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Comments on Effects and Fate Information Requirements Regarding Biotechnology Products under the Proposed Canadian Environmental Protection Act Biotechnology Regulation

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I. Introduction

The following discussion is based on the background materials provided by Environment Canada and CIELAP's existing work on the environmental regulation of biotechnology applications. These comments are preliminary in nature and are open to further discussion. Furthermore, Environment Canada and Health and Welfare Canada are reminded that a number of serious issues related to this proposed regulation, particularly regarding access to information and decision-making processes, have been raised. These matters have yet to be addressed by Environment Canada and Health and Welfare Canada.

II. General Approach to the Environmental Regulation of Biotechnology Products

It has been suggested by some sectors that Canada should seek to harmonize its approach to biotechnology regulation with that of other nations, particularly the United States. The Biotechnology

Caucus is strongly of the view that the Canadian regulatory system for biotechnology applications must be designed and implemented in a manner which Canadians believe serves their public interest. In particular, the system must ensure the protection of human health and well-being, and the integrity of the natural environment. Furthermore, in order to be credible and legitimate, the system must be transparent and open to public input. Consistency with other jurisdictions should be a secondary consideration.

In addition, with respect to the question of the harmonization of Canadian approaches with those of the United States, it should be kept in mind that the U.S. approach is out of step with that of most other OECD nations. This is especially true in Western Europe, where the European Community has adopted a process, as opposed to product, based approach to biotechnology regulation. The possibility of alterations in the U.S. approach resulting from the change in administration must also be considered.

III. The Applicability of Effects and Fate Testing Information Requirements

The assessment of the environmental effects of biotechnology products is complicated by the consideration that unlike chemicals, the products of biotechnology are often living creatures. As such they can reproduce and multiply (Ecological Society, Smit et. al.). Indeed, in some cases biotechnology products must spread and multiply to work (Alexander).

As a result, consideration must be given to the potential of organisms to survive and even multiply over time. As Alexander points out, this implies that even when the initial release is small, a large number of organisms may ultimately find their way into the environment. Consequently, environmental effects and fate must be taken into account where deliberate, incidental or accidental releases into the environment are possible. Potential exposure pathways of this type are described in some detail by Alexander in the cases of bioremediation, biomass conversion, waste treatment, fuel conversion, mineral leaching, ore mining, oil recovery and coal scrubbing.

Effects vs. Fate Testing

It has been suggested that, following USEPA proposals, a tiering approach be employed in the application of effects and fate information requirements. This would distinguish between the short-term effects of an introduced organism and its longer term fate. Fate information would only be required if "effects" were in evidence.

This approach suffers from a number of problems. The foregoing discussion regarding the survivability of organisms indicates that fates must be considered when attempting to determine long-term environmental effects. The comments of the Ecological Society regarding the possibility of delayed effects (p.305) should be noted as well. Past experiences with other substances suggest that

the possibility of such effects must be given serious consideration.

These factors lead to the conclusion that the distinction between short-term "effects" and long-term "fates" is not an appropriate approach to the structuring of effects and fate information requirements. The short- and long-term consequences of the introduction of an organism into the environment must be given attention. As Alexander concludes, exposure and hazard assessments must be considered together.

Furthermore, when considering the scope of the information needed to assess environmental effects and fate, attention must be given to the possibility of the survival of heterologous genetic elements independently of the organism through which they were originally introduced (Ecological Society, Smit et. al.). Therefore, effects and fate information must include not only the effects and fates of the genetically modified organisms themselves, but also of the heterologous elements introduced through them which might be transferred to other organisms. In the course of the consultation Prof. Dubow has stressed this point on a number of occasions.

IV. The Parameters of Effects and Fate and Information Requirements

There appear to be four broad categories of potential effects of introduced organisms or their genes.

1) **Harm to non-target species** (Ecological Society, Alexander)

2) **Disruption of existing biotic communities** (Ecological Society, Alexander)

3) **Adverse Effects on Ecosystem Process and Functioning** (Ecological Society, Alexander) Possible examples include effects on primary production of algae, cycling of limiting nutrients (i.e. N and P) or turnover of organic matter (Alexander p. 4).

