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Labelling of Genetically Modified Foods in Canada

By

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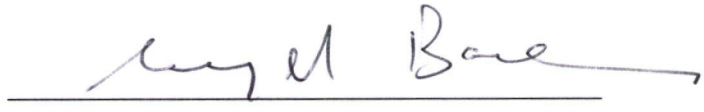
The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Labelling of Genetically Modified Foods in Canada" submitted by Janet L. McCready in partial fulfillment of the requirements for the degree of Master of Laws.



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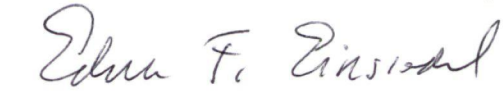

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ABSTRACT

This thesis argues that genetically modified foods should be subject to mandatory labelling requirements. Genetically modified foods have both ardent supporters and vehement detractors, and these polarized views pose a tremendous challenge to regulators. Mandatory labelling represents a compromise on the spectrum of regulatory measures that could be undertaken to achieve the two goals of the food regulatory system: to ensure the safety and certainty of the food supply for Canadian consumers. Because neither safety nor certainty can be guaranteed, the role of the regulatory system in ensuring safety is really about effective risk management and risk communication, while its role in ensuring certainty is really about allowing consumers to make their own choices based on full information. Further, a review of theoretical approaches to risk assessment, risk management and risk communication, along with the economic principles of providing full consumer information, all support the view that consumers should be able to identify genetically modified foods. This thesis concludes that mandatory labelling is the best way to achieve the provision of full information, and that the concerns of proponents of genetically modified foods with respect to labelling can best be addressed by extending the existing ingredient labelling regulations to genetically modified foods.

Dedication

I would like to dedicate this work to the men in my life,
Brad, Alex and Will
who are my world.

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This thesis would not have come to fruition without
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Chapter 1 – Introduction

We are living in an era of rapid technological change – and have been for the better part of the last century. But over the last decade or two, there has been a significant change. We have gone from primarily inorganic technologies to a boom in the technologies of life – biotechnologies. These developments do not sit well with everyone, and it is perhaps inevitable that many individuals and organizations would protest. This thesis, however, is not about whether such technologies should be developed and used; rather, it is about whether consumers of products developed through biotechnology, specifically foods that have been genetically modified, should be informed that the item they intend to purchase and consume was produced through a biotechnological process.

Throughout human history, we have developed and embraced new technologies. From industrialization to modern medicine, most people, at least in North America, would agree that our incredible technological innovations have resulted in a tremendous improvement in our living conditions. Yet technology has its negative impacts as well, including the degradation of the natural environment, cultural impacts and social effects. It seems as though the pace of technological change has been increasing over the last century, reaching a point where many of us are unaware of or bewildered by the daily parade of new technologies. When it comes to biotechnologies, the confusion is perhaps greater than in other fields.

Biotechnologies deal with the molecular building blocks of life itself. Scientists are describing, mapping and manipulating genes – the molecules contained in the nucleus of every cell of every living thing. Genes prescribe everything from appearance to function, from the level of single cells to the entire organism. Genetic biotechnologies comprise a wide variety of technologies that, generally speaking, alter the existing genetic code of an organism in some way. These technologies include medical technologies, such as gene

therapy, which is predicted eventually to be a solution for illnesses and conditions that have a genetic component. Biotechnologies also include the genetic modification of organisms that are destined to become part of the human food supply.

Proponents declare that these brave new technologies will be the source of medical and agricultural improvements that will change all our lives for the better. Gene therapy and pest-resistant crops are promising in many ways, but the reality is that our understanding of how genes work does not yet match our ability to manipulate them.[1] Moreover, what scientists understand about genes goes far beyond what the average layperson understands. Biotechnology and genetics are undoubtedly complex, but it often seems that there is a dearth of information available for the layperson. This situation is arguably more likely to increase public fear and apprehension regarding new technologies than to decrease it.

The genetic modification of crops and domesticated animals destined for human consumption has become particularly contentious. Modification of the genetic code of organisms that are part of our food supply is not entirely new – one of the very earliest technologies developed, and one which made the development of human societies possible, was agriculture. Wild plants and animals were gradually domesticated and, through selective breeding, improved for more reliable and more prolific production, greater appeal as foodstuffs, and greater variety.[2] For example, different strains of wheat were cross-bred to create new strains with desired improvements such as adaptation to a short growing season.

The type of genetic modification that will be explored in this thesis is the molecular type.[3] In this case, the genes of an organism are modified at the nuclear level, or introduced from one organism into another totally unrelated one, to produce a desired improvement much more

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[1] This point is argued in Chapter 2.
[2] Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (Ottawa: Royal Society of Canada, January 2001) at 14-15.
[3] Throughout the thesis, the abbreviation "GM" will be used to indicate genetic modification, and genetically modified food will be referred to as GM food.

quickly. The first major breakthroughs in the science of genetic modification came in the late 1960s and early 1970s.[4] In 1972, the first genetic transformation of a micro-organism was achieved. After the initial excitement, progress was quite slow for two decades. It was not until the late 1980s that grains such as rice and corn were successfully modified. The slow progress was partly due to the process itself, and partly due to a lack of raw material, i.e. actual genes with which to modify plants.[5] The tremendous advances in techniques of gene isolation and identification over the last decade have made it possible for scientists to select virtually any trait that they wish to add to a particular plant – and then add it.

So far, regulation has lagged behind scientific developments in biotechnology. Ethics, which may influence the direction of regulatory policy, has made some effort to keep up but has not really addressed genetic modification of foodstuffs. Advocates of the technology tend to argue that new regulation is not necessary – this is simply the latest development in a long chain of genetic modifications undertaken over the history of human agriculture. Opponents are fearful that such modifications could result in unintended and drastic consequences for the environment and argue that it is foolhardy to exchange genes between species that could never cross-breed in nature. What if we inadvertently create superweeds, or superbacteria, or irreversibly diminish the tremendous pool of genetic variety in the natural world by interfering with the processes of life at such a fundamental level? And what about the health of people who consume foods made from GM ingredients – do we really know what the effects of eating these foods might be?

Meanwhile, the average person is uncertain how she is affected. What do GM foods have to do with her – she never buys them. Then she is told that she is probably consuming GM products already without knowing it, and has probably been doing so for at least a decade. How could this be? Because the regulatory agencies in Canada and the United States have

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[4] Royal Society of Canada, *supra* note 2, at 15.
[5] McHughen, Alan, *Pandora's Picnic Basket: The Potential and Hazards of Genetically Modified Foods* (Oxford: Oxford University Press, 2000) at 122-125.

concluded that GM foods are substantially equivalent to the traditional varieties, and accordingly can be used in food products without being identified as genetically modified.[6]

Some people are alarmed by this situation, while others are unmoved. If the government has decided these foods are safe, they will accept that decision. But there is a segment of the population, albeit more vocal in Europe than in North America, arguing that it is wrong for corporations to put GM foods on the market without identifying them as such. After all, new products are tested in a free market by their acceptability to purchasers, who must therefore know what they are purchasing. If consumers don't want a tomato that ripens on the vine because one of its genes was inserted upside-down, they won't buy it and the product will fail. If they do want it and buy it, the technology will be a commercial success.

However, the large corporations that produce GM foods, the majority of which are located in the United States, generally oppose the idea of mandatory labelling of GM products.[7] They argue that such labels will put their products at a disadvantage, as these labels would appear to be a warning and give the public the idea that the products are not safe. This is unfair, they say, as the products have been judged safe by the appropriate regulators. They argue further that it would be much too difficult and expensive to segregate their GM products from the traditional varieties, and that those wishing to purchase GM-free foods would have to bear the additional costs of segregation and labelling.

This last argument is interesting given that one would expect the improvements achieved through GM to be trumpeted by the companies and used to market their products. One would expect that the vine-ripened tomato would be highly desirable to consumers and that the producers would jealously guard their produce and keep it separate so that it could be marketed as a superior product, perhaps at a premium price. However, the majority of GM

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[6] The concept of "substantial equivalence" is discussed in Chapter 4.
[7] The arguments against mandatory labelling are discussed in Chapters 5 and 6.

products now on the market have not been modified to provide any benefit to the consumer.[8] They have been engineered for such qualities as pest resistance or herbicide resistance, qualities which are of benefit to farmers and particularly to the producers of GM seed and agricultural chemicals, as they can engineer resistance to the herbicides they manufacture under patent and thus capture two markets at once. Producers advise, however, that the next generation of GM products will be beneficial to consumers – for example, by providing enhanced nutritional value.[9] We may expect to hear the concerns about segregation and labelling disappear with respect to those products, as the producers will no doubt wish to keep the modified foods entirely separate from the traditional (and inferior) ones.

But what of the argument that GM foods have been judged safe and therefore need not, and should not, be labelled? Another aspect of this argument is that foods should be regulated on the basis of their characteristics as individual products, and not according to the process, genetic modification, by which they have been produced. But whether it is the product or the process that has been judged safe, the argument that such a judgment has been made, and that regulators can and should make that judgment on behalf of consumers, requires an examination of the regulatory system to determine how GM foods have been tested and judged safe. Moreover, what does "safe" mean? Any regulator or manufacturer would agree that "safe" does not mean risk-free, but the public may interpret it as such.

And what if the public does not accept the regulatory judgment as to safety? Should people not still have a choice with respect to the products they choose? If people do not wish to consume nuts because they have a life-threatening allergy, they do not have to accept a regulator's decision that nuts are perfectly safe – they are entitled to be informed whether nuts are present in a product and decide for themselves whether they wish to consume that product. Should GM foods not be subject to the same level of disclosure if there are any risks associated with consuming them?

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[8] Royal Society of Canada, *supra* note 2, at 21.
[9] McHughen, *supra* note 5, at 122-125.

Recent crises in risk management in various countries have shaken the public faith in the ability of government to protect people from risks of which they are unaware or which they are unable to manage on their own.[10] The incidence of "mad cow disease" or bovine spongiform encephalopathy (BSE) in Europe, and more recently in North America, is a case in point. In the United Kingdom there have been dozens of cases of Creutzfeldt-Jakob Disease (CJD) in humans that may be linked to BSE in the beef supply. This situation, with its ongoing potential for further problems, is an example of government apparently failing to adequately protect the general public from a risk of which it had knowledge but the people did not.

With the speed of technological advancements, including biotechnology applied to foods, many people are becoming more concerned about their own powerlessness to protect themselves and their children from potential dangers that they can neither see nor assess without expert advice. They depend on government to provide that expertise and that protection for them, but they are not always satisfied with the decisions government makes. They cannot escape the feeling that there is risk involved in consuming these foods.

And government confirms that there is some level of risk.[11] For example, it is possible that a new and toxic compound could unexpectedly occur in a GM product. Genetic modification could also introduce allergens into crop plants on which we depend. An example is the introduction of a Brazil nut gene into soy, which resulted in the soy plant being just as dangerous to people who are allergic to Brazil nuts as the nut itself.[12] Moreover, given that some introduced genes come from bacteria and other organisms that have never been a food source for humans, it is impossible to be absolutely certain that new allergens are not being

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[10] This argument is made in Chapter 5.
[11] The risks associated with GM foods are described in Chapter 2 and the view of the Government of Canada is discussed in Chapter 4.
[12] Note that this product never reached market, as the testing which detected the transfer of allergenicity was done before any attempt was made to seek approval for marketing.

introduced into our food supply. And without segregation and labelling of these GM foods, our ability to track and identify potential new allergens is severely restricted.

Given the potential health risks, the appearance of genetically modified foods in the Canadian marketplace certainly warrants a regulatory response of some sort. Generally speaking, the regulatory options would be to (a) allow genetically modified foods on the market freely with no restrictions; (b) ban genetically modified foods altogether; (c) carefully review each new proposed genetically modified food product before making a decision as to whether to allow it to be released to the market; and (d) require producers of GM foods to label their products as genetically modified to allow consumers to decide for themselves whether they want to assume these risks or avoid them. The regulatory options are not entirely exclusive; regulators could impose both options (c) and (d). In practice, option (c) is used in Canada, but without mandatory labelling. Apparently regulators have concluded that any risk associated with the specific food products reviewed is acceptable and does not warrant mandatory labelling of GM foods.

For those who are not satisfied with this determination, the natural question to ask is: How do regulators assess and manage risk? This thesis will address this question in order to determine whether risk analysis principles suggest that mandatory labelling of GM foods should be implemented. Various terms will be used to describe the steps in the risk analysis process.[13] The process begins with a scientific risk assessment, which provides quantitative data from which regulators can draw conclusions. The next step is for the regulators

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[13] The terms used here are those adopted by the Codex Alimentarius Commission ("Codex"), an international body of which Canada is a member. Codex was set up by the World Health Organization ("WHO") and the Food and Agriculture Organization of the United Nations ("FAO"). Codex sets international standards for the regulation of all issues relating to the food trade. Risk analysis is composed of three elements – scientific risk assessment, regulatory risk management, and risk communication among all stakeholders: Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, ALINORM 03/41. Most risk assessors use this approach, where risk analysis consists of these three components: Hester, R.E. and R.M. Harrison, eds., *Food Safety and Food Quality* (Cambridge, U.K.: The Royal Society of Chemistry, 2001) at 2. The FAO and WHO also endorse this risk analysis framework: Food and Agriculture Organization of the United Nations, *The Application of Risk Communication to Food Standards and Safety Matters* (Rome: FAO, 1998) at 1.

(government agencies or departments empowered to make and enforce regulations) to make their own risk management decisions, based on the scientific data and various other considerations. Risk management includes all regulatory measures imposed on the GM product in question – pre-market testing and review, labelling, limited use or distribution, or an outright ban. The efforts made by both producers of GM foods and by regulators to communicate their risk assessment and risk management practices, and the results thereof, is referred to as risk communication. The overall process, from assessment through management and communication, will be referred to as risk analysis.

One of the difficulties inherent in our risk analysis system for new technologies is that the type of risk assessment done by the scientific community is based on different criteria and different concerns than those of the general public.[14] Regulators are caught in the middle, trying to make risk decisions based on sound scientific data while responding to the less quantitative concerns of laypeople who will be exposed to the risks. For the regulatory system to meet the needs of consumers without placing unreasonable limits on innovation, important questions must be considered. How should risk be assessed? What is an acceptable level of risk? Where the public are out of step with scientists as to the methodology and conclusions drawn in the risk assessment process, should regulators invoke risk communication as the preferred risk management strategy, so that individuals are given the tools and information they need to make their own informed risk management decisions? Further, there is the issue of consumer choice and the provision of full information to consumers, which allows the market to determine the acceptability of new products such as GM foods.

