

BIOTECHNOLOGY: A CANADIAN PERSPECTIVE

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I. INTRODUCTION

WHEN NEWS OF THE SUCCESSFUL CLONING of the sheep named Dolly was broadcast throughout the world a few years ago, the public was shocked. People were in wonder of science and yet they were also afraid of the future that genetic engineering might create for them and their children. Today words such as “novel foods,” “genetically modified organisms,” and “biotechnology” are frequently seen in the newspapers and heard on the radio or television. While the Canadian public has some experience with genetically modified products, many of them lack knowledge as to what the genetic engineering process really involves. They are also largely unaware as to what sort of genetically modified products have been approved and are currently being marketed. As a result, while some of the Canadian population may feel optimistic about biotechnology and its potential for the future, many Canadians are pessimistic, feeling doubtful as to the safety of this new technique. An exploration of current literature illustrates the tremendous potential which biotechnology can generate for the earth’s inhabitants. Public anxiety cannot, however, be ignored. Rather, the future of biotechnology rests on the examination of public fears, the assessment of risks inherent in genetic engineering, and the analysis of the regulation process as it exists today. The exploration of these aspects will provide insight as to what needs to be done to ensure that Canadians, together with the rest of the world, will reap the benefits of biotechnology in the future.

II. BIOTECHNOLOGY: ITS POTENTIAL

BIOTECHNOLOGY, AS DEFINED IN the “Guidelines for the Safety Assessment of Novel Foods,” Volume I, “is the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.”¹ While the application of modern biotechnology may

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seem relatively new, farmers and scientists have, in reality, been working to improve plants and animals for years. Farmers, for example, have traditionally saved seeds from their finest plants in the hope of producing superior crops. As selective breeding processes were developed, they allowed for the creation of many of the hybrid fruits and vegetables we still purchase in the supermarket today.² Broccoli, cabbage, cauliflower, and kale, for example, all originate from the same ancestor and have been developed into different foods over hundreds of years of selective breeding.³

Genetic engineering allows for the direct introduction of desirable traits into organisms more quickly and precisely than traditional breeding methods. While breeding a disease-resistant plant using traditional breeding methods may take up to 12 years, genetic engineering techniques can produce the same result in just a few years. Genetic modification is achieved by manipulating the genetic material of a cell. A cell's chromosomes (which are made of deoxyribonucleic acid – DNA) are arranged in sections of genes that control the production of specific proteins. These proteins determine the attributes of an organism.⁴ When an organism's gene is inserted into another organism that specific trait is transferred from one to the other.

Genetic modification can be used to enhance the world food supply in a variety of ways. As the world population expands rapidly, food shortage will become an ever-increasing reality. Using modern biotechnology, plants can be engineered to resist disease or to tolerate cold, drought, and salinity. Genetically modified plants such as this can then be grown in areas where they would not previously have survived. By transferring an "antifreeze" gene from cold-water fish into potato plants, for example, the genetically modified plant can withstand colder temperatures.⁵ Performance Plants, a Canadian biotechnology company, has created strains of canola, some of which require less fertilizer, flourish in poor quality soil, and resist drought.⁶ Rice varieties, which can tolerate drought or prolonged submergence, are also under development.⁷ In addition to creating hardier varieties, genetic engineering can be used to

¹ *Guidelines for the Safety Assessment of Novel Foods*, volume I, annex I (Health Canada: Food Directorate, Health Protection Branch 1994) at 6.

² I. Boyans, *Unnatural Harvest: How Corporate Science is Secretly Altering Our Food* (Toronto: Doubleday Canada Ltd., 1999) at 18.

³ M. Specter, "The Pharmageddon Riddle" (2000) 76 *The New Yorker* 58 at 60.

⁴ "Biotechnology and Agriculture in Canada" (August 1997), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/gen/canadae.shtml>> at 1.

⁵ D. B. Whitman, "Genetically Modified Foods: Harmful or Helpful?" (April 2000), online: Cambridge Scientific Abstracts <<http://www.csa.com/hottopics/gmfood/overview.html>> pagination unavailable.

⁶ M. Smith, "Food Fright" *The Globe and Mail* (29 October 1999) at 128.

⁷ "Franken Sense" *National Post* (24 January 2000) (pagination unavailable).

develop species that mature more quickly and ripen faster.⁸ The development of species such as these clearly offers promise for the increased food production that will be required by a growing world population.

In addition to increased productivity, genetic engineering can be used to improve the nutritional content in food. In developing countries, where rice is the main staple for most people, malnutrition is common. "Golden" rice has been developed to include higher than normal amounts of vitamin A. Blindness, which is caused by a vitamin A deficiency (common in developing countries), can thus be prevented.⁹ Similarly, rice with a higher iron content has also been engineered.¹⁰ Other examples of enhanced foods include cereals with additional nutrients; increased unsaturated fat content in canola, soybean, and corn; animals with leaner meat; and potatoes that absorb less oil when cooked.¹¹

Significant improvements to world health can also be achieved by modifying plants to include various antibodies and vaccines. Researchers at Cornell's Boyce Thompson Institute for Plant Research, for example, are in the process of developing vaccines for both diarrhea and hepatitis B which will be inserted into the cells of bananas. This process will be significantly cheaper and easier to distribute than the current vaccines.¹² Research is also underway to develop plants that produce antibodies to fight measles, tooth decay, and sexually transmitted diseases.¹³ Finally, work is being done to alter tobacco plants so that they will produce proteins that can be used to treat diabetes.¹⁴

Genetic modification is also being used to create so-called "designer foods." Examples of this include fast-rising dough and processes that clarify wine and fruit-juices. Fruits and vegetables, engineered to have longer shelf lives, are also being designed.¹⁵

⁸ S. K. Lewis, "Attack of the Killer Tomatoes?" Corporate Liability for the International Propagation of Genetically Altered Agricultural Products" (1997) 10 *Transnational Lawyer* 153 at 158.

