option consommateurs

l'association des consommateurs du québec

The benefits and risks related to consumer access to second generation genetically modified foods

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1. Introduction

Genetically modified organisms (GMO)[1] and the foods containing them ("GM foods") are still the subject of intense debate around the world. Some countries, like those of the European Union and Australia, have instituted mandatory labeling of these foods. For its part, Canada opted to develop a voluntary labeling standard in response to consumers' reaction to these foods. Indeed, many people are concerned about the health and environmental impacts of first-generation GMOs; that is, those developed with the stated purpose of offering benefits to farmers. While this first generation is still raising a number of questions, research is underway to develop a new generation of GM foods with a view to offering direct benefits to consumers. Included in this second generation of GMOs are crops that have been manipulated to improve their nutritional profile. These "enriched" or "functional" GM foods[2] should make their appearance on supermarket shelves in the near future.

For these reasons, Option consommateurs, which is playing an active part in the debate on GM food labeling,[3] chose to study the issues raised by these new foods. The study aims to focus on the long-term outlook for biotechnology and to foresee any difficulties that might arise from the marketing of second-generation GM foods, and more precisely GM functional foods. Although these foods seem to be more accepted by consumers, they nevertheless represent a new variable in the food industry, in terms of how they are

[1] The acronym GMO, as used in this report, designates organisms produced by new recombinant DNA technologies only. These are the technologies of greatest concern to consumers at present.

[2] For the purposes of this report, second-generation foods modified genetically to improve their nutritional characteristics will be called "GM functional foods."

[3] Option consommateurs is a voting member of the Committee for the Voluntary Labelling of Foods Obtained or Not Obtained Through Genetic Modification on Voluntary Labeling of Genetically Engineered Foods under the Canadian General Standards Board (CGSB).

marketed and explained to consumers. The project also aims to propose measures that will help to overcome the difficulties identified.

The study begins in Section 2 with an overview of the history of GM foods. It describes what is entailed by the second generation of these foods, and by GM functional foods. Section 3 is a literature review on GM functional foods. In the following section we present the regulatory and scientific challenges posed by the new generation, in terms of their assessment and marketing, as well as possible solutions to these challenges. This is followed by a discussion of the risks and benefits of these new foods to consumer health. In Section 7, the report addresses consumers' perceptions and knowledge of GM functional foods. Finally, in our conclusion, we reiterate the important points of the study and present a set of recommendations which, if these foods should be allowed on the market, could be implemented to provide an acceptable level of control that would inspire consumer confidence.

2. Definitions

2.1 Overview of the History of GM Foods and Crops

GM foods and crops have been developed in three successive waves or generations. The first generation comprises crops that are genetically modified for agronomic reasons: plant species are manipulated to withstand insect pests or viruses, or to make them tolerant to herbicides. This first generation is now well established and has been cultivated extensively in the field since the mid-1990s (Conseil de la science et de la technologie, 2002). These plants were genetically modified with the stated purpose of offering farmers alternative weed and insect control methods, i.e., to benefit the producers, but consumers derived no special benefits from these products.

The second generation of GM crops and foods could, however, offer direct benefits to consumers and the environment. Research is now being conducted to develop crop varieties resistant to various environmental stresses, such as cold, drought, contaminated soil, or acid or saline soil. Other research seeks to improve the appearance (texture, color) and storage properties of certain foods. Scientists are attempting to use biotechnological processes to develop higher-yielding plant varieties.[4] Finally, certain products derived from the second wave of biotechnological developments in agriculture promise direct consumer health benefits.[5] Along with vitamins and minerals, plants synthesize thousands of secondary metabolites[6] that may play a beneficial role in human health. Research in this field is now trying to determine the mechanisms by which certain foods produce these beneficial compounds. Then, through genetic manipulation, the nutritional characteristics of certain crops will be modified so as to produce more of these

[4] For example, some studies are attempting to improve the agronomic attributes of certain crops to increase their photosynthetic activity and make their use of nitrogen more efficient.

[5] Currently, GM foods derived from GM crops that are approved for human consumption are deemed to have nutritional value equivalent to that of their non-GM counterparts. Thus, by definition, they offer no added nutritional benefits to consumers (Royal Society of Canada, 2001).

[6] Product of the transformation of an organic body within a cell, a tissue or in the blood stream (Conseil de la Science et de la technologie, 2002).

compounds and/or synthesize compounds they would not produce naturally, without genetic manipulation.

Finally, the scientific literature refers to a third generation of genetic modifications defined as the use of plants to produce biomolecules useful in industry, medicine and science. Plant molecular farming[7] belongs to this generation. Crops used to produce these biomolecules will not, however, be used in the production of foods for human consumption.

2.2 Second-Generation GM Functional Foods and Non-GM Functional Foods

Functional foods that have been genetically modified to improve their nutritional quality should not be confused with standard or enriched functional foods.[8] The fundamental difference between these two food categories, although they are similar in terms of their DNA,[9] is that one is genetically manipulated and the other is not. Also, unlike non-GM functional foods, second-generation GM functional foods are not yet available on the market and are still undergoing research. Furthermore, they are defined as never having

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[7] The Canadian Food Inspection Agency (CIFA) defines plant molecular farming as follows: "The use of plants in agriculture to produce biomolecules instead of food, feed and fibre. Plants with introduced novel traits that produce scientifically, medically or industrially interesting biomolecules are grown as crops and harvested for the biomolecules. " For more information on plant molecular farming, see the website of the Plant Biosafety Office at http://www. inspection. gc. ca/english/plaveg/pbo/pbobbve. shtml.

