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# THE REGULATION OF AGRICULTURAL BIOTECHNOLOGY IN CANADA

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**November 1999**

CIELAP Shelf:  
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The Regulation of Agricultural Biotechnology in Canada

RN 27125

*Advancing the Environmental Agenda*

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**Printed in Canada.**

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**ISBN: 1-896588-40-9**

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## **BACKGROUND**

Founded in 1970, The Canadian Institute for Environmental Law and Policy (CIELAP) is a not-for-profit environmental research and education organization. CIELAP is incorporated under the laws of the Province of Ontario and registered with Revenue Canada as a charity.

CIELAP has been involved in biotechnology issues for over 15 years. In 1984, CIELAP organized the first conference in Canada on environmental issues regarding biotechnology. Since then, CIELAP has participated in many workshops and consultations with health, environmental, and public interest organizations, industry and government concerning the regulation of biotechnology. In particular, the Institute has a long history of involvement with the biotechnology provisions in the *Canadian Environmental Protection Act (CEPA)* and actively participated in the recent CEPA review process.

The Institute has produced a number of publications and briefs regarding biotechnology. These include Enabling Biotechnology?, an overview study of environmental, social, economic and ethical issues related to biotechnology, and the Citizen's Guide to Biotechnology.

CIELAP has also recently been expanding its work on biotechnology into the international arena. The Institute, for example, has been actively participating in negotiations regarding the development of an international Biosafety Protocol under the United Nations Biodiversity Convention.

## **EXECUTIVE SUMMARY**

Genetically engineered (GE) agricultural products pose significant environmental, health and social risks, and also raise serious ethical questions. These risks include:

- threats to biological diversity;
- possible adverse health implications; and
- threats to environmentally and socially sustainable farming practices.

Over 160 nations recognized these risks in signing *The United Nations Convention on Biological Diversity*, which stipulates that all countries must establish an effective means to protect the environment and public health from the potential adverse impacts of genetic engineering.

Although Canada showed leadership in signing this convention, it has since failed to live up to its international promises. Canada has no comprehensive legislation addressing the environmental and health risks of biotechnology. Instead, the products

of biotechnology are regulated under a patchwork of existing statutes, many of which do not and were not intended to safeguard the environment and human health. Moreover, the one piece of legislation which did explicitly address the environmental and health aspects of biotechnology, the *Canadian Environmental Protection Act*, has just been significantly weakened.

The federal government's framework for the regulation of biotechnology has, therefore, been criticized by many environmental, agricultural, labour, public health, social justice and animal welfare organizations. These organizations have identified several significant problems with the regulatory framework, including the fact that it:

- is based on a poor institutional design, where promoters of biotechnology are also in charge of regulating genetically modified products;
- has an inadequate legislative basis;
- is based on questionable science;
- does not provide opportunities for public input in decision-making; and
- contains significant gaps for genetically modified products, such as fish and animals, and the environmental aspects of food.

The Canadian government's regulatory priority is clearly to create a strong, innovative and competitive biotechnology industry. The government does not appear to want to risk slowing down the development of this technology by subjecting GE products to extensive, long-term health and environmental testing prior their introduction. The commercialization of GE agricultural products in Canada is moving ahead, while the development of an effective environmental and health safeguards lags behind.

In order to fulfil its international commitment and protect public health and the environment, the government must strengthen Canada's biotechnology regulatory framework. Specifically, a revised regulatory system must provide for:

- full and independent environmental and health reviews of products before they enter the Canadian marketplace;
- clear separation of regulatory and promotional functions between government agencies;
- public participation and accountability in decision-making;
- investments in independent research and monitoring for potential and actual ecological and health effects; and
- mandatory labelling of GE foods in the Canadian marketplace.

Until these regulatory issues are fully addressed, Canadians cannot be confident that our health and the environment are adequately protected from the risks of agricultural biotechnology.

## INTRODUCTION

Biotechnology provides a powerful means to modify existing agricultural plants and animals. Proponents of agricultural biotechnology insist that it will bring a broad range of benefits to society, such as healthier, more abundant produce and crops that require fewer chemical inputs.

However, modern agricultural biotechnology also presents unprecedented potential risks to human health and the environment, raises serious ethical questions, and may have significant international implications. Creating laws and policies that adequately address these issues is, therefore, one of the most challenging regulatory tasks facing governments today.

The environmental and health risks associated with biotechnology were explicitly recognized in the 1992 *United Nations Convention on Biological Diversity (CBD)*, an international convention signed by over 160 nations, which is designed to protect the broad range of living organisms and ecosystems which sustain our planet.<sup>1</sup> Specifically, article 8(g) of this convention stipulates that each contracting party must:

Establish or maintain a means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.<sup>2</sup>

The Canadian Government was in the forefront in the development of the CBD and was the first industrialized nation to sign and ratify this convention. However, the government has failed to fulfil its international promise to control the environmental and health risks of biotechnology. It appears to have placed a desire to build a competitive biotechnology industry ahead of the public need for an effective regulatory framework that ensures environmental and health protection. Early warning signs show that this regulatory approach may be endangering both ecosystem and public health.

The following paper reviews and critiques Canada's biotechnology regulatory framework, focusing on the regulation of the products of agricultural biotechnology. Section one of this study outlines the major environmental and health issues regarding

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<sup>1</sup> *United Nations Convention on Biological Diversity*, June 1992, Can. T.S. 1993, No. 24

<sup>2</sup> *United Nations Convention on Biological Diversity*, June 1992, Article 8(g).

agricultural biotechnology. It also discusses some of the international implications of the commercialization of genetically modified crops and briefly reviews several ethical questions relating to biotechnology.

The second section provides an overview of the evolution of Canada's regulatory framework for biotechnology and a critique of Canada's current regulatory approach. Section three makes suggestions for improving Canada's biotechnology regulations.

## **THE DEFINITION OF BIOTECHNOLOGY**

There is no universally accepted definition of biotechnology, but essentially any process in which biology is used to make a product is called biotechnology.<sup>3</sup> *The Canadian Environmental Protection Act (CEPA)* defines biotechnology as:

the application of science and engineering in the direct use of living organisms or parts or products of living organisms in their natural or modified forms.

This definition covers a wide range of processes, from fermentation to the latest reproduction methods, such as cloning and genetic engineering. Biotechnology may, therefore, be broken down into two categories for clarification: traditional biotechnology and modern biotechnology.

Examples of traditional biotechnology include plant cultivation, animal husbandry, and the selective breeding of plants and animals. In these processes, "human intervention appears as the manipulation of processes that are otherwise occurring in nature routinely".<sup>4</sup>

Modern biotechnology is, however, quite distinctive from traditional techniques as it entails inter-species transfer, a process which does not occur spontaneously or frequently in nature. Specifically, modern biotechnology involves recombinant-DNA technology (rDNA - also known as genetic engineering) which is "the process of artificially moving genes among unrelated organisms, across normally impenetrable species barriers, which specifically excludes conventional plant breeding or genetic

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<sup>3</sup> Paul Muldoon and Burkhard Mausberg, "The Regulation of Biotechnology", in *Environment on Trial*, 3rd. edition, eds. Estrin and Swaigen, Toronto: Emond Montgomery Publications Limited, 1993. p. 237.

<sup>4</sup> Dr. William Leiss, "Biotechnology in Canada Today: Not more regulation, but more credible regulation", a presentation to the House of Commons Standing Committee on Environment and Sustainable Development, June 1996, p. 12

improvement within a species".<sup>5</sup>

## **SECTION 1: CONCERNS ABOUT MODERN BIOTECHNOLOGY**

### **1.1 Environmental Concerns**

Identifying the potential environmental risks posed by genetically engineered (GE) crops is a major challenge for scientists. Different GE crops may present different environmental risks, depending on a wide variety of factors including the characteristics of the GE crops and the location in which they are planted. Margaret Mellon and Jane Rissler from the Union of Concerned Scientists have outlined two of the most significant and well-understood categories of environmental risk in The Ecological risks of Engineered Crops.<sup>6</sup> These are: 1) risks related to GE plants themselves, and 2) risks associated with the movement of transgenes (foreign genes spliced into plants) into other plants.<sup>7</sup> Both of these categories are explored below.

#### *Environmental Risks of GE Plants*

Genetic engineers have specific goals in mind when they splice transgenes into plants, such as enabling a plant to ripen faster or to survive in harsh climates. In addition to these expected effects, though, a new gene may alter the characteristics of a plant in other, less predictable ways.

An example of this phenomenon occurred in the United States' Mississippi Delta in the summer of 1997 when farmers experienced serious problems with Monsanto's Round-up Ready cotton. This cotton was genetically engineered to resist the pesticide company's best-selling weed killer, Roundup. However, approximately 30,000 acres which had been sown with these GE crops failed to produce cotton bolls or produced bolls that were deformed, reducing yield by nearly 40%.<sup>8</sup>

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<sup>5</sup> Ann Clark, Environmental Risks of Genetic Engineering. Presented to the NAEC workshop: Factoring in the Environment for Decisions on Biotechnology in Agricultural Production, July 1998.

<sup>6</sup> Jane Rissler and Margaret Mellon, The Ecological Risks of Engineered Crops, Cambridge, MA: The MIT Press, 1996.

<sup>7</sup> For a more detailed discussion of these categories, see *ibid* and also J. Rissler and M. Mellon, Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market, Union of Concerned Scientists, December 1993.

<sup>8</sup> Myerson, Allen R. "Seeds of discontent: cotton growers say strain cuts yields", in New York Times, Nov. 1997. Several farmers who planted the cotton asked the Mississippi Seed Arbitration Council to cover their losses. This Council ruled that Monsanto's product failed to



Another unintentional outcome of genetic modification is the possibility that transgenes may enhance a crop's capacity to become a weed; that is, to persist unwanted in a field or pasture, or invade a wild habitat.<sup>9</sup> This risk is particularly problematic because, according to Ann Clark, Professor of Plant Agriculture at the University of Guelph in Canada, "The potential for a GE entity...to become invasive cannot be predicted without targeted study."<sup>10</sup>

Once a GE organism becomes a weed, other problems relating to weediness may arise, including ecosystem disturbances. A simple example of a GE organism's potential to disrupt an ecosystem is described below:

...genetic engineering's potential to ultimately alter community structure might begin with transgenic salt-tolerant rice planted near coastal wetlands. It is conceivable that the rice could invade the salt-water ecosystems, displacing native salt-tolerant species. As the native populations declined, other organisms typically associated with them - algae, microorganisms, insects, other arthropods, amphibians, birds might not be compatible with the invading rice. Different organisms, new to the salt-water marsh, might find homes in the new rice-dominated ecosystem.<sup>11</sup>

Some transgenic crops may also pose problems to non-target species. Plants genetically modified to resist certain insects or pests may, for instance, result in harm to beneficial organisms that feed off these plants. Several recent studies point to troubling and unexpected effects of GE insect-resistant crops on beneficial insects:

- Scientists at Cornell University in the United States have discovered that GE

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perform as advertised and recommended payments of nearly \$2 million to three cotton farmers who suffered severe losses.