Underlying it all is the role of the regulator in protecting the public interest. Since innovation, commercial success, transparency in the regulatory system and in the market, consumer choice, and the minimization of public health risks are all in the public interest, one would expect the regulators to be subject to some conflicts of interest in the course of

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[14] This argument is made in Chapter 5.

managing the risks of GM foods. This thesis examines the federal regulatory system in Canada governing the sale of GM foods. It attempts to identify the views of different stakeholders, including proponents, risk assessors, regulators and consumers, and to determine how and to what extent the regulatory scheme can most effectively respond to all of these views. The conclusion is that mandatory labelling of GM foods is the best regulatory solution for all stakeholders, for reasons of both risk management and consumer choice.

Chapter 2 provides background to the debate through a discussion of the potential risks and benefits inherent in GM foods, beginning with a description of the science and technology behind the creation and production of GM organisms intended for consumption as food.

Chapter 3 reviews the legislative and regulatory provisions of Canada governing food, and how they apply specifically to GM foods. It also considers the way labelling requirements are imposed on particular foods, and the policy issues behind these labelling requirements. The chapter proposes that the two primary public interest goals in the regulation of food are the protection of public health, by managing the risks inherent in GM foods, and the prevention of consumer deception (referred to throughout as the "safety" and "certainty" goals). These public interest goals dovetail with the overall functions of labelling – effective management and communication of the risks (safety) and facilitation of consumer choice (certainty).

Chapter 4 looks at how the regulatory goals are achieved with respect to genetically modified foods. The chapter looks at the actual application of the legislative framework (discussed in Chapter 3) and of the risk analysis process, specifically scientific risk assessment and the regulatory risk management process.

Chapter 5 focuses on the safety goal by reviewing some theoretical perspectives on risk assessment, risk management and risk communication, and how they apply to the issue of

labelling GM foods. This chapter considers the clash between the scientific perspective on risk assessment and the public perspective, including the social factors that colour public opinion and ultimately impact on risk management decisions such as the decision whether to impose mandatory labelling. The chapter then attempts to draw the perspectives together by examining principles from the discipline of risk communication and then considering how the fundamental disagreement can best be managed. The arguments on both sides of the debate over mandatory labelling are considered according to the theoretical perspectives considered in this chapter.

Chapter 6 considers the issues involved in consumer choice and in achieving the certainty goal with respect to GM foods. It will consider labelling theory and the economic arguments for and against mandatory labelling.

Chapter 7 summarizes the material reviewed and concludes with a suggested regulatory approach to the labelling of genetically modified foods.

In researching this thesis, I have found it necessary to go outside the usual parameters of legal research in order to develop a theoretical framework. While the regulation of food and food labelling in Canada is stringent and involves lengthy and very detailed regulations, there are virtually no secondary sources on this topic. I have looked at case law and legal texts with respect to issues that have come before the courts, primarily involving the constitutionality of the federal government prescribing standards that are not related to safety. Beyond this, very little case law exists with respect to the issues examined in this thesis.

Accordingly, I have undertaken an analysis of the *Food and Drugs Act* and its Regulations with a view to determining the regulatory goals of the legislative and regulatory framework. I have attempted to situate this framework in the larger background of the role taken on by government in consumer protection generally. After concluding that the regulation of food

is, much like the regulation of all consumer goods, geared to ensuring that consumers are not put at any physical risk and not deceived with respect to the products they purchase, at least with respect to characteristics and qualities of those products that they cannot determine by examination of the products, I then turned to the more specific issues of how genetically modified foods might be viewed in light of the regulatory concern for what I have termed "safety" and "certainty".

In order to consider the safety issue, I have read books and articles that discuss in some detail the scientific method of genetic modification. The discussion included in Chapter 2 of the thesis is admittedly cursory, as it is based on my understanding of the science as a non-scientist. However, a variety of sources indicate that there can be no certainty that genetically modified foods are completely safe. Accordingly, I have then looked at the ways in which regulators attempt to ensure safety to the best of their ability, given that absolute safety can never be guaranteed with respect to any product.

I have then reviewed literature involving various aspects of risk analysis, including scientific risk assessment and principles of risk communication. I rely primarily on literature that has attempted to tie principles of risk analysis into legal theory, most notably law and economics theory. However, I have reviewed some literature outside of the legal literature in an effort to bring in general principles of risk communication. The latter review is not comprehensive with respect to the literature on risk communication, given that such a review would be beyond the scope of this thesis. However, I have made an effort to tie together some of the legal theory currently in development with regulatory principles, both Canadian and international, and with the principles of the discipline of risk communication.

Finally, as the arguments against mandatory labelling of GM foods are primarily economic ones, I have also looked at some literature involving the issue of labelling from an economic perspective. I have again tried to tie these ideas into legal theory with respect to law and economics, and to tie them into the regulatory framework and the basic economics of GM

foods. Again, I have not done a comprehensive review of economic literature with respect to the labelling issue; however, I have searched for books and articles relating to labelling and labelling theory in an effort to ensure that I have considered the most up-to-date ideas in this field. In particular, I have focused on literature of the Organization of Economic Cooperation and Development ("OECD"), but I have also looked for and reviewed other literature in this area.

Overall, I have found that the literature on GM foods ranges from helpful analysis to repetitive diatribe, from proponents of genetically modified foods on one side and detractors on the other. Most of the literature comes back to the same arguments for and against mandatory labelling, and I have endeavoured to address all of the arguments that I have encountered on both sides. In the end, law, risk assessment and market principles all provide support for the view that GM foods should be identified as such on product labels. Given that there is clearly public demand for full information with respect to the genetic modification of food products,[15] it would be strange indeed for a system geared to the protection of consumers to allow proponents of GM foods to refuse to advise people that they are consuming genetically modified products.

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[15] Lang, Michelle, "Coming to Grips with GM: New Poll Shows Overwhelming Number of Canadians Want Mandatory Identification on Genetically Modified Food" (December 4, 2003) Calgary Herald A3.

Chapter 2 – Biotechnology

2.0 Introduction

There are numerous biotechnologies that can be applied to plants and other organisms that become part of the human food chain. Examples include such technologies as the age-old agricultural technology of hybridization and more recent technologies such as mutagenesis, protoplast fusion, embryo rescue and somaclonal variation, to name a few.[16]

However, for the purposes of this thesis, the type of biotechnology that is being considered, and that is referred to as genetic modification, or GM, is recombinant DNA technology. This narrowing of terminology is used in the Royal Society of Canada report on the regulation of food biotechnology, which states as follows:

> A primary substantive issue in the food biotechnology debate, and in the mandate of this panel, is that of *whether* the new recombinant DNA technologies pose unique issues and risks requiring special regulatory expertise and techniques. ... Since one of the important questions involved in the assessment of the potential hazards of these products and techniques is that of how they differ, if at all, from traditional means of modifying the genetic character of organisms, the Panel found it necessary at points to evaluate the new technologies against the traditional ones. In order to make this project transparent, we needed to adopt clear terms that refer to the different techniques.
>
> For the purposes of this Report, therefore, the Panel uses the terms "Genetic Engineering", "Genetic Modification" and "Biotechnology" as fully synonymous terms, referring exclusively to the direct transfer or modification of genetic material using recombinant DNA techniques. They do not refer to other traditional breeding and hybridization techniques not involving these techniques.[17]

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[16] Benda, Stan, "It's All About Elmer Gantry...There Is No Frankenstein!!!: Ideology is Toxic to Genetically Modified Crops and Food; The Process Versus Product Debate as Manifested in the Currents of IP and Regulatory Laws and Treaties" (2003) Part I and Part II, 16 I.P.J. 221 and 393.
[17] Royal Society of Canada, *supra* note 2, at 11.

As discussed in Chapter 1, the regulation of foods developed through GM techniques is really about the assessment and management of risks, and about consumer choice. Most of this thesis will deal with the legal and regulatory approaches to these issues. However, in order to consider the issues of risk (safety) and choice (certainty), it is necessary to have a basic understanding of the science behind GM foods. This chapter will provide an overview of the science behind GM technology, and the scientific basis for the potential risks associated with GM foods and crops.

2.1 The Science of Genetic Modification

Recombinant DNA technology ("rDNA") includes a variety of techniques, which have been described as follows:

> Genetic modification (GM), also known as genetic engineering or rDNA technology, is actually a collection of many technologies. These begin, perhaps, with the molecular identification and analysis of genes and DNA. They include extraction and isolation, then "cloning" or multiplying fragments of DNA or genes. They include gene-splicing, cutting pieces of DNA, and connecting together fragments from different sources. They also include shifting the DNA from test tube to Petri dish, or from bacteria to other bacteria. They may involve subtle or substantial directed alteration of the DNA along the way. They could also include transferring or inserting the DNA into the cell of a higher plant or animal, then recovering a complete new organism. Only this last stage is what most of us consider when defining "genetic engineering".[18]

Even reading this paragraph could be daunting for consumers who do not feel well-versed in scientific principles. This view that the science is incredibly complicated can lead to the belief that only scientists can understand the processes involved, and therefore scientists should make the decisions as to whether risks are acceptable. However, this attitude

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[18] McHughen, *supra* note 5, at 9.

discounts the importance of personal preferences in determining which risks are worth taking and which are not.

A brief overview of the science of genetics and of the rDNA process follows. This overview is general and represents the understanding of a non-scientist. However, although it may not be presented in the way that a scientist would prefer, it is hoped that this summary helps illuminate the concepts of genetic modification at the scientific level.

2.1.1 Genetic Variety

Genetic variety is the raw material of evolution. Sexual reproduction and recombination allow for changes in the genetic makeup of a population, thus permitting various beneficial traits to be passed on to subsequent individuals and increase their competitiveness. It is also commonplace for individual genes to mutate due to environmental or other factors. Sometimes such a natural mutation is associated with a harmful trait, in which case those individuals carrying the mutated gene are unlikely to reproduce and pass it on to the next generation. But when a mutation confers a trait that is beneficial, it provides the carrier with a competitive advantage over other members of the population. The carrier is more likely to survive and reproduce, thus increasing the likelihood that the next generation will inherit the gene and, therefore, the trait. This is the process of natural selection. In this way beneficial mutations can result in evolutionary changes within species and, ultimately, result in the evolution of new species.

Evolution has also occurred in organisms used by humans, such as crop plants, but it is driven by human selection. When humans began developing agriculture some 10,000 years ago to create a more reliable food supply for themselves, they learned how to manipulate the reproductive processes of their crop plants to produce genetic changes that were beneficial to

themselves as producers and consumers of the plants.[19] For example, wild strawberries are extremely small, but selective breeding of plants carrying larger fruit, gradually developed over multiple generations of the strawberry plant, resulted in the gigantic strawberries we now enjoy. Plant breeders today continue to modify crop plants in ways that are beneficial to producers, consumers or both, and have helped to provide a more dependable food supply.

Because of the profound genetic changes achieved over thousands of generations through the processes of natural selection and human selection of crop varieties, proponents of GM foods argue that the use of rDNA technology has only taken the process one step further. The benefit is that the length of time required to produce new varieties has been shortened and the possibilities for new varieties vastly expanded. According to this line of thinking, rDNA is not a frightening new technology that fundamentally changes life itself, but is simply the most recent advancement in a science that humans have been developing for millennia.

2.1.2 Genes and Traits

The science of genetic modification takes evolution and human selection to the molecular level. Rather than cross-breeding different varieties that exhibit desirable traits, rDNA technology allows the identification of the particular gene that controls the expression of the desirable trait, and adds it to the genetic code of the species that is to be modified. To understand, at least a little, the molecular process, it is necessary to consider how genetic variety occurs through reproduction and how particular traits are passed on through generations.

As most people know, any trait expressed by an organism is contained in the genetic code carried in its chromosomes. For a human example, such a superficial trait as eye colour is the result of the particular variety of eye colour gene that we carry. All of our genes are

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[19] Diamond, Jared, *Guns, Germs, and Steel: The Fates of Human Societies* (New York: W.W. Norton & Company, 1999) at 114 et seq.

contained in our 21 chromosomes, and we have two copies of each chromosome in the nucleus of almost every cell in our bodies – one copy from our mother and one copy from our father. The variety of genes, together with the presence of two copies of each chromosome (and therefore two copies of each gene) allows the genetic variety that we see among individual members of a species.

For illustrative purposes, imagine that the gene for eye colour is carried on chromosome 21. Every individual would have an eye colour gene on each copy of chromosome 21, copy 1 and copy 2. The eye colour gene would always occur at the same point on chromosome 21, not only in that individual but in all humans. But there are different varieties of the eye colour gene. Each variety contains a code that dictates the actual eye colour for that individual. So, for example, an individual might have a blue eye gene on copy 1 of chromosome 21 (from the mother) and a brown eye gene on copy 2 of chromosome 21 (from the father). The dominant gene will determine what eye colour is expressed in that individual.

In many plants and animals, sexual reproduction is the vehicle for genetic change over a number of generations. Continuing with the eye colour example, imagine that the parents of a child each have a blue eye gene on copy 1 of chromosome 21 and a brown eye gene on copy 2 of that chromosome. In the production of gametes (ovum or sperm) in each of the parents, each ovum or sperm receives only one copy of each chromosome. Accordingly, each gamete from each parent could carry either the blue eye gene or the brown eye gene on chromosome 21. When the ovum is fertilized and an embryo is created, the genome of the embryo will have one copy of each chromosome from each parent. The resulting child could have two blue eye genes, two brown eye genes, or one of each. Another offspring will likely receive a different combination of genes.

Even greater variety in the genetic makeup of different offspring of the same two parents is achieved through the process of recombination.[20] In the process of cell division that forms the gametes in individuals, there is some crossing over between the two copies of each chromosome that were found in the parent cell. In the process, some genes are switched from copy 1 of the chromosome to copy 2, and vice versa. After recombination, each copy of the chromosome still has the same genes in the same positions, but may now carry different varieties of certain genes.

