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Comments to Agriculture and Agri-food Canada re:

Pro94-01, *Assessment Criteria for Determining Environmental Safety of Genetically Modified Plants*

Pro94-02,*Guidelines for Determining Environmental Safety of Genetically Modified* **Brassica napus L.**

Pro94-03, *Guidelines for Determining Environmental Safety of Genetically Modified Flax* **Linum usitatissimum L.**

CIELAP Brief 94/6

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I. INTRODUCTION

The Canadian Institute for Environmental Law and Policy (CIELAP) was pleased to be invited to comment on Agriculture and Agri-Food Canada's regulatory proposals 94-01, 02, and 03. CIELAP has taken a strong interest in the environmental regulation of biotechnology applications over the past decade[1] and has participated in the Environment Canada/Health Canada consultations on the development of biotechnology notification regulations under *The Canadian Environmental Protection Act* (*CEPA*). CIELAP has a number of serious concerns regarding Agriculture and Agri-food Canada's regulatory proposals regarding genetically modified plants.

II. SPECIFIC CONCERNS REGARDING THE REGULATORY PROPOSALS

1. Legal Basis for Regulation

The legal basis for the proposed regulations remains unclear. Concerns regarding the adequacy of the *Seeds Act* provisions in this regard, and the consequent possibility of legal challenges to Agriculture Canada's regulatory approach were raised by representatives of the Biotechnology Caucus Canadian Environment Network (CEN) during the November 1993 consultation on agricultural biotechnology and in the Caucus' subsequent submission to Agriculture Canada.[2] The basis of these concerns has been articulated in detail by researchers with the Alberta Environmental Law Centre on a number of occasions.[3] The relationship between Agriculture Canada's regulatory proposals for genetically modified plants and the equivalent process requirements of the New Substances provisions of *CEPA*[4] also remains unclear.

2. Transparency and Accountability in Decision-Making

Detailed proposals regarding how Agriculture Canada might make its assessment and decision-making process regarding field-tests of genetically modified plants more transparent and accountable were made by CEN Biotechnology Caucus members following the November 1993 consultation at the request of the Department.[5] The regulatory proposals provide no indication of any consideration of these suggestions. CIELAP continues to regard the establishment of procedures to provide for public notice and opportunities to comment prior to the approval of field tests and the establishment of mechanisms to address situations in which members of the public, and particularly the owners or occupiers of neighbouring lands, object to the conduct of field tests.

It is the public which is put at risk by the release of genetically modified plants and their genetic material into the environment, and therefore the public has a right to be consulted on the approval of such activities. We remind Agriculture Canada of the provisions with respect to public participation in environmental decision-making of Principle 10 of the Rio Declaration, of which the government of Canada is a signatory, in this regard.

3. References to "toxic" in the Regulatory Proposals

Part F, sections 2.1(1) and (2) of regulatory proposals 94-02 and 94-03 make reference to "toxic" novel genes. No definition of "toxic" is provided in the regulatory proposals. Is the definition of "toxic" the same as that employed in *CEPA*? If not, then what does this term mean in the context of Agriculture Canada's regulatory proposals?

4. Test Locations

The information requirements contained in the regulatory proposals do not appear to require the identification of the precise location of proposed field tests. Nor do the regulatory proposals require information regarding the proximity of the proposed test sites to population centres or significant natural areas or features. Indeed, a description of the test site does not appear to be required at all. It is difficult to conceive of how a meaningful environmental assessment of a proposed field-test can be carried out without such information. We note that information requirements of this nature have been agreed to as part of the draft *CEPA* Biotechnology Notification regulation's provisions regarding field tests.[6]

5. Confinement and Termination Procedures

Although the regulatory proposals are made in relation to "confined" field tests of genetically modified plants, the proposed guidelines do not appear to require any information on the confinement procedures to be employed by the proponent. Similarly, there are no information requirements regarding termination procedures or contingency plans in the event of the test plants or their genetic material escaping confinement. Provisions for information on these matters are included in the draft *CEPA* regulations.[7]

