A Submission Regarding the Proposed Notification Regulations for Biotechnology Products under the Canadian Environmental Protection Act

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On Behalf of:

All About Us Canada Foundation

Canadian Environmental Law Association

The Canadian Institute for Environmental Law and Policy

Canadian Labour Congress

Canadian Organic Growers

Citizens Environmental Alliance

Conservation Strategy Association

Environmental Law Centre (Alberta)

Nechako Environmental Coalition

Ontario Public Interest Research Group - Guelph

Pollution Probe

The Toronto Environmental Alliance

The Ram's Horn

Waterloo Public Interest Research Group

World Society for the Protection

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1. Introduction

Canadian environmental groups have welcomed the opportunity to participate in the development of notification regulations for new biotechnology products under the Canadian Environmental Protection Act (CEPA). In the past, the environmental community and other groups have been frustrated by the closed approach employed by the government of Canada in developing biotechnology policy. In this context, the format of the December 1992 consultation was praiseworthy in terms of the wide range of interests which were represented in the consultation. We hope that their input will be considered seriously.

This said, the environmental community has a number of specific concerns regarding the proposed Regulation and its broader policy and regulatory framework. As we stated during the December consultation, we find it difficult to evaluate the adequacy of the proposed Regulation in the absence of a more complete policy framework. While the components of this structure contained in the Green Plan[1] provide a reasonable starting point, they are incomplete at best. Furthermore, the long-standing National Biotechnology Strategy lacks legitimacy due to the limited range of interests involved in its development.

These considerations indicate a need for a wider consultative process regarding the government's approach to biotechnology regulation. This would address such issues as the relationship between biotechnology applications and sustainable development. The government's approach to the problem of uncertainty, due to an inadequate scientific knowledge base, in regulatory decision-making could also be examined.

The following submission deals with issues directly related to the proposed regulation and with broader policy matters that the Regulation raises. The discussions are by no means exhaustive, but instead, consider only some of the more important issues that environmentalists have identified.

2. Evaluative Principles

The responses of the environmental community to the proposed Regulation are based upon three evaluative principles. These are: effectiveness; fairness; and efficiency. We define these terms in the following manner.

Effectiveness - The regulatory structure must provide for the protection of human safety, health and well-being, and environmental integrity. These matters should be addressed in terms of the needs of present and future generations, in a manner consistent with the principles of sustainable development. In this context, a precautionary approach ought to underlie the regulatory decision-making process, especially where significant uncertainties exist with the available knowledge base. The onus of proof must be upon proponents to demonstrate safety and environmental soundness, rather than the state and other societal actors to demonstrate hazards.[2]

Fairness - The costs and risks related to biotechnology development and applications should be borne by those who will benefit economically from these activities. This is consistent with the polluter pay principle. However, given the types of biotechnology applications governed by the proposed regulation, the imposition of substantial involuntary risks on the public may occur. These risks include the dangers of physical harm or illness, reduced environmental quality, and the economic costs of remedial actions, if required, when they exceed the financial resources of the responsible party. Experience with site contamination from toxic chemicals suggests that this will frequently be the case.[3]

The determination of the appropriate distribution of health, environmental and economic risks in relation to the potential benefits of biotechnology applications within society presents a number of serious challenges. Given the widely held view of the inability of any theory of distributive justice to prescribe, in a substantive way, socially just levels of safety and risk, it is generally considered necessary to settle for procedural notions of justice in situations of this nature.[4] This necessitates public consultative processes involving all interested groups. Such processes must be designed to both elicit consensus on possible risk levels associated with alternative courses of action, and to arrive at ethically acceptable levels of risk.[5] There is implicit in this requirement a need for fundamental openness and transparency in the decision-making process.

Efficiency - Regulatory requirements must be clear and understandable to members of the public and the affected economic interests.

3. Implications for CEPA Notification Regulations for Biotechnology Products and Regulatory Process

The application of the above principles to the proposed CEPA Notification Regulation has a number of implications. They involve the general information and monitoring requirements for field-trials, and public involvement in the regulatory decision-making process.

3.1. Information Requirements

In a general sense, the information requirements contained in the Notification Regulation should verify that:

(a) the microbe is non-pathogenic and non-toxic to micro-organisms, plants, animals, and humans;

(b) the microbe is not a pest to plants, animals or other micro-organisms;

(c) the organism will not survive after its intended function is fulfilled and will not disperse in the environment;

(d) the introduced genes are stable and not transferred to other species; and

(e) the micro-organism does not disrupt biogeochemical and ecological cycles.

Specific recommendations with regard to information requirements have been submitted to Environment Canada and Health and Welfare Canada as part of the work by the three Task-Forces under the consultation. These recommendations form part of this submission. However, we emphasize the need to incorporate inclusive language in the Regulation.