Thus, in the eye colour example, each gamete will have one copy of chromosome 21, but the varieties of the other genes located on the gamete's chromosome 21 may not correspond exactly to either copy of the parent's chromosome 21. There might be a brown eye gene with a brown hair gene on the parent's copy of one chromosome, but in the gamete the brown hair gene might be coupled with a blue eye gene. As each chromosome carries many genes, particular varieties of each different gene could be combined in many different ways. This increases the probability that no two offspring will be too much alike.[21]

2.1.3 Genetic Modification

Natural selection could be considered a form of natural genetic modification, and is an ongoing process in all species through the vehicle of sexual reproduction. Recombinant DNA technology takes human selection to the next level and refines it.[22] The name reflects the fact that it will result in a recombination of genetic material, not entirely unlike the recombination that occurs when cells divide to produce gametes. However, the significant difference is that rDNA does not just lead to a reshuffling of the varieties of genes on a particular chromosome – it usually leads to the introduction of entirely new genes that have never before been found in the transformed species.

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[20] Suzuki, David T. et al., *An Introduction to Genetic Analysis*, 2d ed. (New York: W.H. Freeman and Company, 1981) at 690 et seq.
[21] Unless they are identical twins.
[22] The discussion in this section is taken from McHughen, *supra* note 5, at 21-60.

Plants are currently the only type of organisms that have been approved in Canada as sources of GM food. At the molecular level, plants are essentially no different than animals. The nucleus of every plant cell has a set of chromosomes containing all the genes the cell needs to do its work.[23] As in animals, humans, bacteria and all other forms of life, plant genes are composed of deoxyribonucleic acid (DNA), a long double string made up of molecules known as bases. There are four different varieties of bases, known in short form as A, T, G and C. Each gene consists of a segment of the DNA on a chromosome, made up of a sequence of bases in a specific order. Each base has a corresponding amino acid, the building blocks of protein molecules. Each gene therefore codes for a particular protein which is needed for some particular cellular process. When the protein is needed, it is manufactured from the DNA template by other molecules in the cell, such as ribonucleic acid (RNA).

When scientists say they have decoded a particular gene, they mean that they have worked out the sequence of bases that make up that gene. The sequence of bases can be translated into a sequence of amino acids, which make up a particular protein. The gene includes not only base sequences that correspond to the specific amino acids making up the protein in question, but also sequences that provide instructions for the production of the amino acid – a promoter sequence that instructs RNA molecules to begin production of the protein, (sometimes) sequences that appear to be superfluous and are not included in the final protein, and a termination sequence that indicates the end of the gene. Somewhere down the chromosome, a new promoter sequence will be found that indicates the beginning of the next gene.[24]

The proteins produced from the plant's genetic code carry out the basic functions of each cell. Some proteins act as the building blocks of tissues, while others are enzymes that

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[23] McHughen, *supra* note 5, at 25 et seq.
[24] *Ibid.* at 31-32.

catalyze the chemical reactions that occur in the processes of photosynthesis, cellular respiration, breakdown of food particles, and so on. Not all genes operate at all times; some are turned on or off by other genes or by conditions within the cell.[25] Nor are all genes needed in every cell, since plants, like other complex organisms, contain specialized tissues which carry out different functions. For example, the proteins that are needed for photosynthesis will be produced in leaf cells, but genes coding for proteins needed in root cells will be turned off. The mechanisms for turning genes on and off are complex and governed by DNA sequences within the gene (introns) that do not actually code for specific amino acids.[26]

There are numerous technical hurdles to be surmounted in order to achieve a successful GM plant. The desired trait must be traced to a particular gene in some other organism, and the gene must then be isolated and reproduced. The process by which this is achieved is too complex to delve into here. It will suffice to say that scientists are able to replicate genes outside the organism from which they are taken. Then the new gene must be introduced into cells from the plant which the scientist wishes to modify, and then a whole new plant must be generated from the individual modified cells.

The method by which the genetic modification of a plant cell is achieved is surprisingly haphazard. One of the methods is sometimes called the shotgun method, and literally involves a microscopic firing of genetic material at the cells which the scientist wishes to transform. This method will generally result in a small percentage of the subject cells taking up the new DNA into their own genetic code, a process that occurs by a mechanism that is not fully understood.[27]

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[25] *Ibid.*
[26] *Ibid.*
[27] *Ibid.* at 51-52; Royal Society of Canada, *supra* note 2, at 17.

Another method which is not completely understood but frequently used involves the Agrobacterium microbe. This is an infectious bacterium that invades the tissue of plants and injects its own DNA into some of the plant cells. Scientists can insert the desired gene into the Agrobacterium, which will take it up and add it to the Agrobacterium DNA for injection into the host cells. This method is limited in that it only works for certain types of plants.[28]

Since only a few cells will adopt the new gene, and it is generally for a trait that will be expressed by a mature plant and not by a single cell, it is impossible at this stage for scientists to identify which cells have been successfully transformed. For example, if the modification will lead to frost resistance in seedlings and mature plants, a single cell will not demonstrate whether it has acquired this characteristic. Moreover, the success rate for growing complete plants from these transformed cells is quite low, and as a result it would be an arduous task to attempt to grow all of the transformed cells into mature plants and then determine which ones carry the desired trait – in the case of our example, frost resistance.

It is for this reason that the gene coding for frost resistance, or any other plant trait, is combined with a marker gene before the genetic modification is performed. The marker is usually a gene that produces a protein which makes the modified cell resistant to an antibiotic or pesticide. This type of resistance, unlike frost resistance, can be detected at the cellular level. The scientist can attempt to grow all of the subject cells on a medium containing the appropriate antibiotic or pesticide, which would normally be lethal to the subject cells. Those which survive and grow on the medium can then be identified as cells that have been transformed with the marker gene and therefore also with the frost resistance gene, since both genes were contained in the DNA introduced to the subject cells. The scientist then takes the modified cells and puts them through the process of developing into a mature plant knowing that whichever ones survive that process will ultimately express the frost resistance trait.[29]

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[28] McHughen, *supra* note 5, at 52-55; Royal Society of Canada, *supra* note 2, at 17.
[29] McHughen, *supra* note 5, at 56-59; Royal Society of Canada, *supra* note 2, at 18-19.

2.1.4 GM Products on the Market

In some cases genetic modification does not involve the introduction of a gene from a foreign organism, but rather a change to one of its own genes. For example, in the Flavr-Savr tomato, a gene that caused the tomato to begin rotting shortly after it ripened was excised from its chromosome, inverted and reinserted. First produced in the early 80s, the tomato was designed not to rot immediately upon ripening. This allowed the tomatoes to be ripened on the vine, which would make them more flavourful, but also to remain fresh for weeks. However, the tomato was a failure on the market, probably because the flavour was not really superior to other tomatoes and because it was far too expensive.[30]

The types of traits that were added to the first GM plants have typically involved some form of built-in pest resistance or resistance to herbicides. From the point of view of consumer advocates, it would appear that the technology has so far been used primarily to benefit large agrifood corporations and possibly smaller food producers. However, scientists say that these were the easiest GM strains to develop in the early days of the technology, because of the types of genes that had been isolated and identified, and were available for introduction into other organisms.[31] The argument is also made that the development of insect and disease-resistant crops will increase overall yields, providing a benefit for farmers in developing countries.[32]

Now that huge advances have been made in the techniques and new strains can be developed in a matter of weeks or months, rather than years, crop scientists are aiming to introduce modifications of more direct benefit to consumers. For example, they will try to introduce genes that will promote the production of a vital nutrient that is lacking in the diets of people in developing countries. Proponents often cite the example of attempts to make rice more

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[30] McHughen, *supra* note 5, at 157-158.
[31] *Ibid.* at 122-125.
[32] Benda, *supra* note 16, at 252-260.

nutritious – so-called golden rice, which contains an increased amount of certain essential nutrients including Vitamin A.[33] It is anticipated that consumer demand for these foods, and other crop plants that will be modified to bio-manufacture pharmaceutical products, will be significant.[34]

2.2 Potential Risks of GM Foods[35]

For many people, the rDNA process sounds frightening in itself. It is apparent that there are steps in the process that occur for reasons that scientists don't fully understand. Not only is the mechanism for the take-up of foreign DNA by the subject cells unknown, but scientists generally are unable to pinpoint exactly where on the chromosomes of the subject cells the new gene will end up.[36] It is unclear whether the location matters, just as it is unclear whether the gene will remain in that location through multiple generations of the subject plant, given that cells divide and chromosomes recombine through sexual reproduction.

Although we do not know whether these uncertainties add to the risks of consuming foods derived from GM organisms, there are several potential risks that come up repeatedly in the literature.

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[33] Ackerman, Jennifer, "Food: How Safe?" (May 2002) 201 (5) National Geographic 2 at 13.
[34] McHughen, *supra* note 5, at 125.
[35] The identification of the potential risks of GM foods and crops comes from a variety of sources, but largely from two books: Busch, Lawrence, William B. Lacy, Jeffrey Burkhardt and Laura R. Lacy, *Plants, Power and Profit: Social, Economic, and Ethical Consequences of the New Biotechnologies* (Cambridge, MA: Basil Blackwell, 1991); and Rifkin, Jeremy, *The Biotech Century: Harnessing the Gene and Remaking the World* (New York: Tarcher/Putnam, 1998). Note that Health Canada has acknowledged the possibility of risk in its Guidelines on the assessment of GM organisms: Health Canada (Food Directorate, Health Protection Branch), Guidelines for the Safety Assessment of Novel Foods, Vol II: Genetically Modified Microorganisms and Plants (September, 1994) at 4:

> "... the wide variety of modifications possible through genetic manipulation, and the potential for the introduction of toxic compounds, unexpected secondary effects, and changes in nutritional and toxicological characteristics may give rise to safety concerns."

[36] Royal Society of Canada, *supra* note 2, at 18-19.

2.2.1 Potential Health Risks

There are three major concerns addressed in the literature regarding the possible human health risks associated with GM foods. These are: (1) the possibility of foods containing unknown or unexpected proteins, which could cause allergic reactions in vulnerable individuals; (2) increased bacterial resistance to antibiotics due to the use of antibiotic resistance genes as markers; and (3) unexpected toxins or interactive effects from increasing the content of nutrients in food.[37]

(a) Unknown or Unexpected Proteins

Unknown or unexpected proteins in food could arise from the introduction of any DNA, but cause particular concern when the DNA is taken from foods which are known allergens or from organisms which have never knowingly been consumed as food. Research has revealed that these are not idle fears. An experiment with soy modified with a gene from the Brazil nut plant has shown that highly allergenic substances can be transferred unintentionally, placing at risk anyone with a known allergy.[38] Critics have pointed out that many crops are being modified with genes that come from organisms that have never before been a human food source.[39] As a result, there could be new substances appearing in our food that are highly allergenic without our knowing it. It could also be quite difficult to identify the source of these new allergens if genetically modified foods are not segregated or labelled, because it will be impossible to determine what people have been consuming. According to the British Medical Association:

> GM foodstuffs should be segregated at the source, to enable identification and traceability of GM products. This is important as there are considerable doubts about the behaviour of GMOs once they are released into the

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[37]For example, see Whittaker, M. "Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods" (1998) 35 San Diego L. Rev. 1215 at 1220-1222.
[38] Rifkin, *supra* note 35, at 104.
[39] *Ibid.* at 104.

> environment and this will also facilitate monitoring in the interests of public health. It is unacceptable that at present some GM and non-GM products are mixed at source, and are not adequately labelled. ... Governments should ensure that non-genetically modified foods continue to be widely available and affordable to consumers, and that GM foods are labelled in a consistent and understandable manner.[40]

A more recent interim statement from the British Medical Association has stated that there is no evidence that existing GM foods cause allergic reactions, but that there should be further research and surveillance to provide convincing evidence of safety, and that it remains possible that any new food products could elicit new allergies. This interim statement also continues to call for "adequate post marketing surveillance".[41]

The Royal Society of Canada has also stated that, although there is no evidence that current GM products have caused any allergic reactions, the identification of potential allergens in GMOs is only accurate and reliable when the transgenes come from known allergenic sources. When GM foods contain novel proteins from sources without a history of extensive human exposure, assessment becomes more difficult:

> There is currently no single assay or combination of assays that will accurately predict the allergenic potential of protein from sources not known to be allergenic. Nevertheless, using an array of properly designed and executed assays, and knowledge regarding the characteristics of the transgene, a GM food may then be considered relatively safe for allergic consumers and comparable to its non-GM counterpart, if all tests are negative. Notwithstanding negative allergenicity assessments, however, if the transgene is derived from a source of unknown allergenicity, post-introduction surveillance may be prudent to monitor for any unanticipated allergic effects, recognizing that this may be more difficult without corresponding labelling of GM foods.[42]

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[40] British Medical Association, *The Impact of Genetic Modification on Agriculture, Food and Health – An Interim Statement* (May 1999) BMA website at www.bma.org.uk/public/science/genmod.htm.
[41] British Medical Association, Board of Science and Education, *Genetically Modified Foods and Health: A Second Interim Statement* (March 2004) BMA website at www.bma.org.uk/ap.nsf/Content/GMFoods.
[42] Royal Society of Canada, *supra* note 2, at 72.

The Canadian Biotechnology Advisory Committee ("CBAC"), a non-governmental group reporting to the Minister of Health with respect to issues arising from the development of new biotechnologies, has noted the potential risks of GM foods with respect to new allergens, but concluded that post-market surveillance is difficult to implement in Canada. There are no existing programs and no post-market data available. Nonetheless, "post-market monitoring to test specific risk hypotheses, such as the effects of changing eating habits or exposure to novel foods on individual susceptibility to food allergies, would provide important information for evaluating the potential allergenicity of new foods."[43]

The CBAC also notes a concern for the future:

> The GM foods commercialized to date involve primarily single-gene insertions, whereas the products being developed involve the introduction of multi-gene traits that either produce entirely new metabolic pathways or significantly alter existing ones. This will make the prediction and assessment of side effects more difficult.
> ...
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> The potential for inadvertently introducing an allergen is a key consideration during the development and safety assessment of GM foods. The products currently in the marketplace have been assessed for potential allergenicity, accomplished by investigating the breakdown of new proteins under physiologic conditions in the stomach and intestinal tract, and by searching for similarities with known allergenic proteins. A limitation of this approach is that it becomes difficult to predict the allergenic potential of proteins that have some of the properties of both non-allergens (for example, if they have no sequence similarity to known allergens) and allergens (for example, if they are not broken down by digestion). To properly assess future food products that may express a much broader range of novel proteins, improved predictive tools – perhaps including animal models – will have to be developed.[44]

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[43] Canadian Biotechnology Advisory Committee, *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Ottawa: 2002) at 32.
[44] *Ibid.* at 10-11.

