CANADA: BUILDING A REGULATORY FRAMEWORK

Canada has not yet arrived at a national policy to guide the deliberate release of genetically engineered organisms (GEOs) into the environment. The federal Departments of Environment, Agriculture, and National Health and Welfare are responsible for protecting human health and the environment from any negative effects of such release. These departments are presently assessing the adequacies of current regulations and of the data requirements and approval procedures to govern deliberate release of GEOs.

The only regulatory tool specifically aimed at biohazards of biotechnology is the "Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells" (Medical Research Council, 1980, 3rd edition), designed for small-scale laboratory work. The risks posed by deliberate release exceed the scope of these guidelines.

The U.S. has distinguished GEOs as potentially more dangerous than naturally occurring organisms[1]. Canada, on the other hand, might opt for a pre-release assessment system for organisms with altered genetic material, regardless of how these changes arose. Organisms with foreign DNA might receive special scrutiny because of a higher level of uncertainty[2]. Canada's existing environmental regulations developed from concern over nuclear and chemical technologies; they must now be evaluated for their suitability for controlling organisms that can reproduce, mutate, exchange material with other organisms, and migrate. The risks involved may be conjectural, but, as the Committee on Science and Technology of the U.S. House of Representatives stated, "while there is only a small possibility that damage could occur, the damage that could occur is great."[3] Canada has not decided how to deal with such risks.

The fact that the federal and provincial governments share the responsibility for protection of the environment and human health complicate regulation of biotechnology in Canada. Because released organisms have the capacity to migrate across borders—both provincial and national—the federal government may play a larger role in regulating biological contaminants than it has with chemical contaminants. An effective regulatory process must be a cooperative one between the two levels of government.

Major Federal legislation that could be used to regulate deliberate release of GEOs includes the Pest Control Products Act (PCP Act), the Canada Seeds Act, and the Environmental Contaminants Act (EC Act). The PCP Act, administered by the Minister of Agriculture, provides a good management base for biotechnologically-engineered biological control products. It requires evaluation of products prior to commercialization. The Act regulates "any product, device, organism, substance, or thing that is manufactured, represented, sold, or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting, or repelling any pest." Pests are broadly defined as "any injurious, noxious, or troublesome insect, fungus, bacterial organism, virus, weed, rodent, or other plant or animal pest and includes any injurious, noxious, or troublesome organic function of a plant or animal." This Act has been interpreted broadly to apply to biotechnology products such as ice minus bacteria, as well as microbial pesticides.

The applicant is responsible for proving the safety of any product intended for use or sale in Canada and for discussing detailed data requirements with officials of the Health Protection Branch of Health and Welfare Canada which advises the Pesticides Division of Agriculture Canada concerning possible hazards. Testing varies from product to product, but generally includes hierarchical tier studies to assess persistence, infectivity, toxicity, and irritation. Such criteria would seem to apply equally to naturally-occurring and genetically-manipulated organisms. Since biotechnology takes advantage of genetic manipulation and exchange, however, additional assessment may be needed to consider the genetic stability, capacity for genetic exchange, and the potential for inadvertent introduction of new material.

Agriculture Canada is reviewing its legislation to determine if changes are necessary; it is approving applications for biological pesticides on a case-by-case basis. The Department of Agriculture should soon release a memorandum concerning the data requirements generally required from manufacturers.

The PCP Act requires only changes in data requirements to accommodate GEOs; however, the environmental release of GEOs which are *not* biological control agents is poorly addressed by current legislation. The Canada Seeds Act and Regulations, for example, sets standards for seeds in terms of commercially desirable properties, rather than on an ecological basis. While licensing would require assurances that the seed is safe, field testing of new seed—provided the seed is developed in Canada—can occur without informing Agriculture Canada. Ecological criteria and control over field testing need to be added to either this Act or a new one to accommodate advances in biotechnology[4].

The EC Act, jointly administered by Environment and National Health and Welfare, also has severe limitations for regulation of deliberate release of GEOs. The EC Act aims "to protect human health and the environment from substances that contaminate the environment." This Act entitles the federal government to establish the maximum quantity or concentration of a substance released into the environment by any commer-

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cial, manufacturing, or processing activity, and to forbid import, manufacture, processing, use or sale of substances the government specifies. The EC Act, however, has no provision for testing prior to such use and applies only to chemical—not biological—substances. The burden of proof of hazard is on the government, a difficult burden with the current predictive capabilities of ecology. The EC Act now applies to biotechnology only insofar as biotechnology produces chemical hazards in the environment. This statute is under review. Amendments might allow the Act to apply to environmental release of GEOs.

The Federal Interdepartmental Committee on Biotechnology established the Working Group on Safety and Regulations in Biotechnology (WG) in February 1985. Cochaired by Environment and National Health and Welfare, the WG is mandated to identify and assess the adequacy of existing laws applicable to biotechnology and to recommend appropriate actions to fill gaps. The WG has initiated a review of federal and provincial regulatory policies that may be applicable to the safe use of biotechnology. The WG is also examining the approaches that other countries have taken to manage potential hazards of biotechnology.

Identification of the adequacy of current legislation is only a first step in the definition and implementation of what regulation *ought* to be. This will ultimately depend on increased knowledge of hazards from release, on development of improved risk assessment and control techniques, and on an appreciation of what implementations are feasible. The goal is to limit risk to acceptable levels while fostering enjoyment of the many beneficial opportunities of biotechnology in Canada.

REFERENCES

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