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Report on the July Consultations Regarding the CEPA New Substances Notification Regulations for Biotechnology Products

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and Health and Welfare Canada

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1. Introduction

The Biotechnology Caucus welcomes the efforts made by Environment Canada and Health and Welfare Canada to include ENGOs in the consultations on the New Substances Notification Regulation under the Canadian Environmental Protection Act (CEPA). The purpose of this report is to clarify a number of issues raised at the July consultation session and to identify the remaining concerns of the environmental group representatives.

The report is divided into five sections. Section I outlines specific actions which we request that the federal agencies undertake prior to the next consultation in early 1994. Section II contains questions and queries related to the proposed regulations which require clarifications and responses from the federal government. Section III lists a number of recommendations which we believe will improve the regulations. Section IV requests follow-up responses to issues raised by the environmental community in earlier submissions regarding the proposed regulations. Section V provides a commentary on the likely economic impact of the proposed regulations.

We ask that Environment Canada and Health and Welfare Canada respond to our requested actions, and questions and recommendations at their earliest convenience.

SECTION I: REQUESTED ACTIONS

(1) DECISION-MAKING PROCESS

During the consultation it became clear that a flow-chart and description of the full notification decision-making process is required. This should span the period from a proponent's first contact with Environment Canada/Health and Welfare Canada to the DSL listing, the imposition of terms and conditions on use, or the establishment of a Board of Review. The flow-chart should include all the decision points, the points at which notices will appear in the Canada Gazette, and the opportunities for public input and comment into the decision-making process.

Requested Action:

Please prepare a detailed flow-chart of the notification decision-making process and make it available prior to the next consultation.

(2) CRITERIA FOR DECLARING BIOTECHNOLOGY PRODUCTS "TOXIC"

The information requirements outlined in the proposed regulation will be used to

determine whether a particular application or use of a biotechnology product is toxic or not. However, the information in and of itself will not be sufficient to determine toxicity. Federal officials have indicated that criteria are being developed to establish "toxicity."

Requested Action:

Please make available the draft toxicity determination criteria, and the draft decision-making path for applying the criteria, to consultation stakeholders at least two months prior to the next consultation.

(3) DSL UNDER DEVELOPMENT

The *Canada Gazette*, Part 1, published on June 13, 1992, indicated that the federal government is currently developing a DSL for biotechnology products. This DSL will contain biotechnology products if manufacturers or importers can provide satisfactory evidence indicating that specific products were in commerce in Canada within the time-frame specified in CEPA.

Requested Action:

Please make available the draft DSL for biotechnology products and the associated report prepared by the consultant. If the draft DSL cannot be made available, please provide information regarding the number of items, and types of products, it is likely to contain.

SECTION II: QUESTIONS AND QUERIES

(1) PUBLICLY AVAILABLE INFORMATION

During the July consultations, it was unclear which information items will be made available to the public. Environment Canada indicated that summaries of information submitted in support of DSL listing applications will be made available to the public upon request.

Questions:

What information will the summaries contain? How will requests for additional information be dealt with? In particular, on what basis will information be declared confidential business information?

(2) CEPA AND PERMITS

With regard to field-tests of biotechnology products, questions have been raised regarding whether or not permits for field-tests would be required.

Questions:

Please clarify whether or not permits will be required to conduct field-tests of biotechnology products. What statutory tools would be used to set the terms and conditions of field tests? Also, what would be the legal status of the tests? In particular, for liability purposes, would they be considered to be "statutorily authorized" under CEPA?

(3) APPLICATION OF 'SAME HABITAT' SCHEDULE (XVIII)

We agree with the definition of same habitat as one "where the microorganisms is known to occur naturally." Given that the latest version of the regulation does not contain the term "genetically modified," it is unclear whether or not the "same habitat" Schedule applies to genetically modified organisms.

Question:

Please clarify whether or not Schedule XVII can ever be applied to microorganisms which have been genetically modified?

(4) INTERIM MEASURES

Question:

Given that the regulation is unlikely to come into force for more than a year, what interim measures are Environment Canada and Health and Welfare Canada applying to oversee environmental releases of biotechnology products?

SECTION III: RECOMMENDATIONS

(1) RISK ASSESSMENT AND RISK-BENEFIT ANALYSIS

Environmental standard setting processes occur through two distinct phases:

(a) the technical question of determining or assessing the threats posed to

environmental quality, to human health and animal health, by particular events, activities or situations; and

(b) the determination of the acceptability of those risks to the affected parties.

The first stage of this process is complicated by the consideration that scientists are often asked to make determinations of risk or hazard on the basis of incomplete information (this will be especially true in the case of the environmental effects of biotechnology products). As a consequence, scientists are frequently required to employ their judgement in making such decisions. As a result, the values, interests or beliefs of the researchers may be, consciously or unconsciously, reflected in their conclusions.

The second component of the standard setting process is even more complex, as the issue of what constitutes an acceptable level of risk relates to the appropriate distribution of risk, costs, and benefits in society. Traditional risk assessment models attempt to address this question through risk-benefit analysis. However, this approach suffers from a number of serious limitations. Indeed, it fails to acknowledge the political and moral character of these decisions at all, attempting to deal with them as technical questions amenable to scientific resolution. This is a fundamental flaw which fails to recognize the epistemological distinction between values and facts. In other words, the risk-benefit model attempts to use science to resolve political and moral questions, something which science itself insists it cannot do. Furthermore, traditional risk-benefit models have tended to ignore or underplay the significance of negative environmental and social externalities, and have ignored the question of the fairness of the distribution of a given set of risks and benefits within society altogether.