(b) Increased Antibiotic Resistance

Increased antibiotic resistance is unlikely to arise from our consumption of foods containing proteins that confer such resistance on the food organism, but could result from the fact that the use of antibiotics to detect transformed cells results in a greater exposure of bacteria to the antibiotic.[45] Greater exposure increases the likelihood that a bacterial cell that has developed resistance through a spontaneous mutation will obtain a selective advantage and produce a much larger number of offspring containing the resistance gene. It has also been shown that bacteria have the ability to transfer or take up genetic material across their cellular walls, and there is a possibility that bacteria will be able to obtain the resistance genes via a gene transfer from the transformed cells.[46]

(c) New Toxins

As for the possibility of new toxins in our foods, plans to increase the amount of a particular nutrient in a particular food item could increase the risk of spoilage or the growth of pathogenic bacteria which also thrive on that nutrient.[47] Additionally, the boosted nutrient could interfere with some other essential nutrient. The fact is that we don't completely understand the complex molecular interactions in our food that make it healthy for us to eat.

The Royal Society of Canada has noted that, if the contents of certain nutrients in a food fall at or beyond the extremes of the range that are used by nutritionists in determining the parameters of a healthy diet, "there could be health implications, particularly for humans who rely heavily on that foodstuff in their diet". The Royal Society goes on to consider the

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[45] Royal Society of Canada, *supra* note 2, at 49.
[46] In fact, the ability of bacteria to "take up pieces of DNA from their surrounding environment and insert the foreign DNA into their own gnomes" is a mechanism used for some of the earliest successes in genetic modification: McHughen, *supra* note 5, at 47.
[47] Busch, *supra* note 35, at 186.

testing that might be necessary to assess possible changes in nutrient content in novel food, and says:

> Over the many decades of human life, foods are expected to provide all recognized nutritional requirements. Relatively short-term animal tests may yield valuable information, but establishing the impacts of long-term ingestion of a food would involve the systematic monitoring of human populations. This issue is clearly related to the question of labelling of GM foods...[48]

Moreover, it is possible that a transplanted gene will produce a toxic secondary metabolite or protein toxin,[49] or the protein produced by the "transgene" might interact with the proteins produced by the organism's own DNA. The Royal Society of Canada has also noted that:

> Potential adverse health effects from GM food could result from over-expression of an existing protein or other toxicologically active constituent, resulting in much greater exposure to that constituent than previously encountered by humans in their diet. While exposure in this case would be to the same constituent as in the native food, and is thus likely to result in the toxicological end point, exposure to much greater levels of the constituent in the GM food could lead to adverse health effects which could not be predicted by the absence of these effects at much lower levels of exposure to the constituent in the native food. In other words, the likelihood of a toxicological effect is very much related not only to the nature of the substance to which we are exposed, but also to the amount of the exposure as well.
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> ...
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> The Panel recognized that genetic engineering of crop plants may also result in the expression of a constituent which would not otherwise be found in the plant species, but which does occur naturally.[50]

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[48] Royal Society of Canada, *supra* note 2, at 84.
[49] Busch, *supra* note 35, at 11.
[50] Royal Society of Canada, *supra* note 2, at 46-47.

(d) Predictability

Could there be additional risks from introduced genes interacting with genes already present to create an unanticipated effect? One often hears that, because each gene corresponds to a particular protein, the effects of genetic modification are highly predictable. The following analogy for the human genome effectively illustrates why the single-gene approach currently used in genetic engineering of food items may not be as straightforward as one might think:

> ... a simple recitation of the [genetic] code would give no hint of the way it makes a human life. Instead of thinking of the genome as a book, imagine it as a piano keyboard. Each piano key represents one gene. If you press down on a key, you hear a single note. That note corresponds to the protein that the gene specifies. If you press the key again, you will hear the same note, and again, monotonously, every time the key is played.
>
> But if you have lots of keys, you can make music. Just so, our various cell types play upon the immense keyboard of the genome: They combine notes, playing some genes together as chords, tripping several together in a phrase, gathering bundles of notes to create the complex and wonderful effects that find expression in our biological being. Just as a pianist doesn't play all the keys in every piece, only some of the genes get played in the cells of each organ.[51]

Moreover, many desirable crop characteristics are far too complicated to be produced by just one gene and one protein. According to the Royal Society of Canada:

> Few transgenic plants currently contain more than two or three genes. A number of transgene combinations are in trials, where traits such as herbicide resistance and fertility management are "stacked" in one variety. However, most scientists agree that many important crop plant characteristics result from the combined action of many genes, sometimes as many as several dozens.[52]

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[51] Shreeve, James, "Secrets of the Gene" (October 1999) 196 (4) National Geographic 42 at 55.
[52] Royal Society of Canada, *supra* note 2, at 21.

2.2.2 Other Concerns

There are, of course, other concerns expressed by people who are unhappy with the rapid introduction of GM foods into the marketplace. Many of these concerns are environmental and could ultimately have health impacts as well. Some of these concerns are summarized briefly here, although addressing them is beyond the scope of this thesis. Among the agricultural concerns are the reductions in the availability of genetic raw material due to over-reliance on particular strains, and the market effects of the monopolization of so many aspects of agriculture by a very few multinational corporations.

The development of the ultimate strain has resulted in farmers relying on one or two varieties in their crops because they are the most competitive producers. But these crops often become vulnerable to disease or blight, and when there is only one plant variety present, disease can wipe out the entire crop.[53] When such blights have occurred in the past, such as the 19th Century potato blights in Ireland, researchers returned to the wild potato species of the high Andes to find strains that were resistant to blight. But there are fears that wild species could be transformed by "genetic pollution." If the genetically modified varieties are able to crossbreed with the original native species or traditional domesticated species, much of the existing biodiversity in edible plants could be eliminated. This is particularly true if the bioengineered crops have an advantage over the native species conferred by the genetic modification

While a genetic modification to resist pests or disease is currently achieved by the introduction of one gene, many wild species have resistance to a variety of pests and diseases conferred by a host of genes acting together.[54] The temporary advantage of a genetically modified crop could allow it to displace its native forebear species, but as pests evolve

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[53] Rifkin, *supra* note 35, at 107-115.
[54] *Ibid.* at 112-113.

resistance to the new crop and the crop becomes less able to fend off the pests, the genetic raw material available for further "improvements" of the crop will have been depleted. It is ironic that genetically modified crops could result in huge losses of the very raw material on which the biotechnology industry depends.

There have also been many concerns about genetic modification expressed by environmentalists, largely stemming from the potential for lost genetic variety and concerns about the ability of wild species to compete with "escaped" genetically improved varieties. The possibility of cross-breeding is also a concern for environmentalists.[55]

Other concerns are more political. Like the growing concentration of genetic material, the biotechnological revolution is rapidly concentrating control of most of the world's food system in the hands of a small number of multinational corporations.[56] Genetically modified seeds are often designed to work only with pesticides or fertilizers produced by the same manufacturer, which will undoubtedly lead to higher prices for all of a farmer's inputs. For farmers in developing countries, it may be difficult to obtain bioengineered varieties, making it harder for them to compete with foreign producers.

2.3 Conclusion

There is a general suspicion, at least in certain segments of the population or in certain parts of the world, about new technologies. Do we really need these new technologies? When the first generation of GM foods has so clearly been derived to benefit the producers and not the consumers, while the consumers are expected to accept the foods and their safety without question, these suspicions become more deeply rooted. We begin to wonder who is driving the technology agenda. Corporations seek out larger market share and, with their

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[55] *Ibid.* at 81-91.
[56] Busch, *supra* note 35, at 25-26.

involvement in the initial research, influence the direction of technological change.[57] Large corporations produce transgenic crops that are resistant to the very herbicides that they manufacture.[58] This results in a greater market share of both seeds and pesticides, but the companies claim that such innovations are a response to the needs of farmers. Proponents argue that herbicide-tolerant crops will result in more efficient eradication of weeds, but critics are concerned that farmers will simply spray more often and closer to the time of harvest because they can do so without fear of harming the crop.[59]

Perhaps this pattern helps explain the pervasive feeling that we are not controlling technology – rather, it is controlling us. This is coupled with a feeling that technology is developing too quickly, before we can get a handle on what is happening. As a result, our culture is following the development of technologies and being changed by them without the general public having much of an opportunity to voice concerns.

It is likely that part of the reason consumers in some parts of the world have rejected GM foods, while even those in North America have displayed some skepticism, is because they see no benefits to themselves in consuming these foods. But the issue that is probably of far greater concern is food safety. Numerous food and water safety scares in Europe and, more recently, North America, have doubtless contributed to consumer skepticism about any new technology used in the production of our food. For the consumer, acceptance of GM foods depends upon assurances that they are safe. For many consumers, there is also an issue of choice, or certainty – that is, to know when they are consuming GM foods.

Although liability concerns may go some way to encouraging producers of GM foods to ensure that their products are safe, there is currently no way to trace any health effects of GM

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[57] Taylor, Daphne S. and Truman P. Phillips, "Economics and Ethics of Technological Change" in Nef, Jorge, Jokelee Vanderkop and Henry Wiseman, eds., *Ethics and Technology: Ethical Choices in the Age of Pervasive Technology* (Guelph: University of Guelph, 1989) 81.
[58] Rifkin, *supra* note 35, at 82-3.
[59] *Ibid.*

foods back to a particular food. Lack of segregation and lack of labelling are problems not just in terms of preventing consumer choice; they also make it effectively impossible to determine whether any such effects are being suffered by any consumers. Accordingly, it falls to regulators to provide the best assurances of safety that they are able to provide. Safety, as will be seen in Chapter 4, is really an exercise in the minimization of risks that are deemed acceptable for a variety of reasons.

Before turning to a discussion of the role of regulators in assessing, managing and communicating the risks of GM foods, it is necessary to consider the statutory and regulatory framework that provides regulators with their mandate. This legislative framework, which is structured around the regulatory goals of safety and certainty, is described in detail in Chapter 3.

Chapter 3 – The Regulation of Food in Canada

3.0 Introduction

Why do we regulate food? Government has undertaken the task of regulating the sale of food products to protect the public who are the consumers of the products. While the principle of *caveat emptor* may apply to the sale of many products, some products do not reveal their true characteristics to a purchaser upon examination. The nature of food, especially pre-packaged and processed goods, is such that consumers cannot possibly know the true nature of what they are buying, nor can they be sure the food they are buying is safe, unless the producers of the food provide accurate information. And as with many other products, regulation took hold because some producers would not provide accurate information unless compelled by government to do so.

Regulation of the food trade began about a century ago throughout North America, largely because consumers were finding themselves victims of unconscionable practices. The American experience with problems in the food trade has been summarized as follows:

> During the period from 1879 when the first congressional bill was introduced until 1906 when the Federal Food and Drug Act was enacted into law, Americans were becoming increasingly concerned over the safety of their food supply for several reasons, all relating to the fact that much of the food was no longer produced in the home or in the neighborhood and that incidents of adulteration had increased. Unwholesome imports were being "dumped" into the United States, and domestic food was being debased by intentional substitution of inferior substances. Damage was concealed and some food was simply filthy. Proponents of the 1906 act were also alarmed by the accumulating number of unfamiliar chemicals that were added to preserve food and improve its appearance and texture, a problem created by the necessity to store food longer and transport it further.[60]

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[60] Scheuplein, Robert J., "*De Minimis* Risk from Chemicals in Food" in Covello, Vincent T. et al., eds., *Effective Risk Communication: the Role and Responsibility of Government and Nongovernment Organizations* (New York: Plenum Press, 1987) 67 at 67-68.

These concerns have not disappeared, despite ever-tightening regulation of food:

> Whether people are getting sicker from food today than they were 50 years ago is a matter of debate. What is different are the pathogens. Advances in processing and sanitation in the developed world have diminished food borne threats such as cholera and botulism, but new hazards come with imported foods, changes in the scale of food production, and the decline in home cooking.[61]

The Government of Canada has commented on its responsibility to regulate the food trade to ensure that the food supply of Canadians is as safe and free of deception as possible. According to one document:

> Products are regulated by government in order to protect human, animal and environmental health and to protect consumers against fraud. Regulations also serve to maintain international quality and safety standards that facilitate trade.[62]

The regulation of food is in many ways similar to the regulation of any other product for sale, a form of regulation that has a long history in common law jurisdictions.[63] To fulfill its mandate to protect consumers who are unable to ascertain the information necessary to protect themselves, the state uses legislation and regulation to help ensure that a product is of reasonable quality, that there is no deception as to the nature of the product, and that the consumer is alerted to all potential hazards in the use of the product. In other words, the state requires marketers of products to fulfill their contractual responsibilities to ensure that the

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[61] Ackerman, *supra* note 33, at 13.

[62] Canadian Food Inspection Agency, Office of Biotechnology, "Regulating Agricultural Biotechnology in Canada: an Overview" (February 2001) Canadian Food Inspection Agency ("CFIA") website at www.inspection.gc.ca/english/ppc/biotech/reg/bioage.shtml.

[63] The regulation of products for sale is governed by longstanding provincial statutes modelled on the original British *Sale of Goods Act*, 1893. The various provincial statutes "by and large, follow faithfully the language of the original 1893 Act": Fridman, G.H.L., *Sale of Goods in Canada*, 4th ed. (Scarborough: Carswell, 1995) at 2. In Alberta the current version is still called the *Sale of Goods Act*, R.S.A. 2000, c. S-2.

consumer obtains what he bargains for in entering into a purchase contract, and further requires marketers to adhere to their legal duties to exercise all due care to ensure that the product is safe and of good quality.

When the product is food, these concerns are acute because any unknown hazard in the product is particularly dangerous, and because poor quality can directly impact the health of the consumer. Accordingly, the federal government endeavours to protect consumers of food products in the same way that provincial governments endeavour to protect consumers of goods. However, this is by way of a legislative and regulatory framework that relates specifically to food and recognizes that the issues are primarily related to the health of consumers. In the case of food, that consumer group is the entire population.

This thesis argues that the legislation and regulations governing food in Canada are aimed at achieving two primary goals:

1) To protect the health of consumers by ensuring the safety of the food supply; and
2) To prevent consumer deception and fraud.

These two goals will be referred to throughout this thesis as "safety" and "certainty." Both are implicitly contemplated in the *Food and Drugs Act*,[64] a federal statute, and the Food and Drug Regulations.[65] It is illegal, and punishable by criminal sanctions, to sell food that is adulterated, toxic, or otherwise manifestly unsafe. Likewise, it is illegal for manufacturers to mislead consumers, for example through labelling, packaging or advertising, as to the true character or quality of food offered for sale.

