PRB 99-12E

Library of Parliament Bibliothèque du Parlement

GENETICALLY MODIFIED FOODS

Frédéric Forge
Science and Technology Division

1 November 1999

PARLIAMENTARY RESEARCH BRANCH
DIRECTION DE LA RECHERCHE PARLEMENTAIRE

The Parliamentary Research Branch of the Library of Parliament works exclusively for Parliament, conducting research and providing information for Committees and Members of the Senate and the House of Commons. This service is extended without partisan bias in such forms as Reports, Background Papers and Issue Reviews. Research Officers in the Branch are also available for personal consultation in their respective fields of expertise.

CE DOCUMENT EST AUSSI PUBLIÉ EN FRANÇAIS

TABLE OF CONTENTS

GENETICALLY MODIFIED FOODS

PAGE

CANADA

LIBRARY OF PARLIAMENT
BIBLIOTHÈQUE DU PARLEMENT

GENETICALLY MODIFIED FOODS

INTRODUCTION

Theoretical and technological advances in the life sciences have gradually transformed the health and food industries, which, after all, only exist to deal with living organisms. However, while new vaccines and drugs for human use encounter very little public opposition, the situation is different when it comes to those affecting agriculture and the food supply.(1) Concerns about genetically modified foods have made biotechnology the focus of regulatory proposals. This paper will provide an overview of genetically modified foods and their regulation in Canada. Various aspects of the debate on the use of these products in Europe and in North America will also be discussed.

DESCRIPTION OF GENETICALLY MODIFIED FOODS

The term "genetically modified food" (or GM food) refers to products developed through biotechnology. Since "biotechnology" can include numerous processes and applications, the term "genetically modified" is applied only to products that have been genetically engineered;(2) that is, where genetic material (deoxyribonucleic acid or DNA) has been manipulated or where genes from one organism (animal, plant species or microorganism) have been transferred to the genetic material of another. Several terms are used in the scientific literature to describe the products that result from the use of these techniques: for example, "transgenic organism," "genetically modified organism (GMO)," "genetically enhanced organism," or "living modified organism (LMO)."

---

(1) D.J. Johnston, "A Defence of Modern Biotechnology," *OECD Observer*, Issue No. 216, March 1999.

(2) Genetic engineering is also referred to as the recombinant DNA method. Other methods used to induce genetic alterations include viral vectors, protoplast fusion and mutagenesis.

One example of the use of these techniques in the health field is the development of genetically engineered bacteria containing a human gene that can produce the insulin needed to treat diabetics. Food products derived from genetic engineering are primarily in the plant world. In Canada, 42 genetically modified plants have been approved for human consumption; they include certain varieties of canola, tomatoes, potatoes, corn, soya, flax, cotton and squash.(3) These plants are used in a range of food products; for instance, soya is used in processed products such as chocolate, baby food and cake mixes. Transgenic animals have been produced for research purposes or for manufacturing pharmaceutical products but, for the moment, these have not entered the food chain.

The term "genetically modified food" is used when the GMO is consumed in plant form (tomatoes, potatoes), or processed (in tomato sauce, canola oil), or used as an additive in more complex products (cornstarch, soya lecithin). A genetically modified food product does not necessarily contain biologically active DNA, but may contain new proteins derived from the activity of the *transgene* or new compounds or metabolites derived from the activity of these new proteins.

HOW GENETICALLY MODIFIED FOODS ARE ASSESSED AND LABELLED IN CANADA

In Canada, genetically modified foods are not treated any differently from conventional products. Each food item is assessed according to its own characteristics, rather than according to the production method employed. Responsibility for regulating these products is shared by Health Canada and the Canadian Food Inspection Agency (CFIA).

Pursuant to the *Food and Drugs Act* and its regulations, Health Canada requires prior notification of the sale or advertising of any "novel food" product in advance of its sale.(4) This applies to food products that have been genetically engineered or produced by other processes. This prior notification enables Health Canada to undertake a safety assessment of each novel food. The Guidelines for Safety Assessment of Novel Foods Volume II (Genetically

---

(3) Health Canada website, as updated 10 June 1999 http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novel_foods_and_ingredient.html

(4) Food and Drugs Regulations, Part B, 28.002.