These considerations make it essential that the assumptions which will underlie the determination of the level of hazard posed by biotechnology products be subject to discussion and debate among the stakeholders.

Recommendations:

The actual criteria, once developed, must be applied in a manner which is open and accountable. Determinations of what constitutes acceptable levels and distributions of risk within society must be made through procedurally just consultative processes which involve all of the affected stakeholders. If the public is to bear the environmental and human health risks resulting from the employment of biotechnology products, then it must have a voice in the determination of the acceptability of those risks.

(2) NOTIFICATION OF LOCAL RESIDENTS AND/OR AUTHORITIES

Related to the issues of risk-assessment and the legal authority to permit field-tests, are the rights of local residents. Given the above discussions, citizens have a right to be informed of the risks to which they will be exposed.

Recommendations:

Federal officials or the proponent should notify local residents and authorities prior to field-tests, and prior to an application of a biotechnology product. Environment Canada and Health and Welfare Canada should make a clear policy statement in this regard. In addition, federal authorities should develop mechanisms to respond to objections by local residents and/or authorities to the field-tests or open-environment applications. A fair process should be developed to deal with cases where local residents or authorities object to a field-test or application.

(3) ASSESSMENT PERIODS

The assessment periods have been reduced from previous drafts of the regulation (s. 24). Given the level of uncertainty regarding the interpretation of environmental effects data, are these time-lines sufficient? In addition, do they provide sufficient time for members of the public to prepare and submit comments on the substances in question?

Industry representatives asked that if federal officials complete an assessment before the end of the assessment period, the decision should be released immediately. This would obviously significantly effect the ability of members of the public to make comments, and the proposal therefore should be rejected.

Recommendations:

(a) The assessment periods should be lengthened in light of the scientific uncertainty in assessing the toxicity of biotechnology products.

(b) If federal agencies have completed an assessment prior to the assigned assessment period, a minimum comment public period of 90 days should still be provided.

(4) CONFINEMENT

As the regulation is currently written, the category of "confinement" could be interpreted as "limited" or "incidental" release. Thus, information requirements should

reflect that biotechnology products in this category are likely to be released into the environment, albeit "incidentally."

Recommendation:

Schedule XV (confined uses) should be dropped from the regulation. Biotechnology applications falling into this category should be placed under the requirements of Schedule XIV.

(5) ENCLOSED USES

Schedule XVI outlines information requirements for enclosed uses of biotechnology products and Section 20 requires contingency plans. However, designing meaningful contingency plans will require some knowledge of the likely environmental fate and effects of the microorganism. However, this consideration is not directly reflected in Schedule XVI. The same considerations apply to Schedule XX ("contained" uses).

Recommendations:

The sections of the "Enclosed" (XVI, s. 20) and "Contained" (XX, s. 6) use schedules related to contingency plans should reflect the need for some fate and effects information to develop contingency plans in the event of accidental release. This could include:

* any known involvement of the microorganism in adverse environmental effects; and

* possible effects of the microorganism on target and non-target substances including:

    (a) infectivity, toxicity and pathogenicity on non-target organisms;

    (b) degradation or other modifications of the structural integrity of target and non-target substances; and

    (c) effects on ecosystem functions.

(6) APPLICATION OF SCHEDULE XVIII (USED IN U.S. FOR FIVE YEARS)

It is unclear whether or not federal officials can require Canadian proponents using U.S. biotechnology products to gather further information on their environmental

effects.

Recommendations:

The application of this schedule should be made conditional on the existence of the necessary data, particularly regarding environmental effects. A requirement for monitoring data on ecosystem structure and function effects should also be added. If an organism is placed under this schedule and the necessary information is not available from the U.S., it should be made possible for the federal departments to require further information from the proponent, or to reassign the biotechnology product to a different schedule.

(7) CLARIFICATION OF DECISION-MAKING AUTHORITY

The proposed regulation does not clearly indicate where the authority lies to make determinations regarding under which schedule a given biotechnology product will fall.

Recommendation:

The proposed regulation should clearly establish that the decision to assign a biotechnology product to a particular regulatory schedule resides with the appropriate officials of Environment Canada and/or Health and Welfare Canada.

SECTION IV: FOLLOW-UP ON PREVIOUS RECOMMENDATIONS REQUIRING FORMAL RESPONSE FROM THE GOVERNMENT OF CANADA

(1) ADDITIONAL INFORMATION

In previous submissions, the ENGO representatives have argued for insertion of 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." Federal officials responded that section 20 of the various schedules covers this item. However, the wording of this section 20 is not strong enough because the current wording does not require proponents to gather information or undertake their own tests. In addition, it will be difficult to prove that the proponent "ought reasonably to have access" to relevant data.

Recommendation:

Environment Canada and Health and Welfare Canada should include the following as section 25 of the regulation:

"25. 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."

(2) NATIONAL BIOTECHNOLOGY RELEASE INVENTORY

Recommendation:

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."

(3) MONITORING

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:

(a) 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.

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

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

(4) MECHANISMS TO FACILITATE PUBLIC INPUT

Recommendation:

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

SECTION V: THE ECONOMIC IMPACT OF REGULATORY REQUIREMENTS ON THE BIOREMEDIATION INDUSTRY

As a result of the CCME and provincial processes regarding contaminated sites, the market for remediation services is likely to be very strong in the next few years. Indeed, suppliers of effective and safe techniques will be well placed to set prices to cover their costs, including regulatory costs, and recover substantial profits. In this context, regulatory costs related to the proposed regulation are unlikely to have a major impact on the long-term well-being of the bioremediation sector. Furthermore, it should be remembered that lower regulatory standards will impose higher risks on the public at large for the benefit of the bioremediation sector and its investors. This would be unfair and unacceptable.