4) **Other Possible Negative Effects.** This category could include the incomplete degradation of hazardous chemicals by GEMS used for bioremediation or waste treatment, leading to worse by-products than the original chemicals (Ecological Society). Alexander also notes possible effects arising from the use of genetically modified organisms for mineral leaching from mine tailings or in ore mining itself.

In developing effects and fate information requirements it is important to note the limitations of techniques which focus on effects on single species ("rarely good indicators of hazards" - Alexander) or effects on the biotic community (Alexander pp. 3-4). This indicates that a comprehensive body of effects and fate information, including all of the categories outlined above, should be required in all cases. Alexander suggests a need for a particular focus on ecosystem-level functions (Alexander p. 4).

The problems raised by the Ecological Society (p. 305) regarding the extrapolation of laboratory experiences to predict behaviour in real environments must be taken into account both in the establishment of information requirements and the interpretation of the data received. The Ecological Society's concerns (pg. 306) regarding the extrapolation of experiences with the behaviour of an unmodified species in its native environment to a modified species in a non-native environment as a predictive tool deserve serious attention as well.

V. Implications for Regulatory Design

All of the background materials which addressed the question of the drafting of regulatory language emphasized the need for a case by case approach, and the use of broad language in the drafting of information requirements (Ecological Society, NIH, Alexander, Smit et. al.). This reflects the need for flexibility to include new information and developments in fate and effects testing. This could include both the addition of new requirements and the dropping of requirements which prove unhelpful in determining ecological effects.

This approach should be reflected in the drafting of the legal language of the regulation. The language should be broad and general in nature. The NIH "Points to Consider" document may provide a starting point in this regard, although it would need to have additions to cover the types of effects in category **4 Other**

Effects (toxics production or enhancement, metal mine drainage, etc. outlined by Alexander). Mr. Mausberg of the Biotechnology Caucus has provided an outline of a fairly comprehensive set of considerations in his submission to the Field Testing Data Task Force of the Consultation Group. A residual clause permitting Environment Canada and Health and Welfare Canada to require "any other effects and fate information deemed necessary to assess the toxicity of the organism in question" should also be included in the regulation.

More specific testing requirements, if they can be developed, should be included in the guidelines to accompany the regulations, where they can be modified more readily on the basis of new information. A wide range of specific parameters regarding ecological effects are suggested by Smit et. al. (p. 272) and Seidler (pg. 152). At this stage, a broad range should be employed until there are some indications of those which are most useful, and those which are of little assistance. This is especially true in light of Alexander's conclusions regarding the existing knowledge base. New parameters, beyond the suggested lists must also be considered if they have the potential to provide useful information. The best language to use in the guideline may be of a "may include, but not limited to, the following parameters" character.

VI. Wider Issues Raised by Fate and Effects Testing Considerations

The problems of continuing uncertainty and the of existence major knowledge gaps in effects and fate testing information and techniques raise a number of important issues beyond their immediate technical aspects. In the absence of a complete body of information, the exercise of a degree of judgement, both in determinations of "toxicity," and ultimately, in the determination of terms and conditions of use if a substance is determined to be toxic, is inevitable.

In this context, it is critical to the credibility of the regulatory process that the assumptions which underlie these decisions be made explicit, and be subject to some public discussion. The environmental community is strongly of the view that the precautionary principle must be central in these decisions. Openness in terms of the available information base regarding effects and fate, and transparency in decision-making regarding "toxicity," will also be critical.

Regarding the broader question of the imposition of terms and conditions on the use of substances deemed to be "toxic," the distributional nature of questions of this type must be recognized, and appropriate decision-making processes put in place. In particular, in order to be legitimate and credible, the decision-making process must be open to, and accessible by, members of the public in terms of both its design and actual operation.

The current consultation provides a welcome first step in this regard. However, the "technical" discussions presently before the consultation group need to be placed in a wider policy context in order to be meaningful. A forum should be provided in which the assumptions and values which underlie the government's policy approach to biotechnology development and regulation can be examined and discussed in a substantive way. This is an necessity if the regulatory system proposed by Environment Canada and Health and Welfare Canada is to be credible and legitimate.

References

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