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l'Association pour la santé publique de l'Ontario
Established/Établi 1949

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Protecting our Food Supply: Public Health Implications of Food Biotechnology

A Position Paper for the Ontario Public Health Association

Code: 2001-01 (PP)

Status: Active

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November 2001

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GLOSSARY OF TERMS

The following definitions are derived mostly from the Royal Society of Canada report, *Elements of Precaution* (1):

| | |
|--|--|
| Allergen | A substance, usually a protein, capable of inducing a specific immune hypersensitivity response, often resulting in immunoglobulin E production. |
| Biodiversity | The number and types of organisms in a region or environment. Includes both species diversity and genetic diversity within the species. |
| Biotechnology | A set of biological techniques developed through basic research and now applied to research and product development. In particular, the use of recombinant DNA techniques. |
| Bt, <i>Bacillus thuringiensis</i> | A soil bacterium that produces a toxin that is deadly to some insects. Many strains exist, each with great specificity as to the type of insect it can affect. |
| rBST | (recombinant) Bovine somatotropin, a genetically modified version of a hormone that controls a cow's metabolism and increased milk production. Its use is approved in the USA but not in Canada. |
| Canadian Nutrient File | A compilation of nutrient values for foods available in Canada, produced by Health Canada. |
| Confined Field Trial | Field trial carried out with specific restrictions on location, plot size, etc. |
| GE | Genetically Engineered (see GM) |
| Gene | The fundamental physical and functional unit of heredity. A gene is a specific stretch of DNA located in a particular position on a particular chromosome that encodes a specific functional product (i.e. a protein or RNA molecule). |
| Gene flow | The movement of genes from one population to another. |
| Gene gun | A device for propelling DNA molecules into living cells. |
| Gene product | The biochemical material, either RNA or protein, resulting from expression of a gene. |
| Gene stacking | Simultaneous presence of more than one transgene in an organism, usually a GM organism. |
| Genome | The total genetic information (all chromosomes) of an organism. |

| | |
|-----------------------------------|---|
| GM | Genetically Modified; in this context, an organism into whose genome has been deliberately inserted one or more pieces of new DNA (also called Genetically Engineered, or GE) |
| GMOs | Genetically Modified Organisms (microorganisms, plants or animals) |
| Intellectual property (IP) | Legal rights associated with inventions, artistic expressions and other products of the imagination (e.g. patent, copyright and trade-mark law) |
| Lateral gene transfer | Gene transfer between closely related and very distantly related microorganisms; an integral part of species evolution in microbial communities. |
| Marker gene | A gene whose gene product is easily detected (eg. a gene coding for an antibiotic) |
| Novel foods | Products that have never been used as a food, foods which result from a process that has not previously been used for food; or foods that have been modified by genetic engineering. |
| Outcrossing | Mating between different genotypes (organisms with different hereditary constitutions). |
| Patent | A limited term monopoly, usually 20 years, granted to inventors of new, useful and non-obvious ideas with industrial application. |
| Precautionary principle | A regulatory mechanism for managing environmental and health risk, arising from incomplete scientific knowledge of the impact of a proposed activity or technology. |
| Recombinant DNA (rDNA) | DNA molecules created by splicing together two or more different pieces of DNA. |
| Secondary pests | Those species within an ecosystem that are normally kept in check by natural enemies, but which, following certain agronomic practices (e.g. application of pesticides against primary pest), reach densities that cause economic losses. |
| Substantial Equivalence | An assessment approach which is an early criterion in the regulatory decision tree. It states conditions under which it can be assumed that a new crop or novel food poses no more risks than a non-modified counterpart that is already considered safe. |
| Transcription | The synthesis of RNA (ribonucleic acid) molecules concerned in translating the structure of DNA into the structure of protein molecules. |
| Transgene | A gene from one organism inserted into the genome of another. |

OPHA Position Paper on Food Biotechnology

OUTLINE:

| | | |
|--|--|------|
| A. Preface..... | | p.4 |
| B. Introduction..... | | p.5 |
| C. Issue Identification..... | | p.7 |
| 1. Characteristics of our food supply to achieve optimum public health. | | |
| 2. Genetic engineering can affect our food supply and our health | | |
| 3. GMOs which affect our food supply require rigorous and on-going assessment, monitoring and regulation | | |
| D. Conclusion | | p.22 |
| E. Recommendations for OPHA Action | | p.24 |
| F. References and Further Reading | | p.25 |

A. PREFACE

Food biotechnology is a new, complex, controversial and rapidly-growing science and industry. The OPHA Food Biotechnology Workgroup believes it is a public health issue because:

- it affects the food supply of the entire population
- it has strong impact on agriculture and the environment
- it is a new technology with unpredictable consequences, and therefore requires reliable policies and methods for assessment, monitoring and regulation.

The role of the federal government is to develop policy and legislation around the purpose, use, regulation and monitoring of food biotechnology. A major role of Public Health at the provincial and municipal levels can be to influence policy development in response to local concerns and needs, both rural and urban.

The Food Biotechnology Workgroup was formed in the fall of 2000 at the request of OPHA, to develop a position paper on the subject. An invitation for membership went out to all OPHA members through their constituent societies, so that the Workgroup would represent various public health disciplines. A workshop was hosted by the Workgroup in May 2001, which was also open to all OPHA members. Here, a discussion on public health issues related to food biotechnology served as a basis for a position paper. Given the near absence of peer reviewed literature on the scientific methods and assessment of genetically modified (GM) crops and foods (due to the proprietary nature of this data), lack of trans-parency of the federal review process and lack of reliable data on the health, agricultural, environmental, social and economic impacts of food biotechnology, the Workgroup faces a unique challenge.

During 1999 and 2000, several workshops and symposia were hosted by the food biotechnology industry and relevant branches of the federal and provincial governments in order to educate, solicit opinions from and gain the support of public health professionals regarding food biotechnology. At that time, there was still a dearth of critical and explanatory information on biotechnology, its use and regulation. This situation improved in 2001 with the appearance of some important Canadian documents authored by groups external to commercial interests. Section 3(a) provides more detail on the context.

The first was *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, by an expert panel of The Royal Society of Canada (February 2001) (1). This report reviewed historical, present and future issues, and described areas of controversy and diverse international perspectives. It provided expertise from a wide range of relevant areas, including botany, entomology, ethics, biochemistry, philosophy, immunology, ecology, nutrition, toxicology and health law.

The second came in March, 2001 from the Canadian Biotechnology Advisory Committee (CBAC), entitled *Regulation of Genetically Modified Food: Consultation Document 2001* (2). It presented a range of issues and challenges inherent in the current regulatory system, offered options for solutions as “some possible ways forward”, and asked for input. This document, however, had no specific reference to health issues.

A third major contribution was a report by Toronto Public Health, *Genetically Engineered Foods*, approved by their Board of Health on April 10, 2001. It served as a technical report that looked at what is known and not known about the area food biotechnology, viewed in terms of public health principles (3).

These documents were valuable in rounding out the complex set of issues brought about by food biotechnology, as well as exposing some significant gaps in information.