[8] Standard functional foods, unlike second generation GM foods, are already available in supermarkets and gaining in popularity. These foods include high fiber cereals and breads, calcium-enriched orange juice, soybean, fish oils, omega 3-rich eggs, kefir, and various brands of yogurt and milk to which bacterial strains known for their beneficial health effects have been added. A new margarine that can lower blood cholesterol and heart disease is expected to make its appearance soon (Gravel, 2001). Research on functional foods is making swift progress. Scientists are now able to identity food compounds with beneficial effects on human health. Researchers are trying to understand how these compounds work individually and in synergy in the human body. Another term used in the field of nutrition is "nutraceutical," which again should not be confused with functional foods. Nutraceuticals are made from foods, but they are sold in pill or powder form or in other medicinal forms not generally associated with foods (NIN, 2000).

[9] DNA (deoxyribonucleic acid) is a molecule formed of segments called genes. Each gene represents a characteristic or contribution to a characteristic of an organism, and is located at a specific site along a chromosome. The chromosome is inside the nucleus of the cells making up living beings. DNA is the physical matter in which the genetic information of almost all living organisms is coded (Conseil de la science et de la technologie, 2002).

been used as foods before and/or are derived from a process that has never been used in food production.

GM functional foods and non-GM functional foods have the same objective: to procure proven physiological benefits and reduce the risk of various diseases such as cancer, cardiovascular diseases and diabetes. Tomatoes rich in lycopene, a powerful antioxidant, or spinach rich in iron and folic acid, compounds that help to prevent heart disease, are examples of functional foods — foods whose basic nutritional qualities have been augmented.

Although crops that are genetically modified to improve their nutritional characteristics are not yet marketed in Canada, by November 2000, 1372 field trial permits had been issued in the United States. Field trials are still dominated by the multinationals. Meanwhile, smaller companies, universities and government institutes are taking an interest in this field, conducting research and testing second-generation GM foods with approved nutritional profiles. It is planned to place these foods on the market in the next ten years (OECD, 2001).

3. Research on GM Functional Foods

The genetic modifications being researched at present aim to create new profiles of lipids (saturated and essential fatty acids), proteins (content, essential amino acids, allergens), carbohydrates (sugars, starch, fibre), vitamins, trace elements or compounds (carotenoids, polyphenols, etc.) or to eliminate undesirable or toxic compounds (phytates, etc.)[10] by modifying the expression or causing the overexpression of specific molecules.

[10] These last are secondary metabolites of certain plants which seem to have long-term harmful effects on human and animal health. Examples are glucosinolates in rapeseed, cyanogenic glycosides in flax, and glycoalkaloids in potatoes (Royal Society of Canada, 2001). Other research is attempting to control the levels of soluble and insoluble calcium oxalates in plants. These two very common compounds consumed in the vital functions of certain plants may have antinutritional properties in humans, since they are fixed by the bones. Soluble and insoluble calcium oxalates may cause kidney stones and other kidney problems (Franceschi, 2001).

Nutritional genomics is defined as the description and analysis of the genomes[11] of living organisms to discover genes coding for compounds with promising nutritional properties. For example, it is used to study the metabolism involved in the production of vitamins E and C. This approach will also make it possible to study other metabolic pathways in the coming years.

The conference titled "Plant Foods for Human Health: Manipulating Plant Metabolism to Enhance Nutritional Quality" held in Colorado on 6–11 April 2001, under the aegis of the Keystone Symposia on Molecular and Cellular Biology, was a forum for the latest discoveries on genetic modification to improve the nutritional profile of foods and crops. The table below summarizes the papers presented at this symposium, and reviews other scientific literature on the manipulation of crops to improve their nutritional profile. Though not exhaustive, this table does contain the principal research currently being done in this field.

Table 1: Research on GM Functional Foods

Crop (Bibliographic Reference)	**Genetic Modification**	**Benefits**
Golden rice (Ye *et al*., 2000; Beyer *et al.,* 2001)	▪ Insertion of a gene from narcissus (*Phytoene desaturase),* another from a bacteria (*Phytoene desaturase* of bacterial origin) and a third conferring resistance to hygromycine (an antibiotic used in the selection of transgenic plants) into rice so that it produces beta-carotene, the precursor to vitamin A.	• This rice could help prevent vitamin A deficiencies, which can cause diarrhea, measles, eye diseases and other health problems.

[11] The genome is defined as the complete DNA sequence of all the chromosomes of an organism or the complete genetic profile of an organism (Conseil de la science et de la technologie, 2002).

Table 1: (Continued)

Crop (Bibliographic Reference)	Genetic Modification	Benefits
Rice (and other plants) (Goto, 1999; Grusak, 2001)	▪ Incorporation of iron-containing soy proteins into rice seed so that the latter produces about three times more of this mineral than conventional rice. Research is also being done to increase the iron content of other plants using components of pea (*Pisum sativum*).	• Iron prevents anemia and certain learning disorders in children. It also increases resistance to infection.
Rice (Potrykus *et al*., 1999)	▪ Genetic modification of rice through the insertion of a fungus (*Aspergillus niger)* which codes for a phytase that breaks down phytate, a carbohydrate composed of six phosphate groups.	• Phytate binds iron, calcium, zinc and other metal ions, playing an antinutritional role in our diet. Genetic manipulation seeks to counter these antinutritional properties.
Rape, canola, soy (Shintani and Della Penna, 1998; Della Penna, 2001)	▪ Insertion of a gene (from *Arabidopsis thaliana)* into rapeseed, canola and soy seeds to produce more alpha-tocopherols, a vitamin substance of plant origin (vitamin E).	• Vitamin E is a water-soluble antioxidant. It is linked to a number of cardiovascular benefits.
Potato (Gachet *et al*., 1999)	▪ Modification of potato to produce more starch.	• By producing more starch, the potato absorbs less fat when it is deep-fried.
Tomato (Ausich,1997; Hirschberg *et al.,* 2001)	▪ Tomato is genetically modified to contain four times the normal quantity of lycopene, a carotenoid. The biosynthesis of this compound with the help of enzymes is now a well-understood process. All these enzymes were cloned, and research is now attempting to make them build up in tomato.	• The carotenoids are powerful antioxidants. They can decrease the risk of heart disease and certain types of cancer.