<sup>9</sup> See, for example, M. Crawley, "The ecology of genetically engineered organisms: assessing the environmental risks. In Introduction of Genetically Modified Organisms Into the Environment, ed. Mooney and Bernardi, NY: John Wiley and Sons, 1990, pp. 133-50. Also, M. Williamson, "Environmental risks from the release of genetically modified organisms - the need for molecular ecology", in Molecular Ecology, vol. 1, pp. 3-8.

<sup>10</sup> Ann Clark, "Risks of Genetic Engineering in Agriculture", adapted from a speech to the annual meeting of the National Farmers Union, Nov. 1997, URL: <http://www.oac.uoguelph.ca/www.CRSC/faculty/eac/risks.htm>.

<sup>11</sup> J. Rissler and M. Mellon, supra endnote 7.

corn crops may threaten the survival of the monarch butterfly. In laboratory studies, these scientists mimicked the natural process of pollen from one plant dispersing onto the leaves of nearby plants. They powdered milkweed plants, the exclusive food upon which monarch larvae feed, with pollen from GE corn which had been modified to exude a natural pesticide, bacillus thuringiensis (Bt), to kill corn-boring caterpillars. The scientists studied the growth and survival of monarch butterfly larvae that fed on the GE powdered milkweed leaves and found that 56% died, while none of the larvae fed on leaves powdered with natural corn pollen died.<sup>12</sup>

- Scientists at the Scottish Crop Research Institute found that ladybird beetles (ladybugs) which fed on aphids reared on transgenic potatoes experienced reproductive problems and failed to live as long as ladybugs fed aphids from ordinary potatoes. The potatoes were engineered to produce insecticidal lectins, which are proteins from the snowdrop plant that bind to the surface of insect cells causing the cells to stop functioning.<sup>13</sup>
- Swiss scientists from the Federal Research Station for Agroecology and Agriculture found similar results in their studies of green lacewing insects, which play a critical role in maintaining the equilibrium of insect populations. These researchers found that the mortality rate of lacewing larvae increased significantly after eating corn borers reared on GE corn.<sup>14</sup>

None of these studies have been extended to field situations, so it is unclear whether the laboratory results will reflect what might happen in nature. However, if field results do show similar effects, use of GE crops may have serious implications for biological diversity.

In addition to the possibility that some GE crops may become weeds or endanger non-target organisms, farmers may also have to deal with some less direct impacts of GE crops; mainly, changes to their farm management practices. For instance, transgenic crops containing bacillus thuringiensis, may have a deleterious impact on the efficacy of Bt, a relatively safe biological insecticide. Bt is a naturally-occurring soil organism that kills many kinds of insect pests that eat the leaves of crops. It is, therefore, often used

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<sup>12</sup> See Losey, John E. Raynor, Linda S. Carter, and Maureen E., "Transgenic pollen harms monarch larvae", in *Nature*, May 20 1999, pp. 399-214; and "Altered Corn Called Threat to Butterfly", in *The Toronto Star*, May 20, 1999, p. A16.

<sup>13</sup> The Physicians and Scientists for the Responsible Application of Science and Technology, "Genetically Engineered Crops May Threaten Beneficial Insects", Aug. 31, 1998, <http://www.psrast.org/insects.htm>

<sup>14</sup> Ibid.

in low-chemical use farming and organic farming. Monsanto has, however, taken the Bt gene and engineered it into cotton, corn and potatoes, so that these crops will produce the toxin as they grow.<sup>15</sup> Scientific studies show reason for concern that widespread use of crops containing Bt could accelerate the development of insect pest resistance to Bt, rendering this natural insecticide useless.<sup>16</sup> The loss of Bt's effectiveness would cause serious problems for farmers, particularly organic farmers who have relied on this natural pesticide for decades.

GE crops could also increase farmers' dependency on herbicides and pesticides. Many of the GE crops that have recently been commercialized (corn, soybean, cotton and potato) are herbicide tolerant plants. These plants are designed to withstand lethal doses of specific weed and pest sprays which are often produced by the companies that are selling the GE plant seeds. As a result, farmers can apply broad-spectrum, non-selective herbicides several times throughout a season, rather than just once during pre-planting. For example, Monsanto is selling a line of "Roundup Ready" products that has been genetically engineered to withstand heavy doses of Monsanto's herbicide, "Roundup".<sup>17</sup> While these GE crops may provide a financial boon for some agrochemical companies by increasing the sale of pesticides and herbicides, they may also harm the environment and human health by promoting the increased use of toxic chemicals which will ultimately end up on harvested crops and in ground water.

#### *Risk of Gene Flow to Other Plants*

Another major category of risk associated with large-scale releases of GE crops is that the transgenes in these crops may be transferred, by wind, water or other natural means, to other wild plants which may then become weeds (known as 'gene transfer' or 'outcrossing'). As Professor Joy Bergelson from the University of Chicago explains, "Crops engineered to contain genes that give them resistance to pests or the ability to produce lots of seeds, could pass these genes to their weedier cousins, producing hybrid strains of superweeds."<sup>18</sup>

These 'superweeds' would present risks similar to those posed by the transgenic crops themselves. For example, if corn (which is a grass) crossed with timothy grass, an abundant weed, resulting in a weedy, pest-resistant hybrid, it could outcompete beneficial plants for water and nutrients upsetting ecosystem structure and function.

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<sup>15</sup> Rachel's Environment and Health Weekly, "Against the Grain", February 11, 1999.

<sup>16</sup> Ann Clark, "Debunking the Myths of Genetic Engineering in Field Crops", March 1999, URL: <http://www.oac.uoguelph.ca/www/CRSC/faculty/eac/myths.htm>

<sup>17</sup> Rachel's Environment and Health Weekly, "Against the Grain", February 11, 1999.

<sup>18</sup> "Engineered Plants May Spread Genes to Weeds", in *Nature (U.K.)*, September, 1998.

Evidence summarized in the New Scientist in 1997 showed that genetically modified traits can readily move into adjoining populations.<sup>19</sup> For example, research has demonstrated the ease of trait transfer from oilseed rape (canola) into a wild weedy relative.<sup>20</sup> Also, studies of transgenic oilseed rape and wild radish have demonstrated potential for rapid spread of herbicide resistance into wild populations.<sup>21</sup>

Proponents of biotechnology argue that the risk of outcrossing is negligible because there are no known weedy or naturalized relatives of the crops which are currently being modified.<sup>22</sup> This argument has some validity, because the majority of crops grown in North America and, hence, their wild, weedy ancestors, evolved elsewhere (for example, beans, potatoes, and cotton evolved in South America).<sup>23</sup>

But, despite the fact that most crops did evolve elsewhere, many of the wild or weedy relatives for important crops now exist in North America. Moreover, the risk of outcrossing will increase as the variety of crops being genetically modified continues to expand. Ecological geneticist Norm Ellestrand from the University of California predicts that outcrossing "...will probably happen in far less than 1% of [GE] products, but within ten years we will have a moderate-to-large scale ecological or economic catastrophe, because there will be so many [GE] products being released."<sup>24</sup>

Furthermore, industrialized countries that are developing and exporting GE crops must recognize the global risks involved. As Professor Clark explains, "the risk of outcrossing is amplified, with potentially devastating repercussions for germplasm

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<sup>19</sup> Gledhill, M. and P. McGrath, "Call for a Spin Doctor", in New Scientist, November 1997.

<sup>20</sup> Thomas R. Mikkelsen, Anderson and Jorgensen. "The risk of crop transgene spread", in Nature, vol. 380, March 7, 1996.

<sup>21</sup> Chevre et al., in Nature, 1997.

<sup>22</sup> See Canadian decision documents authorizing commercial release of genetically engineered field crop cultivars. For example:

Decision Document DD96009

Determination of Environmental Safety of Event 176 Bt Corn (*Zea mays* L.) developed by Ciba Seeds and Mycogen Corporation: "The biology of corn...indicates that there are no wild relatives in Canada that can freely hybridize with *Zea mays* L....AAFC therefore concludes that gene flow from Event 176 to corn relatives is not possible in Canada."

<sup>23</sup> Ann Clark, supra endnote 9.

<sup>24</sup> As quoted in James Kling, "Could Transgenic Supercrops One Day Breed Superweeds?", in Science, vol. 274, October 11, 1996, pp. 180-181.

conservation, when transgenic crops are grown in developing countries, where most food crops evolved."<sup>25</sup> Selling GE crops, like corn and alfalfa, in the regions from which they evolved could affect the survival of wild, weedy ancestors, whose genes are needed for agricultural production around the world. According to the Union of Concerned Scientists, "these plants are the genetic basis of the world's future food supply. They are the source of new genes that plant breeders and genetic engineers use to adapt crops to changing environmental conditions."<sup>26</sup>

## 1.2 Health Concerns

Proponents of biotechnology maintain that GE crops are not substantively different from conventional food products and that they should, therefore, be regulated in the same manner. Several recent scientific studies suggest, however, that a more precautionary approach to regulating GE crops may be necessary as these crops may pose unique and substantial health risks.

In February 1999, for example, the first evidence of the potential for GE food to cause health damage emerged. Dr. Arpad Pusztai, an internationally respected senior scientist at the Rowett Research Institute in Scotland, presented evidence that rats fed with GE potatoes modified to express snowdrop lectin experienced shunted growth, damaged immune systems, and damage to several major organs. In contrast, unmodified potatoes had a much milder effect on the rats. From this evidence, Pusztai tentatively attributed the adverse responses to the transgenes in the GE potatoes.<sup>27</sup>

Dr. Stanley Ewen, a consulting histopathologist at the University of Aberdeen Medical School, furthered Pusztai's studies and found even more disturbing results. Ewen found that the adverse health effects from the GE potatoes may not have come from the lectin transgenes, but from the promoter genes (derived from cauliflower mosaic virus, CaMV) which were used to drive the expression of the transgene within the GE potatoes. The CaMV promoter has been widely used in making GE tomatoes, corn and soybean cultivars which are already in the marketplace.<sup>28</sup>

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<sup>25</sup> Ann Clark, *supra* endnote 9.

<sup>26</sup> Rissler and Mellon, *supra* endnote 7, p. 69.

<sup>27</sup> Rachel's Environment and Health Weekly, "Biotech: The Pendulum Swings Back", May 6, 1999, no. 649, p. 2. Pusztai's results sparked a storm of criticism from proponents of GE and Pusztai was forced to resign from the Institute. He was, however, exonerated when an international group of 22 scientists attacked the behaviour of the institute and re-affirmed the scientific soundness of Pusztai's conclusions.