Modified Microorganisms and Plants) were developed for novel plants and microorganisms.[5] At present, there are no guidelines in place for transgenic animals (including fish and other aquatic organisms) which might at some future time be considered for entry into the food chain. As of June 1999, Health Canada was working on updating the guidelines so that they would cover transgenic animals.

The food safety assessment approach adopted in the guidelines is based on the concept of "substantial equivalence," as defined in 1993 by experts from the Organisation for Economic Co-operation and Development (OECD) who based their work on studies done in the 1980s. This concept is recognized by international agencies such as the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

In assessing the safety of a novel food, Health Canada compares its nutrient value and composition with those of a traditional food.[6] When a new gene is introduced into an organism, new protein(s) may be produced. Consequently, Health Canada also reviews existing data to check for the presence of toxicants or anti-nutrients, and for the potential allergenicity[7] of any proteins introduced into the food product.[8] Once a food product has been deemed equivalent to its traditional counterpart according to the substantial equivalence concept, Health Canada is ready to accept that it poses no different risks, including the risk of long-term adverse effects. A novel food product that does not have a traditional counterpart is assessed on the basis of its own unique properties and composition.

Although guidelines have yet to be drafted for assessing the safety of products derived from genetically modified animals, 1988 consultations on regulating bioengineered

---

(5) Once a novel plant has been assessed and deemed safe, its by-products are also deemed to be safe. For example, if Health Canada deems that a variety of canola or genetically modified corn is safe, there is no need to do an assessment of the genetically modified canola oil or of the products containing such oil.

(6) For example, a variety of corn genetically modified to produce its own insecticide in order to battle a particular pest can be compared with a non-bioengineered variety of corn already used in human food products.

(7) "Allergenicity" describes the likelihood that substance will induce an allergic reaction.

(8) New proteins are compared to the database of known protein toxins and known allergens. Toxicity is evaluated partly by reviewing acute toxicity tests supplied by companies. Potential for allergenicity is assessed by comparing characteristics of known allergens (stability to processing, molecular weight, etc.).

livestock led to a recommendation that the substantial equivalence approach should also be applied here.(9)

No specific regulation exists for assessing the environmental impact of novel food products but, under the *Seeds Act* (clause 4(1)(b)), the CFIA carries out environmental assessments of plants with novel traits (PNTs)(10) before authorizing their release into the environment. The regulatory directive setting criteria for such assessment gives the different environmental risk factors that the CFIA must take into account before it can give authorization. The safety assessments of PNTs that are of concern (i.e., that are not familiar or substantially equivalent to products already on the market, in use and generally regarded as safe) include a detailed examination of the identity of the PNT, its relative phenotypic expression and its potential interaction with other life forms.

At present, transgenic animals are kept in containment facilities because they have significant value and are used for very specific purposes (pharmaceutical production, research, etc.). In the not-too-distant future, however, animals with enhanced traits may be developed for breeding purposes; this means that these animals could eventually be part of "traditional" animal breeding operations in the country. The CFIA is currently drafting guidelines for the release of transgenic animals into the environment and the federal Department of Fisheries and Oceans is hoping to adopt regulations providing for environmental assessments of transgenic aquatic organisms. For the moment, any product that is derived from biotechnology but that is not regulated under sectoral laws and regulations is subject to the provisions of the *Canadian Environmental Protection Act* (Part 6, clause 106(6)(a)).

Health Canada has responsibility for mandatory labelling of novel products with respect to health or food safety, their potential for causing allergic reaction, and their nutritional composition. The CFIA is responsible for voluntary labelling and for labelling designed to protect consumers against fraud. Because Canadian law requires that food products sold in this country must pose no health risk to consumers,(11) labels on novel foods must indicate whether an

---

(9) Consultation on Regulating Livestock Animals and Fish Derived from Biotechnology, Session Report, April 1999, Sponsored and Supported by Canadian Food Inspection Agency, Health Canada, Agriculture and Agri-Food Canada, Fisheries and Oceans Canada.

(10) This applies whether or not the plants are intended for human consumption or are bioengineered or produced using another method.

