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Comments on Proposed Regulations For Environmental Safety Assessments of Releases of Plants with Novel Traits under the *Seeds Act*.

CIELAP Brief 96/9

Canadian Institute for Environmental Law and Policy
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1. Introduction

The Canadian Institute for Environmental Law and Policy (CIELAP) is pleased to comment on proposed regulations for Environmental Safety Assessments of Releases of Plants with Novel Traits under the *Seeds 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] 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.

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.

2. Agriculture and Agri-Food Canada's (AACF) Role in the Regulation of Agricultural Products of Biotechnology

In addition to being responsible for the environmental and human health regulation of agricultural biotechnology products, the AAFC has emerged as one of the leading developers and testers of agricultural products of biotechnology in Canada. The department has also dedicated significant resources to the support of the development of such products by private sector and academic researchers, and to the promotion of their adoption by farmers.

Over the past five years CIELAP, along with other non-governmental organizations from a variety of sectors and members of the academic community, has questioned the appropriateness of these multiple roles. The current arrangements provide the appearance, if the not reality, of a fundamental conflict of interest. The past thirty years provide numerous examples of the negative consequences regulatory and promotional functions in relation to a given industry being housed in the same government agency. The role of the Department of Fisheries and Oceans in relation to the East Coast groundfish fishery in Atlantic Canada provides an obvious illustration of these perils.

It considerations of this kind that lead the government transfer responsibility for the regulation of pesticides from Agriculture Canada to Health Canada last year. Over the years, Agriculture Canada's active promotion of the use of pesticides in agriculture undermined its credibility as an evaluator and regulator of their health, safety and environmental impacts.

Although it regarded the current situation with respect to the promotion and regulatory roles of AAFC unsatisfactory, in presenting its recommendations to the House of Commons Standing Committee on Environment and Sustainable Development regarding the regulation of biotechnology for the purposes of the review of the *Canadian Environmental Protection Act* (CEPA), CIELAP did not propose a fundamental change in the responsibilities of regulatory agencies. Rather, the Institute sought the strengthening of the existing "equivalency" framework provided by section 26(iii)(a) of CEPA, particularly through the expansion and clarification of evaluative criteria, and the establishment of provisions for public participation in decision-making.[6] The Standing Committee adopted this approach in its June 1995 report, It's About Our Health!.[7]

The government's December 1995 response to the Standing Committee's report, Entitled Environmental Protection Legislation Designed for the Future, rejected these recommendations. Instead, the government proposed to substantially weaken the existing minimum requirements for the environmental and human health assessments of biotechnology products under CEPA.[8] In the following months, the question which had been raised regarding Agriculture and Agri-Food Canada's role in the regulation of biotechnology products were reinforced as it became clear that the Department, along with other agencies, had played a significant role in the promotion and adoption of this proposal.

It was for these reasons that, in their response to the Government's proposals, CIELAP and the Canadian Environmental Law Association (CELA) recommended that the future regulatory framework for products of biotechnology by based on a clear separation of promotional and regulatory roles among agencies. In particular, they recommended that responsibility for the environmental and human health regulation of products of biotechnology which may enter the environment be assigned to

Environment Canada and Health Canada.[9] A similar proposal, developed for the Biotechnology Caucus of the Canadian Environmental Network, was submitted to the government with endorsements from 89 environmental, consumers', public health, professional, farm, labour, church, animal welfare and other non-governmental organizations from across Canada.[10]

The government is expected to introduce amendments to CEPA in the fall of 1996. In the interim, CIELAP supports in principle the completion of a framework of regulations for the pre-manufacturing, import or release evaluation of products of biotechnology which may enter the environment, based on the existing provisions of section 26(iii)(a) of CEPA through the promulgation of notification and assessment regulations under CEPA and other appropriate legislation.

