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Comments Regarding the New Substances Notification Regulations, Part II.1 (Organisms) to be made under the *Canadian Environmental Protection Act* (CEPA)

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1. Introduction

The Canadian Institute for Environmental Law and Policy (CIELAP) is pleased to comment on the proposed New Substances Notification Regulation Party III (Biotechnology Products) to be made under the *Canadian Environmental Protection Act*. CIELAP has been involved in environmental law and policy development related to biotechnology over the past 12 years. CIELAP's predecessor, the Canadian Environmental Law Research Foundation (CELRF) organized the first conference in Canada on environmental law and policy issues regarding biotechnology in 1984.[1]

The Institute has produced a number of major publications regarding biotechnology.[2] These include a study of environmental law and policy issues in the regulation of biotechnology for the Ontario Ministry of the Environment in 1987,[3] and an overview study of environmental, social, economic and ethical issues related to biotechnology completed for the Ontario Ministry of Economic Development and Trade in 1995.[4] The Institute has also published a Citizen's Guide to Biotechnology.

In addition, CIELAP and CELRF have developed detailed legislative proposals for the environmental regulation of biotechnology products.[5] These proposes have been intended to address the gaps and inconsistencies in the existing product-based legislation under which the government of Canada has proposed to regulate products of biotechnology, ensure adequate environmental and human health impact assessments of biotechnology products prior to field testing or commercialization, and public participation and accountability in decision-making.

CELRF and CIELAP have participated in numerous consultations with Environment Canada, Health Canada, Agriculture and Agri-Food Canada, and the government of Ontario regarding biotechnology and the environment over the years. Specifically with respect to the CEPA biotechnology notification regulation, CIELAP participated as a delegate of the Biotechnology Caucus of the Canadian Environmental Network in the September 1992, July 1993 and December 1994 working group consultations on the proposed regulations.

CIELAP welcomes the establishment of a regulatory framework for such previously unregulated activities as the use of genetically engineered microorganisms in bioremediation, sewage treatment, mining and chemical and drug manufacturing through these proposed regulations. These activities pose potentially significant threats to human health and the environment. The delays in the completion of the CEPA regulations have created a dangerous vacuum, as the number of biotechnology products reaching the market increases.

At the same time, however, CIELAP is seriously concerned by the exemption contained in the draft regulation from the requirements of CEPA of agricultural products of biotechnology regulated under the *Feeds Act*, *Fertilizers Act*, *Health of Animals Act*, *Pest Control Products Act* and *Seeds Act*.

2. Specific Comments Regarding Draft Regulations.

i) Section.3.(1) Equivalency

CIELAP has serious concerns regarding the explicit exemption of products of biotechnology regulated under the *Feeds Act*, *Fertilizers Act*, *Health of Animals Act*, *Pest Control Products Act* and *Seeds Act* from CEPA provided by this section. Explicit exemptions of this nature undermine the objective legal test for equivalency with respect to notification and assessments of toxicity of new substances conducted under other acts of Parliament, established by s.26(iii)(a) of CEPA, and thereby thwarts will of Parliament in the drafting of this section of CEPA.

CIELAP and others regarding the adequacy of authority for conduct of assessments of CEPA toxicity under *Feeds Act*, *Fertilizers Act*, *Health of Animals Act*, and *Seeds Act*. Indeed, these statutes contain no clear legislative authority for the evaluation of regulated products from an environmental or human health perspective.

Furthermore, an examination of the legislative record in relation to these statutes indicates that they were drafted primarily for the purpose of the prevention of fraud, and that no reference was made to the conduct evaluations for the purpose of the protection of the environment or human health.[6]

This situation leaves significant portions of the government's proposed regulatory framework vulnerable to legal challenge. At best, the proposal to establish regulations for the environmental and human health assessment of biotechnology products under statutes which make no reference to biotechnology, and which provide no explicit authority for such evaluations amounts to a form of legislative amendment through regulation. This practice has been strongly criticized on numerous occasions by Parliamentary Committees[7] and by legal and constitutional scholars.[8]

In addition, it clear from our examination of proposed biotechnology notification regulations under the *Seeds Act*, *Fertilizers Act*, *Feeds Act*, or *Health of Animals Act* published in the *Canada Gazette* at the same time as the proposed CEPA notification regulations, that the proposed agricultural regulations are <u>not</u> equivalent to the CEPA regulations in terms of their scope and information requirements.[9]

In light of these considerations, we recommend that the exemption for biotechnology products regulated under the *Feeds Act*, *Fertilizers Act*, *Health of Animals Act*, *Pest Control Products Act* and *Seeds Act* be deleted from the proposed CEPA biotechnology regulation.

ii) Section 15.1 and 16 Time Lines for Information 1988-1994 on Substances During the Transitional Period