Table 1: (Continued)

Crop (Bibliographic Reference)	Genetic Modification	Benefits
Oilseed crops Examples: Soy, canola (Ohlorogge *et al*., 2000; Browse, 2001; Kinney, 2001; Debbie *et al*., 2001)	▪ Oilseed crops are genetically manipulated to change their lipid profile. Research has led to a good understanding of the enzymology and molecular genetics of these species. All the genes involved in the production of edible oils have been isolated. It is now possible to modify the saturated and polyunsaturated fatty acid profiles.	• For example, soya oil is rich in polyunsaturated fatty acids, which are often chemically hydrogenated to increase their shelf life and to make them more stable during cooking. However, hydrogenation yields trans fatty acids, which increase the risk of heart disease. Genetic manipulation seeks to produce trans fat free soy beans. • Another example: Omega-3 fatty acids are important in human health. Studies have shown that this compound can prevent heart disease. Certain populations do not consume enough of these fatty acids and research is seeking to incorporate them into a wide variety of staple foods.
Broccoli (Gachet *et al*., 1999)	▪ Manipulation of broccoli to produce anti-oxidants and anti-carcinogens such as glucosinolate.	• Antioxidants and anti-carcinogens prevent or slow down the aging of human cells.
Peanuts (Meagher-Gallo and Kang, 2001)	▪ Modification of peanuts to control the expression of two genes responsible for allergies, *arah1* and *arah2*.	• Decrease the risk of allergies in certain individuals.
Various plants	▪ Genetic modification to increase amino acid content (lysine, methionine) in plants (grains for example) (Tang *et al*., 2001). ▪ Genetic modifications of certain vegetables to accumulate isoflavonoids, which are present naturally only in legumes (Dixon *et al*., 2001). ▪ Genetic modification of certain plants to produce resveratrol (Paiva *et al*., 2001). ▪ Genetic modification of certain plants by inserting a gene coding for lignans, compounds found in grains (Lewis, 2001).	• Lysine is an amino acid essential to the growth of humans and animals. • Isoflavonoids are compounds known to play a role in preventing cancer, osteoporosis and heart disease. • Resveratrol is a phenolic compound that acts as an antioxidant, a phytoestrogen, and inhibits the formation, growth and progression of tumors. There are very few natural sources of resveratrol. • Lignans help prevent certain diseases, such as breast, prostrate and testicular cancers.

These crops may be on the market within about ten years, but some are already authorized for field trials. These include corn, soybean, tomato, potato, canola, rice, wheat, oats, alfalfa, lettuce, flax, coffee, grapes, pear, apple, melon, pepper and plum (OECD, 2001). Moreover, the development of second-generation GM foods and crops is being accelerated by the sciences of genomics and proteomics.[12] The genomes of certain plants have now been worked out. These developments have made it possible to characterize and clone useful nutritional genes more rapidly so as to transfer them into crops lacking the corresponding properties.

But improvement of nutritional qualities extends to the animal realm as well. According to a report by the Royal Society of Canada, an application could be made to the Canadian Food Inspection Agency (CFIA) in the next ten years to modify the biochemical characteristics of fish flesh to improve its nutritional value or organoleptic properties. Other researchers are working on nutritional improvement of livestock, and hence meat, eggs and milk (Royal Society of Canada, 2001).

3.1 The Controversy Around Golden Rice

The GM functional food that has received the most media coverage so far is so-called "golden rice. " Rice is the staple of nearly half the world's population. This plant is not a natural producer of beta-carotene, the precursor to vitamin A, and 250 million people suffer from vitamin A deficiency.[13] Scientists have turned to genetic manipulation of rice to produce it.

Rice cannot produce beta-carotene because it is missing four enzymes. Scientists inserted four genes. Two of these are from narcissus (*phytoene synthetase and lycopene b-cyclase*), a third is from a bacterium (*phytoene desaturase*), and a fourth is a gene

[12] Proteomics is an area of research that seeks to identify and characterize all the proteins present in a living organism (Conseil de la science et de la technologie, 2002).

[13] A vitamin A deficiency can cause health problems such as eye diseases, diarrhea and measles.

conferring resistance to hygromycine, an antibiotic used in the selection of transgenic plants. After several trials, the manipulations produced a GM rice variety containing significant levels of beta-carotene in its endosperm, the tissue providing nutrition to the embryo. The beta-carotene lends the rice the orange colour from which it derives its name.

An article in the January 2000 issue of *Science* presents the data for one variety of transgenic rice. This variety produced 1. 6 mg of carotenoids per gram of endosperm. The authors expect 2 mg/g in future varieties, for a ratio of 100 mg of vitamin A per 300 g of rice eaten. But this is far below the daily allowance of 600 mg recommended by the U.N. Food and Agriculture Organization (FAO). To get this amount, a person would have to eat two dry kilograms of golden rice per day, or nine kilograms of cooked rice! (FAO, WHO, 1998).

There is disagreement in the golden rice literature on how much rice a person would have to eat to obtain sufficient vitamin A. As well, a host of other questions remain unanswered about this technological advance. Would the beta-carotene be assimilable? In what form is it stored by the plant? Is it in a form that would withstand heat or would it be destroyed by cooking? What are the harmful effects (allergies, toxicity) on the body? What are the effects on the environment? From a political standpoint, would countries of the South, where the rice would be grown over large expanses, have the resources to conduct the field trials necessary to ensure that the crops have no harmful effects in terms of public health, agriculture or the environment? Is the development of this GM rice variety merely a public relations exercise?