The OPHA Workgroup recognizes that there are both benefits and threats posed by food biotechnology. Since it is a growing industry with massive public and private investment, its benefits are already well promoted. Hence, this position paper will focus mainly on the public health implications of food biotechnology, and will offer action recommendations for maintaining a healthy, safe and sustainable food supply that is adequately regulated, transparent and associated with freedom of choice.

This position paper cannot stand alone as an educational source for readers who are not acquainted with the technical and regulatory details surrounding food biotechnology. The workgroup has attempted to present the major issues as they pertain to public health, with the expectation that readers will access key references and websites provided for their further information.

The OPHA Workgroup also recognizes that the need for public health policy development and education (for both professionals and consumers) will continue to grow along with expansion in the biotechnology industry, changes in public policy, international trade agreements, media exposure and a burgeoning array of electronic and published information. While originating in the lab, the experiment of food biotechnology will continue in the public arena on a global scale. It will be an on-going challenge for public health professionals as a group to remain informed, involved and capable of responding to issues of food biotechnology as they emerge.

B. INTRODUCTION

This position paper provides a public health perspective on the potential impacts of genetic engineering, and of current regulatory practices, on our food supply. It focusses on the current political framework in which policy decisions are being developed. It aims to encourage OPHA members to become informed, voice their concerns and influence public policy regarding food biotechnology.

This position paper will also serve, in part, as a follow-up to Toronto Board of Health report of April 10, 2001, entitled *Genetically Engineered Foods*, which recommended that there be:

"a consultation with other Public Health stakeholders (e.g., the Ontario Public Health Association, the Canadian Public Health Association, Boards of Health in Ontario) to develop recommendations that will address the public health implications of GE food".

Brief History of Genetic Engineering:

The early work of genetic engineering occurred during the 1970's, when it was discovered that different DNA fragments could be spliced together to form a new functional hybrid DNA molecule, or *recombinant DNA (rDNA)*. This process is now referred to interchangeably as "genetic engineering" (GE), "genetic modification" (GM), or "biotechnology". Genetically modified organisms (GMOs) are microbes, plants or animals whose cells all contain, and express, the new rDNA molecule(s), or transgenes (4).

At first, work centered on GM *microbial* strains which were commercially valuable for enhanced fermentation and the production of antibiotics, vaccines, insulin, amino acids, enzymes, rennet, etc. It involved major financial investment into research, coupled with the potential of highly profitable financial return. Precedent was set with the 1980 U.S. Supreme Court decision to grant the first patent protection for a life form, in this case a GM bacterial strain. This set the stage for "intellectual property rights" over the research data as well as patents on the living products (microbes, plants, animals, seeds) of genetic engineering (4, 41). Patenting of life forms is an on-going source of debate internationally.

The next stage of research involved the transfer of genes into *plant or animal* genomes; this is much more difficult than into microbes. DNA is inserted into the nucleus of a plant cell by means of a "gene gun" (DNA fragments on gold or tungsten pellets) or via a bacterial vector. Numerous experiments are needed before the desired traits are created. This process may include an additional "marker gene" (although it has been strongly recommended that antibiotic resistance marker genes be discontinued). Using such new techniques, the first transgenic plant, an herbicide-resistant tobacco plant, was licenced in 1983. The number rose to 48 GM plants approved worldwide by 1997 (4).

Canada is now the third largest grower of GM crops in the world, behind the U.S. and Argentina (1). By now, Health Canada has issued letters indicating "no objection" to the use of about 45 GM food crops, textile crops and animal feeds. These include soybeans, cotton, corn, flax, canola, tomatoes, squash and potatoes (for a list of approved novel food products, see <www.hc-sc.gc.gc/food-aliment>). Since soy, canola, corn and their products are used so widely in the food system, an estimated 60 to 70% of retail processed food in Canada now contains GM ingredients (2). So far, these plants have been genetically changed mostly for characteristics like insect resistance and herbicide tolerance, with no more than 2 or 3 added genes (see page 12).

In the near future, many more types of GMOs (the so-called "*second generation*") will reach the commercial release stage, some with multiple, "stacked" gene transfer. Some will address agricultural concerns (eg. disease/pest/drought resistance; altered flowering or ripening time, fertility, susceptibility to spoilage, etc). Others may alter micro-nutrient or phytochemical content of plants. Transgenic (growth-enhanced) salmon and a few dozen other GM fish species have been developed (1). Research is well underway to improve methods of somatic cell nuclear transfer in livestock so that more GM animals will become a reality – for both altered agricultural and nutritional traits.

The "vision" of the federal government regarding biotechnology is stated on the Industry Canada website:

"To enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in biotechnology." (5)

Faced with the prospect (and pressure) of these corporately-driven developments, and to ensure that Canadians are well served and not burdened by the outcome of industry, the role of government must be to ensure that a solid regulatory system is in place. There must be clear policy regarding liability issues and the protection of public health. The December 2000 Report of the Auditor General of Canada stated that, "Canadians have become more aware of personal implications of regulatory decisions. These trends

have partly occurred because many health and safety regulatory issues involve rapid and major changes in science and technology and an increased possibility of significant error...” (6)

To help clarify the issues in terms of public health, the following principles are useful. Originally, they were developed for a Health Canada policy review on the addition of vitamins and minerals to foods (7) by a nation-wide, multi-sectoral stakeholder consultation and an expert advisory panel. The authors of the Toronto Board of Health Report on GM foods adapted these principles for their discussion. The OPHA Food Biotechnology Workgroup has further modified them to take into account the unique characteristics of, and the issues surrounding, GM foods. We believe these principles should be the basis for policy development around the *regulation* of GM foods in Canada.

PUBLIC HEALTH PRINCIPLES REGARDING THE REGULATION OF GM FOODS:

- Principle 1: Policies and regulations must ensure that approval is granted only to those GM foods which maintain and improve the quality of the food supply in a manner that is consistent with public health priorities and goals.
- Principle 2: The policies related to GM foods must ensure that GM foods do not result in health hazards.
- Principle 3: The policies must ensure that decisions regarding approval of GM foods are based on on-going, rigorous, peer-reviewed evidence from multi-disciplinary sources (including life sciences, environmental science, toxicology, agriculture, ethics, health law, etc.)
- Principle 4: The “precautionary principle” must be applied in the regulation of GM foods.
- Principle 5: The policies must help prevent practices that may mislead, deceive or confuse the consumer, and promote practices which facilitate consumer choice.
- Principle 6: The policies must be responsive to the varied demographics, food habits and expressed concerns of the Canadian population.

C. ISSUE IDENTIFICATION

1. Characteristics of the food supply necessary for optimum public health

A healthy food supply for all is considered to be a determinant of health (Ottawa Charter for Health Promotion, 1986).

To ensure optimum health, a population's food supply would typically incorporate the following characteristics:

- (a) Food safety
- (b) Capacity to supply nutritional adequacy for all
- (c) Sustainability
- (d) Capacity for consumer choice
- (e) Accessibility and affordability by all

2. Genetic engineering can affect our food supply and our health in multiple ways

Genetically modified organisms in the agriculture and food industry have the potential of affecting each of the above food supply characteristics. This includes not only the health and safety of food/food ingredients that we consume directly, but also the crops, animals and micro-organisms from which the foods are derived, the psycho-social issues of consumer/farmer choice and the environmental/economic issues surrounding agriculture and food distribution. These issues are listed and described under the above five characteristics.