The legislation and regulations therefore include prohibitory elements. For example, certain food products or ingredients, which are determined to be unsafe, cannot be sold. But the

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[64] R.S.C. 1985, c. F-27.
[65] C.R.C. 1978, c. 870.

prohibitions are rarely complete bans, as many ingredients or even contaminants are considered safe in small enough quantities. Regulation also governs the types of representations that can or cannot be made in the effort to sell a product. Producers cannot claim that a product has specific positive health effects, unless regulators are satisfied that the claim is accurate.[66] Information provided by producers about their food products must be accurate, a requirement that helps achieve both the safety and certainty goals.

This obligation to provide accurate information is not purely negative – there are also positive obligations to advise consumers as to certain qualities of food products. These positive duties are usually met through product labels. Ingredient labelling is an example of the duties imposed on food producers to advise consumers as to those qualities of a food product that they cannot determine through their own direct examination.

Labels therefore have a role in allowing consumers to take on some responsibility for ensuring the safety and certainty of the food products they purchase. That is, the system of food regulation is not purely of prohibitions and total bans, but also compels food producers to disclose all pertinent information to allow consumer choice. Only with consumer choice does the market begin to have some role in the regulation of food, beyond the regulation exercised by government. By ensuring that consumers can satisfy themselves as to their own personal concerns about the safety and certainty of the products they choose, the provision of adequate information through labelling allows consumers to make their own choices.

However, it is not at all clear where the responsibility of government to ensure safety ends and where the consumer's own responsibility begins. Is it up to government alone to define a hazard to health, or do consumers have some responsibility to decide for themselves what

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[66] Claims made as to whether foods contain or do not contain GM ingredients must conform to recently established national standards: Canadian General Standards Board, *Voluntary Labelling and Advertising of Foods that are and are not Products of Genetic Engineering* (Gatineau, 2004).

they consider too risky?[67] The most obvious example of the shifting of responsibility for safety from government to consumers is in the case of individuals who suffer from allergic reactions to particular foods. For most consumers, such foods are perfectly safe and often desirable and nutritious. For those with allergies, they are potentially deadly. But do these consumers have the ability to make decisions as to whether certain food products are safe for them based on the information available?

With regard to the certainty of the food supply, consumer preference is even more difficult to generalize. How do we define deception? Different consumers have different ideas about the characteristics of food products that are important to them, including content, growing or processing methods, or other considerations. One could suggest that deception is any failure to identify food items, ingredients or processing methods as being different in a significant way from what the consumer reasonably expects. But what is significant, and what is a reasonable expectation? One of the arguments made by proponents against mandatory labelling is that regulation is based on the product itself – that is, content – and not on process issues. However, this chapter shows that many aspects of food production are regulated, and that labelling in particular is applied to a variety of food attributes, including process considerations.

These questions become more complicated when applied to GM and other novel foods. If a GM product could possibly be a health hazard for a person who may be allergic to it, but not for others, how should it be regulated? If a person wishes to avoid genetically modified foods but they are not labelled as such, does this constitute deception? And if it is a legitimate goal of food regulation to ensure that consumers can make informed choices,

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[67] Health Canada has recognized this shifting responsibility, noting that adverse food reactions and nutritional concerns have increased the need for consumer protection information. "Consumers have been asked to take more responsibility for their own protection, and, to achieve this, adequate consumer information must be made available": Health Protection Branch, *A Strategic Direction for Change: A Review of the Regulations Under the Food and Drugs Act* (Ottawa: Health Canada, 1993) at 18.

should reasonable limits be set on disclosure requirements and, if so, what should those limits be?

These questions will be elaborated upon in subsequent chapters. This chapter will review the legislative framework for regulating the sale of food in Canada and, in particular, how the regulatory system has addressed the arrival in the marketplace of GM foods. The focus will be on the relevant legislative and regulatory provisions that are aimed at the two policy goals of safety and certainty, and how they relate to the issue of labelling GM foods. [68]

3.1 Regulation of Food: The Legislative Framework

At the constitutional level, there are arguments for the involvement of both the provincial and federal levels of government in the regulation of food. The dual goals of safety and certainty could fall under more than one head of power under sections 91 and 92 of the *Constitution Act, 1867*. However, the federal government has almost entirely taken over the regulation of food. Both of the goals, safety and certainty, have been recognized in the case law as the pith and substance of key provisions of the *Food and Drugs Act*, bringing it within the legislative competence of the federal government through its constitutional power to legislate with respect to criminal law.[69]

However, it is unclear how broad the jurisdiction of the federal government actually is with respect to food labelling. Whether certain labelling requirements are *intra vires* the federal

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[68] The *Food and Drugs Act* and its Regulations form a highly detailed legislative and regulatory framework, which is further refined in practice by guidelines, policies and other regulatory documents. In order to make some sense of the Act and Regulations, and given that there are few secondary sources with respect to this regulatory framework, and very little case law, I have used the "safety" and "certainty" framework in an effort to distill those elements of the *Act* and the Regulations that are pertinent to these regulatory goals that I have identified. Ultimately, this framework will tie into the theoretical analysis in Chapters 5 and 6 of the thesis.

[69] Most recently in *R. v. Wetmore*, [1983] 2 S.C.R. 284, in which the prohibitions contained in the Act against insanitary storage and deceptive labelling of drugs were upheld as a valid exercise of the criminal law power.

government is questionable;[70] however, a long history of cooperative federalism in this area makes it unlikely that a labelling initiative involving GM foods would be challenged.[71]

At the legislative level, the system strives to achieve its two policy goals through the *Food and Drugs Act* and its Regulations. The principal tools in the legislative scheme are prohibitions on specified practices, which are moderated by tolerances,[72] compositional standards and labelling requirements, and backed up by enforcement mechanisms that include monitoring, inspections and criminal sanctions. Each of these aspects of the regulatory framework will be examined in this section. The following sections provide an overview of the way the *Food and Drugs Act* and its Regulations operate, with a specific discussion of those sections that are relevant to the two policy goals and to the labelling of GM foods. Reference will also be made to another federal statute that imposes food labelling requirements, the *Consumer Packaging and Labelling Act*.[73]

Section 3.1.1 provides a brief overview of the way the *Food and Drugs Act* enforces the prohibitions that aim to achieve the goals of safety and certainty. Subsection (a) then describes the sections of the *Act* that deal with food safety, together with an example of how the Regulations give effect to those sections. Subsection (b) fulfills the same function with respect to the way the *Food and Drugs Act* and related legislation aim to achieve certainty in the food supply.

Section 3.1.2 provides a more detailed discussion of certain aspects of the Food and Drug Regulations and how they help to achieve safety and certainty. The section begins with a review of the enabling provisions in the *Food and Drugs Act*, which determine the scope of regulations that can be enacted by the federal cabinet. Subsection (a) then describes the

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[70] See discussion re: unconstitutionality of standards promulgated under the Regulations, *infra*, at footnote 82.
[71] Monahan, Patrick, *Politics and the Constitution: The Charter, Federalism and the Supreme Court of Canada* (Toronto: Carswell, 1987) at 228-234.
[72] Tolerances are the allowable limits of objectionable substances in food products, and are discussed in detail *infra*, at section 3.1.2(a).
[73] R.S.C. 1985, c. C-38.

regulatory provisions that prescribe tolerances, which are aimed primarily at the safety goal. Subsection (b) reviews regulatory standards that are set for particular processed foods, and that are primarily geared to the certainty goal. Subsection (c) then looks at the labelling requirements in the Regulations, which address both the safety and certainty goals.

Despite this detailed legislative framework, cabinet has introduced new regulatory provisions that apply specifically to genetically modified and other "novel" foods. Section 3.2 looks at this "Novel Foods Regulation". The concluding section of the chapter, Section 3.3, summarizes the legislative and regulatory framework set up to achieve the goals of safety and certainty and considers the application of the Novel Foods Regulation to the regulatory goals.

3.1.1 The Food and Drugs Act

As described above, the goals of safety and certainty are clearly reflected in the *Food and Drugs Act* (the "Act"), one of the oldest statutes in Canada. Most of the wording of the current Act dates back to a major revision undertaken in 1953.[74] Key terms[75] are defined in section 2 of the Act; these definitions also apply in the much more detailed Food and Drug Regulations. The Act itself is brief, confined mostly to setting out the prohibitions that aim to achieve the two goals of safety and certainty.

To be effective, these prohibitions must be accompanied by a system for inspecting and monitoring food products. Section 22 of the Act permits inspections and seizures at any reasonable time, and provides for the issuance of warrants and the use of force in limited circumstances. Seized items can be submitted to any analyst designated as such by the

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[74] S.C. 1952-53, c. 38.

[75] "Food" is defined to include "any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever". "Label" includes "any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package". "Package" includes "any thing in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed". "Sell" includes "offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration."

Minister. Further, as an exercise of the federal government's constitutional power to legislate in the field of criminal law, the Act provides sanctions for any breach of its prohibitions. Pursuant to section 31.1:

> 31.1 Every person who contravenes any provision of this Act or the regulations, as it relates to food, is guilty of an offence and liable
>
> (a) on summary conviction, to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months or to both; or
> (b) on conviction by indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding three years or to both.

The Act provides a sort of due diligence defence in section 34. Where a person simply re-sells, without altering, a food item packaged by another party, and could not with reasonable diligence have known or determined that the sale of the item would contravene the Act, that person must be acquitted.

(a) Safety

Section 4 of the Act prohibits the sale of food that is manifestly unsafe:

> 4. No person shall sell an article of food that
> (a) has in or on it any poisonous or harmful substance;
> (b) is unfit for human consumption;
> (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
> (d) is adulterated; or
> (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.[76]

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[76] According to the definitions in the Act:

> 2. In this Act
> ...
> "unsanitary conditions" means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic.

"Poisonous", "harmful" and "unfit for human consumption" are not specifically defined in the Act, but "adulterated" is dealt with in various sections of the Regulations (as discussed in the next paragraph).

Despite the strong language of section 4, the prohibitions are not absolute. It is not strictly true to say that a person cannot sell an item of food containing *any* poisonous or harmful substance – this would be all but impossible to guarantee. For example, there are substances such as arsenic that are poisonous by any reasonable definition; yet arsenic occurs naturally in certain foods, at levels that are not harmful, and is therefore considered safe at those levels.[77] Therefore tolerances for many specific substances are set out in the Regulations, but a food that contains the substance in a concentration exceeding the tolerance is considered adulterated and in breach of section 4(d) of the Act.

One example of the way tolerances are structured is found in the sections of the Regulations dealing with pesticides:

> **B.15.001.** A food named in Column III of an item of Table I to this Division is adulterated if the substance named in Column I of that item is present therein or has been added thereto in an amount exceeding the amount, expressed in parts per million, shown in Column II of that item for that food.
> **B.15.002.** (1) Subject to subsections (2) and (3), a food is adulterated if an agricultural chemical or any of its derivatives is present therein or has been added thereto, singly or in any combination, in an amount exceeding 0.1 part per million, unless it is listed and used in accordance with the tables to Division 16.[78]

Section 4 is the only section of the Act that imposes mandatory obligations directly related to safety, but various provisions of the Regulations also aid in achieving the safety goal. Tolerances are the most obvious of these provisions, but some of the standards for food production and processing are also set for safety purposes.[79] Further, there are several examples of labelling requirements that help to fulfill both the safety and certainty goals.[80]

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[77] McHughen, *supra* note 5, at 90-92.
[78] Further discussion of tolerances follows *infra* at section 3.1.2(a).
[79] Standards are discussed in section 3.1.2(b).
[80] Labelling is discussed in section 3.1.2(c).

(b) Certainty

The *Food and Drugs Act* uses food standards as one tool to promote the goal of certainty.[81] Section 6(3) of the Act states:

> 6. ...
> (3) Where a standard for a food has been prescribed, no person shall label, package, sell or advertise any article that
>
> (a) has been imported into Canada,
> (b) has been sent or conveyed from one province to another, or
> (c) is intended to be sent or conveyed from one province to another
>
> in such a manner that it is likely to be mistaken for that food unless the article complies with the prescribed standard.

Likewise, section 6(1) prohibits any person from importing into Canada or conveying from one province to another any food item intended for sale that does not comply with any standard prescribed for that particular food item. Section 6.1 contains a further prohibition:

> 6.1 (1) The Governor in Council may, by regulation, identify a standard prescribed for a food, or any portion of the standard, as being necessary to prevent injury to the health of the consumer or purchaser of the food.
>
> (2) Where a standard or any portion of a standard prescribed for a food is identified by the Governor in Council pursuant to subsection (1), no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that food unless the article complies with the standard or portion of a standard so identified. [82]

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[81] The term "standard" is not defined in the Act, but the Regulations prescribe numerous standards for foods which are described by a particular name. See discussion *infra*, section 3.1.2(b).

[82] The structure of these sections reflects the striking down of a predecessor section 6 under which the federal government purported to prescribe a standard for light beer. The Supreme Court of Canada found that the standard was not a valid exercise of the criminal law power, as it was not necessary for health, nor did it fall within the trade and commerce head as it had the effect of regulating the production process of a single industry. Nor was it a matter of national concern or an emergency so as to bring it within the residual power: *Labatt Brewing Co. v. Canada*, [1980] 1 S.C.R. 914. It has been argued that the decision was wrong because it failed to acknowledge that the prescription of the standard could be intended to prevent consumer deception, which

The protection of consumers from deception is further achieved through labelling requirements. Labelling food in a manner contrary to that prescribed by the Regulations,[83] or in a deceptive manner, is prohibited by section 5 of the Act:

> 5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.
>
> (2) An article of food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Further labelling requirements are contained in the *Consumer Packaging and Labelling Act*,[84] which is administered by Industry Canada. This statute is focused on the certainty goal, as section 7 demonstrates:

> 7. (1) No dealer shall apply to any prepackaged product or sell, import into Canada or advertise any prepackaged product[85] that has applied to it a label containing any false or misleading representation that relates to or may reasonably be regarded as relating to that product.
>
> (2) For the purposes of this section, "false or misleading representation" includes
>
> (a) any representation in which expressions, words, figures, depictions or symbols are used, arranged or shown in a manner that may reasonably be regarded as qualifying the declared net quantity of a prepackaged product

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would make it a valid exercise of the criminal law power: Hogg, Peter, *Constitutional Law in Canada*, 4th ed. (Toronto: Carswell, 1997-) at 18-7 – 18-9.

[83] The details of the labelling requirements in the Regulations are discussed *infra*, in section 3.1.2(c).