There is not yet enough data to answer these questions. It has been stated that golden rice seed will not be available before 2003. However, before it is marketed and distributed, golden rice will be subjected to rigorous testing to detect any presence of toxins or allergens.

4. Evaluating Second-Generation GM Foods and Crops: Regulatory and Scientific Challenges

4.1 Regulatory Challenges

In Canada, as in many other countries, the evaluation of GM or novel foods[14] is based on the concept of substantial equivalence. Determination of substantial equivalence involves the comparison and identification of differences (new DNA sequence, missing native DNA sequence, presence or absence of a protein) between a GM food and its conventional counterpart. Once a GM crop variety has been declared "substantially equivalent" to a non-GM variety, the new variety is spared any further testing to determine whether unanticipated characteristics may exist. In 1995, the World Health Organization (WHO) published a report in which this concept, as the decision threshold tool, was presented as the basis for decisions about the relative safety of GMOs. At present, the concept of substantial equivalence as a regulatory decision threshold tool is very controversial; several delegations and observer organizations have stressed the need for a more detailed examination of this concept and its applicability to the assessment of safety. This was also the conclusion of the Royal Society of Canada Report on the future of biotechnology, which proposes that the routine use of this concept as a regulatory threshold tool be replaced by testing (Royal Society of Canada).

4.2 Scientific Challenges

It appears that the concept of substantial equivalence used until now to approve various GM crops will be difficult to apply to second-generation GM foods and crops that have been manipulated to improve their conventional profiles. The problem is that previously, GM foods were described as having a nutritional value equivalent to their conventional counterparts; but it is difficult to find these counterparts to GM functional foods because a larger number of genes are involved. The new generation of GM foods is the result of

[14] Foods modified by genetic manipulation (GM foods) are defined in Canada as "novel foods. " (*Food and Drug Regulation,* C. R. C.*,* multi. 870, art. B 28. 001.

much more complex modification than the first generation. The manipulations may modify metabolic functions[15] and entail the insertion of new genes that may have undesirable effects. More precise methods must be developed so that these unexpected side effects can identified. (Canadian Biotechnology Advisory Committee, 2001).

According to the OECD report on the nutritional evaluation of novel foods, no specific guide has been developed to the evaluation of these foods. To assess their safety, one must take into account all the interactions among all the nutrients. That is, the effectiveness of a metabolism and the safety of a nutrient may reach thresholds varying from optimal to adequate to toxic. Moreover, it may take 30–40 years to identify a diet causing harmful effects. Finally, the consumption profiles of different populations must be taken into consideration. Currently, research disciplines such as classical toxicology, nutrition and kinetic studies can answer some questions about safety, but only based on animal studies, whose scientific interpretation has limits.

4.3 Possible Solutions

Several organizations, including the OECD, the Agence française de sécurité sanitaire des aliments (Afssa)[16] and the Royal Society of Canada Expert Panel on the Future of Food Biotechnology have recently reflected on the problems of evaluating novel foods. They have proposed suggestions and lines of research that will be useful in assessing second-generation GM functional foods:

1. The concept of substantial equivalence could serve as a point of departure for an assessment of these foods. Comparison with conventional equivalents, as a method for assessing GM functional foods, could provide information on the nutritional content and predict possible unforeseen side effects. However, it must not be the main decision-making tool in the assessment process.

[15] Metabolic functions are defined as the chemical processes governing plant physiology and growth (Conseil de la science et de la technologie, 2002).

2. Where significant variations in the profile of a food component are found, it would be advisable to test the whole food to assess bioavailability of nutrients. These assessments should focus more specifically on the metabolism and physiology of the nutrients.

3. Before these foods are marketed, studies should be conducted on the diets representative of the nutritional habits of populations. The polymorphism of populations must be considered, along with age and status differences (infants, adolescents, pregnant women, menopausal women, elderly people) and interactions with other lifestyle factors. A food must be determined to be safe for an entire population, not just a particular group. In addition, these studies should be done on animals and humans, anticipating regular and maximum exposure. The reason is that animal testing can provide useful information, but it cannot determine the impacts of the long-term ingestion of a food, because animals live shorter lives than humans.

4. Because of the numerous variables mentioned in point 3, it is clear that it will be much easier to demonstrate the benefits of these foods, as well as to develop new markers and epidemiological studies to measure their health effects, after they have been placed on the market and are being consumed by large populations. Obviously, systematic surveillance of human populations will be necessary to determine the long-term impact on human health of ingesting any given GM food. Post-marketing surveillance can confirm the data collected during the testing done earlier. However, such surveillance will require the use of more advanced data collection methods, such as biomarkers,[17] which may not currently be at a stage of development and availability sufficient for them to be used.

These solutions show that it will be necessary to assess the impact of GM functional foods on the total diet of an individual before and after marketing; it does not suffice to

[16] These solutions are found in the proceedings of a conference entitled "OGM et alimentation: peut-on évaluer des bénéfices pour la santé?" held by Afssa in December 2001. The proceedings are available at: http://www. afssa. fr/dossiers/index. asp?id_dossier=4438.

[17] Biomarkers serve to assess the safety and nutritional efficacy of various food compounds in living organisms.

assess a specific characteristic of a food. The multiple metabolic responses of individuals following the ingestion of a novel food or nutrient will have to be better understood and evaluated. This done, it will be possible to determine the impacts of these novel foods on public health generally. This type of assessment was not conducted with the first generation of GM foods; it represents a challenge to several scientific disciples, which will have to develop new analytical methods.