(a) Food Safety:

Public Health Issues:

- Food allergenicity
- Food toxicity
- Capacity for epidemiological monitoring and assessment

Food allergenicity

Food allergy is manifested as an immune system response to a *protein* in food that is recognized by the body as a foreign substance. The symptoms of food allergy can range from mild irritation to anaphylactic shock and death. While the incidence of food allergy is relatively small (1-2% of the adult population), it has been growing over the past few decades (1).

The immediate product of a gene is a protein, thus the product of a transgene is a new protein (e.g. an enzyme). The final product of the new metabolic process introduced by the gene may also be a protein. A new gene continuously expresses itself in every cell of the GE plant, since technology does not yet exist to include corresponding regulatory genes.

Possible consequences of the presence of a transgene (a new gene introduced through recombinant DNA technology) are:

- increased or decreased activity or "silencing" of a pre-existing gene
- new gene expression resulting in novel protein production

Thus, genetic engineering has the potential to:

- eliminate common allergenic food proteins, thus benefiting individuals with food allergies
- introduce new food allergens into novel foods
e.g. Brazil nut protein transferred to soybeans was highly allergenic and not commercialized (8)

The *degree of presence* of a new protein in a food product of the plant depends on the type of food or ingredient. For example, the new protein will be present in any food derived from a whole part of the plant (leaf, grain, root, stem, fruit, bean, kernel), but will be minimally present in a processed plant oil.

If a novel protein is present in a staple food (eg. corn), a large part of the population will be exposed to it, thereby increasing the overall risk of allergic response to the novel protein (1).

If the new protein degrades during digestion, it will not likely be allergenic. If it is stable to digestion, however, (increased stability may result from food processing), then it *may or may not* have allergenic potential.

Methodology for allergenicity testing:

Regarding tests for allergenicity of a new protein which is stable to human digestion:

1. if it is a common, known allergen – tests exist
This may be the case if the gene originates from an organism which is already in the food system and is not generally allergenic
2. if it is of unknown allergenicity – the “weight of evidence” approach is used (9,10)

Weight of evidence approach:

To assess a protein of unknown allergenicity (part of the pre-regulatory assessment of a novel food), the new protein’s structure and other biochemical attributes are compared to those of an existing known allergen.

- If it is deemed similar, assessment can be attempted using existing serum tests for the known allergen.
- If it is not similar, then *no assessment procedure currently exists.* (9, 10)

Health Canada’s approach to allergenicity assessment described above is similar to that developed by the US Food and Drug Administration in 1992. A recent US National Research Council Report recommended that “priority should be given to the development of improved methods for identifying potential allergens in GM pest-protected plants, specifically in the development of tests with human immune system endpoints and more reliable animal models” (11)

The Royal Society of Canada has made a number of recommendations regarding allergenicity resulting from food biotechnology (1), namely:

- that the Canadian government support research initiatives to increase the reliability, accuracy and sensitivity of current methodologies to assess the allergenicity of (GM) food proteins
- the strengthening or development of infrastructures to facilitate evaluation of the allergenicity of GM proteins (could include a bank of serum from screened individuals allergic to proteins)
- the development of mechanisms for after-market surveillance of GM foods incorporating a novel protein... to detect the emergence of consumers developing allergies to such a food
- that the appropriate government regulatory agencies have in place a specific, scientifically-based comprehensive approach for ensuring that adequate allergenicity assessment will be performed on a GM food
- that approvals should not be given for GM products with human food counterparts that carry restrictions on their use for non-food purposes (e.g. crops approved for animal feed but not for human food).

Food toxicity

Allergenicity may affect a relatively small proportion of the general population, but the potential for more widespread toxicity also exists with GM foods. Toxic elements in food could be created due to:

- unexpected metabolites of new gene combinations
- over-expression of a transgene resulting in higher enzyme activity or micro-nutrient production than was expected.

Traditional risk assessment models for the evaluation of health risks from food toxins consider the amount of toxin typically encountered (exposure) and the ability of the toxin to produce an adverse response (dose-response). For this model to be effective, the food toxin must first be identified as such. The current regulatory approach to novel foods in Canada, based on “substantial equivalence” (see page 19), may not be sensitive or extensive enough to detect a potential toxin in food. The true test would only come after it enters the food supply (13).

With the **substantial equivalence** approach, data on nutrient composition, extent of dietary exposure and nutrient bioavailability of a novel food is used to decide whether or not it is substantially equivalent to a traditional food. If it is deemed "substantially equivalent, then no further tests are required. If it appears that the product of gene expression makes the food significantly different, then further tests are required (9,10,14).

Toxic characteristics, if present, may not be apparent at the first stage of testing. This underscores the importance of:

- (a) the requirement of more stringent pre-market tests, including testing of toxic potential of whole foods rather than specific food constituents only, and
- (b) a post-approval surveillance system, since capacity for toxicity can change over time (13).

The Royal Society Panel (1) recommended that:

- federal regulatory officials in Canada establish clear criteria regarding when and what types of toxicological studies are required to support the safety of novel constituents derived from transgenic plants
- regulatory authorities establish a scientific rationale that will allow the safety evaluation of whole foods derived from transgenic plants.

Capacity for epidemiological monitoring and assessment

The present regulatory system requires that approved novel foods which are found to have allergenic or toxic properties resulting from gene transfer be either removed from the market, or be properly labelled. However, the capacity for public health to trace allergens or toxic compounds in the food supply to a GM source is only possible with GM food labelling (see page 14). As well, effective response would require a reliable means of segregating or recalling GM foods if necessary.

To this end, an appropriate after-market surveillance system needs to be developed that can link long-term dietary exposure of any GM food to the possible occurrence of unanticipated allergic response.

(b) Nutrition:

Public Health Issue:

- *Nutrient content (e.g. altered nutrient levels)*

Deliberate changes to nutrient composition of foods through GM are not yet commercialized (most are still in the developmental stage), and their potential effects are more chronic in nature than the unanticipated toxicological/allergenic possibilities inherent in the GM process itself. The latter was discussed under the Food Safety section.

Claims and predictions have been made by the biotechnology industry (15) that foods can be genetically altered for traits such as:

- altered fatty acid profile (e.g. of dairy products)
- added nutrients (e.g. iron or vitamin A to rice)
- reduced food components such as allergens, lactose or phytates

While this may be laudable in some circumstances, the response of public health nutrition professionals is that:

- GM foods will not solve the dietary challenge related to obesity and chronic lifestyle diseases (a total dietary approach and increased consumption of whole foods is needed; there is no “magic bullet” in the form of single altered foods)
- there is a risk of toxicity from micronutrient over-consumption in some population groups (especially for iron and vitamin A) if staple foods have increased content of such nutrients
- “Golden Rice”, or a future vitamin-A enhanced rice, may be useful to some but will not solve the problem of vitamin A deficiency in developing countries, for reasons of vitamin A metabolism and continuing poverty (16)
- there is no way of monitoring the effects of nutrient-altered GM foods without a Canadian dietary monitoring/surveillance system
- federal and provincial food policy should be driven by goals of population health, not only business interests.