The time lines proposed for the delivery of notification information on products in use in Canada between 1988 and 1994 are far too long (up to 7 years). We note that the maximum time line for the provision of notification information on chemical new substances introduced during the transitional period under the New Substances Notification Regulations, Parts I and II, is 4 years. The same standard should be applied to biotechnology products (See CIELAP December 12, 1994 comments on draft regulations).

ii) Section 29.11 Ecozones

CIELAP welcomes the effort to introduce consideration of receiving environment for products of biotechnology products into the assessment process through the ecozone concept. However, we do not believe that the proposed ecozones provide an adequate level of detail for useful assessments of the likely impacts of introduced organisms (See CIELAP December 12, 1994 comment on draft regulations).

iii) Section 29.13 Assessment Periods

We continue to be concerned that the proposed assessment periods may be inadequate for a complete and thorough evaluation of notification data by Environment Canada and Health Canada officials. This concern is reinforced by the potential complexity of the data likely to be received and the level of uncertainty which exists regarding its interpretation. We propose the following time-frames:

ss. 29.13(a) - 180 days
ss. 29.13(b) - 90 days - a longer assessment time frame seems particularly appropriate here given the need to assess the adequacy and effectiveness of containment arrangements and contingency plans in the event of accidental release.
ss.29.12(c) - 120 days

iv) Schedules

Schedule XV s.5(c) and equivalent provision in Other schedules

CIELAP welcomes the reference to impacts on the conservation and sustainable use of biodiversity, based on the requirements of Article 8(g) of the *United Nations Convention on Biological Diversity*. However, we have question whether consideration of impacts on the sustainable use of biological diversity can be accommodated within the current definition of CEPA "toxic" (specifically s.11(b)). This is of particular concern given the very narrow interpretation of CEPA "toxic" applied in the Priority Substances List I process.

This issue should be addressed through an amendment to CEPA as part of the current CEPA review process to specifically provide for consideration of the potential impact of a biotechnology product on the "conservation and sustainable use of biodiversity."

Schedule XVII - Field Studies

Provision should be made for public notice of proposed field study and reasonable public comment periods (i.e. 60 days) established. Particular attention should be given to the notification of the owners and occupiers of lands neighbouring proposed field study sites. Comments received in response to public notice should be considered in decision-making regarding proposed tests.

3. Conclusions

CIELAP strongly supports the adoption of the proposed regulation in principle. However, the proposed exemption for products of biotechnology regulated under *Feeds Act*, *Fertilizers Act*, *Health of Animals Act*, *Pest Control Products Act* and *Seeds Act* should be deleted from the draft regulation. The maintenance of the existing objective legal test for equivalency with CEPA for the purposes of notification and toxicity assessments is necessary to ensure that all biotechnology products are subject to adequate pre-manufacturing or import environmental and human health assessments, and to ensure a degree of consistency in the treatment of products of biotechnology among different federal agencies.

In addition, we recommend that the notification periods for biotechnology products imported or manufactured during the transitional period be shortened, the assessment periods extended, and provisions made for public notice and comment periods regarding field tests of biotechnology products. Amendments to CEPA should also be considered to fully accommodate the requirements of the *United Nations Convention on Biological Diversity*.

Endnotes

1.The Regulation of Biotechnology: Conference Proceedings (Toronto: Canadian Environmental Law Research Foundation, 1984).

2.See Biotechnology Policy Development (Toronto: Canadian Institute for Environmental Law and Policy, 1987).

3.Biotechnology Policy Development (2 Volumes) (Toronto: Canadian Environmental Law Research Foundation, 1987).

4.M.Winfield and M.Press-Merkur, Enabling Biotechnology? A Response to the Report of the Biotechnology Council of Ontario (Toronto: Canadian Institute for Environmental Law and Policy, January 1995).

5.See M.A. Valiante, and P.R. Muldoon, "Biotechnology and the Environment: A Regulatory Proposal," Osgoode Hall Law Journal (Summer 1985), pp.359-94, and M.Winfield and B.Mausberg, "CEPA, Chemical New Substances and Biotechnology," in M.Winfield, ed., Reforming the Canadian Environmental Protection Act (Toronto: Canadian Institute for Environmental Law and Policy, September 1994).

6.See the Hon. D. Harkness, Minister of Agriculture, House of Commons Debates June 29, 1959 on the occasion of the second reading debate of the current version of the *Seeds Act*.

7.See, for example, Standing Joint Committee of the Senate and House of Commons on Regulations and Other Statutory Instruments, Fourth Report (1980) para 81 and Appendix II.

8.See, for example, D.P. Jones and A.S. de Villars, Principles of Administrative Law (Toronto: Carswell 1985).

9.See Comments on Proposed Regulations for Environmental Safety Assessments of Releases of Plants with Novel Traits under the *Seeds Act* (CIELAP Brief 96/7)(Toronto: Canadian Institute for Environmental Law and Policy, October 1996)