⁹ Because the Rockefeller Foundation (non-profit organization) funded the rice, the Swiss Federal Institute of Technology Institute for Plant Sciences plans to offer the rice free to any developing country that requests it. See Whitman, *supra* note 5.

¹⁰ "CBAC Program Plan 2000" (21 February 2000), online: Canadian Biotechnology Advisory Committee: Work Plans <<http://cbac.gc.ca>>.

¹¹ "Agricultural Products of Biotechnology: What are the Benefits?" (May 1998), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/gen/bene.shtml>> at 1; *supra* note 4.

¹² Specter, *supra* note 3 at 70.

¹³ *Supra* note 7.

¹⁴ *Supra* note 10.

¹⁵ Boyans, *supra* note 2 at 37; *supra* note 4.

While the processes discussed above serve to benefit people by increasing food production and health, genetic modification can also be used to reduce environmental hazards. The most widely known example of this is canola which is modified to resist herbicides such as Round-up. Because Round-up kills virtually everything it comes into contact with, it cannot be used on traditional canola strains. This forces farmers to use a number of herbicides on their canola crops. However, only one or two applications of Round-up are required on genetically modified canola which means that less herbicide is used.¹⁶ In addition to the creation of herbicide-resistant plants, plants are being modified to be pest-resistant. Potatoes and corn, modified to contain the natural organic pesticide *Bacillus thuringiensis* (Bt), are toxic to the Colorado potato beetle and the corn borer, respectively, but are not harmful to humans.¹⁷ As with herbicide-resistant crops, fewer chemicals are released into the environment because pesticides do not have to be applied. Thirdly, work is being done to enable bacteria to be more efficient in fixing nitrogen, reducing the amount of nitrogen fertilizer applied by farmers.¹⁸ Lastly, a process called phytoremediation involves the use of genetically engineered plants which actually reduce heavy metal pollution in contaminated soil when planted.¹⁹ While the food supply is still safe for human consumption, these techniques mean that the risk of agricultural waste contaminating the water supply or causing overall environmental damage is lessened.

It is clear, therefore, that modern biotechnology – whether by increasing the earth's food supply, improving the nutritional elements in food, providing more affordable medical care, or reducing environmental pollution – can benefit society immensely. Unfortunately, however, the exploration of genetic engineering cannot stop there. This is because, while the new science has many advocates, it has also met with much opposition. A balanced perspective cannot be achieved without a more thorough analysis of the issue.

III. PUBLIC CONFIDENCE: DOES BIOTECHNOLOGY HAVE IT?

IT IS NOT DIFFICULT to find those who oppose genetic engineering. While researchers are in their laboratories transferring genetic information from one plant to another, protestors work to put a stop to the entire process. Opposition to genetic modification is especially prevalent in Europe. In England, for example, activists are known to break into government-sponsored test sites to destroy genetically modified crops in

¹⁶ Smith, *supra* note 6 at 128.

¹⁷ Boyans, *supra* note 2 at 41; Whitman, *supra* note 5.

¹⁸ *Supra* note 4 at 3.

¹⁹ Whitman, *supra* note 5.

an effort to “decontaminate” the fields.²⁰ In the United States – the world’s largest producer of genetically engineered products, concern is also mounting. Last year the US Congress received petitions with half a million signatures requesting that genetically modified products be labelled.²¹ Canadians are also becoming increasingly concerned. According to a recent Angus Reid survey, 67% of Canadians would be less likely to purchase a food product if they knew it had been genetically engineered.²² Statistics such as these are causing some leading companies to stop using genetically modified products. McCain Foods, for example, recently announced that it would stop using genetically modified potatoes. While Mr. McCain reportedly believes that the technology is sound, he wants to ensure the public believes in it before the company utilizes the products.²³ Similarly, Heinz Canada recently declared its intention to remove all genetically modified additives in its baby food.²⁴

The prevalence of public apprehension of genetically enhanced products stems from a number of factors. First of all, public fear exists because the process is new and the actual effects of genetic engineering are not yet fully known.²⁵ Secondly, the public is concerned because genetic engineering affects our food supply. While consumers may tolerate abstract risks where the cause and effect relationship is not as clear, such as the chance of developing cancer from air pollutants, they are less willing to accept risks in their diet because the relationship is less abstract and is, therefore, more easily grasped. That is, instead of analysing the process from a statistical scientific perspective, consumers tend to formulate their decisions from an anecdotal, emotional standpoint. Thirdly, neither the government nor the corporations designing and selling genetically modified products have provided well-balanced information to the public. Many consumers do not actually know what genetic modification involves and are, therefore, apprehensive of it. In a recent study sponsored by the Canadian government, for example, a consumer expressed the view that genetically modified corn was “...not grown in a farmer’s field, but somehow chemically grown.”²⁶

²⁰ Smith, *supra* note 6 at 128.

²¹ J. Grogan and C. Long, “The Problem with Genetic Engineering” (2000) 47 *Organic Gardening* (pagination unavailable).

²² A. McIlroy, “Canadians Wary of Genetically Altered Foods” *The Globe and Mail* (15 January 2000) A2.