(11) *Food and Drugs Act*, Part 1, clause 4.

ingredient might be a potential health risk to certain individuals or to certain segments of the population.(12) Product labelling must also disclose any way in which the composition or nutrient value of the food has been changed from that of the traditional counterpart.(13) The promoter of the product is free to decide whether or not to disclose that a food product is the result of genetic engineering. Accordingly, provided the product poses no known health risk (e.g., potential for causing an allergic reaction) or has not undergone a change in nutrient value, the decision to label that particular product as genetically engineered is strictly voluntary. Moreover, there are currently no standards or guidelines for such labelling. In September 1999, the Canadian Council of Grocery Distributors (CCGD) and the Canadian General Standards Board (CGSB)(14) launched a project for developing a Canadian standard for the voluntary labelling of foods derived from biotechnology; this would provide further guidance for food companies and manufacturers. Agriculture and Agri-Food Canada (AAC) is supporting this project through the AAC Agri-Food Trade 2000 program.

THE CONTROVERSY SURROUNDING THE SAFETY OF GM FOOD

Attitudes toward genetically modified foods have varied widely. While the response in North America has been relatively favourable, at least until recently, that in Europe has been quite different. The European Union has not approved any GM crops since April 1998, and Austria and Luxemburg have even banned them. Campaigns against GMOs have also been waged in the British press.

In Canada and the United States, the majority of GMOs currently on the market were developed in order to enhance plant traits or characteristics. Plants have been genetically modified to increase their resistance to broad-spectrum herbicides; to make them produce their

---

(12) House of Commons Standing Committee on Agriculture and Agri-Food, *Capturing the Advantage: Agricultural Biotechnology in the New Millennium*, Third Report, May 1998, p. 12.

(13) *Ibid*., p. 12.

(14) CGSB works in the National Systems of Canada to develop voluntary consensus standards, which are then approved by a committee of experts representing users, producers and general interest members. It most recently completed the standard for organic agriculture through the work of a diverse group of stakeholders and interested Canadians. The CCGD represents about 80% of major food retailers in Canada and is involved in public awareness and education activities with respect to biotechnology.

own pesticide and thus combat certain pests (insects or viruses); or to delay the ripening process. The next generation of GMOs is expected to have characteristics even more appealing to consumers, such as improved nutrient value or medicinal properties, which may ward off certain illnesses (as is the case with nutraceuticals(15)).

In Europe, the attitude to genetically modified foods has been affected by a series of crises in the food industry (mad cow disease and, more recently, dioxin-contaminated poultry). The lack of solid scientific evidence in these cases and confusion in how they were handled have helped to fuel public uneasiness about the quality of foodstuffs on the market. As a result, consumer and environmental protection groups remain concerned about the long-term effects of GMOs on human health and the environment.

A. Human Health

Opponents of genetically modified foods claim that, because these products have not been adequately tested, their long-term effects on human health remain unknown, particularly because interaction between genes is not yet fully understood. Although the recent "anti-GMO" campaign waged in Great Britain was based on a single and very controversial study,(16) doubts with respect to safety persist in the scientific community. The potential of these products for causing allergic reactions in human beings is not fully known and it is sometimes difficult to make assessments about as yet unidentified toxic substances.(17) Some scientists claim, however, that an unidentified toxic substance would be more likely to appear in a conventional new variety crop, where many new, and often unidentified, genes are routinely introduced, rather than in a genetically modified plant containing a single characterized gene and its protein products.(18) It has also been suggested that the potential effects of the introduction of a single gene in a GMO are more predictable than the effects of a new variety crop produced by

(15) Nutraceuticals ("functional foods") are foodstuffs containing additives with specific properties for improving human health.

(16) "GM Foods Debate Needs a Recipe for Restoring Trust," *Nature*, Vol. 398, No. 6729, 22 April 1999.

(17) Butler *et al*., "Long-term Effect of GM Crops Serves Up Food for Thought," *Nature*, Vol. 398, No. 6729, 22 April 1999.