<sup>28</sup> Ann Clark, "Genetic Engineering in Field Crops: Ethics and Academia", Presented to the Annual Meeting of the Saskatchewan Institute of Agrologists, April 1999,

### *New Allergens in the Food Supply*

Genetically modified crops could bring new allergens into foods that sensitive individuals would not know to avoid, unless these foods were appropriately labelled. Empirical evidence regarding the generation of allergenic foods through GE is limited, since few of these foods have been thoroughly tested for allergenicity.<sup>29</sup>

However, one example has already surfaced which demonstrates that the transfer of allergens through genetic modification is, in fact, possible. Pioneer Hybrid developed soybeans with nutritionally balanced amino acid composition by genetically engineering the beans' DNA to contain the gene for a brazil nut storage protein. Scientists discovered, though, that soybeans set off a strong, potentially deadly, allergic reaction in people sensitive to Brazil nuts.<sup>30</sup> Pioneer Hybrid therefore decided to terminate plans to commercialize this product.

### *Antibiotic Resistance*

Another health concern about some GE crops, such as corn used for animal fodder, is that these crops may include a gene for antibiotic resistance that could create antibiotic resistant pathogens. Antibiotic resistance genes are used to track the uptake of modified genes in GE crops. Some scientists fear that these antibiotic resistance genes could move into microorganisms in the guts of livestock, creating antibiotic resistant pathogens.

Proponents of GE have argued that there is no risk of this happening because modified genetic material breaks down so quickly. However, recent Dutch research casts doubt on these assurances. Studies conducted by Robert Havenaar and his colleagues at the TNO Nutrition and Food Research Institute in the Netherlands showed that DNA can, in fact, linger in the intestine. Thus, they concluded that it may be possible for genetically modified bacteria to transfer their antibiotic resistance genes to bacteria in the gut.<sup>31</sup>

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<http://www.oac.uoguelph.ca/www/CRSC/faculty/eac/ethics.htm>

<sup>29</sup> John Fagan, "Safety Concerns About Allergenicity", <http://www.psrast.org/jflabel.htm>, p. 6.

<sup>30</sup> Julie Norlee et al., "Identification of a Brazil Nut Allergen in Transgenic Soybeans", New England Journal of Medicine, March 14, 1996.

<sup>31</sup> Debora Mackenzie, "Gut Reaction", <http://www.newscientist.com>. See also, "Doubts Raised on Genetically Altered Food", in Globe and Mail, January 27, 1999.

### 1.3 International Implications

Multinational biotechnology companies are rapidly developing GE agricultural products for international markets. They maintain that these products will help to address food shortages in developing countries. Monsanto, for instance, suggests that biotechnology can contribute to higher productivity and efficiency on the farm, thereby increasing food supply and helping to solve the world hunger crisis.<sup>32</sup>

The suggestion that GE crops can alleviate world hunger by increasing food production is, however, quite problematic. As the Union of Concerned Scientists explains, there are many complex reasons for food shortages, including lack of income to buy food, trade and land-use policies that disadvantage farmers in the developing world, and lack of appropriate inputs such as fertilizer.<sup>33</sup> GE crops may do little to alleviate hunger until these political and economic problems are addressed.<sup>34</sup> In fact, GE crops may actually worsen the plight of third world farmers, not only due to their environmental implications, but for other reasons as well.

#### *High Cost of GE Crops*

Many critics of GE argue that genetically modified products are unlikely to benefit resource-poor farmers because these products are too expensive. Biotechnology companies need to sell their products at premium prices in order to cover their high research and development costs.<sup>35</sup> Hybrid seeds typically cost three times as much as traditional seeds and patented GE seeds can cost up to five times more than regular seeds.<sup>36</sup> Moreover, new genetically engineered seeds often require high-quality soils, large investments in machinery and fertilizer, and increased use of chemicals and water.<sup>37</sup> In short, "these products are of virtually no value to hungry farmers...who cannot afford the products of traditional technology, much less these expensive

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<sup>32</sup> See, for example, Monsanto's advertising campaign, "Let the Harvest Begin".

<sup>33</sup> Union of Concerned Scientists, "Biotechnology and the World Food Supply", <http://www.ucsus.org/agriculture/index.html>

<sup>34</sup> Ibid.

<sup>35</sup> Ibid.

<sup>36</sup> Personal communications with Brewster Kneen, Executive Director of Ram's Horn, June 25, 1999.

<sup>37</sup> Rachel's Environment and Health Weekly, "Against the Grain", February 11, 1999, <http://www.rachel.org>

genetically engineered products."<sup>38</sup>

These costs may also be compounded by patent fees. Many biotechnology companies place patents on GE products which prohibit farmers and other individuals from using these products unless they pay royalties. Agracetus Inc. (a subsidiary of W.R. Grace and Co.), for instance, received a patent for genetically engineered cotton that will give the company monopoly control over all transgenic cotton plants and seeds until the year 2008.<sup>39</sup> This patent gives Agracetus the right to decide when and if it chooses to license its technology and under what conditions. Cotton is a self-pollinating crop and farmers in many parts of the world save seeds from their harvest to re-plant. Under industrial patent law, however, it will be illegal for farmers to save seeds from transgenic cotton plants without payment of royalties to the patent owner. The company has similar patent applications pending in countries such as Brazil, China and India.<sup>40</sup>

Premium prices, technology fees and royalties may make GE crops too expensive for small, resource-poor farmers. Moreover, these crops may be impractical for small farmers in developing countries. Critics of GE argue that if these crops were meant to feed the hungry, they would have special characteristics to help poorer farmers, such as the ability to grow on marginal soil, or to produce more high-quality protein, with increased yields and without expensive inputs.<sup>41</sup> However, the two leading applications of GE crops in North America, herbicide tolerance and pest resistance, are simply not relevant to the challenges facing the world's food supply, particularly in the developing south.<sup>42</sup>

Instead, most of the GE products in development are intended to mainly serve large farming operations in developed countries and wealthy producers in less developed regions. Monsanto, for example, recently announced that it will spend \$550 million in Brazil to build a factory to produce Roundup pesticide for use in Roundup Ready soybeans. It is unlikely that this factory will benefit the poor, though, as "most rural Brazilians are subsistence farmers who do not grow soybeans", but will only serve wealthy farmers serving export markets.<sup>43</sup>

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<sup>38</sup> Union of Concerned Scientists, *supra* endnote 34.

<sup>39</sup> U.S. Patent No. 5,159,135, October 27, 1992.

<sup>40</sup> RAFI Communique, "Control of Cotton: The Patenting of Transgenic Cotton", July/August 1993, <http://www.rafi.org/communique/19934.html>

<sup>41</sup> *Supra* endnote 35.

<sup>42</sup> Mark Winfield, "Agricultural Biotechnology and Sustainable Development", CIELAP, notes for presentation, June 1997.

<sup>43</sup> As noted in Ann Clark, "Debunking the Myths of Genetic Engineering in Field Crops",



### *Control Over the Agricultural Sector*

Another issue which arises from the development and sale of GE agricultural products is the biotechnology industry's growing control over farmers and the food production process. Many small and medium-sized farming operations are concerned that biotechnology will further centralize power over agricultural production into the hands of a few large multinational companies. They worry that as agricultural biotechnology companies develop interlinked products, such as herbicides and herbicide tolerant seeds, farmers will become dependent on their products, increasing the ability of these companies to gain control over the food production process.<sup>44</sup>

Control over production is, in fact, the goal of many biotechnology companies. As the Vice-President of the American biotechnology company, Calgene, once stated:

Our objective is to control production with our partners from the production of foundation seed to the sale of the oil to our customers. We want complete control...The way you capture value added is selling oil -- value-added oil at a premium to customers, period. So we and our partners will maintain complete control of the process."<sup>45</sup>

Consolidation of the agricultural biotechnology industry is happening at a rapid rate. DuPont, for example, one of America's leading producers of chemical pesticides, has recently announced its purchase of Pioneer HiBred, the world's largest seed company.<sup>46</sup> The two companies have had a long-standing joint venture in the production of GE grains. Monsanto has also been rapidly taking over seed companies. The company has, in fact, paid over \$8 billion in the past four years to buy companies such as Delta and Pine Land, and Holden Seeds, putting it in command of roughly 80% of American cotton-seed production.<sup>47</sup>

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URL: <http://www.oac.uoguelph.ca/www/CRSC/faculty/eac/myths.htm>

<sup>44</sup> "In the Mill", in The Economist, pp. 64-65, March 20th, 1999.

<sup>45</sup> Manitoba Cooperator, March 23, 1993, in B. Kneen, From Land to Mouth, p. 140.

<sup>46</sup> The Economist, supra endnote 45.

<sup>47</sup> Ibid.

### *Threats to Traditional Agricultural Practices*

GE products may not only be unaffordable and impractical for many poorer farmers in developing countries, but they may also threaten traditions on the farm. This is the case with a new seed product created by the United States Department of Agriculture and Pine Land Company. This product is deemed "terminator technology" by its opponents as its purpose is to kill off the second generation of plants by rendering seeds sterile after one planting. Terminator technology thus obliges farmers to buy more seed on a yearly basis, rather than saving seed for re-planting.

However, GE seed designed to prevent farmers from saving seed could have adverse implications for resource poor farmers in developing countries. Pat Mooney of the Rural Advancement Foundation International (RAFI) explains that, "If they [poorer farmers] can't save seed and do plant breeding to adapt the seed to their own growing conditions, then they can't be farmers. They can't afford to buy seed every year."<sup>48</sup> Up to 1.4 billion resource poor farmers in the South depend on farm-saved seed and seeds exchanged with farm neighbours as their primary seed source.<sup>49</sup> Mooney argues that "A technology that threatens to restrict farmer expertise in selecting seed and developing locally adopted strains is a threat to food security and agricultural biodiversity, especially for the poor."<sup>50</sup>

Moreover, terminator technology may endanger other crops through outcrossing. Pollen from Terminator Technology can move substantial distances away from a GE field, inadvertently fertilizing plants in neighbouring fields and rendering their seeds sterile.<sup>51</sup> Ann Clark notes that "with 80% of crops in the developing world sown from farmer-saved seed, genetic pollution from Terminator-enhanced fields could exacerbate, rather than reduce, world food deficits."<sup>52</sup>

Concerns about the potential social and economic implications of Terminator Technology recently prompted Monsanto's Chairman and CEO, Robert Shapiro, to make a public commitment to not, at present, commercialize sterile seed technologies, such as the Terminator.<sup>53</sup> Shapiro stated that Monsanto "...will not make any decision

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<sup>48</sup> Pat Mooney, as quoted in "Genetic Engineering Threatens Traditions on the Farm", Globe and Mail, November 16, 1998, p. A13.

<sup>49</sup> Pat Mooney, "The Terminator Technology", in RAFI Communique, March/April 1998.

<sup>50</sup> Ibid.

<sup>51</sup> Ibid.

<sup>52</sup> Ann Clark, *supra* endnote 28, p. 6.

<sup>53</sup> Robert Shapiro, "Open Letter From Monsanto CEO Robert B. Shapiro to Rockefeller

to commercialize a gene protection technology until a full airing of the issues is complete and we have responded publicly to the concerns that are raised."<sup>54</sup>

#### **1.4 Social and Ethical Issues**

Genetic engineering raises many significant ethical concerns and questions. These issues cannot be explored in detail within the scope of this paper, but following is a brief overview of some these issues.