(c) Sustainability of the Food Supply:

Public Health Issues:

- *Pesticide use*
- *Threats to organic farming methods and biodiversity*
- *Farmers' livelihood and freedom of choice*
- *Community food insecurity*

Sustainability of our food supply is closely related to environmental stewardship. It is a key characteristic of our food supply because it encompasses issues involved in maintaining healthy viable local food systems over time, and is therefore significant to public health. It requires that food production causes minimum damage to the environment (soil, water, air), and that energy comes from sources that are renewable and non-polluting. Agricultural sustainability also includes the maintenance of a wide diversity of genotypes of living organisms, because these enhance adaptability to various and changing environmental conditions (30).

Another aspect of sustainability of the food supply is the sustained capacity of local farmers to make a fair income, rely on reasonably secure markets for their products and to have freedom of choice with respect to farming practices (within a framework of safety and environmental stewardship) (42).

It should be noted that the word “sustainability” is used in a multitude of different ways (17); it is important to see how it is interpreted in Canadian government and related documents. Agricultural sustainability is often associated with strong international trade relations and (national) economic prosperity. For example, the Canadian Biotechnology Advisory Group (CBAC) stated:

“(Environmental) stewardship involves the larger question of sustainability and the effective integration of key societal goals such as *population health and social well-being, environmental conservation and economic prosperity.*” (3)

Similarly, in its endorsement of the World Food Security (WFS) Plan of Action at the World Food Summit (Rome, 1996), Canada committed to the following statement -- which is open to the inclusion of food biotechnology as part of a sustainable world food supply:

“We will pursue participatory and *sustainable* food, agriculture, fisheries, forestry and rural development policies and practices in high and low potential areas, which are essential to adequate and reliable food supplies at the household, national, regional and global levels, and combat pests, drought and desertification, considering the multifunctional character of agriculture.” (18)

In terms of the environmental consequences of GM crops, CBAC acknowledged that:

“Environmental assessment of GM crops is challenging since there is a potential for impacts to extend well beyond the time and place of their introduction; both natural and agricultural systems are of concern,” and
 “With regard to the more complex ‘second generation’ GM foods and crops expected in the coming years, a resurgence of research in ecosystem science may be needed to provide a stronger scientific foundation for the effective assessment of these products.” (3)

Pesticide Use

The most immediate environmental risk of the present, existing generation of GM crops is the altered use of pesticides. There is a growing concern about the impact of pesticides on the environment and on human health (nervous, renal, respiratory and reproductive system effects have been documented) (2).

A major claim of GM crops which are *herbicide resistant* (eg. Round-up Ready® soy or corn), or which are “*insect protected*” because pesticides are produced within the plant (eg. Bt corn, soy, canola), is that they result in reduced pesticide applications (15).

Glyphosate is a popular broad-spectrum herbicide, used in agriculture, forestry, aquatic weed control and residential lawns. When a crop is genetically modified to be resistant to glyphosate, this herbicide can be applied freely for weed control, allowing only the GM plants to survive. Thus, the potential for increased herbicide use exists.

Bacillus thuringiensis (Bt) produces a natural toxin for some pests (eg. European corn borer) and is therefore an important tool for organic farming and integrated pest management (IPM). GM Bt crops contain a gene derived from the soil bacterium Bt, so that all of their own cells produce the toxin continuously. Thus, if pests are present which are susceptible to the effect of the Bt toxin, no external pesticide application is needed.

It is unclear if the use of GM crops has resulted in overall pesticide reduction, since other plans are in place with the same goal. For example, the *Ontario Environmental Farm Plan Program* (EFP) claims that pesticide usage has decreased significantly in Ontario over the past decade, and that the plan for continuation of this trend will include techniques such as IPM (19).

Yet, it is uncertain to what extent IPM, conventional pesticide use, GM crops and organic methods are practised in Ontario. Farmers are not required to provide information on the type, quantity and frequency of pesticides or agricultural methods that they use. If such statistics were available, matched with other data such as crop yield, farm income, weather conditions, types of pests present at a given time, soil fertility and various environmental indicators, it would give a clearer picture of the true effectiveness of various methods under given circumstances. It would help inform those who develop policy that determines allocation of resources and affects the sustainability of our food supply.

The following chart illustrates the pros and cons of the above two common types of GM crops:

| <i>Proposed benefits</i> | <i>Potential risks</i> |
|--|--|
| (a) Herbicide-resistant GM crops | |
| <ul style="list-style-type: none"> - herbicide eliminates weeds; crop stays unharmed - possible use of fewer different types of herbicides, since glyphosate covers a broad spectrum of weeds - glyphosate is more biodegradable than other chemical herbicides - weed elimination leads to reduced need for tillage (helps soil conservation) | <ul style="list-style-type: none"> - use of GM crops fosters dependence on herbicides and reduces biodiversity - development of herbicide-resistant weeds (several already exist) - elimination of weeds reduces non-pest insect habitat - destruction of more vulnerable weeds allows domination of “superweeds” - regular herbicide use destroys soil microflora - a larger number/intensity of herbicide applications are possible - herbicide-resistant GM plants can become “weeds” themselves if seeds sprout within another crop |
| (b) Insect-protected GM crops | |
| <ul style="list-style-type: none"> - Bt toxin is a “biopesticide” – i.e. biodegradable - reduced pesticide applications for specific pests vulnerable to Bt toxin, because it is produced in the GM plant - “management plans”, if carried out effectively, are designed to provide insect refuges to encourage maintenance of biodiversity | <ul style="list-style-type: none"> - Bt toxin does not bio-degrade rapidly - if pests are present that are not vulnerable to Bt toxin, other pesticides are still required - toxin is continuously produced throughout the GM plant, therefore: <ul style="list-style-type: none"> - some insect resistance to the toxin is inevitable - non-target pests may be susceptible (e.g. monarch butterfly larvae feeding on Bt pollen) - toxin released into the soil from the roots may influence soil microbes - compliance with the use of management plans or buffer zones is not assured - toxin which continually targets one set of pests could result in increase of secondary pests |

Threats to Organic Farming Methods and Biodiversity

According to Canadian Organic Growers (COG), the main advantage of organic farming is the techniques of sustainable agriculture that are used, especially the maintenance of natural soil micro-organisms and active use of plant diversity (20).

There is a concern that the presence of neighbouring GM crops, with their corresponding agricultural practices, will threaten the ecological components which are basic to organic farming as well as IPM in conventional farming, by:

- reducing the population of beneficial insects
- cross-pollination from GM crops to non-GM crops (“lateral gene transfer”)
- cross-pollination from GM crops to weeds or wild “relatives” in adjacent fields
- development of Bt-toxin resistant pests (Bt is used in organic farming)
- loss of biodiversity, through extensive promotion and protection of GM “monocultures”

Farmers' livelihood and freedom of choice

Agricultural biotechnology is product driven (21), and industry has specific goals and marketing techniques for continued growth. The dominance of one farming method over others, coupled with government policy for this trend (i.e. clear federal government support for food biotechnology and inadequate support for smaller-size and organic farms) leads to pressure on farmers to conform. Farmers producing food for small markets are most often at the lower end of the size spectrum, and are least likely to benefit from new and costly technologies. Thus far, GM technology is more affordable and applicable to large-scale production systems (42).