(18) Anthony Trewavas and C.J. Leaver, "Conventional Crops Are the Test of GM Prejudice," in *Nature*, 14 October 1999.

conventional selection methods. Even in conventional crop lines, of the many produced, only two have shown the environmental induction of a toxic compound that had not been detected during routine testing. It was found that one of these (psoralen), which had accumulated in insect-resistant non-GM celery in response to light, causes skin burns. Toxic accumulations of solanine, induced by cold weather, caused the withdrawal of the non-GM Magnum Bonum potato line in Sweden.(19)

The concept of "substantial equivalence," used by regulatory authorities including those in Canada, has also been criticized. According to an article published in *Nature*,(20) this concept has never been properly defined, and scientists are not yet able to predict reliably the biochemical or toxicological effects of a GM food from knowledge of its chemical composition. Others believe that substantial equivalence is a useful tool that identifies differences between a GM crop and a non-GM crop so that they can receive further scrutiny.

In spite of the many proponents of GMOs who argue that there is currently no evidence that genetically modified foods pose a greater risk than traditional foods, opponents point to the lessons of the mad cow disease crisis in Europe: just because there is no proof that a food product poses a risk does not necessarily mean that it is safe. The best that science can do is to dispel some of the uncertainty on both sides of this issue.

B. Environmental Impacts

The environmental impacts of GMOs vary depending on the type of the modification used. With respect to plants, some risks are that the GMO might become a weed or begin to invade natural habitats, or that the gene could be passed on so that hybrid offspring might become more harmful or more invasive. There might be an impact on non-target organisms or on biodiversity.

One widely publicised example of an adverse environmental impact was the effect of Bt corn on the monarch butterfly. Bt corn is a variety that has been genetically modified to produce an insecticide (a substance that naturally occurs in a bacteria called *Bacillus thuringiensis* or Bt) that is lethal to the European corn borer, a pest found in corn fields in North

(19) *Ibid*.

(20) Erik Millstone *et al*., "Beyond Substantial Equivalence," in *Nature*, 7 October 1999.

America. In May 1999, the results of a study carried out at Cornell University showed that Bt corn might have a lethal effect on non-target species. In experiments described in the journal *Nature* (Vol. 399, p. 14), entomologists found that 44% of monarch larvae died when they were reared on milkweed leaves dusted with pollen from Bt corn. The main criticism of the study was that the experiments had not mimicked natural conditions. Further studies to determine the ecological impact of Bt corn on populations of non-target species are currently being conducted at the University of Guelph. Furthermore, research conducted at the Arable Crops Research Institute in the United Kingdom found that the pest control of crops through the use of Bt corn might be less harmful to wildlife than conventional spraying with pesticides. In this field-scale study, reported in the journal *Nature* in August 1999, scientists found that Bt corn had no effect on beneficial insects. This study seems to support those farm groups who claim that the use of Bt crops allows reduced application of agricultural pesticides and that Bt crops are less likely to damage beneficial wildlife than are chemical sprays, which may also kill non-target insects.

Not all GM crops lead to a reduction in pesticide use, however. For instance, the growing of crops genetically modified to be resistant to broad-spectrum herbicides (such as Roundup-Ready*TM* canola) simplifies weed management, but does not necessarily reduce the use of herbicides.(21) Each genetic modification brings its own risks and benefits; claims with respect to the environmental impacts of some GMOs (whether made by proponents or opponents) do not necessarily apply to all GMOs.

The risk of creating "super weeds," a concern of opponents of GMOs, is believed by many scientists to be overestimated.(22) A broader consensus exists, however, with respect to the potential for an ecological imbalance resulting from producers' increasing dependence on genetically modified crops. Environmental groups such as Green Alliance, a British organization not opposed to genetic alterations, has proposed that a large-scale "environmental audit" of genetically modified plants be conducted, rather than a targeted assessment of the risks, as provided for in the regulations of some countries, including Canada.(23)

---

(21) Dr. Charles Benbrook, "Evidence of the Magnitude and Consequences of the Roundup Ready Soybean Yield Drag from University-Based Varietal Trials in 1998," Ag Biotech InfoNet Technical Paper, July 1999.

(22) The argument is that transgenic crops do not always have a wild relative with which they can be interbred or to which their genetic material can be transmitted.