A major area of ethical concern regarding GE is the impact that this technology may have on the health and welfare of animals. For some people, plants and animals are seen as utilitarian objects that can be legitimately modified and manipulated for human purposes. For others, though, plants and animals are culturally and/or religiously significant beings evoking respect. These individuals see the manipulation of the genetic material of other species as a violation of species integrity and the laws of nature. They thus fundamentally object to many applications of modern biotechnology.

Genetic engineering also raises serious ethical concerns about the patenting of living organisms. In 1980, the United States Supreme Court granted the first patent on a life form.<sup>55</sup> Since then, patents have been granted on plant and animal strains, as well as on individual genes. For some people, though, the patenting of life is unethical. As one critic noted, "I never imagined that people would patent plants and animals. It's fundamentally immoral...[and] violates the integrity of life itself, and our deepest sense of morality."<sup>56</sup>

Patenting life forms also raises questions regarding intellectual property rights. Genetic material, such as plants used in traditional society for medicinal purposes, are now being collected from indigenous peoples by multinational biotechnology companies. This activity raises many complex issues, such as how and if consent to

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Foundation President Gordon Conway", October 4, 1999.

<sup>54</sup> Ibid.

<sup>55</sup> Clark, *supra* endnote 40, p. 7.

<sup>56</sup> Isidro Acosta, President of the Guaymi General Congress, as quoted in The Citizen's Guide to Biotechnology, CIELAP, p. 37.

use these materials should be obtained, who owns such material and knowledge, and if and how indigenous societies should receive royalties from any GE products discovered in this way.<sup>57</sup>

Several other ethical questions often raised concerning modern biotechnology include:

- Who owns genetic information? Is ownership of genetic material a right? What are the implications of this kind of ownership?
- Do we need genetically altered food?
- Should animals be used in genetic experimentation?
- When a plant receives an animal gene, should vegetarians be informed?
- Do we want private companies, like insurance companies, to have access to genetic information?
- Who will pay for failed technology? Who is responsible for potential adverse environmental or health reactions?

Although these questions are difficult to answer, open discussion of the ethical issues regarding genetic engineering should be encouraged and supported by governments. Until recently, however, ethical concerns were ignored by governments in both Canada and the United States. This behaviour contrasts sharply with the approach taken by a number of Western European governments, which have facilitated societal debates around these issues, and demonstrated a willingness to act on the results of such decisions.<sup>58</sup>

## **SECTION 2.0: CANADA'S REGULATORY FRAMEWORK FOR BIOTECHNOLOGY**

### **2.1 The History of Federal Biotechnology Regulations**

The commercialization of modern biotechnology began in Canada, in earnest, in the early 1980's when the Canadian government facilitated research and development to

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<sup>57</sup> Maureen Press-Merkur and Mark Winfield, "Enabling Biotechnology? An analysis of the report of the Biotechnology Council of Ontario", CIELAP, 1995.

<sup>58</sup> Mark Winfield, *supra* endnote 42, p. 2. A Canadian Biotechnology Advisory Committee (CBAC) was established on September 27, 1999, "to provide advice to a Coordinating Committee of federal Ministers on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology." In fulfilling its mandate, the CBAC is to raise public awareness and engage Canadians in an open dialogue on all aspects of biotechnology.

build a biotechnology industry.<sup>59</sup> In 1983, the National Biotechnology Strategy (NBS) was introduced by the Ministry of State for Science and Technology. Under the NBS, the National Biotechnology Advisory Committee was formed to advise the minister of state for science and technology on issues related to the subject. The NBS focused mostly on the economic development aspects of biotechnology, rather than on the development of regulations for the industry. The government deemed biotechnology "a national priority for economic development" and \$11.9 million per annum in government funding was allocated to the NBS to foster the industrial development of this technology.<sup>60</sup>

While the industry grew steadily, regulatory concerns began to surface. The government recognized that a regulatory framework would be an essential component of the NBS in order to meet standards for safety and to send a signal of confidence to the market. As a result, in 1986 the government commissioned a report, "Coordinated Study on Government Processes in the Safety and Regulation of Modern Biotechnology," to review existing federal and provincial statutes which could be used to regulate biotechnology products.

The government formally addressed the issue of biotechnology regulation with the development of the *Canadian Environmental Protection Act* (CEPA) in 1988, which is legislation aimed at protecting human health and ecosystems. During consultations on the draft bill, environmentalists called for a new biotechnology statute or a specific biotechnology part in the Act to provide an overall legislative framework for GE products.<sup>61</sup> However, the government decided that biotechnology would be regulated through existing law, administered mostly by the federal departments of agriculture and health. CEPA would only empower Environment Canada to regulate products of biotechnology not regulated under other legislation. It would, though, give Environment Canada the legislative authority to set minimum standards for notice and assessment of all products of biotechnology.<sup>62</sup>

Under the original CEPA, products of biotechnology were specifically included in Part II, and could be assessed as new substances in much the same way as chemicals are assessed. CEPA's provisions prevented new biotechnology products from being manufactured in, or imported into Canada until the federal government had an opportunity to assess them. Specifically, section 26 of CEPA stated that notice be

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<sup>59</sup> Envision Research, Socioethical Implications of Biotechnology, March 1997, p. 10.

<sup>60</sup> *ibid.*

<sup>61</sup> Muldoon and Mausberg, *supra* endnote 3, p. 244.

<sup>62</sup> Canadian Environmental Protection Act, section 26(3)(a).

given to EC and HC prior to the import, manufacture, sale or use of a new substance and that it be assessed for whether the substance is capable of becoming "toxic" as defined for the purposes of CEPA.<sup>63</sup>

Conditions or prohibitions on the import, manufacture, use or sale of a new substance could be imposed by the Ministers of Environment and Health on substances "suspected of being toxic", but prohibitions were limited to under two years.<sup>64</sup> If a new substance was found to be toxic, its import, manufacture, sale or use could be regulated or prohibited under section 34 of the Act.

One of the most important aspects of the original CEPA was that it ensured that all new substances were subject to pre-manufacturing, import or sale notification and assessment of "toxicity". Under section 26 (3) (a), however, new substances, including biotechnology products, could be exempt from the requirements of CEPA if they met CEPA's minimum requirements:

Section 26 does not apply if (a) a substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given prior to the manufacture, import or sale of the substance and for an assessment of whether it is toxic.<sup>65</sup>

In other words, if genetically modified products were regulated under another act of Parliament that provided for a regulatory assessment similar to that in CEPA, then CEPA would not apply. CEPA thus served to ensure that a common minimum standard of review was used in all biotechnology assessments.

In December 1990, the government of Canada released its "Green Plan", which outlined its environmental agenda. In this plan, the government committed itself to a national regulatory regime to address the environmental risks of biotechnology. This system was to be in place by 1995. It was to include national standards and codes of practice to prevent problems arising from accidental or deliberate releases of

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<sup>63</sup> According to s.11 of CEPA, a substance is considered "toxic" for the purposes of the Act if "it is entering or may enter the environment in a quantity or concentration or under conditions

a) having or that may have an immediate or long-term harmful effect on the environment;  
b) constituting or may constitute a danger to the environment on which human life depends; or  
c) constituting or may constitute a danger in Canada to human life or health."

<sup>64</sup> *Canadian Environmental Protection Act*, RSC 1985, s. 29.

<sup>65</sup> *Canadian Environmental Protection Act*, RSC 1985, s. 26 (3) (a).

genetically engineered microorganisms. The government also promised to develop regulations to operationalize the *Canadian Environmental Protection Act* provisions requiring that Environment Canada and Health Canada be notified of any new biotechnology products before they are introduced to the market or released in the environment.<sup>66</sup>

In 1993, the federal government announced the following basic principles for Canada's Regulatory Framework for Biotechnology:

1. maintaining Canada's high standards for the protection of human health and the environment;
2. building on existing legislation and institutions, clarifying jurisdictional responsibilities, and avoiding duplication;
3. developing guidelines, standards, codes of practice and monitoring capabilities for pre-release assessment of the risks associated with release to the environment;
4. developing a sound scientific data base upon which risk assessments and evaluation of products can be made;
5. promoting development and enforcement of Canadian regulations in an open and consultative manner, in harmony with national priorities and international approaches; and
6. fostering a favourable climate for development of sustainable Canadian biotechnology products and processes.<sup>67</sup>

The government indicated that the decision to use existing legislation and institutions to implement the framework built upon long-standing expertise within the federal government in specific product areas and would speed up the regulatory process. This decision meant that GE products would be regulated in the same way as traditional products. Only the direct environmental and health risks of GE products would be investigated; assessments of the broader long-term social, economic, and ethical implications of these products would not be required. Moreover, no new legislation or departments would be created to specifically regulate the products of modern biotechnology.

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<sup>66</sup> Environment Canada, "Canada's Green Plan for a Healthy Environment, (Ottawa: Supply and Services, 1990), p. 50.

<sup>67</sup> Government of Canada, "Federal Government Agrees on New Regulatory Framework for Biotechnology", New Release, Ottawa, January 1993, p. 1.

Since its development, the 1993 Regulatory Framework has faced strong criticism from environmental and other public interest groups, and Committees of the House of Commons. These criticisms are highlighted in several House of Commons Committee reports. In April 1994, for example, the Standing Committee on Agriculture and Agri-Food report on the proposed use of genetically engineered bovine growth hormone (BGH, a protein hormone designed to bolster milk production in cows), recommended, among other things, that,

...the federal government make provision for assessing the possible socio-economic and environmental effects of biotechnology that might affect human or animal health, or the environment.<sup>68</sup>

The government response, however, rejected the notion of assessing socio-economic effects stating that,

The standard procedure in Canada and other industrialized countries is to regulate products based on scientific principles...Once safety and effectiveness have been reviewed, it is the marketplace in Canada which then decides on the market acceptance of the product, based on benefits such as price and individual values and preferences.<sup>69</sup>

## **2.2 The Federal Regulatory Framework for Agricultural Biotechnology**

### *Basic Principles of the Canadian Regulatory Framework*

The basic principles for regulating biotechnology in Canada are outlined in the 1993 Federal Regulatory Framework. This framework dictates that rather than creating new legislation for GE agricultural products, these products should be regulated by existing legislation and institutions. In other words, GE products should be treated the same as traditional agricultural products. As Dr. Brian Morrissey of Agriculture and Agri-Food Canada explains,

The legislation...does not categorise products based on the techniques used in their development. The safety and efficacy assessments are risk-based and apply to all products, regardless of the developmental method. It's for this reason that the Canadian regulatory system is said to regulate the product, not the process. As such, the existing regulatory

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<sup>68</sup> Report of the Standing Committee on Agriculture and Agri-Food, "rbST in Canada", April, 1994.