Policy is needed in Canada to support the freedom of farmers to grow non-GMO crops if they object to the use, cost or re-planting policy of GM seeds. Programs also need to be put in place to support the segregation of GM and non-GM crops, in order to prevent lateral gene transfer from GM crops in neighbouring areas and to prevent potential loss of international markets to countries with anti-GM policy (the UK, EU and Japan).

Community food insecurity

Government policy that promotes the large scale agri-business and globalization of food markets which complement food biotechnology will lead to the increased delocalization of our food supply. Producers become increasingly dependent on external markets and vulnerable to shifts in prices and markets. As a greater percentage of household and institutional food is imported, vulnerability to community-wide food insecurity grows. (42).

(d) Capacity for Consumer Choice

Public Health Issues:

- *Freedom of choice through food labelling*

Labelling of GM food products:

The *Ottawa Charter for Health Promotion* (1986) stresses the importance of supporting citizens in their capacity to take greater control over their health. Access to information is central to informed decision making, and can be seen as a social determinant of health (respect for religious, ethical, cultural and personal values and beliefs has an impact on health). Mandatory food labelling for GM content of food is necessary to enable consumer choice.

A related public health issue is the capacity for epidemiological tracking in the case of food toxicity or increased incidence of allergy that may be associated with a GM product in the food system. Such an assessment is not possible without a system of food labelling so that the origins of the causative agent can be traced. Moreover, it would be difficult to give consumers advice regarding food choices in such a situation.

The present system of food labelling laws in Canada are regulated primarily under the authority of the *Food and Drugs Act*. Labelling of GM ingredients is voluntary, and allows either a positive statement (the food/ingredients are genetically modified) or a negative one (the food is not genetically modified or is free of GM ingredients). Mandatory labelling is only required if there are safety concerns (eg. the presence of a potential allergen) or has undergone significant compositional change as a result of genetic engineering. To date, no GM food in Canada has required mandatory labelling (2). There is no way for consumers, epidemiologists and others to know if food has originated from GMOs or not.

Due to the sensitivity of DNA testing, some members of the food industry have suggested that the message "GM-free" cannot be proven true, as even stray GM pollens in a non-GM food would show up in tests. From this came the suggestion that the labelling message, "may contain..." would cover the liability issue (22). However, this message would be useless to help Canadians make choices.

It has been suggested that mandatory labelling of GM food might not be necessary if rigorous regulatory procedures were in place (1). Others, including the Consumers Association of Canada, argue that there is no justification for a mandatory labelling requirement because:

- the knowledge of the origin of their food would not make a difference to people's health
- most people lack sufficient knowledge for informed decision making on food biotechnology, and mandatory labelling would only confuse, not inform them
- it is the safety of the food product itself that is relevant to health, not the method of production.

Industry members have also argued that mandatory GM food labelling would be prohibitively expensive due to the need for segregation of GM foods "from farm to fork" (i.e. separate harvesting equipment, storage, transportation, processing and packaging, etc., as well as the prevention of GM foods meant for animal feed to end up in human food). This cost would then be reflected in the price of food (22).

Cost estimates conducted by the international financial consulting firm KPMG for industry are often quoted. For example, the Australia/New Zealand system of mandatory labelling was estimated at \$394 million to implement and \$55 million per year for compliance (23). However, this is an overestimate, as it included labelling of GM ingredients plus an ingredient list, nutrition information and "best before" dates. A similar estimate by KPMG for a food industry group in Canada was \$700-950 million per year. They warned that the cost of foods which contain major oilseed products could rise by as much as 40% of the current price (22). In BC, a government discussion paper on GE labelling estimated that "the actual cost to BC business can be... substantially less, under \$9 million per year" for GM food labelling only (24).

Repeated surveys of Canadians have shown that the vast majority want labelling of GM foods (25). And, in spite of all the obstacles, it is possible to have mandatory labelling laws. This is the case in the UK, for example, where the Food Standards Agency policy states that it "supports consumer choice and recognises that some people will wish to choose not to buy or eat GM foods however carefully they have been assessed for safety. The current rules require that all foods which contain GM material should be clearly labelled." (26)

The European Commission has developed a set of regulations for the mandatory labelling of novel foods and ingredients that were approved after 1997 as well as GM herbicide tolerant soy and GM insect-protected maize approved before that time. They set a threshold of maximum 1% GM contamination of non-GM material to waive the labelling requirement (26).

The issue of GM food labelling is vast, with global implications. In February 2000, a Joint FAO/WHO (Food and Agriculture Organization and World Health Organization) Committee on Food Labelling, part of the Codex Alimentarius Commission, released a draft document, *Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology*. Comments were invited with a deadline of April, 2000. Redrafting of the material was assigned to a Working Group (consisting of 23 member countries, the European Commission and 9 international organizations) coordinated by the Canadian delegation. The next set of revisions is now being considered (27).

In April, 2001, an exposure bill (for public input) was introduced in the BC legislature called the *Genetically Engineered Food Labelling Act* (Bill 18). Its stated purpose is "to provide consumers with information for making choices respecting food composed of, containing or derived from genetically engineered materials." It would enable the BC government to establish mandatory labelling for GE food sold in BC. The bill sets forth the requirements and standards, but does not set up the system for such labelling. It also establishes a GE Food Labelling Advisory Panel, consisting of experts in GE, consumers and members from the food industry. Public opportunity to comment was provided until July 31, 2001 (24).

In August, 2001, a draft standard (for public comment over 60 days) was released by a Canadian General

Standards Board Committee on Voluntary Labelling of Foods Obtained or Not Obtained Through Genetic Modification. If this standard were approved, it would set the stage to allow foods to be labelled “GMO free” if they contain up to 5% GM material. The draft standard was developed “to ensure that any such claims on a label or in advertising made by manufacturers and/or distributors are consistent with an appropriate set of parameters.” (28)

In September, 2001, the Canadian House of Commons will vote on the first stage of Bill C-287, which would implement the mandatory labelling of genetically engineered food in Canada. It is comprised of a letter outlining reasons for mandatory labelling, prepared by The Biotechnology Caucus of the Canadian Environmental Network (CEN), and was introduced as a private member's bill (29).

(e) Affordability and Accessibility:

Public Health Issues:

- *Food biotechnology and food accessibility*
- *Food biotechnology and food affordability*

Food accessibility and affordability are components of most definitions of community food security. The overall food supply of a population can be abundant, safe and healthy. However, if it is not distributed fairly or is unaffordable to some (usually due to budgets that are consumed by other essential costs, or by inadequate wages), these are problems which must be addressed.