(23) Julie Hill, "A Public Perspective," *OECD Observer*, Issue No. 216, March 1999.

THE LABELLING ISSUE

In Europe, consumer concerns and public debate extend beyond the safety of these products *per se* to the production methods employed, to animal protection issues and to cultural and ethical differences.(24) Genetic manipulations are not always well received, particularly if they involve animals and the benefits to the consumer are not clear.

To address this consumer reluctance, the European Union has brought in regulations for the mandatory labelling of genetically modified foods. Other countries, such as Australia, New Zealand, Japan and South Korea, have introduced similar legislation or regulations. In May 1999, seven European supermarket chains and three multinational food suppliers announced plans to carry products certified "GMO free." This decision will, however, mean additional costs because it necessitates reorganization of transportation, processing and distribution routes. The British Wye Institute estimates that food prices will likely rise by 5% to 15% to offset these additional costs.

The debate on GMOs in Europe is reverberating in Canada and in the United States. Certain North American milling industries, including CASCO Inc., one of the major processors of corn in Canada, announced in the spring of 1999 that, in order to retain its European customers, it would no longer be buying varieties of genetically modified corn. In September 1999, the agribusiness company Archer Daniels Midland Co. asked corn and soybean suppliers to keep their genetically modified crops separate from traditionally grown grains. U.S. suppliers contend that keeping genetic crop varieties separate is impossible at most grain

(24) Wayne Jones, "Food Safety: Protection or Protectionism," *OECD Observer*, Issue No. 216, March 1999.

elevators because they are not currently equipped to segregate large amounts of corn and soybeans.

Taking up the arguments voiced in Europe, Canadian and American environmental groups are beginning to publicize the alleged risks associated with genetically modified foods. They are also starting to call for mandatory labelling of all such foods, claiming that consumers have a right to know what they are buying. The CFIA estimates that mandatory labelling would create enormous technical problems; the complexity of the production chain and the fact that so many food products contain plants derived from biotechnology mean that virtually every product could require to be labelled. On the other hand, labelling could have positive effects. For example, the public could be familiarized with such new technologies as the slow-ripening tomato developed by Calgene,(25) which has been well received by consumers, when marketed and voluntarily labelled as genetically modified to slow the ripening process.

CONCLUSION

Although few people believe that biotechnology is a bad thing, particularly when it comes to its medical applications, the issue of genetically modified foods raises a number of concerns. Many scientists feel that the risks associated with GMOs are largely hypothetical and that adequate protective measures are already in place.(26) Even some of the staunchest supporters of genetically modified foods, however, are now calling for more research into the potential associated health risks and for a monitoring system capable of quickly identifying any long-term problems.(27) By looking to existing regulations for guidance and by applying internationally recognized scientific concepts, Canada has ensured that its producers have been able to benefit from plants with novel traits. However, with the gradual introduction of the European debate into North America, and with the arrival of new animal-based genetically

(25) McMillan D'Arce, "Labelling Can Have a Positive Effect," *Ontario Farmer*, 8 June 1999.

(26) Butler (1999).

(27) *Ibid*.

modified products, regulators and policy setters will face a number of challenges. Not only must they find ways of giving consumers the latest scientific information, but they must also address more ethical questions concerning, for instance, labelling and the introduction of transgenic animals into the food chain.

APPENDIX

Definition of "novel food" as proposed by Health Canada in: the Food and Drugs Regulations - Amendment (Schedule No. 948), as published in the *Canada Gazette, Part I* - 26 September 1998:

> a) a substance, including a microorganism, that does not have a history of safe use as a food;
>
> b) a food that has been manufactured, prepared, preserved or packaged by a process that
>
> i) has not been previously applied to that food, and
> ii) causes the food to undergo a major change;
>
> "major change" means, in respect to a food, a change in the food that, based on the manufacturer's experience or generally accepted theory, may have an adverse affect on
>
> (a) the composition, structure or nutritional value of the food or its generally recognized physiological effects,
>
> (b) the manner in which the food is metabolized in the body, or
>
> (c) the microbiological safety, the chemical safety or the safe use of the food.
>
> c) 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.