5. Control and Marketing of GM Functional Foods

5.1 Risks and Benefits of GM Functional Foods

GM functional foods may constitute a useful and attractive option for certain groups of consumers with special needs, e.g., those with predispositions to certain diseases. However, not everyone can benefit from this type of product. People who eat a variety of foods and get regular exercise do not necessarily need to eat "enriched" foods. In fact, some health professionals fear that these foods could give people susceptible to certain diseases, or suffering from chronic diseases, a false sense of security about their diet and lifestyle. For example, people might be led to believe that they are in no danger if they consume foods genetically manipulated to produce omega-3, a substance providing some protection against heart disease. It would be counterproductive for them to then go off their diets and increase their consumption of saturated fats. To take another example, people eating calcium-enriched broccoli might be tempted to eat fewer dairy products.

Another danger is that these foods might exceed the acceptable limits for certain vitamins, proteins and minerals. At present, to establish the nutritional makeup of foods, nutritionists, dieticians and other food specialists consult databases like the Canadian Nutrient Data File.[18] This database contains information on the average nutritional

[18] This database is used in the compilation of nutritional surveys, but also for many other purposes such as risk assessments. For more information on this database, see the website of Health Canada's Nutrition Research Division.

content of various foods as derived from measurements of different varieties of commercial food crops, such as potatoes or corn. Subsequently, the concentration of nutrients in any given crop must fall within the known range; if it does not, there could be harmful health effects for people who consume a great deal of the food. For example, an excess of vitamin D can be dangerous for people suffering from kidney stones, since vitamin D promotes calcium absorption by the bones. An excess of vitamin A taken by pregnant women can cause birth defects. Finally, overconsumption of beta-carotene can cause cancer in smokers, according to certain studies. Another potential problem is the antagonism between different food components; an example would be where a new product containing a non-absorbable fat were also enriched with vitamin A, and the two effects cancelled each other out.

5.2 Consumer Information

Should GM functional foods eventually make their way onto supermarket shelves, consumers will have to be informed of the fact. Companies will have to warn people, through appropriate labeling, that these products have been enriched by genetic modification. This raises two issues: the labeling of GM foods, and the matter of health claims. Canada, under the auspices of the Canadian General Standards Board (CGSB) is still in the process of developing voluntary labeling standards for GM and non-GM foods. This committee has still not reached any consensus on this standard, and its application has been postponed for an indefinite period. Canada does not currently have any official guidelines on the labeling of GM foods, nor any regulations on traceability,[19], nor yet any standards making it possible to identify GM foods and crops. Such a tracking system is necessary if GM functional foods are to be identified and labeled. Otherwise, there is no way to verify the information appearing on product labels.

The second issue is that of health claims. First, current research on functional foods is inconclusive; our knowledge of them is quite fragmentary. Second, nutrients do not have

[19] The traceability of GM foods and crops involves a system that can be used to track products from field to table; that is, all stages in their production and processing.

the same effect on each individual in a population, and may vary by age and sex, for example, which renders research more complex (OECD, 2000). The challenge of GM functional foods is to offer consumers foods or food ingredients with significant health benefits that have been proven by valid scientific research and can be communicated through appropriate claims. The difficulty resides in the development of requirements for proof of health claims in a manner that is both practical and credible. Health Canada's current regulatory framework was not designed to promote the health benefits of foods. The phrases "calcium builds strong bones," "a calcium-rich diet can reduce the risk of osteoporosis," or similar claims of nutritional benefits, cannot legally appear on the labels of functional foods. However, Health Canada is currently reviewing its policies and guidelines on nutritional labeling information, and some nutritional claims will henceforth be allowed.[20]

Finally, as mentioned above with regard to the assessment of these foods, a robust tracking system will have to be implemented for GM functional foods after they are marketed. The following questions must be answerable: Who uses these products? With what frequency? At what dosage? What are the cumulative effects? What is the influence of these products on other food choices? How will the scientific basis of a claim be demonstrated? What type of communication with consumers is necessary? What level of proof will be required? How can consumers be warned that certain enriched foods are reserved for athletes and people on special diets? If we do not know what Canadian consumers are eating, we will not be able to assess and measure the impact of these products. According to the National Institute of Nutrition (NIN), it is up to governments, industry and nutritionists to take this initiative (NIN, 2000).

[20] For more information on the draft regulation to amend the Food and Drug Regulation (nutritional labeling, nutritional claims and health claims), see: http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs_aliments-drogues/part-partie_1/f_1172_index. html.

5.3 Necessity of Developing GM Functional Foods

Industrialized Countries

Dietary deficiencies and malnutrition are almost unknown in Canada. In fact, many Canadians are "overnourished." If some people are suffering from "nutritional imbalances," it is because they are buying foods for their taste, and not for their nutritional value. Nutritionists and health professionals incessantly repeat that a variety of fresh foods is necessary. However, for a variety of reasons including a lack of time, many people have poorly balanced diets. They eat certain foods in excess and suffer from deficiencies of vitamins, trace elements, fatty acids and food fibre. These nutritional problems are worsened by the food industry and its mass marketing of refined foods.

Many consumers today are replacing fresh fruits and vegetables, which contain a great variety of nutraceuticals, with vitamin pills, and the market for functional foods and nutraceuticals is growing fast in Canada, the United States and several European countries. Kellogg's, Novartis and Nestlé, among others, are developing an increasing variety of enriched products, all the while asserting that the purpose of food is to cure our ills. However, many health professionals still doubt the value of developing such foods for the industrialized countries.