Food Biotechnology and Food Accessibility

The food biotechnology industry, as part of its advertising campaign for public acceptance, now promotes an image of genetic engineering as necessary "to feed the world". The messages are that GM crops, fish and livestock will bring increased yield, provide more nutrients and have the capacity to survive on presently unarable land or withstand extremes of temperature or disease. Such outcomes will be welcome under certain conditions or circumstances.

The arrival of GM foods and the application of GE to agriculture illustrate what is referred to as the “*productionist*” paradigm in food policy, a perspective in which the needs of production take precedence over other considerations (21). Experts in global food security point out that in most parts of the world (and certainly in Canada) there is not a problem of food supply, as agricultural surpluses exist. Moreover, because of industry's main goal of profitable business investment, and because the high costs associated with GM agriculture will likely make it prohibitive to small farmers (eg. high cost of seed, herbicide, fertilizer, illegality of replanting GM seed), this "social justice" image seems more of a public relations strategy than an attainable solution to hunger (4, 30, 42).

Food security advocates argue that it would be more profitable in human health terms to invest resources into sustainable local agriculture methods than to focus all attention on the growth of agribusiness aimed at global markets (30). The latter will likely be of most benefit to industry and large-scale landowners, widening the gap (in terms of income and power) between rich and poor. Debate on these issues will occur at the next World Food Summit in Rome, in November 2001 (18).

Food Biotechnology and Food Affordability

It should be noted that food prices in Canada are the lowest (approximately 11% of average annual net income) in the world (30). High agricultural production levels and low labour cost (at a global level) keep retail food prices low. Consumer surveys have consistently shown that this is a priority for Canadians (25).

Public acceptance of (or lack of protest against) food biotechnology depends in part upon preserving this situation; and the threat of “raised food prices as a result of GM labelling” is an effective means to

maintain the status quo (no labelling). As food insecurity is on the rise in Canada (31), the lobby for preventing increased food prices comes even stronger and broad-based.

At the same time, a significant percentage of Canadian farmers are not making an adequate income from farming, and receive a very small percentage of the retail price of food (32). For many farmers, a greater yield from GM crops does not necessarily lead to greater profit, due to increased up front costs and possibly lower market values. Therefore, the strategy for increased affordability of food may not be to lower the price of food, but to ensure that Canadians have adequate income to purchase food and that farmers receive fair payment for their commodities. The expectation that greater yield from GM crops will ensure a more “just” food system for all is not to be taken for granted.

Some ways in which the proliferation of GM foods may affect affordability and accessibility of food:

Positive:

- Possible adaptation of crops and other foods to grow in harsh climates
- Possible reduced damage to and loss of crops
- Possible enhanced competitiveness on the global market, affecting food prices and availability in Canada.

Negative:

- Cost of mandatory labelling, if implemented, may lead to higher food costs
- Concentration of the agronomic industry in the hands of a few multinational companies has a potential for tighter corporate control over price (eg. of GM seeds) and subsequent affordability of foods;
- Shift in consumer demand for non-GM foods (as is happening in Europe and Japan) could result in a higher price for non-GM foods
- The development of new GM niche products with high value-added returns would cost more because of their specialized nature.

3. GMOs which affect our food supply require rigorous and on-going assessment, monitoring and regulation.

Presently, there are serious concerns regarding:

- (a) federal regulatory capacity and protocol for assessment and approval of GM foods
- (b) lack of transparency of the experimental data, environmental and health assessment, and the decision-making process for federal approval
- (c) lack of data to inform policy and decision-making

(a) *Protocol for assessment and approval of GM foods:*

Public Health Issues:

- *Adequacy of Substantial Equivalence as an assessment tool*
- *Application of the Precautionary Principle in the regulation of GM foods.*

The present Canadian regulatory system for approval of the commercialization of GMOs falls under several types of legislation within several different federal ministries. These are not formally integrated, nor specially adapted for the unique characteristics of organisms altered through genetic engineering. Agriculture and Agri-food Canada actively promotes the business and use of biotechnology in agriculture; Health Canada is responsible for the approval process of novel *foods*, and the Canadian Food Inspection Agency (CFIA) regulates the release of GM *crops and seeds* as well as their importation and use in animal feed (3).

The CFIA reports directly to the Ministry of Agriculture and Agri-Food, and there is concern about the need for separating a regulatory body from a ministry that formally supports biotechnology.

In 1998, a renewed Canadian Biotechnology Strategy was announced. Industry Canada stated that this strategy included “the need for better internal coordination since multiple departments and agencies deal with biotechnology” (5). To this end, the *Federal Biotechnology Ministerial Coordinating Committee* (BMCC) was struck; members included the Ministers of Agriculture and Agri-Food, Environment, Fisheries and Oceans, Foreign Affairs & International Trade, Health, Industry and Natural Resources (3). The strategy also stated that “the need for an external advisory body was identified.”

Hence, the *Canadian Biotechnology Advisory Committee* (CBAC) was created and the *Royal Society of Canada* (RSC) appointed an Expert Panel on the future of biotechnology. CBAC (with an indefinite lifespan) was to organize public consultations and provide advice on the formulation of federal public policy on biotechnology. The RSC Expert Panel (formed to prepare a report only) was mandated to provide the ministries with advice on Canada’s regulatory system and scientific capacity required “to ensure safety of new foods developed through biotechnology” (5).

In its report of February 2001, the RSC Expert Panel made strong recommendations (52 in all) to improve the Canadian regulatory system. These recommendations included an overall precautionary stance, improved standards and protocol, more rigorous assessment, external peer review of data, increased transparency, clarity regarding liability, long term monitoring, moratoria on antibiotic resistance markers and on rearing GM fish in aquatic pens, support for genetic diversity and national investment in research (1).

CBAC also stated in its Consultation document (2001) on the *Regulation of Genetically Modified Food* that it “has not located what it considers to be a clear description for the pathway followed by applications for the approval of new foods as they progress through the system”, and that “there appears to be a lack of standardized procedures for dealing with some situations or issues...”. (3)

The first round of CBAC consultation (ending April 2001) was sought on the following themes:

1. *Good Governance*
(transparency; separation and independence of regulatory functions; ensuring safety during research and development activities; opportunities for public involvement; post-market monitoring for risks and benefits; capability and capacity in the regulatory system)
2. *Information and Choice*
(information provision to support informed choice; labelling)
3. *Social and Ethical Considerations*
(environmental stewardship; broader social and ethical considerations)

It is notable that "health" is not mentioned at all in these themes destined for federal policy development. Environmental stewardship is classified as a "social/ethical consideration", and population health is mentioned only briefly under this same category.

The *Canadian Environmental Protection Act* (CEPA) is the only legislation which refers to environmental and health aspects of biotechnology, but it has a limited role as a regulatory function. On September 1, 2001, Health Canada announced its intention (in the *Canada Gazette*, Part 1) to proceed with the development of environmental assessment regulations for substances in products regulated under the Food and Drugs Act (F&DA). Health Canada will also establish an Environmental Assessment Unit, in consultation with Environment Canada, to undertake assessments of substances in products covered by the F&DA.