²³ D. Powell, “McCain’s Hot Potato” *National Post* (4 December 1999) D5.

²⁴ H. Scofield, “Genetically Modified Food” *The Globe and Mail* (21 August 1999) D5.

²⁵ Lewis, *supra* note 8 at 160.

²⁶ “Voluntary Labelling of Foods from Biotechnology: Report on a Qualitative Study Among Canadian Consumers” (Ottawa: National Institute of Nutrition, 1999), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/labeti/ninlabe.shtml>>.

This consumer went on to state that he would not purchase the corn. To worsen the situation companies have responded to negative consumer reaction by opposing the notion of passing information on to consumers, suggesting that they would not understand it.²⁷ Fourthly, consumers have reacted in a negative fashion because the corporate world is the motivating force behind the technology. The UK-based non-profit organization Christian Aid certainly expresses this view in its report which states: "GM crops...are driven by commercial interests, not a concern to 'feed the world' or raise productivity."²⁸ In the public's view, this may be a situation where there is too much power in the hands of just a few people. Finally, negative consumer perception may arise from the absence of independent testing within the regulatory process. When the government approves a genetically modified product for sale within Canada, the assessment information is supplied by the company that is designing and marketing the product. Additionally, government researchers often have connections to the industry itself. For example, when the Canadian government recently selected researchers to do a study on Bt corn, they chose Mark Sears, the head of the Bt Corn Coalition of Growers, to perform the study.²⁹ It is not difficult to understand the public's perception that self-interest may cloud a person's perspective in a situation such as this.

IV. BIOTECHNOLOGY: ITS RISKS

WHILE SOME OF THESE CONCERNS may be excessive, scientific breakthroughs are rarely made without any risk. It is not surprising, therefore, that there are some hazards involved in genetic engineering techniques. Human health is, naturally, one of the greatest concerns. Because DNA controls the production of proteins, the transfer of DNA from one life form to another can, inadvertently, result in the transfer of allergens to the new organism.³⁰ The modification of a soybean by adding a gene from the Brazil nut, for example, triggered an allergic reaction in people who were sensitive to the nuts.³¹ A second health risk is caused by the antibiotic-resistant marker genes that scientists use to transfer genetic information from one organism to

²⁷ K. S. Beaudoin, "Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century" (1999) 83 *Marquette Law Review* 237 at 243.

²⁸ "Christian Aid Argues Biotech Won't Help Developing Countries" (May 1999), online: Agbiotech <<http://www.agbiotech.net/topics/devco.asp#plant32>>.

²⁹ Scofield, *supra* note 24.

³⁰ S. M. Dunn, "From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment" (1998) 9 *Colorado Journal of International Environmental Law and Policy* 145 at 154.

³¹ Grogan and Long, *supra* note 21.

another. This may contribute to antibiotic resistance in humans, a tendency that is becoming increasingly common today.³²

The genetic modification of plants results in the alteration of the environment around them, thereby creating some additional concerns. While herbicide-tolerant crops promise to reduce the use of herbicides, there is a danger that these plants will cross-pollinate with their wild relatives, creating “superweeds” that are immune to the herbicide. This would, therefore, require increased use of herbicides to combat the new strains of weeds. Similarly, pest-resistant plants such as Bt corn, while initially reducing the use of pesticides, may become ineffective if the insects are able to develop a resistance to the toxins produced by the plant.³³ Perhaps the most significant environmental concern created by modern biotechnology is the increased loss of biodiversity. As farmers begin to purchase genetically modified seed, genetic diversity will decrease, resulting in increased vulnerability to diseases and pests. Simple ecosystems are much less stable than complex ecosystems, significantly narrowing options for the future. The Irish potato famine is just one example of the type of disaster that can occur when farmers monocrop.³⁴

Finally, genetic modification may also cause some economic concerns. First of all, if genetic modification methods result in increased output, small farms, that cannot afford large-scale production, may be destroyed by the resulting lower food prices.³⁵ Secondly, biotechnology may destroy some exports within developing countries. This is because some plants, that could traditionally only be grown in developing countries, may be genetically modified to thrive in other climates.³⁶ Clearly, this would have a devastating impact on countries that are already experiencing significant economic difficulties.

Many biotechnology critics, having established potential hazards within the science, urge governments to put a stop to genetic engineering research and production. While this would effectively deal with the risks inherent in the process, it would also destroy each of the benefits which biotechnology promises for the future. For example, the use of penicillin causes allergic reactions within certain segments of the population. Yet the benefits of the drug are clearly believed to transcend the risks. Penicillin, therefore, continues to be used within the medical community today. The risks inherent in the drug are managed so as to allow most people to benefit from its use. Similarly, biotechnology research and production must continue so as to allow people to reap the benefits that it promises to deliver. Risks must not be ignored, however, but must be

³² *Ibid.*

³³ Dunn, *supra* note 30 at 155.

³⁴ Boyans, *supra* note 2 at 165-167.

³⁵ Beaudoin, *supra* note 27 at 243.

³⁶ Lewis, *supra* note 8 at 161.

assessed and dealt with through an efficient and credible regulatory process.