2. Legal Authority

There remain serious questions regarding the adequacy of the legal authority for environmental and human health safety assessments provided by the statutes under which Agriculture and Agri-Food Canada proposes to regulate agricultural products of biotechnology, including the *Seeds Act*. 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. No reference was made to the conduct evaluations for the purpose of the protection of the environment or human health.[11]

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[12] and by legal and constitutional scholars.[13]

We also note number of additional gaps in the legislative authority provided by such statutes as the *Seeds Act*, the *Fertilizers Act* and the *Feeds Act*. These include:

* the absence of any provisions regarding public participation in decision-making, such as notice and comment provisions regarding major decisions, or public access to information regarding new products;

* the absence provisions establishing or designating appellate bodies for appeals of decisions made under these Acts, or regarding standing in, or outlining procedures for, such appeals;

* the absence of any provisions regarding civil liability for harm to the environment or human health by regulated products; and

* weak enforcement and penalty structures in comparison to CEPA.

These fundamental weaknesses arise from the fact that these statutes were drafted for the purpose of the regulation of product quality, and not the protection of human health or the environment. This situation should be addressed either through the enactment of new legislation or amendments to existing statutes to establish an appropriate legal framework.

3. Specific Comments Re: *Seeds Act* Regulations

i) Scope

The approach taken to the definition of the scope of substances to be captured by the proposed regulations deviates significantly from that proposed by Environment Canada and Health Canada in biotechnology regulations to be made under CEPA.

The CEPA regulation require some form of notification for all organisms which do not appear on the Domestic Substances List, which are introduced into a new ecozone, or cultured and reintroduced into their site of origin. Research and development organisms used in containment in quantities below designated trigger quantities are required to adhere to the requirements of the *Laboratory Biosafety Guidelines* or Appendix K of the *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) June 1994.*

In comparison, the proposed *Seeds Act* regulation provides exemptions for varieties which constitute a distinct stable population (i.e. naturally occurring or existing variety?) or derivatives of such a population, or which are "substantially equivalent" to a variety registered for unconfined release. This clearly provides a much wider range of exemptions from notification requirements than is the case under the proposed CEPA regulations. In order to parallel the approach taken in the CEPA regulations, some form of notification would have to be required for all varieties not registered under the *Seeds Act* prior to a given date, and when registered varieties are introduced into new ecozones.

ii) Public Notice and Comment

CIELAP is deeply disappointed by AAFC's decision to remove any requirements for public notice of proposed field tests of plants with novel traits into the environment which had been in contained in the June/94 draft of the proposed regulations.

As members of the public are exposed to the risks and will likely bear costs of remediation in the event of a serious problem, they have a right to be informed of proposed field tests of genetically engineered and other plants with novel traits, and to make their views known regarding the approval of such tests. The case for public notice is particularly compelling in case of occupiers and owners of neighbouring lands who will be placed directly at risk by field tests.

In addition, we note that the proposals made by members organizations of the CEN Biotechnology caucus in their December 1993 paper Growing Safely? Concerns About Biotechnology and the Regulatory Process were no more onerous than those associated with routine environmental approvals under Ontario's *Environmental Bill of Rights* and most U.S. environmental statutes.

The requirements for public notice prior to approval of field tests, and approval of unconfined release of "plants with novel traits" into the environment proposed in the June 1994 draft *Seeds Act* regulation should be restored. Public notice should be followed by a public comment period of not less than sixty days and a requirement that any comments received be considered in decision-making regarding field tests and unconfined releases.

The absence of any appeal process either for proponents or members of the public who may be negatively affected by decisions under the proposed regulations also needs to be addressed. The lack of such processes raise serious issues of natural justice.

iii) Other Specific Comments Regarding Regulations

s.107 - Definitions

The term "substantive equivalence," which is central to the scope of the proposed regulation, is not defined in the regulation.

s.110 - Information Requirements

The information requirements contained in the proposed regulation are very general, particularly in comparison with the provisions of the proposed regulation to

be made under CEPA. The proposed *Seeds Act* regulation only makes general references to information relevant to risk to human health or the environment (s.110(e)), while the proposed CEPA regulation requires detailed information on the characteristics of the organism under assessment relevant to potential impacts on the environment or human health (see, for example, Schedule XIX, sections 1(e), and Schedule XV, sections 1(f) and (i).

In addition, the proposed *Seeds Act* regulation contains no information requirements regarding the characteristics of the receiving environment or the introduced variety's interaction with it. By comparison, the CEPA regulation requires information comparing the natural habitat of an organism with the habitat that it is to be introduced into (Schedule XV, section 3(c), limits releases of organisms to specific "ecozones," and requires very detailed information on the location of proposed field tests (Schedule XVII, section 3).