RECOMMENDATIONS

(1) The Regulation should be drafted in broad and inclusive language with respect to information requirements.

(2) A residual clause along the lines of "The proponent shall provide any additional information deemed necessary by Environment Canada, or Health and Welfare Canada to determine the toxicity of the substance in question" should be included in the regulation.

3.2. Public Notification and Input

As mentioned above, in the absence of a socially accepted theory on how to distribute risks, an open and consultative decision-making process is required for the assessment of genetically modified micro-organisms.

RECOMMENDATIONS

(3) Interested members of the public should be notified directly when applications for the addition of new substances to the CEPA domestic substances list (DSL) are made.

(4) Members of the public should have access to key environmental and health information submitted in response to the proposed regulation. The release of this information is clearly contemplated in s.20(2) of CEPA. This should be provided on a regular basis, without the need to submit freedom of information requests.

(5) Some means of public input into the DSL decision-making process should be provided. This would include opportunities to comment prior to determinations of "toxicity", and to comment on the terms and conditions to be applied to the use of biotechnology products if they are added to the DSL.

(6) A data-base on the releases of genetically modified micro-organisms should be established. The National Pollutant Release Inventory for toxic substances may provide a model for a "National Biotechnology Release Inventory."

(7) Special requirements for notification may be appropriate for citizens living close to test sites for deliberate releases, since modified organisms may be released into the environment prior to determinations of their "toxicity." Under these circumstances, some means of challenging the acceptability of such field tests should be provided to citizens.

(8) Mechanisms to facilitate useful public participation in the decision-making process, such as intervenor funding, should be considered.

3.3. Monitoring Needs

The requirements for monitoring deliberate releases of genetically modified micro-organisms need to be improved. In particular, the requirements need to be specified in more detail. Currently, it is up to the proponent to devise monitoring

procedures, without specific guidance by Environment Canada and Health and Welfare Canada. Furthermore, there is no clear provision for the ongoing monitoring of released organisms by government agencies. Monitoring data supplied by proponents may be considered inadequate due their potential conflicts of interest. Finally, there are no provisions regarding public access to monitoring data.

RECOMMENDATIONS

(9) The Regulation must be more specific in its monitoring requirements, outlining some common requirements for all deliberate releases. At minimum, these should include the frequency and area of monitoring, the duration of the monitoring program, and specifications regarding the types of data to be collected.

(10) The authority of Environment Canada and Health and Welfare Canada to undertake their own monitoring "spot-checks" should be established. Th departments should then publish the reports of the "spot-checks" on a regular basis.

(11) Mechanisms for public access to monitoring data should be established.

3.4 Decision-Making Approach

The work of the consultation Task-Forces indicated the existence of major gaps in the knowledge base necessary to evaluate the environmental effects of biotechnology products. This presents decision-makers with a number of significant challenges and makes the application of a degree of judgement in decision-making inevitable. The approaches of regulatory decision-makers to this question will have a major impact on the effectiveness of the proposed Regulation.

RECOMMENDATION

(12) Environment Canada and Health and Welfare Canada ought to adopt a precautionary, or risk adverse, approach in making decisions when uncertainties exist regarding the likely environmental effects of biotechnology products. Where uncertainties exist, the use the product in question should not be permitted.

3.5 Regulatory Costs

Concerns have been raised regarding the limited resources available to

Environment Canada and Health and Welfare Canada to administer the CEPA regulatory process for biotechnology products.

RECOMMENDATION

(13) In a manner consistent with the polluter pay principle, a form of user-fee should be considered for proponents of DSL listing applications.

3.6 General Regulatory Clarity

During the December consultation many stakeholders raised concerns regarding the lack of clarity in the drafting of the regulation.

RECOMMENDATION

(14) The Regulation should be redrafted to provide for clear information requirements and decision-trees.

4. Wider Issues Raised by the Proposed CEPA Biotechnology Regulation

The proposed CEPA Notification Regulation for Biotechnology Products gives rise to a range of issues which extend beyond notification and the addition of biotechnology products to the Domestic Substances List. The Regulation demonstrates a number of weaknesses with the existing structure of the Canadian Environmental Protection Act. Most of the weaknesses cannot be dealt with under the proposed Regulation. However, they should be considered as part of the CEPA review scheduled to commence later this year.

4.1. Definition of "Toxic" under CEPA

The focus of CEPA on "toxicity," and the definition of "toxic" employed within the statute, leads to a number of problems. These include the absence of mechanisms to determine the need for, or the existence of safer alternatives to particular products or processes. These are standard components of environmental assessment processes.