Developing Countries

Some observers consider second-generation GM foods as the solution to hunger and food scarcity in the world (OECD, 2000). These foods seem to promise numerous benefits for developing countries which are experiencing malnutrition due to vitamin and mineral deficiencies. The *Human Development Report 2001* of the United Nations Development Program (UNDP) admits that it is necessary to manage the environmental and health risks of GMOs, but stresses the exceptional opportunities made available by genetics to produce crops with higher nutritional value. The report goes as far as to contend that new varieties of millet, sorghum and manioc — staple crops in the diet of poor people in numerous developing countries — must be developed without delay. The same report

asserts that biotechnologies can improve food security in Africa, Asia and Latin America. It is argued by some that prohibiting the use of second-generation GMOs is a concern of rich countries blind to the "humanitarian" side of this new biotechnological development. They claim that Europe and the United States are neglecting the concerns and needs of the developing world. A quote from the UNDP report summarizes this point of view:

> Western consumers naturally focus on potential allergic reactions and other food safety issues. People in developing countries however, may be more interested in better crop yield, nutrition, or the reduced need to spray pesticides that can sicken farmers. Meanwhile, multinational biotech companies, eager for sales, tend to play down the difficulties that developing countries may have in managing the environmental risks posed by GMOs. The voices of people in poor countries, who stand to gain or lose the most from these new technologies, have not yet been heard.[21]

However, these assertions have aroused some skepticism. It is true, of course, and statistics show, that more than 800 million people are hungry and that 82 countries, half of them on the African continent, do not produce enough food but cannot afford to import the difference (Ho, 1996). But this poverty is often linked to the political and economic situation of these countries.

Finally, there is no plant or food at present that can contain all the nutrients a human being needs. Eating a variety of foods so as to obtain our daily allowance of nutrients (proteins, carbohydrates, fats, vitamins, minerals, etc.) is the best solution, as many health professionals believe. Genetically manipulating plants to make up for a deficiency in people who subsist on monocultures will not solve anything. A different solution would place the emphasis on a more ecological agriculture, i. e., one that is more respectful of the environment and future generations.

6. Costs to the Consumer

Although no GM functional foods are yet available on the market, it is no stretch to assume that they will cost more than conventional foods. The non-GM functional foods

[21] For more details on this report, visit the UNDP website at http://www.undp.org.

currently available often cost much more than other products. For example, a margarine enriched with phytosterols to reduce "bad cholesterol" is being launched; it costs three times as much as conventional margarines (Gravel, 2001).

Moreover, the implementation of a GMO labeling system in Canada, be it voluntary or mandatory, is likely to increase the cost of GM functional foods. Consumers are increasingly demanding that GM functional foods be labeled, and this will undoubtedly lead to increased costs. Not only will these products necessitate a labeling system, but it will have to be backed up by a system of product detection and traceability. All of this is likely to raise the price to the consumer.

7. Consumer Perception and Knowledge of GM Functional Foods

7.1 Results of a Pan-Canadian Survey on Functional Foods and GMOs

The matter of GM foods is currently arousing a great deal of scientific, economic, political and ethical debate. So far, surveys have shown that consumers want labeling so that they can choose between GM and non-GM foods. In addition to the perceived risks to human health and the environment, consumers do not see how first-generation GM foods can benefit them.

Consumers seem to be more readily accepting of GM functional foods. However, very few studies have been done until now to demonstrate this acceptance, since these foods are relatively new and are not yet on the market. A pan-Canadian survey conducted by the Nutraceuticals and Functional Foods Institute, in cooperation with the Centre de recherche en économie agroalimentaire at Université Laval (CRÉA), illustrated certain consumer trends regarding GM foods and functional foods. The purpose of the survey was to assess consumer beliefs and knowledge about functional foods, nutraceuticals and GMOs; it also sought to estimate how much consumers are willing to spend for the functional properties of foods (see Appendix B for the details and results of this survey).

First, this survey showed that consumers firmly believe in an intimate relationship between the quality of food and its health effects. They also believe that food can prevent certain diseases. On the other hand, they appear to be increasingly dubious about the validity and rigour of food nutritional claims. Furthermore, consumers appear to be increasingly dubious about the information provided by governments; this causes a problem for the functional food and nutraceuticals market, which has health objectives. Consumers would rather refer to specialists such as nutritionists, doctors or other health professionals to obtain information on the nutritional effects of functional foods. Concerning GM foods, 40% of Canadians say that they object to them,[22] but the survey did show that if a functional property were added to a GM food, consumers would be more likely to choose it.

7.2 Results of the Option consommateurs Focus Group

To evaluate the state of consumer knowledge about GM functional foods, Option consommateurs held a focus group. Seven (7) people, four (4) of them women and three (3) men, were recruited by sending out an e-mail (see Appendix A for the text of this e-mail). We chose to distribute this announcement to more informed interest groups, because the general public as a whole is not very familiar with GM functional foods. To discuss the issues and expectations of consumers on this matter, we targeted the announcement at people who are already knowledgeable about GMOs and are participating in the debate. Therefore, this bias has to be factored into the analysis of the results. A problem statement and a list of goals and objectives were presented to the focus group at the outset. The participants answered five open questions concerning second-generation GM functional foods (see Appendix A for the list of questions).