<sup>69</sup> Government Response to the Report of the Standing Committee on Agriculture and Agri-Food, "rbST in Canada", August, 1994.



structure...is equally applicable to the new regulation of new products, whether derived through new or traditional biotechnology.<sup>70</sup>

Legislative responsibility for genetically modified agricultural products thus falls to Health Canada, The Canadian Food Inspection Agency, and Environment Canada. Several other departments, including Industry Canada, also play minor roles in the regulation of biotechnology products.

#### *The Canadian Environmental Protection Act (CEPA)*

As described above, the CEPA is the only legislation where Parliament has spoken directly to the question of how products of biotechnology are to be regulated. Under the original Act, biotechnology products were explicitly included under the Act's provisions dealing with new substances. These provisions required that Environment Canada and Health Canada must be notified of any substance "new" to Canada, including products of biotechnology, and perform an evaluation of the potential "toxicity" of these substances, as defined by section 11 of the Act. The Act also provided authority to the Minister of the Environment to prohibit or impose controls on the manufacturing, import or use of new substances that are found to be "toxic" or are suspected of being "toxic".

Section 26(3)(a) of CEPA permitted new substances to be regulated under other Acts of Parliament, which are administered by agencies other than Environment Canada and Health Canada, provided that notification and an assessment of whether the substance was 'toxic' or capable of becoming 'toxic' took place under those statutes instead. In effect, the notification and assessment process which took place under other Acts of Parliament was required to be as stringent as that which would have taken place under CEPA.<sup>71</sup>

Bill C-32, which made significant changes to the original CEPA, was enacted in September 1999 and will be discussed in detail later in this paper.

#### *The Food and Drugs Act*

Health Canada (HC) has a major role in the regulation of GE food products under The *Food and Drugs Act (FDA)*. Under this Act, HC is responsible for setting food safety standards and undertaking food safety assessments. Prior to October 1999, a voluntary

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<sup>70</sup> Dr. Brian Morrissey, Agriculture and Agri-Food Canada, as quoted in the Report of the Standing Committee on Environment and Sustainable Development, Biotechnology Regulation in Canada - A Matter of Public Confidence, p. 7, May 1996.

<sup>71</sup> CEPA, sec. 26(3)(a).

procedure was used by HC for assessing the safety of "novel foods", which include genetically modified food products. Under this procedure, developers of GE foods could notify the Health Protection Branch of HC prior to the sale of the novel food, allowing for the Branch to review the information for each product voluntarily submitted.

Safety assessments of GE foods were carried out using information and criteria described in HC's *Guidelines for the Safety Assessment of Novel Foods Volume II: Genetically Modified Microorganisms and Plants (Guidelines)*. These guidelines set out the provisions for the pre-market notification and the information required on novel foods. It is important to note that HC's review was based solely on information supplied by the proponent of the product under review.

A key concept used in assessing the safety information of novel foods in the *Guidelines* is "substantial equivalence". According to the *Guidelines*, it is expected that once it can be established that a novel food is substantially equivalent to an existing food, no additional safety testing will be required. Substantial equivalence is determined by comparing molecular, compositional and nutritional data for the modified organism to those of its traditional counterpart. Volume I of the *Guidelines*, the *Preamble and Guidance Scheme for Notification*, adds that,

A determination of the need for notification of novel products will be conducted on a case-by-case basis, and will be based on the comparison of the novel substance to an analogous traditional food, where such exists. Notification may not be required if the modification to the product or process is not significant, or if a high degree of similarity to a traditional products exists. (vol i, pg. 4)

According to these guidelines, it appears that substantial equivalence may be used twice: first by the proponent to determine if notification is necessary, and second by HC, if the Health Protection Branch is notified, to assess safety.

Since 1994, HC has approved the use of 42 genetically modified food products using this voluntary procedure. Most of these products are crop plants, such as corn, canola, potatoes and soybeans that have been genetically modified to improve agronomic characteristics, such as crop yield, insect resistance and herbicide tolerance. Tomatoes that express delayed ripening characteristics have also been approved. A list of foods derived from genetic modifications that have been approved for sale by HC based on the *Guidelines* is provided in the appendices.

A regulation amending the Food and Drug Regulations was passed on October 6, 1999, formalizing the approach to health safety assessments of GE foods established under the *Guidelines*. According to this regulation, a "novel food" is defined (in part) as:

...a food that is derived from a plant, animal or microorganism that has been genetically modified such that

(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,

(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

Under this regulation, developers of novel foods are required to notify the Health Protection Branch prior to the sale or advertising for sale of a novel food. After receiving such notification, the Director of the Branch will review the information on the notification to determine if it will be necessary to assess the safety of the novel food. If a safety assessment is considered necessary, the Director will request that the proponent submit evidence to establish that the novel food is safe for consumption. Submission of such data prior to the request of the Director is at the discretion of the applicant.

Therefore, a manufacturer or importer may not need to conduct a safety assessment of the novel food prior to, or as part of the notification. Moreover, if such an assessment is required, it will be based solely on information provided by the proponent. In contrast to the laws of Europe, Australia and New Zealand, there is no provision in the regulation that explicitly allows HC to examine independently obtained information on the novel food under examination.

The federal government also proposed new regulations, the *Environmental Assessment Regulations*, in July 1999 that would make Health Canada responsible for the environmental review of new substances from biotechnology that are foods, drugs or cosmetics. Under the proposal, the approval process for new GE foods would be done by Health Canada under the FDA. According to the *Canada Gazette* notice of the proposed regulations, the environmental review would be administered by the Canadian Food Inspection Agency (CFIA).

#### *The Seeds, Feeds and Fertilizers Acts*

The Canadian Food Inspection Agency (CFIA) is a lead department in biotechnology, both in terms of product development and regulation. Prior to April 1, 1997, this responsibility fell to the regulatory branch of Agriculture Canada.

The CFIA regulates biotechnology under several Acts including the *Seeds Act*, the

*Fertilizers Act* and the *Feeds Act*. Before describing the regulatory process, it is necessary to point out that, unlike the CEPA, none of these Acts refer specifically to the products of biotechnology. The Acts merely provide the authority to make regulations regarding issues such as product quality and packaging (see Appendix A for details of Acts). The *Seeds Act*, for example, states that the Governor in Council may make regulations establishing grades and grade names for seeds, prescribing the terms and manner in which seed crops may be inspected, prescribing minimum standards for seed quality, and respecting the packing and labelling of seeds.<sup>72</sup>

In other words, the statutes under which agricultural biotechnology products are regulated contain no clear legislative authority for the evaluation of genetically engineered products from an environmental or human health perspective. It is only recently (1997) that regulations were passed describing how AAFC should conduct environmental reviews of agricultural products of biotechnology, this process is described below.

Under the current system, the products of biotechnology are regulated alongside similar products developed using traditional technologies. New crop varieties are assessed using a "safety-based" model (see Appendix B, Figures 1 and 2). The safety-based approach to regulation works in the following way. First, a pre-regulatory review is undertaken to determine if a risk assessment is required. If a new product is found to be "substantially equivalent" to a product already approved by the CFIA, then it will not require a risk assessment. Commodity-specific guidelines are in place to help determine if a novel product is substantially equivalent to those already approved.<sup>73</sup>

Crops that are not found to be "substantially equivalent" undergo a risk assessment process. If a novel plant is required to undergo a risk assessment, the applicant company would have to provide scientific data to prove that the new plant meets the following criteria:

- it is not more weedy,
- it will not pass genes conferring its new characteristics onto relatives that might become weedy,

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<sup>72</sup> The *Seeds Act*, section 4.

<sup>73</sup> According to an information bulletin from the CFIA, Regulating Agricultural Biotechnology in Canada: Environmental Questions, the determination of substantial equivalency is based on whether a product has a history of safe use in Canada, is similar to those products already approved for use in Canada, and whether the product was derived from a technique or process with a history of safe use in Canada. URL: <http://aceis.agr/fpi/agbiotech/geninfo.htm>.

- it will not display greater potential as a pest, and
- it will not show a negative impact on biodiversity.<sup>74</sup>

If these risks are determined to be non-existent, or may be mitigated with risk management strategies that control the product's usage and growing conditions, then the product is issued clearance for commercialization in Canada.

In sum, whether a new crop product has been developed using traditional breeding processes or through genetic engineering, the requirements for health and environmental safety are the same under the CFIA. Either the product is deemed substantially equivalent to a traditional product, or it must undergo a risk assessment in which the applicant is responsible for providing the scientific data to prove the product's safety. A list of the GE products approved by the CFIA is included in Appendix C).

#### *Labelling of Genetically Modified Agricultural Products*

In 1996, the government developed a set of guidelines for the labelling of GE foods. Despite calls for mandatory labelling of genetically altered foods from organizations across Canada and the general public<sup>75</sup>, the government decided not to require mandatory labelling of GE foods. Labelling of GE foods is required only if there are significant compositional or nutritional changes from the traditional food. Otherwise, it is left to the product developer to choose whether to declare that a food has, or has not been developed through biotechnology.

Responsibility for labelling is shared between Health Canada and the Canadian Food Inspection Agency. Health Canada is responsible for obligatory labelling related to health and safety issues. The CFIA is responsible for non-safety related labelling, such as voluntary labelling and labelling for protection against fraud.

On September 17, 1999, the Canadian Council of Grocery Distributors (CCGD) and the Canadian General Standards Board (CGSB) announced they are launching a project to develop a Canadian standard for the voluntary labelling of foods derived from biotechnology. Voluntary labelling by food companies is already permitted, provided that labels are true and not misleading. The CCGD and CGSB project will provide guidance for food companies and manufacturers who wish to voluntarily label their genetically modified foods.

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<sup>74</sup> AAFC, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. Regulatory Directive Dir94-08, December 16, 1994.

<sup>75</sup> See CIELAP, "Mandatory Labelling of Genetically Altered foods Urged By Groups from Across Canada", Press release, January 30, 1996.

On the international front, Canada (along with the United States, Brazil, New Zealand and Australia) has been lobbying against mandatory labelling in Codex Alimentarius Committee negotiations (the United Nations Committee responsible for suggesting international rules concerning food policy). These countries argue that labelling is unnecessary as GE foods are essentially the same as traditional foods, that labelling would be cumbersome and expensive, and that labels would unfairly stigmatize GE products.<sup>76</sup>

### **2.3 Problems with Canada's Regulatory Framework**

The federal Government's decision to use existing legislation and institutions to implement Canada's regulatory framework for biotechnology has received widespread criticism from both academia and non-governmental organisations. Following is an overview of several of the shortcomings of the current regulatory framework.

#### *Institutional Design Issues*

The clear and unambiguous separation of regulatory decision makers from the economic interests under their jurisdiction is fundamental to creating a credible regulatory system.<sup>77</sup> As Justice Krever explained during the Commission of Inquiry on the Blood System in Canada:

The relationship between a regulator and the regulated...must never become one in which the regulator loses sight of the principle that it regulates only in the public interest and not in the interest of the regulated.<sup>78</sup>

Contrary to the advice of Justice Krever, however, Canada's regulatory framework for biotechnology does not clearly separate regulatory and promotional functions. In fact, in some cases, the safety regulators for GE products are also responsible for promoting these products.