Furthermore, the proposed *Seeds Act* regulation contains no specific information requirements regarding the environmental fate or effects of new varieties released into the environment. Again, by comparison, the proposed CEPA regulations contains detailed information requirements in this regard (Schedules XV and XIX, sections 4 and 5).

The definition of "novel trait" makes no reference to impacts on the sustainable use of diversity. Such a reference is necessary to fulfil the requirements of Article 8(g) of the *United Nations Convention on Biological Diversity*. More generally the criteria to be employed in the definition of "novel trait" makes no reference to other potential direct effects of a plant with a novel trait, such as impacts on soil structure and quality, or nutrient cycling.

No specific criteria are identified at all in the definition of "novel traits" with respect to human health impacts. In comparison, the proposed CEPA regulation has detailed information requirements in this regard (Schedule XV, section 6 and Schedule XIX, section 6).

No reference is made in the definition of "novel trait" to indirect environmental or human health effects which may arise from the use of a plant with a "novel trail." The impacts of changes in patterns of herbicide use associated with the commercial scale planting of herbicide resistant crops would be an obvious example of such potential effects.

s. 111 - Decision of the Minister

Sections 1 (a),(b),(c)

The proposed requirement for confined release of plants with novel traits when potential risks to the environment are identified is welcomed. However, we note that while the June 1994 draft required that there be no releases where there are "unacceptable" risks to the environment, this decision is discretionary in the current draft.

We note that these sections make references to potential risk to the environment, but not to risks to human health. This omission must be addressed to meet the equivalency requirements of section 26(iii)(a) of CEPA, as the definition of CEPA "toxic" includes potential to constitute a danger to human life or health.[14]

As noted earlier, we believe that the requirements for public notice of applications for field tests, and unconfined releases of plants with novel traits should be restored, that reasonable public comment periods provided, and that the Minister be required to consider comments received in decision-making. The pre-publication for public comment of the current "decision-documents" for approvals of unconfined releases would be a particularly useful step.

4. Conclusions

CIELAP welcomes the government's efforts to establish a more firm regulatory framework for products of biotechnology. However, we have continuing concerns regarding AAFC's regulatory role, particularly in light of the department's strong commitment to the development and promotion of agricultural products of biotechnology. CIELAP also continues to have serious doubts about the adequacy of the legal authority currently provided by agricultural product statutes, like the *Seeds Act*, for the conduct of environmental and human health impact assessments of agricultural biotechnology products.

The Institute also questions whether the proposed *Seeds Act* regulations meet the equivalency test provided by section 26(iii)(a) of CEPA. CIELAP is particularly concerned by the differences in scope and information requirements between the proposed *Seeds Act* regulation and the biotechnology products notification regulation proposed by Environment Canada and Health Canada.

Finally, CIELAP is disappointed that AAFC has chosen to remove the requirements for public notice of field tests of plants with novel traits which were contained in the June 1994 draft regulation. These provisions should be restored, and provisions for the pre-publication and public comment periods regarding decision-documents for unconfined releases of varieties, established.

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 Winfield and Mausberg, "CEPA, Chemical New Substances and Biotechnology." pp.24-25.

7.Standing Committee on Environment and Sustainable Development, It's About Our Health! (Ottawa: House of Commons, June, 1995), Recommendations 67 and 68.

8.CEPA Review: the Government Response/Environmental Protection Legislation Designed for the Future - A Renewed CEPA/ A Proposal (Ottawa: Government of Canada, December 1995), pg. 52, para, 7.4.

9.It's Still About Our Health! A Submission on CEPA Review: The Government Response Environmental Protection Legislation Designed for the Future - A Renewed CEPA - A Proposal (Toronto: Canadian Institute for Environmental Law and Policy and Canadian Environmental Law Association, March 1996), Recommendation 95.

10.For Whose Future? A Response to the Proposals of the Government of Canada on the Regulation of Biotechnology under the Canadian Environmental Protection Act (Ottawa: Biotechnology Caucus, Canadian Environmental Network, March 1996).

11.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*.

12.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).

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

14.*Canadian Environmental Protection Act*, section 11(c).