Recent decisions regarding "toxicity" under the existing legislative structure give rise to further concerns. This has been especially true in the context of the determinations that the substances chlorobenzene[6] and toluene,[7] which are widely known to pose significant environmental and human health hazards, but are not "toxic" for the purposes of the Act.[8] The key flaw appears to be that the definition of "toxic"

under CEPA is reactive, rather than preventative.

RECOMMENDATIONS

(15) In the upcoming review of CEPA, provisions should be incorporated to permit examinations of the need for, and the purposes of, new substances, including biotechnology products, and possible alternatives to achieve similar purposes.

(16) In the upcoming review of CEPA, the definition of "toxicity" should be revised. In particular, the notion that substances, including biotechnology products, must be present in "toxic" amounts in the environment before actions are undertaken by the Federal Departments, should be removed.

4.2. Liability

Several serious issues related to the environmental aspects of biotechnology applications remain unaddressed. Prominent among these is the question of liability for any environmental, human health or animal health damage caused by the release of genetically modified micro-organisms into the environment. Costs of this nature should not be socialized for the purpose of facilitating the development of the biotechnology industry.[9]

RECOMMENDATIONS

(17) The question of the assignment of liabilities for environmental damage caused by biotechnology products should be clarified. In particular, the costs of remedial actions to repair environmental, human health or animal health damage should be the responsibility of the proponent of the release, or its agents.

(18) The creation of a special remediation fund, funded by all firms releasing genetically modified products, must be implemented for those cases in which the proponent has inadequate financial resources to address remediation costs, or is bankrupt.

4.3. Institutional Arrangements

The residual nature of Environmental Canada's regulatory role regarding

biotechnology also raises a number of important issues. 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, particularly Agriculture Canada, appear to be going out of their way to limit public knowledge and discussion or debate regarding the approval of field-trials or applications of genetically modified plants.[10]

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.[11] 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.

RECOMMENDATION

(19) The Government of Canada should develop models for the creation of a National Biotechnology Commission to consolidate and oversee biotechnology regulation in Canada. The Commission should be an independent agency, representative of a wide range of interests, and is open and accessible to members of the public.

4.4. 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 modified products currently being developed or contemplated for a wide range of applications give rise to a spectrum of economic, environmental and ethical issues.

RECOMMENDATION

(20) 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.

5. Conclusions

The proposed Notification Regulation for Biotechnology Products under CEPA needs to be revised significantly to ensure the protection the public interest, particularly in terms of the protection of human health, animal health and environmental quality. In addition, the proposed regulation reveals a need for revisions to CEPA itself. These changes would include a more open decision-making process and an explicitly precautionary approach to the management of new technologies and products. We hope that Environment Canada and Health and Welfare Canada will act on the substantive changes to the proposed Regulations which have been presented in this submission, and will consider our wider proposals regarding CEPA and the management of biotechnology and other new technologies as well.

ENDNOTES

1. Canada's Green Plan (Ottawa: Supply and Services Canada, 1990), p. 50.

2. On the issue of value assumptions in risk assessment see generally C.G. Brunk, L. Haworth, B. Lee, Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy (Waterloo: Wilfred Laurier Press, 1991).

3. G. Ford, D. Macdonald, M. Winfield, "The Legacy of the Past and Its Implications for the Future: Policy Options in the Rehabilitation of Contaminated Sites in Canada and the Prevention of Future Occurrences," Forthcoming.

4. See generally, C.J. Tuohy and M.J. Trebilcock, Policy Options in Regulation of Asbestos- Related Health Hazards (Toronto: Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario, 1992), Ch. 5.

5. Ibid., pp. 5.22-5.23. See also W.J. Leiss, Risk Management Approaches: Concepts, Issues and Choices (Paper Presented to the Federal Pesticide Review Team)(Vancouver: William Leiss and Associates Ltd., 1989).

6. Canadian Environmental Protection Act Priority Substances List Assessment Report No. 3: Chlorobenzene (Ottawa: Environment Canada and Health and Welfare Canada, 1992).

7. Canadian Environmental Protection Act Priority Substances List Assessment Report No. 4: Toluene (Ottawa: Environment Canada and Health and Welfare Canada, 1993).

8. For example, toluene has a acute toxicity only 5.8 parts per million to rainbow trout (96 hr LC_{50}).

9. For detailed discussions of the issue of environmental liability see D. Saxe, Contaminated Land (Ottawa: Law Reform Commission of Canada, 1990) and G. Ford, Consequences for the Bill 220/90 Amendments to the *Environmental Protection Act*: Defining Responsible Parties under Administrative Orders (Toronto: Canadian Institute for Environmental Law and Policy, 1992).

10. See, for example, G.M. Lewis, "Federal Environmental Assessment of Transgenic Plant Field Tests," (1991), 1 J.E.L.P..

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