V. BIOTECHNOLOGY: NATIONAL REGULATION

IN CANADA TODAY THERE ARE A NUMBER of government organizations that share responsibility for the regulation of products derived from modern biotechnology. The Canadian Food Inspection Agency (CFIA) is primarily responsible for the regulation of agricultural products, including seeds, plants, animal fertilizers and feeds, and veterinary biologics. The CFIA assesses new products to ensure their efficacy, environmental safety, worker, and animal security. By monitoring and inspecting companies and their products, the organization ensures that products that have been registered continue to meet Canadian standards. Through powers obtained under the *Food and Drugs Act*, Health Canada (HC) sets food safety standards and carries out food safety assessments for both traditional foods and novel foods. The specific requirements for the assessment of genetically modified foods are delineated in the “Guidelines for the Safety Assessment of Novel Foods.” These guidelines, together with the “Novel Food Regulations” outline the notification requirements for genetically modified products. While the CFIA and HC are the two main regulatory bodies, Environment Canada is involved in the development of regulatory standards when the product in question may have environmental effects, and the Pest Management Regulatory Agency, Health Canada, registers and regulates all pest control products.³⁷

When a genetically engineered agricultural product is submitted to the CFIA for approval, a four-step process is used to assess the safety of the product. First of all, the CFIA determines whether a risk assessment is necessary. The product is defined according to its characteristics, usage, safety, and environmental effect. Having defined the item in question the agency begins the evaluation process with a focus on three main areas. First, the CFIA tries to establish familiarity by determining whether the product is similar to any other product already approved by

³⁷ “Food Safety Concerns,” online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/safsal/foali.shtml>>; “Biotechnology, Agriculture and Regulation” (May 1998), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/reg/bare.shtml>>; “Food And Drug Amendment – Schedule no. 948: Regulatory Impact Analysis Statement” (24 January 2000), online: Health Canada <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/qa_modification_e.html>; “The Safety of Genetically Modified Food Crops” (October 1999), online: <<http://www.hc-sc.gc.ca/english/archives/genmodebk1.htm>> .

the agency. Because the agency lacks direct experience with the novel product, this procedure enables them to develop a sense of possible risks within the product. If the species has a history of safe usage in Canada, the new characteristic was derived using a method that has traditionally been considered safe in Canada, and the new trait is similar to those of the already approved product, it is considered to be familiar to the other product. If it is not familiar to the other product, a complete safety assessment is required. On the other hand, if the product is considered to be familiar to the other product, the CFIA goes on to determine whether it is substantially equivalent to the approved product. Substantial equivalence is established when the product's traits, effect on the environment, use, and safety are determined to be equivalent to the other product. Finally, products that are both familiar and substantially equivalent undergo the same treatment as traditional food and the CFIA must determine whether there are any existing regulations governing their use.³⁸

Step two of the four-step process consists of a complete risk assessment on the product. At this point all novel traits are evaluated for safety by analysing the product's nutritional quality, the product's characteristics in comparison to those of its traditional counterpart, the method used to develop the novel food, the possibility of any toxins within the food, and the likelihood of allergens within the proteins that have been introduced into the food.³⁹ Because the defined differences of the genetically altered foods assessed to date have been the introduction of new proteins, tests have specifically focused on potential allergenicity and toxicity.⁴⁰ It is important to note that, according to the CFIA, "'safety' does not imply the absence of risk, but rather a level of acceptable risk."⁴¹ If the product is as safe as the traditional product with which it is being compared then the level of risk will be considered acceptable.⁴²

³⁸ "Long Term Testing/Substantial Equivalence" (May 1998), online: Canadian Food Inspection Agency: Office of Biotechnology

<<http://www.cfia-acia.agr.ca/english/ppc/biotech/safsai/longe.shtml>>; "The Safety-Based Approach to Regulation of Agricultural Products" (May 1998), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/reg/bare.shtml>>.

³⁹ "The Safety of Genetically Modified Food Crops" (October 1999), online: <<http://www.hc-sc.gc.ca/english/archives/genmodebk1.htm>>.

⁴⁰ "A Bureau of Food Policy Integration (Food Directorate) Response to: Anne Clark's 'Food Safety of GM Crops in Canada: Toxicity and Allergenicity'" (19 January 2000), online: Food Directorate, Health Canada <http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/health_canada_response_gmo.html>.

⁴¹ *Supra* note 38.

⁴² *Ibid.*

Once the product in question has undergone a comprehensive risk assessment, with the level of risk having been determined to be acceptable, the CFIA engages in risk management. This means that, having identified potential risks, steps are taken to reduce those risks. The release of a product, for example, may be limited by imposing specific confinement conditions on it.⁴³ For pest-resistant plants, this might include planting buffer zones of unmodified plants around the genetically engineered plants so as to slow down the rate at which insects will adapt and develop a tolerance to the pesticide.⁴⁴

Having passed all three levels of analysis, the final step involves the regulation of the product. This means that the product is approved for a specific purpose and is then governed by any relevant legislation to maintain standards or ensure that risk management conditions are kept. These standards continue to change as the CFIA becomes aware of any new information regarding the product.⁴⁵

The entire testing process takes a number of years. According to David T. Dennis of Performance Plants, getting a product approved for release can take up to seven years.⁴⁶ Government organizations do not perform their own research on the product but rely on information supplied by the company that is seeking approval of the product. These organizations insist that their experts have high standards regarding the information that the biotechnology corporations must submit and that, in addition to this data, they keep themselves informed by way of independent studies on topics within the field.⁴⁷

Both HC and the CFIA, under the *Food and Drugs Act*, share responsibility for policies related to the labelling of genetically modified foods. For foods where the modification process has created health issues, such as the potential for allergenicity or nutritional changes, there are mandatory labelling requirements. For genetically modified products where no substantial changes have occurred, however, both positive and negative labelling is permitted but is not mandatory.⁴⁸ The Canadian General Standards Board (CGSB) is currently developing a

⁴³ *Ibid.*

⁴⁴ Boyans, *supra* note 2 at 129.