In the past, Agriculture Canada acted simultaneously as the lead developer, promoter and regulator of agricultural biotechnology products in Canada. The department's regulatory function was, however, recently passed to the Canadian Food Inspection Agency, in attempt to rectify this apparent conflict of interest and to enhance the

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<sup>76</sup> For details see, Physicians and Scientists for the Responsible Application of Science and Technology, <http://www.psrast.org/codex.htm>

<sup>77</sup> William Leiss, "Biotechnology in Canada Today: Not more regulation, but more credible regulation," a presentation to the House of Commons Standing Committee on Environment and Sustainable Development, June 11, 1996.

<sup>78</sup> Justice Krever, Commission of Inquiry on the Blood System in Canada, Vol. III, p. 995.

effectiveness and efficiency of the federal inspection process.

It is doubtful, though, that the conflict of interest problem has been solved. Although Agriculture Canada's regulatory function was passed to the Canadian Food Inspection Agency (CFIA), government documents show that "the CFIA includes what used to be the Food Production and Inspection Branch of AAFC."<sup>79</sup>

Moreover, the duties that have been consolidated into the CFIA are quite conflicting. Both the Act to create the Canadian Food Inspection Agency (CFIA) and the CFIA Business Plan suggest that regulatory duties have, in fact, been mixed with promotional functions. For example, the preamble of the act to establish the CFIA states that this agency is intended to contribute to "consumer protection" while also promoting "trade and commerce."<sup>80</sup>

The CFIA business plan also provides evidence of the Agency's mixed mandate. The stated mission of the CFIA is, for example, to both facilitate "market access" and to provide "safe food" and "consumer protection."<sup>81</sup> There is also a strong focus on enhancing service delivery to clients by providing them with the most "cost-efficient", "effective", and "streamlined" inspections.<sup>82</sup> Although the plan states that this service delivery must be done "without compromising food safety or animal and plant health", several critics have suggested that the Agency's regulatory duties have been overshadowed by its trade and commerce functions.<sup>83</sup>

The CFIA has recently been accused of abandoning its regulatory mandate and acting as an industrial promotional agency. A report by the Professional Institute of the Public Service of Canada claims that "the creation of the CFIA has been a failed experiment...

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<sup>79</sup> Office of Biotechnology, CFIA, Information Bulletin: Regulating Agricultural Biotechnology in Canada, An Overview, p. 2, 1998.

<sup>80</sup> *An Act to establish the Canadian Food Inspection Agency*, Chapter 6, Statutes of Canada, 1997.

<sup>81</sup> Canadian Food Inspection Agency, Corporate Business Plan, 1997-2000, p. 1, [www.cfia-acia.agr.ca/english/corpaffr/busplan97/chap1e.html](http://www.cfia-acia.agr.ca/english/corpaffr/busplan97/chap1e.html).

<sup>82</sup> *ibid*, p. 6.

<sup>83</sup> See, for example, the Canadian Health Coalition, "Who's Protecting Health and the Environment", [www.healthcoalition.ca/c32brief.html](http://www.healthcoalition.ca/c32brief.html).

Since its inception in 1997, the agency has totally abandoned its mandate."<sup>84</sup> Internal statements of complaint say that managers are listening more to industry than to their own staff. In effect, critics say that "it cannot be assumed that what is correct, 'based on science', is what the agency will do. First, one has to be sure there are no negative impacts on industry."<sup>85</sup> Ironically, the CFIA was created by the government in 1997 in order to address concerns over conflict of interest within Agriculture and Agri-Food Canada (AAFC), the department previously responsible for both the promotion and regulation of GE agricultural products.<sup>86</sup>

Ann Clark suggests that the government's "collegial relationship" with industry is also evident in the government's literature on GE.<sup>87</sup> She writes, "Indeed, government promotional literature on GE, such as the 1997 CFIA publication, *Biotechnology in Agriculture*, is distinguishable from that of industry only by the Canadian government logo on the front page."<sup>88</sup> While this book talks about the many benefits of biotechnology for the Canadian economy, Clark complains that "Not even a whisper of the numerous unanswered questions and potential risks to human health or the environment is revealed."<sup>89</sup> This uncritical promotion of genetic engineering is, in Clark's opinion, another illustration of the government abandoning its responsibility for oversight and instead acting as a proponent of industry.

#### *Inadequate Legal Basis*

There is continuing uncertainty about the scope of the legislative authority provided by statutes such as the *Seeds Act*, *the Feeds Act*, and *the Fertilizers Act*, under which departments like the CFIA regulate biotechnology products. As mentioned, CEPA is the only federal regulatory statute which explicitly establishes regulatory authority

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<sup>84</sup> Laura Eggertson, "Food Inspection Agency abandons job, vets say", in The Toronto Star, May 28, 1999.

<sup>85</sup> Ibid.

<sup>86</sup> Office of Biotechnology, CFIA, Information Bulletin...Regulating Agricultural Biotechnology in Canada: An Overview, p. 2, 1998. Perhaps part of the problem stems from the fact that the CFIA is merely a re-grouping of staff from AAFC who probably still have the same industry connections. As the government explains, "the CFIA includes what used to be the Food Production and Inspection Branch of Agriculture and Agri-Food Canada..."

<sup>87</sup> Ann Clark, supra endnote 29.

<sup>88</sup> Ibid. p. 3.

<sup>89</sup> Ibid.



regarding biotechnology. Many of the other statutes under which biotechnology products are regulated contain no clear authority for the evaluation of these products from a human health or environmental perspective.

The Canadian Institute for Environmental Law and Policy (CIELAP) undertook an examination of the legislative record in relation to these statutes and found that they were, in fact, drafted for the primary purpose of preventing fraud.<sup>90</sup> These statutes thus contain no authority enabling their administering departments to conduct health and environmental safety evaluations, leaving the government's regulatory framework vulnerable to legal challenge. CIELAP suggests that:

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 and by legal and constitutional scholars.<sup>91</sup>

The Canadian Institute for Environmental Law and Policy has identified a number of additional gaps in the legislative authority provided by statutes such as the *Seeds Act*, the *Feeds Act* and the *Fertilizers Act*. These include:

- the absence of provisions establishing legislative authority for the evaluation of the transboundary movement of biotechnology products (such a requirement has been called for in the proposed Biodiversity Convention Biosafety Protocol)
- the absence of provisions regarding civil liability for harm to the environmental or health by regulated products;
- weak enforcement and penalty structures in comparison to CEPA;
- the lack of provisions for public participation in decision making and only limited public access to information regarding new products; and,
- the absence of provisions establishing appellate bodies for appeals of decisions made under these Acts.<sup>92</sup>

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<sup>90</sup> 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*.

<sup>91</sup> CIELAP, *Supra* endnote 50, p. 72.

<sup>92</sup> Mark Winfield and Brewster Kneen, For Whose Future? A response to the proposals of the Government of Canada on the regulation of biotechnology under the CEPA, Prepared for the Canadian Environmental Network Biotechnology Caucus, March, 1996.

### *Substantial Equivalence*

The principle of substantial equivalence has become widely used for assessing the safety of GE products. This principle is, for example, applied in Canada, the United States and parts of Europe, although applications vary greatly by region.<sup>93</sup> According to the Organization for Economic Co-operation and Development's (OECD) 1993 report, Safety Evaluation of Foods Derived By Modern Biotechnology: Concepts and Principles, substantial equivalence allows for existing organisms used as food or a source of food to be used as the basis of comparison when assessing the safety of the human consumption of a food or food component that has been modified or is new.

This concept has, however, become widely contested among food safety experts who fear that regulating GE products on the basis that they *appear* to be substantially equivalent to their traditional counterparts carries great risk that harmful substances will pass undetected. For example, scientists from the 29 industrialized countries of the OECD concluded at a meeting in Paris in December 1998 that a new scientific approach to the safety testing of GM foods is necessary. In addition, a recent scientific study released in Nature concluded that "showing that a genetically modified food is chemically similar to its natural counterpart is not adequate evidence that it is safe for human consumption."<sup>94</sup>

The Physicians and Scientists for the Responsible Application of Science and Technology (PSRAST) also oppose the use of this principle on scientific grounds. They argue that "the 'substantial equivalence' procedure has no scientific basis and neglects important facts that call for rigorous testing...foods approved in this way are not safe to eat."<sup>95</sup>

Ann Clark also argues that the principle of substantial equivalence overlooks important characteristics of genetic engineering that differentiate GE products from conventional products. She says that, "Substantial equivalence, particularly as applied in Canada, is obscuring critically important distinctions between conventional and GE crops with the

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<sup>93</sup> Ibid.

<sup>94</sup> Erik Millstone, Eric Brunner, and Sue Mayer, "Beyond Substantial Equivalence", Nature, October 7, 1999.

<sup>95</sup> Physicians and Scientists for the Responsible Application of Science and Technology, "Substantial equivalence versus scientific food safety assessment: An 'at a glance' summary", <http://www.psrast.org/sueqow.htm>

clear intention of expediting commercialization."<sup>96</sup>

Clark outlines several reasons why GE crops are unique, including the facts that: a) many of the traits bred into GE crops are fundamentally different from those assessed through conventional breeding (such as herbicide-resistance and frost tolerance); and, b) a GE crop can have unexpected effects beyond the intended trait (as in the case of premature boll drop experienced by Mississippi cotton growers in 1997). She maintains that substantial equivalence only requires an investigation of surface similarities and that examinations of the unique characteristics of GE are, therefore, overlooked. As a result, in Clark's opinion, substantial equivalence "exposes both society and the environment to significant potential risks."<sup>97</sup>

Critics of substantial equivalence also note that this principle contrasts significantly with the assessment approach applied under the CEPA. CEPA regulations require that every new organism introduced into Canada be assessed on an individual basis. All new lines of microorganisms are, therefore, subject to separate notification. The principle of substantial equivalence, however, allows many new GE products to be exempt. As a result, substantial equivalence creates a perpetually expanding group of products which can be exempted from notification and assessment.

Due to the reliance on the principle of substantial equivalence, Canada's Novel Foods Regulation and Guidelines have been subject to extensive criticism. If these criticisms are valid, it is possible that Canada's current regulatory system does not provide for adequate safety testing of GE foods.