[84] *Supra* note 73. There are also labelling requirements in the regulations made pursuant to the *Canada Agricultural Products Act*, S.C. 1988, c. 27, which set standards and labelling requirements for imported food products and food products destined for export or interprovincial trade.

[85] "Prepackaged product" is defined in the *Consumer Packaging and Labelling Act* as "any product that is packaged in a container in such a manner that it is ordinarily sold to or used or purchased by a consumer without being re-packaged." This definition is slightly (but not significantly) different from the definition in the Regulations, set out *infra* at section 3.1.2(c).

> or as likely to deceive a consumer with respect to the net quantity of a prepackaged product;
> (b) any expression, word, figure, depiction or symbol that implies or may reasonably be regarded as implying that a prepackaged product contains any matter not contained in it or does not contain any matter in fact contained in it; and
> (c) any description or illustration of the type, quality, performance, function, origin or method of manufacture or production of a prepackaged product that may reasonably be regarded as likely to deceive a consumer with respect to the matter so described or illustrated.
>
> [emphasis added]

Section 10 of the *Consumer Packaging and Labelling Act* and its regulations contain further requirements with respect to labelling, particularly with respect to labels that contain a declaration of net quantity. There is very little case law involving these sections, nor are there any definitions in the statute of the key terms of section 7(b), and what a "matter" might be that is or is not contained in it. However, the statute would only apply to labelling of GM foods if there were a misrepresentation on the label. In other words, if a package declares that the product is GM-free, but it is not, charges could be laid against the packager.

3.1.2 The Food and Drug Regulations

The Regulations, which are voluminous, contain the details of the legislative framework. The enabling provisions contained in section 30 of the Act allow the federal cabinet to bring in regulations for a wide variety of purposes, including regulations:

> 30. ...
> (a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein ...
> (b) respecting
> (i) the labelling and packaging and the offering, exposing and advertising for sale of food ...
> to prevent the purchaser or consumer thereof from being deceived or misled in respect of the ... character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;

> (c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food ...
> ...
> (e) respecting the method of manufacture, preparation, preserving, packing, storing and testing of any food ... in the interest of, or for the prevention of injury to, the health of the purchaser or consumer;
> ... [emphasis added]

The Regulations are divided into several Parts and Divisions. Part A contains definitions that apply to all provisions in the Regulations, and deals with administrative issues such as inspections and importations, while Part B governs foods. Part B contains 28 Divisions, most of which set out tolerances or standards. Division 1 is entitled "General" and contains further definitions and some prohibitions.[86]

As discussed above, the safety goals of the regulatory framework, achieved mostly by way of the prohibitions in the Act, are enhanced through the setting of tolerances, discussed below in section 3.1.2(a). The certainty goal is achieved in part through the setting of standards, reviewed below in subsection (b). Labelling, another important part of the effort to achieve certainty, is also a vehicle for achieving the safety goal by providing consumers with information they need to protect their own health, and is discussed in subsection (c).

(a) Tolerances

The legislation strives to assure the safety of the food supply by requiring food to be as pure as possible. However, for almost any substance that could be found in food, there is a tolerance level:

> No food, even pure water, is "pure" in the scientific sense. All foods carry additional substances, either naturally or as contaminants. In practice, when you buy a food item described as "pure", it means the contaminants are

[86]An example of the numbering scheme is as follows: Section 44 of Division 1 of Part B is numbered within the Regulations as section B.01.044. References to a particular division of the Regulations, throughout the thesis, are references to Divisions of Part B of the Regulations

> present within a certain limit of tolerance, and the presence of the contaminants will not cause harm to most consumers. [87]

In practice, it may be impossible to remove all of the undesirable substances from any food. Many of these substances are naturally occurring. In harvested grain, for example, there may be an allowable number of insects in a bushel of corn. There may be the odd mouldy strawberry in a basket. In other words, it is impossible to guarantee an absolutely pristine food supply. Tolerances have been set to ensure that undesirable substances are not present in food in sufficient quantity to pose a health threat.[88]

There are also a number of substances present in food that are considered inevitable by-products of the growing and processing of food. These include additives such as preservatives, pesticides and other chemicals. These are not naturally occurring undesirable substances, but rather have been intentionally added to food at some stage of production for a growing or manufacturing purpose.

Division 1 of the Regulations defines additives as follows:

> **B.01.001.** In this Part,
>
> ...
> "food additive" means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include:
> (a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;
> (b) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16,
> (c) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;
> (d) agricultural chemicals, other than those listed in the tables to Division 16;

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[87] McHughen, *supra* note 5, at 89.
[88] Arguably, tolerances also help achieve the certainty goal, in that they help prevent the deception of consumers as to the quality and purity of the product they are purchasing.

(e) food packaging materials and components thereof; and
(f) drugs recommended for administration to animals that may be consumed as food;

A general prohibition against exceeding the tolerances set for additives is also found in Division 1 of the Regulations:

B.01.043. Subject to section B.25.062,[89] where a standard for a food is not prescribed in this Part,
(a) the food shall not contain any food additives except food additives set out in a table to section B.16.100 for use as additives to that food for the purpose set out in that table; and
(b) each such food additive shall be incorporated in the food in a quantity within any limits prescribed for that food and food additive in that table.

B.01.044. Where the limit prescribed for a food additive in a table to section B.16.100 is stated to be "Good Manufacturing Practice", the amount of the food additive added to a food in manufacturing and processing shall not exceed the amount required to accomplish the purpose for which that additive is permitted to be added to that food.

The Regulations set tolerances for food additives in Division 16. The tolerances for agricultural chemicals, such as pesticides, are found in Division 15.[90] Allowable levels of such artificially added substances, that would or could be harmful if ingested in large quantities, have been set to ensure safety while recognizing their usefulness in sustaining high crop yields and preserving food for transportation and time on retail shelves. In other words, there are limits on the amount of pesticide residues that can remain on produce after harvesting, in order to ensure that consumers are not exposed to higher total concentrations of these chemicals than they can safely tolerate.

There are also certain additives that are banned altogether from use, presumably because they are considered so dangerous that no safe exposure level can be set. Sections B.16.007 and

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[89] This section sets out a different standard for foods intended for infants.
[90] The approach is similar to that for additives.

B.16.100, dealing with additives, state that any substance not listed in the accompanying table cannot be added to food. If such a substance is added, or if a substance is added in a concentration higher than the tolerance set out in the tables, the food is adulterated.

In some cases, the Regulations go beyond merely setting limits on the types of additives that are allowed in food, by prescribing standards for certain processed foods. These standards often appear to be an effort to ensure certainty for consumers, but are also, in many cases, imposed for reasons of the health and safety of consumers.

(b) Standards

Division 1 of the Regulations sets out the general provisions regarding standards:

> **B.01.002.** Each provision in this Part in which the symbol **[S]** appears between the provision number and the name of the food described in that provision prescribes the standard of composition, strength, potency, purity, quality or other property of that food and a provision in which the symbol does not appear does not prescribe a standard for a food.
> ...
>
> **B.01.042.** Where a standard for a food is prescribed in this Part,
> (a) the food shall contain only the ingredients included in the standard for the food;
> (b) each ingredient shall be incorporated in the food in a quantity within any limits prescribed for that ingredient; and
> (c) if the standard includes an ingredient to be used as a food additive for a specified purpose, that ingredient shall be a food additive set out in one of the tables to section B.16.100 for use as an additive to that food for that purpose.

The use of standards primarily addresses the certainty goal in ensuring that people obtain the product they believe that they are purchasing.[91] As an example of the application of standards to the certainty goal, Division 2 of the Regulations sets the standard for beer:

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[91] As discussed above, they may also provide some assurances as to the safety of processed foods.

B.02.130. [S]. Beer
(*a*) shall be the product of the alcoholic fermentation by yeast of an infusion of barley or wheat malt and hops or hop extract in potable water and shall be brewed in such a manner as to possess the aroma, taste and character commonly attributed to beer; and
(*b*) may have added to it during the course of manufacture any of the following ingredients:
(i) cereal grain,
...

Thus consumers expect that beer has been prepared in a certain way. The regulations prevent a manufacturer from producing a beer-like beverage and calling it beer if it is not in fact prepared with barley or wheat and hops. These standards do not deal simply with the contents of food products – they also address issues as to process. Certainly the standard for beer sets requirements not only for the ingredients[92] that must or may be included, but also for how it must be prepared. [93]

Even more specific are the requirements for dairy products such as cream cheese:

B.08.035. (1) **[S]. Cream Cheese**
(*a*) shall
(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and
(ii) contain
(A) not more than 55 per cent moisture, and
(B) not less than 30 per cent milk fat; and
(*b*) may contain
(i) cream added to adjust the milk fat content

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[92] Note that the ingredients themselves are defined and often must conform to the section of the Regulations dealing with common names; see discussion *infra*, in section 3.1.2(c).
[93] Note that section B.01.042 (set out on the previous page) only prohibits a failure to comply with ingredient standards, not process standards. Query whether the process standards are enforceable as the Regulations currently stand. Arguably process standards that relate to health, as in the standard for heat processing canned tomatoes, discussed in the next paragraph, are still constitutional despite the *Labatt* case, but there appears to be no prohibition from failing to meet them.

...

The use of standards applies not only to processed products like beer and cream cheese, but also to processed whole fruits and vegetables:

> **B.11.005. [S]. Tomatoes or Canned Tomatoes**
> (*a*) shall be the product made by heat processing properly prepared fresh ripe tomatoes;
> (*b*) may contain
> (i) a sweetening ingredient in dry form,
> (ii) salt,
> (iii) a firming agent,
> (iv) citric acid, and
> (v) spice or other seasoning; and
> (*c*) shall contain not less than 50 per cent drained tomato solids, as determined by official method FO-18, Determination of Drained Tomato Solids, October 15, 1981.[94]
>
> [emphasis added]

Again, the method of processing is specified in the standard along with the ingredients that may be included. As to the ingredients, these must, of course, not only comply with the standard, but must also be listed on the label of the product.

Labelling, then, works hand in hand with tolerances and standards to ensure that both the goals of safety and certainty can be met by giving the consumer the final opportunity to decide whether the product she is purchasing is safe for her and is the product that she wishes to purchase.

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[94] The standards set out in the Regulations often specify a method to be used to determine if a product is in compliance with the standard.

(c) Labelling

Division 1 of the Regulations mandates the labelling of manufactured food products, and the content of the required labels:

> **B.01.001**
> ...
> "prepackaged product" means any food that is contained in a package in the manner in which it is ordinarily sold to or used or purchased by a person.
>
> **B.01.003.** (1) The following foods shall carry a label when offered for sale:
> (a) all prepackaged products other than
> (i) prepackaged confections, commonly known as one bite confections, that are sold individually, and
> (ii) prepackaged products consisting of fresh fruits or fresh vegetables that are packaged in a wrapper or confining band of less than 1/2 inch in width;
> (b) meat and meat by-products that are barbecued, roasted or broiled on the retail premises;
> (c) poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises;
> (d) horse-meat or horse-meat by-product;
> (e) any substance or mixture of substances for use as a food additive or food additive preparation; and
> (f) flour and whole wheat flour that has been treated with gamma radiation from Cobalt 60 Source.
>
> **B.01.008.** (1) The following information shall be shown grouped together on any part of the label:
> (a) any information required by these Regulations, other than the information required to appear on the principal display panel[95] and the information required by section B.01.007 and B.01.310;[96] and

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[95] Generally "in the case of a label applied to a prepackaged product that is not subject to the *Consumer Packaging and Labelling Act*, that part of the label applied to all or part of the side or surface of the container that is displayed or visible under normal or customary conditions of sale or use, and where the container does not have such a side or surface, that part of the label applied to any part of the container, except the bottom, if any..."

[96] Sections B.01.007 requires the packaging date and section B.01.310 requires certain nutritional information to be added to the label. Nutrition labelling is "designed to provide useful information that is not misleading or deceptive": Canadian Food Inspection Agency, Bureau of Food Safety and Consumer Protection, Fair Labelling Practices Program, *2003 Guides to Food Labelling and Advertising*, Draft Document (2003) at V-1. Nutrition labelling must comply with the requirements of section B.01.401 and the succeeding sections of the

> (b) where a prepackaged product consists of more than one ingredient, a list of all ingredients, including, subject to section B.01.009, components, if any.
> ...[97]
> (3) Ingredients shall be shown in descending order of their proportion of the prepackaged product or as a percentage of the prepackaged product and the order or percentage shall be the order or percentage of the ingredients before they are combined to form the prepackaged product.
>
> [emphasis added]

Ingredient is defined in Division 1 of the Regulations as "an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an integral unit of food that is sold as a prepackaged product." The name by which an ingredient is listed on the label is also addressed:

> **B.01.010.** (1) In this section, "common name" includes a name set out in Column II of the tables to subsection (3).
> (2) An ingredient or component shall be shown in the list of ingredients by its common name.
> (3) For the purposes of subsection (2),
> (*a*) the ingredient or component set out in Column I of an item of the following table shall be shown in the list of ingredients by the common name set out in Column II of that item:
> ... [table] [emphasis added]

The table of ingredients or components identifies the corresponding common names that must be used on the label. The requirement to use common names is another effort to promote both safety and certainty – it is clearly intended to ensure that consumers know what they are buying and are not duped into believing that an ingredient listed on the label of the

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Regulations. There are also prohibitions on making certain health claims with respect to labelling or advertising of products unless the product meets certain standards set in the Regulations with respect to those claims. For example, a product may only be described as "fat-free" if it complies with certain reference amounts of fat contained in particular serving sizes. These new regulations do not apply directly to GM foods, and accordingly a comprehensive review of them is beyond the scope of this thesis.

[97] Subsection 2 lists several exceptions to the requirement for ingredient lists, such as foods packaged at retail premises, individual portions prepared by restaurants, etc.

product purchased is not, in fact, something other than what they expect. For consumers with allergies or sensitivities, getting the product they expect is also a vital issue of safety.