⁴⁵ *Supra* note 38.

⁴⁶ D. T. Dennis, "Why GM Foods Aren't so Scary" *National Post* (25 October 1999) C7.

⁴⁷ Scofield, *supra* note 24.

⁴⁸ "Frequently Asked Questions on Genetically Modified Food" (5 October 1999), online: Health Canada

<<http://www.hcsc.ca/english/archives/genmodebk2.htm>>; "Labelling of Genetically Engineered Foods in Canada" (May 1998), online: Canadian Food Inspection Agency: Office of Biotechnology
<<http://www.cfiaacia.agr.ca/english/ppc/biotech/labeti/response.html>>.

national standard for the voluntary labelling of foods and food ingredients derived from biotechnology and from conventional foods.⁴⁹

VI. BIOTECHNOLOGY: INTERNATIONAL REGULATION

WHILE THE SAFETY OF GENETICALLY modified products must be established for the well-being of the Canadian public, the Canadian government must also meet international standards so as to ensure that the export of agricultural products, such as wheat and canola, continues. The regulatory approach described above is not unique to Canada. The Canadian government's safety assessment approach to the regulation of genetically modified organisms is based on principles developed through consultations by international organizations such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO) of the United Nations, and the Organization for Economic Co-operation and Development (OECD).⁵⁰ While the adoption of these standards is voluntary, the Canadian government must also ensure that it meets the requirements dictated by the agreements to which it belongs. These include the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the new, not yet ratified, Cartagena Protocol on Biosafety (CPB).

The SPS Agreement, which came into force in January 1995, sets out guidelines for the application of food, plant, and animal health standards.⁵¹ This agreement encourages the harmonization of sanitary and phytosanitary measures by stipulating that members must base their measures on international standards.⁵² Additionally, with the emphasis on achieving consistency, the agreement instructs members to avoid arbitrary distinctions in the levels they consider to be appropriate in various situations.⁵³

SPS measures must be based on an analysis of risk, using risk assessment methods established by international organizations, to

⁴⁹ "Developing a Canadian Standard for the Voluntary Labelling of Foods Derived from Biotechnology" (January 2000), online: Canadian Food Inspection Agency: Office of Biotechnology <<http://www.cfia-acia.agr.ca/english/ppc/biotech/labeti/developae.shtml>>.

⁵⁰ *Supra* note 39.

⁵¹ "Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures" (May 1998), online: World Trade Organization <http://www.wto.org/english/tratop_e/spsund.htm>.

⁵² "The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)" (1 January 1995) at Articles 3.1 and 3.3, online: World Trade Organization <http://www.wto.org/english/tratop_e/sps_e/sps_e.htm>.

⁵³ *Ibid.* at Article 5.5.

human, animal, or plant life or health.⁵⁴ The SPS Agreement defines risk assessment as:

“[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease... and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”⁵⁵

While reference to the precautionary principle may be somewhat ambiguous in the SPS Agreement, the WTO’s appellate body clarified its applicability in the Beef Hormone Dispute between the United States and the European Union. The precautionary principle essentially suggests that one need not await scientific certainty before implementing safety measures to protect the environment or public health, especially where the potential damages are irreversible.⁵⁶ It is the notion that novel substances need to be regulated before they are able to cause injury rather than after their potential to cause damage has been proven. Or, as outlined by Jonathon Adler, “regulate first, assess the risks later.”⁵⁷ According to the appellate body, the precautionary principle is reflected in Articles 3.3 and 5.7 of the SPS Agreement because they acknowledge a member’s right to set its own levels of protection, even though these measures may be higher than those suggested by international standards organizations.⁵⁸ Article 3.3 allows for the introduction of greater measures of protection, provided that the measures are justified scientifically.⁵⁹ Article 5.7 provides for the adoption of measures, based on information available to members, in instances where scientific evidence is insufficient.⁶⁰ In determining whether “sufficient scientific evidence” exists, clarified the appellate body, one must remember that governments will act cautiously where serious health risks are present.⁶¹

⁵⁴ *Ibid.* at Article 5.1.

⁵⁵ *Ibid.* at Annex A, para.4.

⁵⁶ D. Bodansky, “International Law and the Protection of Biological Diversity” (1995) 28 *Vanderbilt Journal of Transnational Law* 623 at 627.

⁵⁷ J. Adler, “More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol” (2000) 35 *Texas International Law Journal* 173 at 194.

⁵⁸ “European Communities – Measures Concerning Meat and Meat Products (Hormones)” Report of the Appellate Body WT/DS26/R, WT/DS48/R (1 September 1997 – 12 March 1998) 4 *World Trade Organization Dispute Settlement Decisions: Bernan’s Annotated Reporter* 283 at 315, para.124.

⁵⁹ *Supra* note 52 at Article 3.3.

⁶⁰ *Ibid.* at Article 5.7.

⁶¹ *Supra* note 58.

Despite the statement by the appellate body that the application of the precautionary principle still awaits further formulation,⁶² this decision undoubtedly confirms the existence of the precautionary principle within the SPS Agreement.

