regarding the existence or level of the risk, regulators shall require the proponents to conduct further research to establish that the technology does not cause unacceptable levels of risk;

- Approval of products with potentially serious risks shall not occur unless the scientific uncertainty is reduced to minimum levels. These risks include serious risks to human health, such as potential allergens in food; extensive, irremediable disruptions to natural ecosystems such as gene flow and aggressive, invasive weed species; or serious diminution of biodiversity;

- Regarding risks that are potentially irreversible and/or catastrophic, regulators shall use more conservative safety standards, such as "zero-risk" standards, meaning no tolerance for an increase in risk relative to risk from conventional products.

7. Transparency

Full transparency shall apply to applications for approval, testing protocols, test data requirements, test data results regarding effects on the environment or human and animal health effects, and rationales for regulatory decisions.

8. Public participation

Citizens shall have the benefits of full transparency regarding regulation of these products, including access to applications for approval, testing protocols, test data, and rationales for regulatory decisions. They shall have opportunities to make submissions to the regulatory authority prior to a decision, and the regulatory authority shall consider these submissions.

9. Risk Management

Regulators shall establish appropriate strategies for the management of risks from GMOs which are approved for release, which may include pre-release observation, post-release monitoring, conditions to govern releases, powers of intervention to prevent harm, and other necessary risk management strategies. The regulator shall have the authority to make orders necessary to prevent risks of harm to human and animal health and the environment from GM organisms, and orders to reverse such harms, including by environmental remediation.

10. Protected disclosures (Whistleblower protection)

Individuals shall be protected from employer or other reprisals if they disclose to the regulatory authority information regarding any conditions that create risks from GMOs or actions that may reasonably conflict with these regulations, or if they seek to obtain enforcement of the regulations by the authority. They shall have access to a legal tribunal for relief.

11. Liability regime

Producers of GMOs shall be strictly liable for harm to the environment, human and animal health from the development and use of these products. The producer liability shall continue throughout the use of the product and its progeny, regardless of the contractual relationships between producers, suppliers and purchasers (farmers and consumers) of the

products. Contractual agreements between the producers, suppliers and farmers to limit producer liability shall not be permitted.

Available remedies shall include, but not be limited to, compensation and environmental remediation. Recovery will be facilitated by mechanisms such as requirements for insurance or posting of bonds by GMO developers prior to deployment of the technologies and limitation periods commensurate with the time span of emergence of harm.

12. Administrative provisions:

The regulation shall provide that:

Proponents have a duty to provide correct and complete information to the regulator and to provide relevant new information regarding potential risks after the initial regulatory decision;

Unintentional releases or accidents involving GM organisms shall be promptly reported to the regulator;

The regulator may review, vary or revoke approvals upon receipt of relevant new information regarding potential risks of a GM organism;

Non compliance with the law shall be an offence subject to penalty.

13. Labelling and traceability:

Foods containing or derived from GMOs shall be labelled and traceable through all stages of the production and distribution systems.

14. Import and export:

Transboundary movements of living GMOs shall be in accordance with the provisions of the *Cartagena Protocol on Biosafety*[17], and its elaboration in Meetings and Conferences of the Parties to the Protocol.

Non-living GMOs, when exported and imported, shall be accompanied by information providing labelling and traceability.

[17] These provisions include (but are not limited to) the right of governments of importing countries to assess living GMOs and decide whether or not import will be permitted, and if so on what terms; the application of the precautionary principle to these movements; and requirements for information to accompany shipments.

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