The majority of the participants had already heard of functional foods that are genetically modified to improve their nutritional profile. However, the terms "functional foods," "nutraceuticals," "*nutricaments*," "*alicaments*," mentioned by the participants, were better known than the phrase "second-generation GMOs" or "GM functional foods. " On

[22] However, the survey tempered this opposition by showing that Canadians do not necessarily understand the meaning of the word genetically modified in all its complexity.

this issue, a participant stated that it is very important to do public education about these terms, because the proliferation of terms and expressions relating to GMOs is leading to some confusion in the media and among the general public. The participants doubted that these foods were already on the market, believing that they were still undergoing research. The two best-known examples of functional foods were golden rice and the modifications of the fatty acid profiles of oilseeds to produce omega-3 and other "good fats." The case of golden rice brought up issues about North-South relations. The participants wondered whether people in the South (or developing countries) will have the choice to grow this kind of rice which, after all, was developed with them in mind. They feared that the new GMOs would increase the dependency of developing countries on industrialized countries.

Among the perceived advantages of GM functional foods, two participants mentioned the development of allergen-free peanuts and the substitution of healthier omega-3 for saturated fatty acids. Some of the participants felt that these novel foods might be part of a global strategy to solve certain nutritional problems, and that GMOs should not be rejected *en bloc*. However, the participants unanimously agreed that biotechnology is not a panacea for famine in the world. The participants deplored the resort to roundabout methods for addressing the problem of malnutrition rather than attacking the root of the problem, which they saw as poverty. A consumer contended that second-generation GMOs might be a marketing strategy designed to overcome consumer resistance to GMOs in general. He believed that the companies will play up the beneficial health effects of these foods, and that they will use labeling as a promotional medium for the biotechnology industry.

Another disadvantage to the use of these foods raised by one participant is that, whether they are enriched by genetic modification or not, their health benefits are limited because the body is limited in its ability to absorb nutrients; it simply eliminates whatever it cannot absorb. It was also pointed out that the environmental risks associated with second-generation GMOs (genetic drift, for example) are no different from those of the first generation.

The focus group participants all agreed that more emphasis should be placed on a varied diet and exercise than on the "magical" health effect of enriched foods. They also mistrusted the idea of nutritional claims about foods, arguing that the specific health effects of certain nutrients are still poorly understood. Research is needed on the allergy and toxicity risks of GM foods.

Finally, the participants wanted industry and government to implement tracking systems that will make it possible to determine what is in a food and where it comes from. They also called for mandatory labeling of GMOs, asserting that the CFIA and Health Canada will have to be monitored to ensure that they are obeying consumers' wishes in this matter. These consumers, it seems, have lost confidence in their governments around the GMO debate.

8. Conclusion

8.1 Highlights of the Report

This section summarizes the information on the GM functional foods identified in this report:

Section 2: Definitions

- Crops and foods arising from the second generation of genetic modification are being developed to offer direct benefits to the consumer, which was not the case with the first generation of GMOs.
- One purpose of second-generation GMOs is to improve the nutritional quality of foods through genetic modification. This category of "enriched" foods resembles the functional foods currently available on the market. That is, both GM and non-GM functional foods aim to provide proven physiological benefits and to reduce the risks of various diseases such as cancer, heart disease and diabetes. (For the purposes of the report, we have termed these new foods "GM functional foods").
- GM functional foods are not yet available on supermarket shelves and are still undergoing research.

Section 3: Research on GM functional foods

- The genetic modifications under current study aim to provide:

  1. New lipid profiles (saturated and essential fatty acids);
  2. New protein profiles (content, essential amino acids, allergens);
  3. New carbohydrate profiles: (sugars, starch, fiber);
  4. New vitamin profiles;
  5. New trace element profiles (carotenoids, polyphenols, etc.);
  6. Eliminate toxic and undesirable compounds.

- Golden rice, which has been genetically manipulated to produce vitamin A, is the GM functional food that has received the most media attention. It is still raising numerous scientific and political issues.

Section 4: Evaluating second-generation GM foods and crops: regulatory and scientific challenges

- The principle of substantial equivalence, which depends on a comparison and an identification of differences between a GM food and its conventional counterpart, is the current regulatory decision threshold for assessing the safety of GMOs. It will be more difficult to apply to GM functional foods: it is more difficult to find their counterparts since a larger number of genes have been manipulated.

- There is no specific guide to the evaluation of GM functional foods.

- Various solutions for pre- and post-market assessment are proposed. In assessing these products, it is important to take account of all interactions among nutrients, to assess the impact on the total diet of an individual, and to do long term studies (before and after marketing), taking into consideration all variables (age, sex, consumption habits, etc.).

Section 5: Control and marketing of GM functional foods

- GM functional foods may constitute a useful and valuable option for certain categories of consumers with special needs, such as a disease predisposition. However, they may pose certain hazards to the public, such as overconsumption of certain nutrients.

- A labeling system must inform consumers of GM functional foods on the market. This raises two issues: GMO labeling and the matter of health claims. Canada currently has no regulations on GMO labeling and traceability. And although Health

Canada is now reviewing its nutritional labeling regulations to allow health claims, too little is still known about the health effects of foods on populations. The difficulty resides in the development of requirements for proof of health claims in a manner both practical and credible.

- Many health professionals argue that the industrialized countries do not need "enriched" foods. Canada is a country, they assert, in which many people are "overnourished. " Nutritional imbalances often occur because consumers buy foods for their taste and not for their nutritional value; moreover, the refining of foods by the food industry deprives them of some of their nutritive properties.

- Some people perceive second-generation GM functional foods as a solution to world hunger. These foods seem to have great promise for developing countries whose populations suffer from malnutrition due to vitamin and mineral deficiencies. However, many are skeptical of these assertions, arguing that malnutrition and poverty are often strongly conditioned by political and economic factors.

- Although GM functional foods are not yet available on the market, we can predict that they will cost more than conventional foods. This can already be seen with functional foods such as phytosterol-enriched margarines designed to reduce bad cholesterol, which cost three times as much as conventional margarine. The cost of these foods is also likely to increase if GMO labeling and traceability systems are implemented.