#### *Reliance of Industry Data/Lack of Independent Research*

Regulator's reliance on industry data to gauge the risk of GE crops and monitor the crops after approval has also been identified as a major concern. As Ann Clark notes, we must question the quality and objectivity of the risk assessments for GE crops when,

...all of the data used to make each assessment is provided by the proprietor of the GE entity, whose protocols, replication and analyses are not reported in the Decision Documents. The CFIA simply reviews and accepts the environmental risk data submitted by the manufacturer, while conducting no independent studies to check or verify the manufacturer's

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<sup>96</sup> Ann Clark, "The Faulty Assumptions of Field Crop Genetic Engineering", May 1999, <http://www.oac.uoguelph.ca/www/CRSC/faculty/eac/assumptions.htm>

<sup>97</sup> Ibid.

findings.<sup>98</sup>

Clark argues that the government should act now to avoid similar incidents by implementing a more rigorous and independent risk assessment process and an effective monitoring and tracking system for approved GE crops.<sup>99</sup>

The close relationship that the Canadian government has with the biotechnology industry has also led to a dearth of funding for independent, critical research into the ecological and health effects of GE. The state of science to assess ecological impacts continues to lag far behind the development of new products of biotechnology.<sup>100</sup> Roughly \$700 million is invested annually in GE by provincial and federal governments in Canada.<sup>101</sup> Moreover, in the February 1999 budget \$55 million of funding was added for the Biotechnology Strategy renewal process. None of this money is, however, specifically earmarked for the environmental and health risk assessments of GE products.<sup>102</sup>

The government has also been gradually withdrawing funding for agricultural research in colleges and universities.<sup>103</sup> In order to obtain the small amount of funding that is available, researchers are obligated to seek matching funds from industry.<sup>104</sup> For example, industry partnership is a condition of Canadian Agricultural Research Council funding. As a result, there is hardly any academic research taking place independent of industry support.<sup>105</sup> As a summary of findings from the Citizens Consensus Conference held in Calgary, Alberta in March 1999 noted: "Canadians sorely lack unbiased information about genetically altered food, even though these high technology products

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<sup>98</sup> Ann Clark, *supra* endnote 10.

<sup>99</sup> *Ibid.*

<sup>100</sup> Mark Winfield, *supra* endnote 39, p. 3.

<sup>101</sup> Roy Atkinson, Executive Director, Canadian Biotechnology Strategy Renewal Project, October 1997.

<sup>102</sup> Personal communications with Mark Winfield, June 1999.

<sup>103</sup> Ann Clark, *supra* endnote 29, p. 3.

<sup>104</sup> *Ibid.*

<sup>105</sup> *Ibid.*

are widely available on store shelves."<sup>106</sup>

In contrast to the Canadian situation, the government of the United States allocates one percent of the Department of Agriculture's budget for biotechnology to risk assessment.<sup>107</sup> Although this amount is meagre, it has enabled the production of some of the best critical research on GE in North America.

### *Gaps in Regulations*

Significant gaps remain in Canada's regulatory framework for biotechnology products. Although applications of genetic engineering to animals and fish are now approaching the commercialization stage, regulations to assess the potential environmental and health impacts of these applications have yet to be developed.

In theory, these organisms should be assessed under the "other organisms" schedule of the September 1997 CEPA regulation, but this does not appear to be taking place. Moreover, the existence of legislative authority to conduct environmental, health and biodiversity reviews of these products outside of CEPA is uncertain at best.

## **2.4 Cause for Concern?**

Several early warning signs indicate that there is cause for concern about the safety and adequacy of Canada's regulatory framework. The cases outlined below suggest that a) Canada's system of allowing companies to self-test and monitor their own products may not be providing adequate environmental protection, b) regulators may be putting the commercial interests of biotechnology companies before public health and environmental concerns, and c) lack of government support for independent research into the environmental and health risks of GE has led to an unhealthy dependency of many academic institutions on industry funding for research.

### *Canola Recall*

A recent incident involving genetically modified canola produced by Monsanto Inc. has raised concern over the lack of federal government testing and monitoring of genetically modified crops. Two varieties of GE canola were recently given approval by the CFIA for unconfined environmental release. Following this approval, Monsanto discovered that a portion of the approved GE canola contained an unapproved gene that had

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<sup>106</sup> C. Harrington, "Conference Scrutinizes Designer Food", Canadian Press Calgary, March 1999.

<sup>107</sup> This rule was imposed by the 1990 Farm Bill as cited in Ann Clark, *supra* endnote 5, p.1.

gotten into the product by mistake.<sup>108</sup> The company had to re-call 60,000 bag units of two types of canola seed and several hectares of canola that had already been planted had to be plowed under and destroyed by farmers.<sup>109</sup> The recall was very time-consuming as there is currently no tracking or monitoring system for transgenic seed distribution in Canada, so the seed had to be traced back through retailers.<sup>110</sup>

### *Bovine Growth Hormone*

Recent scandals within Health Canada and the Canadian Food Inspection Agency have heightened concerns about conflict of interest within these departments. Both departments are facing criticism for putting the interests of drug companies before those of Canadians. Last year, for example, scientists and environmentalists accused Health Canada of concealing evidence about the dangers of bovine growth hormone. Health Canada scientists told an internal labour board that they were being pushed to approve the GE growth hormone despite their concerns that it is not safe, "we have been pressured and coerced to pass drugs of questionable safety, including rBST," said Dr. Shiv Chopra of Health Canada.<sup>111</sup> Six scientists said they were ordered by their superiors not to speak publicly about the issue. They were also threatened with transfers if they did not speed up their approval of the drug evaluations. Moreover, one of the scientists, Dr. Margaret Haydon, told an investigating committee that she had been in a meeting when officials from Monsanto Inc., the drug's manufacturer, made an offer of nearly two million dollars to Health Canada scientists -- an offer that she interpreted as a bribe.<sup>112</sup>

### *Bt Corn Conditions*

As mentioned, the advent of plants which express Bt toxins has led to concerns over the eventual development of insect resistance to this natural insecticide. These concerns were recognized by the United States' Environmental Protection Agency and

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<sup>108</sup> Rachel's Environment and Health Weekly, "Genetic Engineering Error", June 5, 1997, no. 549, p. 1.

<sup>109</sup> Ibid.

<sup>110</sup> For further details see Amanda Cliff, Agricultural Biotechnology and the Canadian Regulatory System, Canadian Institute for Environmental Law and Policy briefing paper, 1998.

<sup>111</sup> As quoted in Anne McIlroy, "Cover-up alleged at Health Canada", in The Globe and Mail, September 17, 1998.

<sup>112</sup> James Baxter, "Scientists 'Pressured' to approve cattle drug: Health Canada researchers accuse firm of bribery in bid to OK 'questionable' product", in the Ottawa Citizen, Oct. 23, 1998.

conditions were imposed on the use of Bt corn crops in the United States prior to the commercialization and use of these crops.<sup>113</sup> All companies producing Bt corn in the United States are required, for example, to implement long-term resistance management strategies and undertake extensive new research. The conditions also require farmers who are growing Bt corn crops to plant a certain percentage of their fields with non-Bt crops.<sup>114</sup>

When Bt corn went through the approval process in Canada, however, the same precaution was not taken. Despite serious concerns about insect resistance, which were highlighted by both the scientific and environmental communities<sup>115</sup>, Bt corn was given unconditional approval in Canada in 1996.

However, in December 1998, the Canadian Food Inspection Agency moved to impose new conditions on Bt crops<sup>116</sup> and to conduct research on their potential ecological impacts.<sup>117</sup> This move raises several critical questions. Mainly, why were the scientific concerns about Bt corn crops disregarded at the time of approval? Why were conditions only implemented several years *after* approval was granted for the commercialization of these crops?

## 2.5 "Reforming" the System

The above incidents have raised questions about the ability of the current regulatory system to protect the health and environment of Canadians. At the same time, the controversies over the acceptability of biotechnology products, particularly GE foods continue to grow. In Western Europe, for example, a number of major food retailers, processors and distributors have responded to public concerns by making commitments not to sell GE foods to their customers. Canadian governments have consistently sought to avoid any significant societal debate about the value, purpose and

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<sup>113</sup> Union of Concerned Scientists, "EPA Approves Bt Corn and Cotton with Conditions - Environmental Groups and organic farmers oppose approvals," The Gene Exchange, Volume 6, Numbers 2&3, December 1995.

<sup>114</sup> Ibid.

<sup>115</sup> Ibid.

<sup>116</sup> New requirements were imposed in December 1998. See Plant Biotechnology Office, CFIA, "Insect Resistance Management of Bt Corn in Canada," [http://www.cfia-acia.agr.ca/english/plant/pbo/btweb1\\_e.html](http://www.cfia-acia.agr.ca/english/plant/pbo/btweb1_e.html).

<sup>117</sup> K. Honey, "Scientists to study modified corn's effects on insects," The Globe and Mail, July 14, 1999.

acceptability of applications of biotechnology, particularly with respect to agriculture and food. The government of Canada has also maintained a policy of denying customers the right to choose in the marketplace, by opposing the mandatory labelling of GE foods.

Canada should, therefore, be looking to strengthen its regulatory oversight of biotechnology products. However, as a result of the recent CEPA review process, the existing legal framework for biotechnology products has been significantly weakened.

The CEPA review was initiated in 1993 under a provision of the Act requiring that a Committee of Parliament review the Act five years after its coming into force. The House of Commons Standing Committee on Environment and Sustainable Development tabled its report of the review of CEPA, Its About Our Health!, in June, 1995. The Standing Committee recommended major changes to CEPA with respect to biotechnology. Specifically, the Committee proposed that a new biotechnology part for CEPA be established to provide minimum notice and assessment standards for all products of biotechnology released into the environment, including those regulated under other federal acts. No product could be exempt unless the assessment and regulatory standards under the other acts were proven at least equivalent to those in CEPA.<sup>118</sup> The Committee also recommended that CEPA be amended to require the Governor in Council to publish a list of statutes considered to be at least equivalent to CEPA with respect to their assessment process for products of biotechnology.

These provisions would have provided a benchmark for other federal statutes regulating products of biotechnology. The government's December 1995 response to the Standing Committee Report was not, however, supportive of these changes. In fact, in its response, the government issued proposals that were a significant step back from the existing Act. The government's proposal specifically recommended eliminating CEPA's minimum standards for notification and assessment of all biotechnology products:

...where non-living products of biotechnology are new to Canadian commerce, and *where authority does not exist under other federal acts*, we would maintain the obligation under CEPA for their developers, manufacturers or importers to provide data on these products before they can enter the Canadian marketplace.<sup>119</sup> (emphasis added)

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<sup>118</sup> Report of the House of Commons Standing Committee on Environment and Sustainable Development, It's About Our Health! Towards Pollution Prevention, (Ottawa: Public Works and Government Services, June 1995), p. 124.

<sup>119</sup> Government Response to the Standing Committee on Environment and Sustainable Development, Environmental Protection Legislation Designed for the Future - A Renewed CEPA Proposal, (Ottawa: Government of Canada, 1995).



The government's response provided the impetus for a Second Report of the Standing Committee on Environment and Sustainable Development, issued in November 1996, Biotechnology Regulation in Canada: A Matter of Public Confidence. This report reiterated the recommendations made in the 1995 report. It also recommended the establishment of a National Advisory Commission on Biotechnology that would be at arm's length from both government and industry and that would report directly to the Prime Minister. This Committee would include representatives from the general public, academia, environmental and other sectors. The mandate of the committee would include examining the ethical aspects of biotechnology, the effectiveness of current regulations, alternative regulatory frameworks, and the potential risks of biotechnology.