While the SPS Agreement applies to genetically modified organisms because of its general application to all food, plant, and animal health issues, the CPB was specifically negotiated to regulate the use of products of modern biotechnology. The protocol, which will enter into force when ratified by 50 countries, applies to all living modified organisms that may affect human health or biological diversity in an adverse way.⁶³ As in the SPS Agreement, the CPB requires risk assessments to be carried out in accordance with scientifically established risk assessment methods. Parties to the protocol must then establish strategies and measures to manage any risks that have been identified in the assessment process.⁶⁴ Annex III of the protocol specifies that risks associated with genetically modified organisms must be explored within the context of the risk that might be inherent in the non-modified parent organisms.⁶⁵ It also outlines a methodology for risk assessment which includes the identification of any novel characteristics within the organism that might impact biological diversity negatively or be hazardous to human health. The analysis must also state the likelihood of these risks being realized, the consequences if the risks are realized, and whether the risks can be managed effectively.⁶⁶

The use of the precautionary principle is expressly affirmed in the protocol. While the Preamble reaffirms the precautionary approach as outlined in the Rio Declaration on Environment and Development, Article 1 goes on to explain that, “[i]n accordance with the precautionary approach,...” the objective of the CPB is to guarantee the safe use of products of modern biotechnology which may have a negative impact on biological diversity or human health.⁶⁷ Finally, Articles 10 and 11, which outline the decision procedure for importing parties, allow a party to apply the principle and ban imports in situations where there is a “[l]ack of scientific certainty due to insufficient relevant scientific information and knowledge...” as to the possible risks to health or biological diversity.⁶⁸

⁶² *Ibid.* at 314, para. 123.

⁶³ “Cartagena Protocol on Biosafety to the Convention on Biological Diversity” (29 January 2000) at Articles 4 and 37.1, online: <<http://www.biodiv.org/biosafe/Protocol/Protocol.html>>.

⁶⁴ *Ibid.* at Articles 15.1 and 16.1.

⁶⁵ *Ibid.* at Annex III, para. 5.

⁶⁶ *Ibid.* at Annex III, para. 8.

⁶⁷ *Ibid.* at Preamble and Article 1.

⁶⁸ *Ibid.* at Articles 10 and 11.

The CPB also establishes guidelines pertaining to the labelling of living modified organisms, notification of their transboundary movement, and the sharing of information by means of a Biosafety Clearing House. Through the establishment of an internet Biosafety Clearing House, governments must inform other parties whether they will accept agricultural products which may contain living modified organisms. Stricter advance informed agreement procedures apply with regard to products that are meant for intentional introduction into the party's environment. The exporter must provide information to the importing party and the importer must consent to the shipment.⁶⁹ Genetically engineered products that are meant for direct use as food or feed, or for processing, must state that they "may contain" living modified organisms. When genetically modified products are designed for contained use they must be identified as living modified organisms. If, however, they are meant for intentional introduction into the importing member's environment, additional information, such as the identity, relevant characteristics, and safe handling requirements, must be included.⁷⁰ Additional information, including risk assessments of living modified organisms, relevant laws and regulations, and any arrangements between parties must also be posted on the Biosafety Clearing House.⁷¹

Although application of the standards is voluntary, the international food standards organization Codex Alimentarius Commission (Codex – administered jointly by the WHO and the FAO) is also working to establish guidelines for the products of biotechnology. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology is presently working on two major texts. The first will establish broad principles for the risk analysis of genetically engineered foods and will include information on science-based decision-making, transparency, pre-market assessment, and post-market monitoring. In the second text the task force will set out specific information on the risk assessment of foods that have been genetically modified. This will include issues such as food safety, nutrition, the "substantial equivalence" approach, possible long-term health effects, and non-intentional effects.⁷² The Codex Alimentarius Committee on Food Labelling (CCFL), which is chaired by Canada, is working to establish labelling standards for biotechnology products. In their "Proposed Draft Recommendations for

⁶⁹ "Global Treaty Adopted on Genetically Modified Organisms" (29 January 2000), online: <<http://www.biodiv.org/press/pr-2000-01-28-biosafety.html>>.

⁷⁰ *Supra* note 63 at Article 18.2.

⁷¹ *Ibid.* at Article 20.3.

⁷² "Report of the First Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology" (14-17 March 2000) *Codex Alimentarius Commission: Joint FAO/WHO Food Standard Programme* at 5, online: <ftp://ftp.fao.org/codex/ALINORM01/al01_34e.pdf>.

the Labelling of Food and Food Ingredients Obtained Through Modern Biotechnology,” the CCFL recommends that genetically modified products which are “no longer equivalent to” or “differ significantly from” the original food source with regard to composition, nutritional value, or intended use, should be identified as such by means of a label.⁷³

VII. BIOTECHNOLOGY: RECOMMENDATIONS FOR THE FUTURE

HAVING EXPLORED CANADA’S REGULATORY PROCESS along with international standards and agreements, some recurring themes are evident. A science-based risk assessment is clearly the basis for establishing the safety of genetically modified organisms. The use of the precautionary principle is, however, gaining increased emphasis and poses a threat to this approach. Secondly, while products of biotechnology do not yet require labels, standards organizations are recommending labelling, and the CPB, when ratified, will require the labelling of genetically modified products. Thirdly, while not addressed at the international level, Canada’s regulatory process currently relies on testing which is funded and carried out by corporations looking for approval of their product. Because the development of their product is driven by need for profit, this will have some effect on the quality of their research. Each of these areas needs to be addressed in order to ensure that modern biotechnological processes continue to be pursued within Canada and throughout the rest of the world.