6. Waivers for Modified Plants with Unmodified "Counterparts"

The regulatory proposals propose exempting genetically modified plants from the detailed information requirements regarding Reproductive and Survival Biology contained in Part F of the proposals, if the "species replacement rate is similar or less than the unmodified counterpart or competition studies indicate no change in competitive ability." Concerns were raised during the November 1993 consultations by CEN Biotechnology Caucus representatives and Environment Canada officials regarding the concepts of "familiarity" and "substantive equivalence" proposed by Agriculture Canada as part of its environmental risk assessment process for genetically modified plants. These concerns were strongly reiterated in the Biotechnology Caucus members' subsequent submission to the Department.[8]

CIELAP continues to be strongly of the view, expressed in the Biotechnology Caucus members' December 1993 submission, that given their novelty and the degree of uncertainty regarding their potential environmental impacts, genetically modified plants and other genetically modified organisms under Agriculture Canada's jurisdiction should **not** be exempted from any information requirements contained in the regulatory proposals. This is especially important with respect to reproductive and survival biology features, which are directly relevant to the potential for the transfer of genetic material from the modified plant to other plants.

7. Table 4 Evaluation of Ecosystem Effects of Releases of Genetically Modified Plants

The proposed structure for evaluating the impacts of the releases of genetically modified plants on ecosystems suffers from a number of weaknesses. The division of the environment into two broad categories (natural and agro-ecosystems) seems inappropriate. The broad range of environments included in the category of "agro-ecosystems" is particularly problematic. This category should be sub-divided into a number of sub-categories. At present the category appears to equate the ecosystems of farms with those of industrial and waste disposal sites. The removal of sustainability as an evaluative criteria for effects on natural eco-systems is also problematic. Is not ecosystem sustainability a fundamental goal of environmental stewardship in the context of sustainable development?

make the provisions of Agriculture Canada's proposals more thorough and consistent with the equivalent provisions of the draft *CEPA* Biotechnology notification regulation.

In addition to the need for these technical modifications, the legal basis of the regulatory proposals must be clarified, and adequate provisions made for public notification and access to decision-making regarding field tests. Furthermore, prior to the commercialization of the genetically modified plants for food, fibre or oil production, an evaluation process which is capable of assessing the potential long-term direct and indirect environmental, health and socio-economic effects of such a step must be established. Such an approach would be consistent with widely accepted principles for environmental assessment, and with recommendations contained in the recent report of the House of Commons Standing Committee on Agriculture and Agri-food.

ENDNOTES

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

2.B. Kneen, B. Mausberg, J. Monroe, M.Winfield, Growing Safely: A Report to Agriculture Canada (Ottawa: Biotechnology Caucus, Canadian Environment Network, 1993), pp. 3-4.

3.G. Lewis, "Federal Environmental Assessment of Transgenic Plant Field Tests," Journal of Environmental Law and Practice, Vol; 1., No. 2., March 1991, pp.161-177.

4.*Canadian Environmental Protection Act*, s.26(3)(a).

5.Kneen, Mausberg, Monroe, Winfield, Growing Safely? Recommendation 6, pp. 8-10.

6.See Schedule XVII, s.15(b) and (c), Draft *CEPA* Biotechnology Notification Regulation, July 1993.

7.Ibid., s.16 (f) and (h).

8.Kneen, Mausberg, Monroe, Winfield, Growing Safely? Recommendations 7 - 10.

9.Information supplied to CIELAP by Agriculture and Agri-Food Canada in July 1994, indicates that for the 1994 growing season of 881 trials for which applications were received, 715 were for herbicide resistance.

10.See generally, M. Mellon and J. Rissler, Perils Amidst the Promise: The Ecological Risks of Transgenic Crops on a Global Market (Washington: Union of Concerned Scientists, 1993). See also R. Goldburg, J. Rissler, H. Shand, and C. Hassebrook, Biotechnology's Bitter Harvest: Herbicide-Tolerant Crops and the Threat to Sustainable Agriculture (Washington: Environmental Defense Fund, National Wildlife Federation, Rural Advancement Fund International, and Centre for Rural Affairs (Biotechnology Working Group, March 1990).

11.Standing Committee on Agriculture, rbST in Canada (Ottawa: House of Commons, 1994) esp. Recommendation 7.