In December, 1996, the government introduced Bill C-74. Although this Bill included a new part for biotechnology, its key provision would have permitted Ministers responsible for the administration of other Acts of Parliament to determine for themselves whether the requirements of CEPA regarding the notification and assessment of biotechnology products would be met.<sup>120</sup> In other words, instead of having an objective test for equivalency of regulation under another Act, as established through the existing CEPA, the Minister of Agriculture would determine whether his or her department's approach to the regulation of biotechnology products met the requirements of CEPA. Bill C-74, however, died on the order paper with the call of the June 1997 Federal election.

In March 1998, the government re-introduced CEPA Bill C-32. This Bill included biotechnology provisions similar to those in Bill C-74, as it permitted Ministers to determine whether the regulations in their departments would meet CEPA equivalency requirements. From May 1998 to April 1999, this Bill underwent a clause by clause review by the House of Commons Standing Committee. The Committee amended the Bill so that the Ministers of Environment and Health would determine whether regulations proposed by other Ministers for biotechnology products meet CEPA's equivalency requirements.<sup>121</sup> The Committee also amended the preamble of the Bill and administrative duties sections to explicitly identify biotechnology as a threat to biological diversity, along with the use of toxics substances, pollutants, and other

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<sup>120</sup> Bill C-74, section 106(7).

<sup>121</sup> Bill C-32, Part 6, Reprinted as amended by the Standing Committee on Environment and Sustainable Development as a working copy for the use of the House of Commons at report stage and as reported to the House on April 15, 1999.

wastes.<sup>122</sup> This amendment was consistent with the provisions of Article 8 (g) of the United Nations Convention on Biological Diversity, which obligates parties to the Convention to adopt national legislation to protect biodiversity from the products of biotechnology.

However, at report stage, the government introduced amendments to reverse the Committee's amendments. The government's changes state that the Governor in Council (i.e. Cabinet) would have "exclusive" responsibility for determining if CEPA's requirements are met by another Act of Parliament. The government's amendments also removed the references to biotechnology as a threat to biological diversity in the preamble and replaced them with clauses recognizing the need to protect the environment and human health by ensuring the safe and effective use of biotechnology.<sup>123</sup> This Bill was enacted in September 1999.

In sum, when the government had the opportunity to deal with the weaknesses in the existing system, it failed to act. Instead, it weakened the one piece of federal legislation that spoke directly to the protection of human health and the environment with respect to biotechnology.

## **SECTION 3.0: RECOMMENDATIONS**

### *Designing a Regulatory Framework that Protects the Environment and Public Health*

This report has identified many of the risks associated with the development and commercial use of GE agricultural products. It has also identified the many problems inherent in the Canadian regulatory framework. The following section outlines several basic provisions that could improve Canada's regulatory system.

#### *1. Create clear institutional separation of regulatory and promotional functions within government*

The problems inherent in mixing government regulatory and promotional roles have been demonstrated in several recent cases, such as the contamination of Canada's blood supply and the bovine growth hormone scandal. As Justice Krever explained, the regulator must regulate only in the public interest, not in the interest of the regulated. The regulation of biotechnology by a government agency, the CFIA, which is also

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<sup>122</sup> Ibid.

<sup>123</sup> Bill C-32, Part 6, As passed by the House of Commons, June 1, 1999.

involved in the promotion of this technology, clearly constitutes a conflict of interest. Not only is this mixing of roles not credible from a regulatory standpoint, it also threatens human health and the environment.

The CFIA must therefore either give up its promotional activities, or regulatory responsibility for biotechnology must be transferred to another agency with a clear mandate to protect public safety, health, and the environment.

*2. Enact new legislation establishing clear criteria and processes for the evaluation and approval of products of modern biotechnology.*

The above discussion suggests the importance of having the Legislature articulate an appropriate regulatory framework for the products of agricultural biotechnology that addresses the unique characteristics and risks of these products. Given the intrinsic risks of modern biotechnology, genetically modified products deserves new legislation and should not be forced into an existing regulatory framework that was not specifically intended to deal with these products. This legislation should be administered by a federal department with a mandate to protect the environment and health. Furthermore, this legislation needs to establish clear evaluative criteria (see recommendation 3) and processes for public input in decision making (see recommendation 4).

*3. Require government evaluation prior to import, testing, research and development, manufacturing or use of GE products and establish clear evaluative criteria.*

Evaluative criteria should include an assessment of:

- potential immediate or long-term, direct or indirect, harmful effects on a) human life or health, b) the environment, and c) biological diversity, including an assessment of cumulative impacts;
- the availability and effectiveness of monitoring and emergency response plans with respect to the product;
- the potential effectiveness of the product for its intended purpose; and
- the availability of alternative means of achieving the product's purpose which may present lower potential for harm to the environment and human health.<sup>124</sup>

Moreover, these evaluations must be undertaken by an independent third-party, not just by the proprietor of the GE product. After a product is approved, further monitoring by

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<sup>124</sup> As outlined by Mark Winfield and Brewster Kneen, supra endnote 98, p. 12.

both industry and government is critical to ensure that GE crops are not posing health or environmental risks.

*4. Provide for public participation in decision-making*

Provisions for public participation in decision-making regarding biotechnology should include:

- public notice and comment periods prior to the approval for manufacture, use, import, or export of new biotechnology products;
- public notice in newspapers in the general vicinity of field tests for biotechnology products and direct notification of owners and occupiers of lands adjacent to the test site;
- public records of decisions to approve genetically modified agricultural products and the reasons for those decisions; and
- mechanisms for members of the public to appeal government decisions regarding products of biotechnology.

*5. Provide for the establishment of a database of environmental releases of products of biotechnology*

A biotechnology release data-base would be of assistance to governments, researchers and members of the public in assessing the use and effects of biotechnology products.

*6. Create an independent research fund to investigate the potential environmental and health impacts of GE foods.*

Methods for predicting the consequences of the introduction of genetically modified products into the environment are still under development. The state of science to assess ecological and health impacts continues to lag behind the development of new products of biotechnology. This lack of research is largely a consequence of public policy decisions regarding the funding of biotechnology research in universities and governments. In Canada, most grants require researchers to establish industry partnerships. As a result, research on the ecological impacts of biotechnology that is independent of industry support is scarce in Canada.

Given the gaps in research and knowledge about GE agricultural products, the government should create an independent research fund to investigate the environmental and health risks of these products. This funding should not be tied to

industry partnerships.

#### *7. Require mandatory labelling of GE products*

Mandatory labelling of GE products is essential for several reasons, mainly: i) to protect the health and safety of the public (in particular, those with sensitivity to allergens); ii) to provide the public with adequate information regarding their food supply (in particular, those who have culturally, religiously, or ethically based dietary guidelines); and iii) to give the public the freedom to choose whether they are willing accept the risks of GE foods.

Mandatory labelling of genetically engineered foods is not only essential for safety reasons, it could also ultimately be beneficial for both consumers and the biotechnology industry. Labelling provides consumers with knowledge on which to base their food choices, and provides the industry and regulators with a safety net that will allow them to quickly trace problems that may arise with GE foods, thereby minimizing liability. Moreover, in the long run, if GE foods offer the benefits that the industry expounds, GE labels will indicate a sign of quality which will allow industry to demand a premium for these products.

### **CONCLUDING COMMENTS**

Genetically modified agricultural commodities pose serious health and environmental risks, and raise major ethical and social issues. Concern about genetically modified foods is, therefore, growing steadily throughout the world. In Europe, for example, the seven largest grocery chains have made a commitment not to sell GE foods in response to increasing public opposition towards these foods.<sup>125</sup> They are now establishing long-term contracts with growers who can provide GE-free corn, potatoes, soybeans and wheat.<sup>126</sup> An estimated four hundred million dollars in U.S. corn exports has been lost since last year because of fears in Europe of modified foods.<sup>127</sup>

Moreover, the European Union (EU) ministers of the environment recently announced that the EU will not authorize any new genetically modified organisms in Europe until

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<sup>125</sup> The consortium includes Tesco, Safeway, Sainsbury's, Iceland, Marks and Spencer, the Co-op, and Waitrose grocery chains. Rachel's Environment and Health Weekly, "Biotech: The Pendulum Swings Back", May 6, 1999.

<sup>126</sup> Ibid.

<sup>127</sup> Bill Lambrecht, "Window on Washington", in St. Louis Post-Dispatch, June 27, 1999.

the introduction of strict environmental standards.<sup>128</sup> The agreement also includes tighter regulations on labelling genetically modified organisms and tracing them through the food chain, and an enhanced role for a European Union ethical committee in the decision-making process.<sup>129</sup>

Governments in North America are only beginning to acknowledge the significance of these issues, but have failed to address them in any meaningful way. While countries like those in the EU are strengthening their regulatory frameworks for biotechnology, Canada's regulations have been fundamentally weakened. Canadians have been left with a system that:

- mixes regulatory and promotional functions;
- has an inadequate legislative basis;
- is based on weak science and a reliance on data provided by proponents;
- lacks public input in decision-making; and
- contains significant regulatory gaps.

Moreover, despite the fact that there is no public consensus in favour of adopting the products of agricultural biotechnology, and the level of public concern over GE foods is high,<sup>130</sup> the government continues to pour large sums of public funds into the development of genetically modified commodities. Federal spending on biotechnology is estimated at \$318 million a year.<sup>131</sup> Moreover, \$55 million in new funding for biotechnology was added to the federal budget in February, 1999. Provincial support for biotechnology development is approximately \$250 million a year.<sup>132</sup> Approximately half of this money supports agricultural biotechnology as opposed to medical or industrial applications.

At a minimum, the Canadian public should be entitled to a voice in decisions about the acceptability of GE products and the value of further public investment in them. The

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<sup>128</sup> Michael Mann, "EU close to temporary GMO moratorium", Reuters News Service, June 24, 1999.

<sup>129</sup> "Italy says consumer at risk without GMO moratorium", Reuters News Service, June 29, 1999.

<sup>130</sup> Environics International, International Survey on Food Safety and Biotechnology, September 1999, Canadian Edition.

<sup>131</sup> Estimate provided by Roy Atkinson, Executive Director, National Biotechnology Strategy Renewal, October 1997.

<sup>132</sup> Ibid.

Canadian public also deserves to be protected by a regulatory system for the products of agricultural biotechnology with has rigorous health and environmental safeguards. That is, a regulatory system which:

- clearly separates regulatory duties from promotional functions in governing agencies,
- provides full and independent environmental and health reviews of products before they enter the Canadian marketplace,
- facilitates and encourages public participation in decision-making,
- invests in independant research and monitoring for potential health and environmental implications of GE products, and
- provides for mandatory labelling of GE foods in the Canadian marketplace.

Furthermore, rather than focusing mainly on biotechnology and large-scale, industrialized agri-business, the government should support alternative models for Canada's food system, such as organic agriculture. Such support would faciliate and promote the changes necessary to place Canadian agriculture on a truly environmentally, economically, and socially sustainable path.