The notion of risk assessment is outlined within the SPS Agreement and the CPB. Codex, in its efforts to promote consistent standards for the regulation of biotechnology, also devotes much time to establishing a risk assessment methodology. Finally, Canadian regulatory agencies use the risk assessment approach as part of their four-step regulatory process. The risk assessment methodology, outlined by the organizations and agreements, is similar in many ways. Emphasis is placed on the analysis of potential risks to human health and the environment, along with an assessment as to the likelihood of these hazards being realized. In spite of this, however, the approach to risk assessment seems somewhat ambiguous. Language used to describe the analysis requirements is rather broad. This leaves the specifics of the assessment to the discretion of researchers, that is the corporations that are seeking product approval.

⁷³ “Recommendations for the Labelling of Foods Obtained Through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods)” (February 2000) *Codex Alimentarius Commission: Joint FAO/WHO Food Standards Programme Codex Committee on Food Labelling* at 10, online: <ftp://ftp.fao.org/codex/ccfl28/fl00_06e.pdf>.

The SPS Agreement, as it was interpreted by the appellate body of the WTO dispute resolution panels in the Beef Hormone Dispute, illustrates this ambiguity. According to Ryan Thomas, in “Where’s the Beef? Mad Cows and the Blight of the SPS Agreement,” the agreement is not clear as to whether a risk assessment should include a cost/benefit type of assessment as to the probability and magnitude of the risk.⁷⁴ The dispute panel, in an effort to clarify the requirements for a risk assessment, held that a risk assessment could include considerations other than empirical science.⁷⁵ While the dispute panel held that a risk assessment must include both an identification of adverse effects on human health and the probability of the occurrence of that risk, the appellate body disagreed with this definition. Instead they stated that the possibility of the occurrence of the risk was all that was required.⁷⁶ What is outlined here is, clearly, a broad, ill-defined approach to risk assessment. Much is left to the discretion of individual members of the WTO.

Ambiguities such as these allow for the biotechnology industry to be increasingly dominated by the application of the precautionary principle. Rather than basing a regulatory decision on a comprehensive risk assessment of the genetically modified product, the use of the principle allows decisions which effectively halt the entire research process. The restriction of the development of genetically modified organisms through the application of the precautionary principle can also cause negative effects on human health and the environment. This is because the focus on potential negative effects of genetic modification results in the cessation of research, thereby creating risks due to the failure to develop the technology.⁷⁷ Instead of assessing which risk poses a greater threat, advocates of the precautionary principle place greater emphasis on the risks inherent in biotechnology. This is not, however, a well-balanced approach to biotechnology.

Clearly the risk assessment methodology within the Canadian regulatory system, the SPS Agreement, the CPB, and the various standards organizations must be better defined, so as to ensure a science-based approach to policy-making. As Thomas states: “...science is a norm which could set uniform standards... for public health and welfare because science is precisely what identifies risks to human life or health at the outset.”⁷⁸ It would effectively result in more predictable and less arbitrary decision-making, ensuring a standard of consistency is achieved.

⁷⁴ R. D. Thomas, “Where’s the Beef? Mad Cows and the Blight of the SPS Agreement” (1999) 32 *Vanderbilt Journal of Transnational Law* 487 at 495.

⁷⁵ *Ibid.* at 490.

⁷⁶ *Ibid.* at 502.

⁷⁷ Adler, *supra* note 57 at 195.

⁷⁸ Thomas, *supra* note 74 at 517.

Risk assessment ought to include an analysis based on the cost/benefit paradigm which would assess both the probability and the magnitude of the risk of the new product as compared to maintaining the status quo or other alternatives that are likely to be followed. The analysis should focus on a thorough assessment of the risks posed by the genetically modified product along with the analysis of the benefits of the genetically engineered product. This would include a comparison of the new product's features to those of the similar non-genetically modified product because some of the hazards posed by the non-genetically engineered product may be alleviated within the genetically engineered product. Take the development of a herbicide-tolerant canola, for example. This genetically modified strain of canola brings with it the potential for increased yields and reduced use of herbicide. Thus it will benefit society by addressing food shortages and by reducing environmental pollution. The hazards inherent in the genetically engineered product are the possible creation of a superweed by cross-pollination with relative weeds and the chance that a successfully engineered herbicide-tolerant canola may threaten biological diversity due to increased monocropping by farmers. The probability of these risks coming to fruition must be analysed thoroughly and various ways to manage the risk, such as the creation of buffer zones, must be explored. If, having explored these factors thoroughly, the benefits of the genetically engineered product clearly outweigh the risks, the product should be approved for use within Canada and for export to other nations.

Internationally, the basic principle, that countries can choose to be as demanding as they want to be when establishing safety standards, should continue to apply. That is, in principle societies should be free to determine what level of risk they are willing to tolerate. In situations where standards affect trade, however, it is fair to require countries to conduct a thorough risk analysis before banning imports. Having completed the risk assessment, with a complete cost/benefit analysis, a country should not be permitted to ban an import in instances where the risks are fully commensurable and it can be proven that more risk is caused by banning the genetically modified product than by allowing the import. Where a commensurability problem exists, thereby making it difficult to perform the cost/benefit analysis, countries should still be required to assemble the risk assessment data. In these instances the facts, once gathered, will effectively dictate public policy, usually in favour of open trade. For example, if banning a genetically modified import will eliminate the risk of one cancer per million while substantially increasing the risk of nutrition related illnesses, the answer is obvious. Essentially, trade law should be based on the principle of consistency. While a country should be free to choose its trade-offs, it must be consistent in its decision-making process. If foreign products are

treated with extreme risk aversion, domestic products must be treated in the same fashion and vice versa.