Although most of the labelling requirements centre on the composition of particular food products and their ingredients, there are also process considerations. Section 30(e) of the Act specifically permits the Cabinet to make regulations respecting the method of manufacture of food in the interest of the health of the consumer.[98] One process problem, again relating to allergies, is the possibility of cross-contamination in the manufacturing process. There is no specific requirement to label products that may contain common allergens such as nuts – any allergen that is an intended ingredient of a product ought to be identified in the ingredient list on the label.[99] Where a product may contain common allergens through possible cross-contamination, those allergens do not have to be listed among the ingredients. Government agencies are currently working with manufacturers to address the issue, and are proposing additions to the Regulations. [100]

It is interesting to note that animal fats which have been modified chemically, for example by the removal of a fatty acid group, must be described in the ingredient list as "modified" and must include the name of the meat from which they are derived. If a fat is hydrogenated, it must be specifically named as hydrogenated with the specific name of the fat. However, the requirements as to disclosure of the source of some ingredients are quite different. For example, vegetable oils may be described simply as vegetable oils, without the identification of the specific vegetable used. Added protein need only be identified as "plant" or "animal." Under proposed changes, the source of the protein would have to be identified more specifically, by the type of plant or animal, because of the possibility of ill effects for people

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[98] Quoted *supra,* at section 3.1.2.
[99] Health Canada "Paper on the Allergen Control Activities within the Canadian Food Inspection Agency" (April 2003) Health Canada website at www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_faq_1.html.
[100] Canadian Food Inspection Agency, Office of Biotechnology, "Proposed Labelling of Foods Causing Severe Adverse Reactions in Canadians" (March 2002) CFIA website at www.inspection.gc.ca/english/bureau/inform/pro19e.shtml.

who suffer from allergies or other sensitivities such as celiac disease. This would also apply to the source of vegetable oils. [101]

Another example of the labelling of food products by the process applied to them, and not just their content, is food irradiation. Division 26 of the Regulations sets out definition and a prohibition, subject to tolerances:

> **B.26.001.** In this Division,
> "ionizing radiation" means
> (a) gamma-radiation from a Cobalt-60 or Cesium-137 source,
> (b) X-rays generated from a machine source operated at or below an energy level of 5 MeV, and
> (c) electrons generated from a machine source operated at or below an energy level of 10 MeV;
> "irradiation" means treatment with ionizing radiation.
>
> ...
>
> **B.26.003.** (1) Subject to subsection (2), no person shall sell a food that has been irradiated.
> (2) A food set out in Column I of an item of the table to this Division that has been irradiated may be sold if
> (*a*) the food was irradiated from a source set out in Column II of that item for the purpose set out in Column III of that item; and
> (*b*) the dose of ionizing radiation absorbed by the food is within the permitted absorbed dose set out in Column IV of that item.[102]

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[101] *Ibid.*

[102] There are also extensive requirements regarding record-keeping:

> **B.26.004.** (1) A manufacturer who sells a food that has been irradiated shall keep on his premises, for at least two years after the date of the irradiation, a record containing the following information:
> (*a*) the food irradiated and the quantity and lot numbers of the food;
> (*b*) the purpose of the irradiation;
> (*c*) the date of the irradiation;
> (*d*) the dose of ionizing radiation absorbed by the food;
> (*e*) the source of the ionizing radiation; and
> (*f*) a statement indicating whether the food was irradiated prior to the irradiation by the manufacturer and, if so, the information referred to in paragraphs (*a*) to (*e*) in respect of that prior irradiation.

Division 1 of the Regulations contains the labelling requirements specific to irradiated foods, along with the more general labelling requirements, and a further prohibition:

> **B.01.035.** (1) Subject to subsection (8), where an irradiated food referred to in Column I of the table to Division 26 is offered for sale as a prepackaged product, the principal display panel of the label applied to the package shall carry the symbol described in subsection (5).
> (2) Where an irradiated food referred to in Column I of the table to Division 26 is not a prepackaged product and is offered for sale, a sign that carries the symbol described in subsection (5) shall be displayed immediately next to the food.
> (3) The symbol required pursuant to subsection (1) or (2) shall appear in close proximity on the principal display panel referred to in subsection (1) or on the sign referred to in subsection (2) to one of the following statements or a written statement that has the same meaning:
> (*a*) "treated with radiation";
> (*b*) "treated by irradiation"; or
> (*c*) "irradiated".
> (4) No person shall sell a food referred to in Column I of the table to Division 26 that has been irradiated in the manner set out in subsection B.26.003(2) unless the requirements of subsections (1) to (3) are met.
>
> [emphasis added]

At the time that labelling requirements for irradiated food were introduced in 1989, there was considerable public concern about irradiation. Previously, irradiation was considered a food additive and irradiated foods were regulated in the same way as all additives, without any specific labelling requirements. According to the Regulatory Impact Analysis Statement ("RIAS") issued when Division 26 and the corresponding labelling provisions were added to the Regulations, the change was made in order to:

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(2) Every person who imports a food that is intended for sale in Canada that has been irradiated shall keep on his premises a record of the information referred to in subsection (1) for at least two years after the date of importation.

> ... recognize irradiation as a food process. This legal consideration of food irradiation as a "process" is designed to enhance control over it by developing more meaningful and specific regulations pertaining to it. [103]

The RIAS further states that the process has utility in reducing microbiological contaminants, but that the pre-existing system that did not require labelling was "inadequate in terms of consumer protection and harmonization with international standards."[104] The RIAS notes that the public response to consultation had been to suggest better regulation of irradiated products.[105]

The statement that consumer protection required labelling of irradiated products might suggest that regulators were concerned about possible health effects from the consumption of irradiated foods. However, the RIAS says:

> A fact that seems to be overlooked is that food irradiation has been legal in Canada for over 20 years, being regulated as a food additive. These amendments are designed to improve regulatory control by regulating food irradiation as a process. There has been no scientific evidence presented to show that the currently permitted uses of this process are unsafe.
> ...
>
> ... The new requirement for record-keeping also provides an additional safeguard for the consumer as a mechanism to ensure proper process control.
>
> ... The labelling requirements as developed by this Department will ensure that consumers will know when a food has been irradiated. Health and Welfare Canada has always supported the need for appropriate labelling of irradiated foods so that they can be recognized in the marketplace.[106]

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[103] Food and Drug Regulations, amendment, SOR/89-175 (March 1989), Canada Gazette Part II, Vol. 123, No. 8, p. 1977 at 1980.
[104] *Ibid.*
[105] *Ibid.* at 1982.
[106] *Ibid.* at 1984-1985.

Hence there is a precedent for the conclusion that, even where there is "no scientific evidence" confirming that a process is unsafe, public concern is a factor in influencing regulators to provide closer regulation of a particular food process, including appropriate labelling so that consumers are aware that the products they purchase have been produced by that food process.

The foregoing discussion demonstrates that the labelling requirements contained in the Regulations are designed primarily to meet the certainty goal of food regulation – in other words, they help to prevent consumer deception as to the nature of food products, their ingredients and even the processing methods used to produce them. However, they are also a useful tool in meeting the safety goal, in communicating health issues such as nutritional and additive content and in alerting consumers to ingredients such as allergens that may be dangerous to them.

3.2 Regulation of GM Food

The Federal Government has thus used the legislative and regulatory framework of the Act and Regulations to attempt to achieve safety and certainty in the food system. Chapter 4 will consider how these regulatory goals can be and are achieved in practice, with respect to genetically modified foods.

Interestingly, the regulations have added a new procedure specifically for "novel foods", which requires proponents to provide pre-market notification and detailed information on any novel food the proponent wishes to sell in Canada. There are no general provisions in the Act requiring foods that are new to the Canadian marketplace to be subjected to any kind of testing or approval process before they are put out for sale. However, the Novel Foods Regulation was added as the new Division 28 to the Regulations in 1999,[107] following an

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[107] Food and Drug Regulations, amendment, SOR/99-392 (October 1999), Canada Gazette Part II, Schedule No. 948.

extensive review of the regulation of biotechnology in Canada by the parliamentary Standing Committee on Environment and Sustainable Development. The Committee's 1996 report[108] describes a consultative process by which the Committee considered several different suggestions for the method of regulating the products of biotechnology, including those destined for the food chain. One of the suggestions was that all products of biotechnology should be regulated according to an overarching environmental review process under the *Canadian Environmental Protection Act.*[109] At that time, the Novel Foods Regulation was being developed by Health Canada, and ultimately CEPA became more of a safety net in the regulation of products of biotechnology, catching those products that did not fall under another statute such as the *Food and Drugs Act.*

The Novel Foods Regulation mandates a procedure for approval to market new foods, including GM foods that are found to have undergone a "major change."

> **B.28.001.** The definitions in this section apply in this Division.
>
> "genetically modify" means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.[110]
>
> "major change" means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to
>
> (a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;
> (b) the manner in which the food is metabolized in the body; or
> (c) the microbiological safety, the chemical safety or the safe use of the food.
>
> "novel food" means

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[108] Standing Committee on Environment and Sustainable Development, *Biotechnology Regulation in Canada: a Matter of Public Confidence* (November 1996) Second Session of the Thirty-fifth Parliament.
[109] S.C. 1999, c.33.
[110] Note that this definition could be applied to traditional plant breeding.

(a) a substance, including a microorganism, that does not have a history of safe use as a food;
(b) a food that has been manufactured, prepared, preserved or packaged by a process that
  (i) has not been previously applied to that food, and
  (ii) causes the food to undergo a major change; and
(c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
  (i) the plant, animal or microorganism exhibits characteristics[111] that were not previously observed in that plant, animal or microorganism,
  (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
  (iii)one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

B.28.002. (1) No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food

(a) has notified the Director in writing of their intention to sell or advertise for sale the novel food; and
(b) has received a written notice from the Director under paragraph B.28.003(1)(a) or subsection B.28.003(2).

(2) A notification referred to in paragraph (1)(a) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:

(a) the common name under which the novel food will be sold;
(b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
(c) a description of the novel food, together with
  (i) information respecting its development,
  (ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
  (iii) details of the major change, if any,
  (iv)information respecting its intended use and directions for its preparation,

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[111] This term is not defined in the *Act* or in the Regulations.

(v) information respecting its history of use as a food in a country other that Canada, if applicable, and
(vi) the information relied on to establish that the novel food is safe for consumption;
(d) information respecting the estimated levels of consumption by consumers of the novel food;
(e) the text of all labels to be used in connection with the novel food; and
(f) the name and title of the person who signed the notification and the date of signing.

B.28.003. (1) Within 45 days after receiving a notification referred to in paragraph B.28.002 (1)(a), the Director shall review the information included in the notification and

(a) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or
(b) of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.

(2) Within 90 days after receiving the additional information requested under paragraph (1)(b) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

[emphasis added]

No case law has considered the Novel Foods Regulation. Some of the terms can be interpreted by reference to the definitions found at section 2 of the Act and at section A.01.010 of the Regulations. The Director, for example, is the Assistant Deputy Minister, Health Protection Branch, of the Department of Health. Under the Regulations, "manufacturer" or "distributor" means "a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug."

The details of the information required by Section B.28.002(2), which must be provided along with the notification, are somewhat expanded in a document developed by Health

Canada in 1994, the *Guidelines for the Safety Assessment of Novel Foods*[112] (the "Guidelines"). However, even the Guidelines do not provide mandatory requirements for specific information. Rather, they detail the type of information that may be required, depending on the novel food in question, and encourage proponents to work with Health Canada to determine the types of information that must be provided.

It is interesting that Division 28 contains these requirements with respect to the scientific information that must be provided to Health Canada before a novel food can be marketed.[113] None of the other divisions mandate the provision of this type of information. Yet there is no requirement to track novel foods that have gone out for sale, unlike the requirements placed on irradiated foods. There is also no labelling requirement, which is again different from the system for irradiated foods. This begs the question why different regulatory schemes have been enacted for different types of food, or for foods developed or treated by different processes.

In an article about the regulation of genetically modified crops and foods, Stan Benda takes the position that regulation of foods should be based on individual products and their physical characteristics, not on process characteristics.[114] In discussing the regulation of GM foods in Canada versus other regimes, including those of the United States and the European Union, Benda states that Canada does the best job of defining novel foods according to their individual product characteristics, on a product-by-product basis, rather than distinguishing GM foods for their process characteristics. For example, he notes that the Novel Foods Regulation defines novel foods in a way that is broad enough to capture new products of organic or conventional breeding.[115]

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[112] *Supra* note 35. The Guidelines are considered in more detail in Chapter 4.
[113] Notably, all of the required information is obtained from the proponent of the novel food. Chapters 4 and 5 consider whether government should rely entirely on the proponents' scientific information in determining whether a novel food is safe for consumption.
[114] Benda, *supra* note 16.
[115] *Ibid.* at 247.

Benda sums up the Canadian legislative approach to the safety assessment of GM foods by quoting from the Guidelines as follows:

> Since 1994, 50 novel foods and 43 plants with novel traits have been approved for commercialization. The foregoing regulatory regime is based on the safety of the product.
>
> > In keeping with generally accepted approaches, the emphasis of the safety assessment will be on the product and not on the process to develop it. However to ensure that appropriate concerns are addressed, a clear understanding of the methods used to develop the product is necessary. The fewer uncertainties regarding the nature of a novel product or the method of manufacture that remain, the more likely that nutritional and toxicological concerns will be easily addressed.
>
> In this blizzard of regulations and assumptions something can get missed that is unique to Canada. Canada's definition of novel crop and food is not a euphemism for rDNA process or products. The definition of novel crop and food hinges on *product traits* that are possible by techniques other than rDNA. In other words, the regulatory concept of "novel" captures organic and conventional crops or all genetic modification techniques. This is a reasonable legal and scientific position to adopt when the safety threat lies with the product. One eats the product, not the technology. Conventional – and especially organic farmers – ignore this legal regime, or at least seem to bristle at the notion that "natural" needs to be regulated.[116]

Accordingly, then, a new layer of assessment has been added to the legislative and regulatory scheme to address those foods that are now considered "novel". It would appear that the Canadian regulatory approach has been developed in an effort not to single out GM foods as needing a particular assessment regime, but rather to apply an assessment regime to any food that is "novel" to Canadian consumers. The manner in which the legislative and regulatory framework are put into practice by regulators themselves, which is an exercise in risk analysis, is the subject of the next chapter.

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[116] *Ibid.* at 297.

3.3 Conclusion

Although the Novel Foods Regulation adds a new layer of assessment to the food regulatory scheme to deal with novel foods such as GM foods, one can discern the same regulatory goals of safety and certainty in this new scheme.

With respect to safety, section B.28.003 of the Regulations says that regulators are to make a determination as to whether a novel food is "safe for consumption". This raises again the questions brought up at the beginning of this chapter. How safe must food be? How safe can regulation make it? These questions are more subjective than one might think, given that many additives and pesticides are potentially disease-causing, and are only "safe" at very low levels. What is even more difficult is that, due to allergies and sensitivities, food that is perfectly safe for one person can be deadly for another. Accordingly, the only way to achieve some measure of safety in the food supply is to assess the risks and manage them as effectively as is practicable. Chapter 4 reviews the way in which Canadian regulators carry out risk assessment and risk management in practice. Chapter 5 then considers some theoretical perspectives on how risk assessment and risk management ought to be carried out.