Substantial Equivalence

The current regulatory system is based on the assumption that:

- genetic engineering of organisms is essentially the same as the traditional breeding process, just more speedy and specific
- GM foods can be regulated with the same criteria as other novel foods
- the *product* of a transgene can be assessed independently of the whole organism it comes from.

Thus, the approach of **Substantial Equivalence** (9,10) is used for pre-regulatory review of a novel food, as a *decision threshold*. Regulators review a number of characteristics of the new GM food (treated as a novel food) and compare them to those of the unmodified food in the Canadian diet.

If it is judged that the presence of the new transgene makes no apparent difference to the novel *food* (not the plant), then it is deemed to be "substantially equivalent". In that case, no further assessment of the food is deemed necessary, and a statement of "no objection" is granted. So far, every novel food for which approval has been sought in Canada has been deemed substantially equivalent at the pre-regulatory stage, and has therefore not been subject to further testing (2).

It follows that if regulators ascertain that the effect of the transgene appears to cause changes to the novel food in terms of composition, structure, nutritional quality, metabolism in the body, any physiological effect on the body, microbiological or chemical safety, or safe use of the food, then further assessment and analysis is required.

It is notable that the CBAC consultation document, *Regulation of Genetically Modified Food*, does not mention *substantial equivalence* by name but refers only to an "assessment ...based on an internationally applied principle" (and lists the criteria). Because of the ambiguity and uncertainty inherent in "substantial equivalence", the FAO/WHO Committee on Food Labelling (Feb. 2000) of the Codex Alimentarius decided to remove the term "substantial equivalence" from its draft recommendations for food and food ingredients obtained through biotechnology (27).

The Royal Society of Canada report, *Elements of Precaution*, distinguishes "novelty" from "equivalence", and recommends:

"Approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for causing harm to the environment or to human health. Such testing should replace the current regulatory reliance on 'substantial equivalence' as a decision threshold." (1)

Precautionary Principle

More substantial safety and environmental testing for *every* GM food would be required if the Precautionary Principle were included in the Canadian regulatory framework (as it is in Europe). The **precautionary principle** is defined as "the principle that, when there are threats of serious or irreversible damage to the environment or to human health, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (33,34).

The precautionary principle was included in the Biosafety Protocol adopted in Montreal, in January 2000, and is embedded in The Canadian Environmental Protection Act (CEPA). However, it presently has no bearing on the regulation of GM foods or crops. It would require that manufacturers demonstrate much higher standards of health and environmental safety, to reduce the chance of unexpected toxicity, or other adverse effects (although it would obviously not require proof of "zero risk"). It would also mean a greater investment of research dollars into rigorous assessment and a delay in product approval.

It is the view of the OPHA biotechnology workgroup that the incorporation of the Precautionary Principle into the Canadian regulatory protocol for GM food may, in the long run, result in much greater savings (in financial terms or in terms of human health or life) than any initial increased cost at the regulatory end.

The workgroup agrees with the opinion of the Royal Society of Canada that Substantial Equivalence should be rejected as a decision threshold to exempt new GM foods from rigorous safety assessments on the basis of superficial similarities.

(b) Transparency to the scientific community of the experimental data, environmental and health assessment, and rationale for federal approval

Public Health Issues:

- *Transparency of scientific data and regulatory decisions*
- *Democracy of policy development*

Transparency of scientific data and regulatory decisions

Evidence (experimental data, health and safety information, locations of field tests) submitted for approval of GM foods is generated primarily by the biotechnology companies themselves, and represents a major investment of research dollars. Consequently, this information is regarded as *proprietary* or confidential, and is therefore not available to anyone beyond federal regulators. As a result, there is no opportunity for external groups to assess the quality of research that was conducted.

The details and decisions about the federal review process itself are also non-transparent. Only a summary of the final decisions is made public through the Health Canada website, often many months after the approval is granted (3).

The list of products currently undergoing review is also not available to the public.

Health professionals and the media, among others, have been strongly encouraged by government and food industry groups (e.g. CFIC, the Canadian Food Information Council) to base their understanding/communication of food biotechnology on "sound science" (as opposed to values or unverified information) (35). Without transparency of peer-reviewed data, however, there is no sound science available as an evidence base for local policy making or for public education.

Lack of transparency breeds suspicion and speculation. Unbiased, clear public information on food biotechnology is increasingly needed and demanded. It is important that public education is not equated with product promotion. Public health departments play a key role in food safety and nutrition education. Public health staff cannot, however, be expected to blindly trust in the accuracy and rigour of industry-based data and therefore cannot be expected to promote food biotechnology to the public. A process of making experimental data more open to peer review is urgently needed.

A model exists for a more open and democratic process, namely for the regulation of food additives. The research is mostly done by food companies, but external experts are involved in the review process, and there is a public comment period through the *Health Canada Gazette* (36).

Democracy of policy development

The development of healthy public policy requires participation and input from civil society. An example of an infrastructure that encourages consumer involvement into food and nutrition policy making comes from the Netherlands (37). Two strong consumer-based organizations exist; they have an efficient lobby, and a voice on the Novel Foods Advisory Committee. Dutch legislation for novel foods states that the safety evaluation carried out by the applicant must be judged by an independent group of experts before the petition is approved. Labelling is required for foods containing GM ingredients (as in all of the EU).

In Canada, there has been a limited involvement of consumer groups and NGOs in federal policy decision-making. CBAC released their public consultation document in March of 2001, with a deadline for written comments of less than one month (April, 2001). Stakeholder consultations were held in April, 2001 in Vancouver, Saskatoon, Toronto, Montreal and Halifax. According to CBAC, stakeholders were invited from a broad range of groups.

Results of these written and oral consultations were released on the CBAC website in July, 2001 (38,39). Only 36 submissions were sent in to the written consultation. Most responses to the questionnaire were mixed, according to opposing views held by those who support industry and those with a more cautionary view. The stakeholder workshops included a total of 79 people, in some cases more than one from the same organization. Overall, 67% of the participants were from industry and agriculture organizations (in Toronto it was 80%), and the rest came mostly from academic institutions and government. Consumer groups were inadequately represented, partly because of a boycott of the workshops organized by a group of NGOs. Public health was represented only in BC and Montreal.

In the next phase, CBAC is again inviting comments (this time for a period of 6 months) to its Interim Report, *Improving the Regulation of GM Foods and other Novel Foods in Canada*, August 2001 (43). This report presents issues, options and consequences, as well as *proposed* general directions for future policy recommendations related to GM food. After that, formal recommendations to the Government of Canada will be prepared.

The OPHA Food Biotechnology Workgroup feels that it is important for OPHA to take part in federal consultations and act as a stakeholder on matters of policy around food biotechnology when they arise. This would provide an essential voice for the interests of public health. Designated OPHA members must be ready to respond to relevant issues with very short notice, so must be given the support and resources needed to remain continually informed.

D. CONCLUSION

The issue of GM foods is different from most previous public health issues in that we do not have a solid underpinning of peer-reviewed scientific literature (technical, social and environmental) to serve as an evidence base. What we do have is summarized information and analyses which are usually subject to some degree of bias.