The mandatory labelling of genetically modified products is also a cause for concern. The labelling of genetically modified foods means that genetically engineered products must be segregated from non-genetically modified ones. This would require farmers to separate the two when planting, harvesting, and shipping their crops. Processing plants would be forced to have two separate processing areas so as to ensure they were not mixed. Production costs would, therefore, be greatly increased and the consumer would have to absorb the cost. Secondly, labelling means that companies claiming they will use only non-genetically modified products must be monitored to ensure compliance. This would also have cost repercussions which would result in higher food prices.⁷⁹ Thirdly, it may be difficult to guarantee non-genetically modified crops due to the possibility of cross-pollination.⁸⁰ Current technology cannot detect cross-contamination to the level of zero percent so as to ensure there are no genetically modified elements within a product.⁸¹ Finally, labelling may not actually be the best way to inform consumers about genetically modified products. A recent study of Canadian consumers performed by the National Institute of Nutrition found that many consumers do not actually read labels on the products they are purchasing. Consumers who do look at labels will only do so when they are contemplating the purchase of a new product. Once the product is known the labels are ignored. Moreover, a label stating that a product “may contain” genetically modified materials is not well understood by the general public.⁸² A more detailed label may well become too complex and could force the withdrawal of important nutritional information.

While labelling may not be the best method of passing information on to the consumer, the public does have a right to the information. Efforts must be focused on providing consumers with impartial information instead of bemoaning the lack of public support for biotechnology. In fact, with greater public education and awareness, consumer concerns regarding the safety of genetically engineered products may well disappear. The participants in the nutrition study referred to above, expressed a desire for more information on genetic modification techniques. More specifically, they requested basic explanatory information about the products.⁸³ This type of background information on biotechnology, combined with detailed information on specific genetically modified products, can best be achieved by means of an internet information database established by HC and/or the CFIA. At the

⁷⁹ Whitman, *supra* note 5.

⁸⁰ Scofield, *supra* note 24.

⁸¹ Whitman, *supra* note 5.

⁸² *Supra* note 26.

⁸³ *Ibid.*

international level this could be done as part of the Internet Biosafety Clearing House that is being established by the parties to the CPB. The site could include general educational materials as well as detailed information on specific products. Specific product information would include the results of the cost-benefit risk analysis. In order to ensure that the information is accessible to the public, terminals, providing consumers with access to the info-site, could be set up in grocery stores. While the establishment of a site such as this would ensure the public has easy access to this information, it would still allow grocery store labels to include the traditional, but essential nutritional information. A site, if established by HC or the CFIA, would ensure governmental monitoring which would in turn guarantee consistency in the information provided. Finally, the cost of posting information on the info-site would be substantially lower than the cost of labelling. This is because the information could be posted as part of the government's overall regulatory process.

Finally, Canada's regulatory agencies must address the current approach to the testing of genetically modified products. As previously mentioned, Canadian governmental agencies are currently relying on data submitted by the company seeking to market its genetically modified product. This includes, for example, field trial results, risk assessments, and possible risk management techniques. While researchers at HC and the CFIA then analyse the information submitted, the possibility for bias definitely exists. Although it is not likely that false information would go undetected by the regulatory agencies, it is reasonable to assume that a corporation seeking the approval of a product that they later hope to market would attempt to submit the data in the most positive way possible. This means possible risks might easily be down-played or even ignored, leading to the existence of a public confidence issue with regard to the safety of genetic engineering.

If genetic engineering is to have a future in Canada and throughout the rest of the world, the approach to testing must be altered. It is essential that genetically engineered products undergo safety assessments and that the data be gathered and assessed by an organization with no personal interest in having the product approved for use. This may well be achieved through increased governmental funding of arms-length organizations such as the Natural Sciences and Engineering Research Council of Canada (NSERC).⁸⁴ NSERC researchers, for example, would not stand to gain personally and so would not be at the same risk of bias. And yet they would have the necessary expertise to perform field tests and assess relevant data. A second option would be

⁸⁴ NSERC, which reports to Parliament through the Minister of Industry, supports university research via research grants and other research projects through partnerships of universities with industry; NSERC, online at <http://www.nserc.ca/fact_e.htm>.

the establishment of agricultural and food safety institutes through endowment funds, organized so that they would not be required to obtain on-going governmental support but would be able to operate independently. If, having undergone testing by arms-length organizations such as these, a genetically modified product is approved for production and sale within Canada, the public is much more likely to trust the safety of the product. Because it is consumers who will be purchasing and consuming the products, they must be confident in their safety. Ultimately the producers of genetically modified products stand to gain because of the increased public confidence in biotechnology products, which will result in greater profits.

VIII. CONCLUSION

BECAUSE OF THE TREMENDOUS POTENTIAL which modern biotechnology offers Canadians and the rest of the world, the science must not be abandoned now. While any new technology brings with it concerns and risks, efforts must be made to manage the potential hazards so as to ensure that the world population can reap the benefits of genetically engineered products. The establishment of a strong, credible regulatory process will be the most effective way to manage inherent risks. Along with expert independent research, which will include a well-defined risk assessment methodology, the process must include an internet information site and additional education programs to increase public awareness. By approaching the subject honestly, educating the public as to potential benefits, and explaining risks along with risk management techniques, the fears experienced by consumers today will subside. This will enable Canadians to be at the forefront of this new technology.