Section 7: Consumer perception and knowledge of GM functional foods

- A pan-Canadian survey on functional foods and GMOs showed that consumers need to know that their food is safe, nutritious, and plays a role in disease prevention. However, they seem to be dubious of health claims on product labels, nor do they want information on food safety and benefits to be communicated by the manufacturers.

- The functional properties of foods appear to be appreciated by the consumers surveyed. However, GM functional foods, which promise direct benefits for the consumer, will not be very popular if the public does not feel that it is correctly informed about the production process and the assessment of these foods' safety.

- The survey also showed the popularity of functional foods with consumers, indicating that they might more readily accept GM foods to which a functional property is added.

- The participants in a focus group held by Option consommateurs mentioned that GM functional foods could be part of a global strategy used to solve certain nutritional problems in the world, and that they should not be rejected *en bloc*. On the other hand, the participants unanimously agreed that biotechnology is not a panacea for the problem of famine in certain countries.

- The focus group participants also mentioned that the health benefits of enriched foods are limited, and that these tools are largely marketing vehicles. The consumers in our group doubted the veracity of health claims in general.

- Finally, the discussion group participants would like to see mandatory labeling of GM functional foods. A rigorous labeling system will have to be implemented. On this matter, the consumers doubt the objectivity of the Canadian government. They seem to have lost confidence in the government around the GMO debate.

8.2 Recommendations

This study has enabled Option consommateurs to foresee some of the difficulties associated with the marketing of second-generation GM foods, and to make recommendations for better control of these "enriched" foods should they be placed on the market. In particular:

- Option consommateurs recommends that studies be conducted to assess the need to market GM functional foods in Canada. These studies should be carried out by impartial and independent health professionals such as doctors and nutritionists. Canadian consumers are already "overnourished," and Option consommateurs believes that the marketing of enriched foods will not solve their health problems. Greater emphasis should be placed on public awareness of the importance of a varied diet.

- Option consommateurs recommends that pan-Canadian surveys be conducted to determine whether Canadian consumers want these foods to be marketed. These surveys should be conducted by independent bodies.

However, should these foods be approved:

- Option consommateurs recommends that GM functional foods be subjected to mandatory labeling and traceability so that they are brought to consumers' knowledge. A labeling and traceability system must be implemented to indicate the content of GM material in these foods, the recommended quantities (dosage) so as not to exceed the acceptable limits of vitamins, proteins, minerals and other "added" or "modified" trace elements.

- Option consommateurs recommends that more research be done on the causal links between certain nutrients and health. This research should be based on valid scientific

approaches. Scientific justification of health claims is necessary to provide accurate information to consumers. This information must be explained to consumers by means of a Canadian public education strategy. Information sessions should be given by dietetics professionals and impartial and independent health experts, such as nutritionists and doctors — not by representatives of food companies or government agencies.

- Option consommateurs recommends that the assessment of GM functional foods not be based solely on the principle of substantial equivalence as a regulatory decision threshold tool. This concept is difficult to apply to GM functional foods which involve a larger number of genes than first-generation GM foods.

- Option consommateurs recommends that more research be done to develop specific methods or guides to the assessment of GM functional foods before they are marketed. These methods must be more precise and able to identify unforeseen side effects.

- Option consommateurs recommends that animal and human studies be done on diets representative of the nutritional habits of populations before GM functional foods are marketed, so as to predict regular and maximum exposure and to assess the impacts on the total diet.

- Option consommateurs recommends that a robust tracking system be implemented once GM functional foods go to market. This system must be based on rigorous data collection methods, such as the use of biomarkers.

These recommendations show that there remains much to be done before GM functional foods are placed on the market. Pre- and post-market assessment systems for these foods must be developed. It will be important to manage the consumption of these foods by means of a solid consumer information system. This information must be transmitted through rigourous food labeling and a large-scale public information and awareness campaign.

The task at hand is to keep a close watch on the status of research in the field, as well as the assessment and control methods that will actually be implemented by Health Canada and the CFIA. It will be very important for the various levels of government to consult the population on the development of these methods. The first generation of GM foods is still arousing fears among consumers, many of whom distrust the health and environmental effects of these foods. In fact, no study has yet demonstrated that these products are safe. The second generation of GM foods poses additional challenges which the industry and governments will have to overcome if they want to regain consumer confidence in GM foods.

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10. Appendix A: Documents Used in the Organization of the Focus Group

Announcement

Second-generation transgenic foods

What are the benefits? What are the risks?

Option consommateurs, a nonprofit association dedicated to the defense and promotion of consumer interests, is looking for people to form a focus group on the topic of genetically modified foods promising direct benefits to the consumer. Vitamin-enriched vegetables and fruits containing vaccines are examples of a new group of foods whose purpose is to improve the quality of life of consumers and to prevent disease. You are invited to come discuss your knowledge, demands and expectations of these new foods, as well as the rules that will govern their marketing.

- Remuneration: $25/person.
- Number of people needed: 20
- Number of participants per focus group: 10
- Time: week of 11 February 2002

If interested, please contact **Marie-France Huot at (514) 598-7288 extension 227.**

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Questions

1. Had you already heard about second-generation GM foods (i.e. crops modified to improve their nutritional characteristics)?

2. What do you see as the advantages and disadvantages (or risks) of developing GM foods with "improved" nutritional characteristics?

3. According to you, are there myths associated with second-generation GM foods?

4. Apart from voluntary labeling (which Canada is now developing for GMOs) and assessment by government agencies (Health Canada and the Canadian Food Inspection Agency), what controls can be put in place to guarantee consumer safety, and marketing that respects consumers' rights?

5. If these foods were put on the market, what would be your main expectations or requirements?

11. Appendix B: Survey on Functional Foods and GMOs