The OPHA Food Biotechnology workgroup reviewed a multitude of published documents, articles and electronic information. In general, they can be categorized according to how the issues are framed:

- a) *Promotion of food biotechnology* (i.e. GM foods/crops are safe, subject to rigorous scientific scrutiny and regulation, will lead to more productive agriculture, reduce pesticide use, improve nutrition and alleviate hunger. Those who protest GM are anti-progressive or do not understand the humanitarian potential.)
- b) *Concerned about food biotechnology* (i.e. GM foods/crops/animals are not needed, destructive to the environment, poorly regulated, potentially harmful to health. They are linked with corporate concentration and globalization of food trade which will exacerbate the imbalance of power structures and increase world food insecurity everywhere.)
- c) *A mix of the above*, providing both “pros and cons” in an attempt to inform people so that they can see the complexity and come to their own conclusions.
- d) *Information focussed on regulatory aspects* of the food/agricultural biotechnology system only. It provides information, asks questions and/or gives options around who should make decisions, what the regulatory infrastructure should look like, how rigorous and transparent it should be, etc.
- e) *Analysis of consultation processes*, opinion poll results, surveys of consumer interest and knowledge about food biotechnology.
- f) *Isolated, brief pieces of information*, often out of context of broader considerations, and without clear indication of whose viewpoints/interests are represented (or at stake), e.g. advertisements, media newsclips.

A clear trend comes through from all these various types of discourse, namely that the word “health” is used and interpreted in many different ways. Government and industry-based information tends to present health-related issues in a “box” whose boundaries are defined by specific roles belonging to various federal ministries. Thus the overlap between biotechnology and health often refers to GE drugs and medicines. “Health”-related issues regulated by Health Canada have been defined quite narrowly as those related to specific transgene products within foods; i.e. potential toxicity or allergenicity.

The broader view of health embraced by public health, i.e. the concepts of “health promotion” and the *determinants of health*, is almost never referred to in federal government and industry material about food biotechnology (except perhaps as “social and ethical considerations”, or “values”). Although the parameters of *health* included in this concept vary even among those within the public health field, it is increasingly seen to include issues of environmental stewardship, democracy of decision making, respect for cultural implications of health, community food security, etc. With this framework of health, it becomes clear that food biotechnology can impact several aspects of our food supply: its safety, sustainability, accessibility and affordability, as well as the ability/right of consumers to choose. We in public health at the provincial and municipal level need to promote our concept of health to other sectors involved with food bioethnology.

It would be of limited use for OPHA to merely identify and make general recommendations about the issues we find worrisome about food biotechnology. These issues, for the most part, have already been identified, described and even opened to external/public consultation. The federal government in particular is well aware of its credibility in the eyes of the public and the related issues of transparency, peer review, public consultation, food labelling, patent protection, etc. This is apparent, for example, from the opinion polls it commissions (40).

We in OPHA must be knowledgeable about the overall political process in which key policy decisions are carried out regarding food biotechnology. These decisions are taking place in an arena with a diverse group of players, some with strong and urgent agendas; they relate to the interests of Canadians in different ways. The apparently equitable nature of the regulatory system belies a hierarchy of decision-making bodies. Public consultation processes are short and limited. Policy decisions are being made rapidly – often without what some would consider adequate information – especially within the context of international trade partnerships and obligations. New reports and legislative processes such as new bills are introduced frequently.

Channels of influence exist. The OPHA food biotechnology workgroup suggests that we know where they are, and that we are in a position to provide input effectively and opportunistically. As concluded by David Barling and Tim Lang in an editorial about European public policy on GM agricultural products and food,

“...it is high time the public health movement was more vociferous in debates about food.” (21)

E. RECOMMENDATIONS FOR OPHA ACTION:

1. That OPHA advocate, either directly to the appropriate ministries of the Government of Canada or via formal consultation channels, to indicate our support for the following:

Protocol for Regulation

- a) The establishment of a rigorous, integrated and standardized framework for the assessment of allergenicity and toxicity of GM foods, based on the precautionary principle rather than on substantial equivalence, and including external review of experimental data
- b) The development of a protocol for a more thorough environmental assessment of GMOs before their release, as well as a the monitoring of environmental impacts post-release
- c) The inclusion, in the protocol for GM food assessment, of the evaluation of whole foods rather than the isolated gene product

Research and Methodology

- d) The development of reliable, accurate and sensitive methods for assessing allergenicity of stable novel proteins in foods resulting from genetic engineering
- e) The allocation of research funds to determine ecological impacts of genetic engineering in agriculture

Monitoring and Surveillance

- f) The development of an effective means of segregating and recalling GM foods for the purpose of epidemiological surveillance
- g) The development of an appropriate after-market surveillance system to detect unanticipated health or ecological consequences of GM crops or foods
- h) The development of a national nutrition monitoring and surveillance system to better track the potential for nutrient imbalances that could arise from nutritionally-altered GM foods
- i) The development of an on-going data base on the type, amount and frequency of pesticide use by all farmers in Canada, for the purpose of comparing the outcomes of farming methods under various conditions, and to inform federal policy

Policy and Legislation

- j) The establishment of mandatory labelling laws for foods containing GM ingredients
- k) Policy development regarding increased transparency of research data and details of regulatory approval decisions, involving peer review by experts external to industry/government and opportunity for pre-approval public commentary
- l) The inclusion of consumer groups, NGOs and representatives from civil society on any federal biotechnology advisory group responsible for the development of federal policy around food biotechnology, and their inclusion in all formal consultation processes
- m) Equal support (through research, training, funding, tax rebates, subsidies, marketing) for farmers who do not wish to use GM crops or livestock
- n) The clear separation of the roles of regulator and promoter of food biotechnology in the federal government
- o) The establishment of policy on liability, assuring that public taxes should not have to cover the cost of any catastrophic environmental or health outcomes
- p) Support for ways of maintaining biodiversity of all species, domestic and wild
- q) Application of the Precautionary Principle in the development of policy, methodology and protocol for the regulation of food biotechnology
- r) Action on the recommendations of the Royal Society of Canada Expert Panel Report (1)

2. That OPHA retain a standing workgroup on food biotechnology, with resources to enable the following:

- a) The capacity and readiness of OPHA to respond effectively to proposed legislation, reports, consultations, etc. and to participate in groups for advice on federal policy on food biotechnology
- b) On-going opportunities for education on food biotechnology for public health staff in Ontario
- c) The development of policy on the role of public health in, and strategies for, educating the public on food biotechnology

3. That OPHA approach other groups who have a similar position on food biotechnology, to form partnerships for advocacy and education.

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Regarding resolutions, position papers and motions:

Status: Policy statements (resolutions, position papers and motions) are categorized as:

Active, if:

1. The activities outlined in the policy statement's implementation plan have not yet been completed; or
2. The policy statement addresses an issue that is currently relevant to public health in Ontario.

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2. The policy statement addresses an issue that is not currently relevant to public health in Ontario or is not based upon the most current evidence. The statement remains the position of the OPHA until a new statement is adopted that effectively reverses or essentially negates all or major elements of an earlier statement. In this instance, the former supersedes the latter

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