The second regulatory goal, certainty, is somewhat less evident in the Novel Foods Regulation. The regulator will consider the common name to be used on the labels and the information to be provided with the novel food, as part of the regulatory review, but does not mandate any form of labelling. Further, there is no requirement to identify genetically modified ingredients as such, unlike the requirements to identify certain modified fats, oils and other food constituents.[117] But this raises the question, what level of certainty should the government try to provide to consumers? What constitutes deception? What information must food producers provide, on the label or otherwise, in order to ensure that consumers know what they are buying? It is clearly not practical to advise consumers about every aspect of the production and processing of the food they purchase, from the labour conditions

[117] As discussed in Section 3.1.2(c).

to which employees are subjected to the effluent produced by factories. Accordingly, it will be necessary to determine how policy makers should decide on the types of information that they will require food producers to provide.

Theoretical perspectives on risk analysis and, in particular, risk communication, will be considered in Chapter 5 and applied to the arguments for and against mandatory labelling as a regulatory tool for risk management and communication. Economic theory on labelling, and the economic arguments for and against mandatory labelling, will be reviewed in Chapter 6. These two avenues will be used to demonstrate that the goals of safety and certainty, through the vehicles of risk management and consumer choice, can both be met by mandatory labelling and formulated in a manner that largely addresses the concerns of all stakeholders surrounding the labelling issue.

Chapter 4 – Risk Analysis

4.0 Introduction

As described in Chapter 3, the goals of the food regulation system are to provide consumers with safety and certainty, although safety cannot be guaranteed and certainty cannot be absolute. In practice, both safety and certainty issues, regarding the potential risks of food and its hidden characteristics, are addressed by the federal government in the form of a risk analysis system.[118] The first step in such a system is a risk assessment, typically a quantitative analysis, carried out by scientists. Regulators then determine what risk management measures ought to be applied to minimize the risks of the food product while realizing its benefits. Risk communication is a factor throughout the process, but the most significant aspect of risk communication, in the context of this thesis, is the communication of risks to members of the public who will assume those risks when they consume the food product in question.

The risk analysis framework applied to foods in general is illustrated by the example of irradiated foods.[119] In that case, regulators determined, after consulting with the public, that it was preferable to exercise greater regulatory control over irradiated foods than was possible through the consideration of irradiation as a food additive. Although the RIAS does not specifically identify risk as a factor in the decision to increase regulatory control, it does mention that the requirements for identification of irradiated foods and for record-keeping are "safeguards".[120] So, having determined through some form of risk analysis that there may be some risk in the consumption of irradiated foods, the risk management options taken by the regulators included reporting and record-keeping obligations for marketers of irradiated foods, together with labelling obligations. The labelling of the irradiated food products is

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[118] The elements of risk analysis are described in Chapter 1, *supra*, at note 13.
[119] Discussed in section 3.1.2(c), at note 103.
[120] *Ibid.* at note 106.

part of the risk communication element of the risk analysis process, providing both an effective risk management strategy and consumer choice, thus furthering both the safety and certainty goals.

One could argue that the same process could readily be applied to GM foods. Indeed, the potential health risks of GM foods have been established.[121] Even if those risks are more pronounced for individuals prone to food allergies and sensitivities, the only way that affected individuals can manage their own risks is if they are provided with sufficient information to enable them to do so. However, the Novel Foods Regulation has created a different scheme for the approval and regulation of GM foods, and that scheme seems to be less onerous for proponents of novel foods, and less protective of consumers, than the scheme for irradiated foods.

The Novel Foods Regulation shows the reliance of regulators on science in coming to a conclusion as to whether a novel food carries a risk for consumers, and whether that risk is acceptable. But many consumers would prefer to take on some of the responsibility for protecting both of these interests for themselves, due to individual safety considerations such as allergies and due to individual preferences as to content, processing methods and other factors. The primary function of food labels is the provision of the information necessary for consumers to make their own choices.[122]

However, the extent of the information that manufacturers can provide on labels is limited by practical constraints, including the amount of space available. Therefore there must be some consideration of the usefulness and the importance of particular information before any decision is made to mandate the provision of that information on food labels. For both the policy goals of safety and certainty, this thesis argues that the nature of particular food

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[121] See section 2.2.1.

[122] This argument is made in Chapter 6; further, Health Canada has acknowledged the need for consumers to take more responsibility for their own protection in choosing food products: Health Protection Branch, supra note 67.

characteristics should dictate whether they must be identified on the food label. In other words, characteristics of food that entail some risk, even if it is only to vulnerable members of the population, should be considered differently than characteristics such as labour conditions that do not increase risk for the consumer. Put another way, these "risk characteristics" ought to be given a higher priority in the list of items that consumers ought to be advised about in order to exercise choice and achieve both safety and certainty with respect to the products they are consuming.[123]

Following this line of argument, genetic modification of food products or ingredients is considered in this thesis as a risk characteristic.[124] Where a risk characteristic can be disclosed to consumers by way of a label, the label is a risk management strategy and a vital part of the risk communication aspect of the risk analysis process.

This chapter commences with a review of the risk analysis scheme and the methods used by food regulators in Canada as specifically applied to GM foods. This is followed by a critique of the risk analysis methodology used by Canadian regulators on GM foods, first by comparison to the standards of the Codex Alimentarius Commission, and then against the backdrop of the concerns that some scientists have expressed regarding the scientific risk assessment.[125]

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[123] See the discussion of food safety attributes in section 6.1.2.

[124]Proponents have argued that there is no inherent risk in the GM process, but that risks must be assessed for each product individually: Benda, *supra* note 16, at 297. However, the discussion at section 2.2.1 establishes that there are risks inherent in the GM process, and this thesis will therefore view the genetic modification of food products as a risk characteristic in itself.

[125] The purpose of this chapter is to look at the practical aspects of the food regulatory regime set up by the legislation and regulations to deal with GM foods. Practical criticisms of the system with respect to GM foods are included in this chapter for ease of reference. More theoretical approaches to risk analysis and to labelling are included in Chapters 5 and 6, together with the application of the theoretical approaches to the systems in place in Canada regarding GM foods.

4.1 Risk Analysis of GM Foods

4.1.1 Institutional Framework

The *Food and Drugs Act* falls primarily under the purview of Health Canada, which has responsibility for the development of policies and standards affecting human health issues. This includes labelling related to health and safety issues, such as the possibility of allergenic substances in GM foods. Health Canada is also "solely responsible for assessing the safety of foods for human consumption, including GM foods and other novel foods, and for allowing them to be sold in Canada."[126] Generally, any policies and standards for the safety and nutritional quality of foods sold in Canada are established by Health Canada.

Within Health Canada, the Health Products and Food Branch is responsible for risk management related to health products and food.[127] The Health Protection Branch developed Health Canada's *Guidelines for the Safety Assessment of Novel Foods* in September 1994 (the "Guidelines"). The Guidelines are currently under revision. [128]

Enforcement of the Act and Regulations, as well as the parts of the *Consumer Packaging and Labelling Act* that deal with food, is the responsibility of the Canadian Food Inspection Agency (the "CFIA"). The CFIA was set up by the *Canadian Food Inspection Agency Act*[129] (the "CFIA Act") in 1997, and was pulled out of the former Food Production and Inspection Branch of Agriculture and Agri-Food Canada.[130] The CFIA falls under the umbrella of

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[126] Canadian Biotechnology Advisory Committee, *supra* note 43 at 8.
[127] *Ibid.*
[128] Canadian Food Inspection Agency, Office of Biotechnology, "Joint Health Canada/CFIA Expert/Multistakeholder Consultation on the Revision of Regulatory Directives on Novel Foods, Plants with Novel Traits and Livestock Feeds from Plants with Novel Traits" (January 2003), CFIA website, *supra* note 62, at .../plaveg/bio/gatconsult/consultinte.shtml.
[129] S.C. 1997, c.6.
[130] One of the principles of the federal government's framework for the regulation of biotechnology products is to use existing legislation and regulatory bodies rather than developing new laws and agencies. The *Canadian Environmental Protection Act*, for example, regulates the production or importation of living products of biotechnology.

Agriculture and Agri-Food Canada, and its responsibilities are set out in section 11 of the CFIA Act:

> **11.** (1) The Agency is responsible for the administration and enforcement of the Agriculture and Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Feeds Act, Fertilizers Act, Fish Inspection Act, Health of Animals Act, Meat Inspection Act, Plant Breeders' Rights Act, Plant Protection Act and Seeds Act.
> (2) The Agency is responsible for the enforcement of the *Consumer Packaging and Labelling Act* as it relates to food, as that term is defined in section 2 of the *Food and Drugs Act.*
> (3) The Agency is responsible for
> (*a*) the enforcement of the *Food and Drugs Act* as it relates to food, as defined in section 2 of that Act; and
> (*b*) the administration of the provisions of the *Food and Drugs Act* as they relate to food, as defined in section 2 of that Act, except those provisions that relate to public health, safety or nutrition.
> (4) The Minister of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency's activities related to food safety.

The CFIA primarily deals with those aspects of GM foods that occur at the stage of growing new GM crops. The *Canadian Environmental Protection Act*[131] is also involved at this stage. The involvement of the CFIA is relevant to the issue of mandatory labelling in that it is involved to some extent in determining the possible health effects of a GM crop.

Pursuant to the Novel Foods Regulation, foods which have been genetically modified are considered novel because the method of production is new, involving the manipulation of the genes of a food organism at the molecular level. Health Canada endeavours to assess novel products such as GM foods for human food safety, including potential allergenicity and toxicity, and for nutritional composition and dietary exposure.[132] The methods used by

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[131] *Ibid.*
[132] Canadian Food Inspection Agency, Office of Biotechnology, "Regulatory Approval Process for Products of Biotechnology" (May 2001) CFIA website, *supra* note 62, at .../ppc/biotech/gen/approvale.shtml.

Health Canada in reviewing GM foods are considered by the Royal Society in its report.[133] The Royal Society describes the approval processes of Health Canada and CFIA, both of which are included here for comparative purposes:

> CFIA is the agency that has the first contact with a biotechnology firm wishing to introduce a new GM crop plant. To obtain permission to proceed with confined field trials, the firm first applies to CFIA.
>
> ...
>
> The information that CFIA makes available to the public regarding their approval decisions explains the basis for approval of unconfined release of a GM plant into the environment, such as the criteria to be addressed in deciding whether environmental safety is threatened, but neither the design of the experiments on which the assessment was based, nor the results, are included in the public Decision Documents.
>
> ...
>
> In addition, CFIA directives indicate that statistically valid experimental designs are required for testing plants with novel traits, and that all such work is to be of the standard required for peer-reviewed research publications. In the absence of independent peer-review, however, the Decision Document is in no sense equivalent to a peer-reviewed scientific paper, and in the Panel's view, the decision-making process in general lacks transparency, and thus credibility.
>
> ...
>
> Many GM crops are destined, as a whole or as specifics parts, for the human food supply system. For this reason, they must not only obtain CFIA approval, but must also be assessed by Health Canada. Health Canada gains its jurisdiction to regulate in this area from the Food and Drugs Act and Regulations, within which GM foods come under the Novel Food Regulations. While this regulation establishes important background criteria, such as the defining of novel foods and setting the time frame for a government response, the more instructive document is that entitled *Guidelines for the Safety Assessment of Novel Foods* (Health Canada, 1994). These guidelines (as opposed to regulations) specify that a guiding principle in the safety assessment is based on a "comparison of molecular, compositional and nutritional data for the modified organism to those of its traditional counterpart". They suggest that data should be provided on dietary exposure, nutrient composition, anti-nutrients, and nutrient bioavailability. If concerns still remain following this analysis, "toxicity studies would be required as necessary, on the whole food, food constituent or specific

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[133] Royal Society of Canada, *supra* note 2, at 35-38.

> component in question". Finally, using data supplied by the applicant, Environment Canada and Health Canada consult together to decide whether a product is "toxic" to the environment and human health...
>
> After reviewing the relevant document and holding discussions with Health Canada personnel, it appears to the Panel that no formal criteria or decision-making framework exists for food safety approvals of GM products by Health Canada. Decisions are largely made on a case-by-case, ad hoc basis.
> ...
> As in the CFIA procedures, the applicant is responsible for supplying all of the data to be evaluated, which may be supplemented by any relevant scientific literature. No independent testing of the safety of a GM food by a governmental or other, independent, laboratory is required.
>
> The decisions for approval of a novel food are made public by Health Canada. These documents provide the product name, the name of the proponent, the decision date and further information in a manner similar to the CFIA Decision Document. Again, the data on which the decision was based are not revealed. If an approval is issued, it could be accompanied by specific conditions, such as requiring labelling for possible allergens, because Health Canada has jurisdiction over labelling for health and safety issues.

Accordingly, there are two layers of decision making, the first by CFIA with respect to the growing of GM crops, and the second by Health Canada with respect to the approval of foods derived from those crops. Both agencies clearly develop a relationship with the proponent and exchange information as to the data the proponent must provide, either to Health Canada or to the CFIA, for the purposes of its risk assessment.

4.1.2 Risk Analysis Methodology

As discussed in Chapter 3,[134] neither the Act nor the Regulations define particular methods for assessing the safety of novel products such as GM foods. Nor do they provide a definition of the term "safe." Pursuant to the Novel Foods Regulation, and specifically section B.28.003, Health Canada must determine whether a novel food is safe before

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[134] See section 3.2.

approving it to be marketed in Canada. It is clear that complete safety cannot be guaranteed with respect to GM foods, and accordingly Health Canada determines whether a product is safe for human consumption by conducting a risk analysis.

The risk analysis method used by Health Canada and the CFIA is outlined, in general terms, at the CFIA website. The definition of "safe" and the principles applied to the evaluation of food products are described as follows:

> ... to conduct evaluations for each product on the basis of its unique characteristics and to establish appropriate safety levels based on the best scientific information. Safety is defined, not as the complete absence of risk, but rather as the level of "acceptable risk". If the risk is not acceptable, the applications will be refused.[135]

Although safety is defined as "acceptable risk", no definition of acceptable risk could be found in the website documents. This is a fundamental problem in risk management, because the opinions of the scientific community and the regulators do not always coincide with the opinions of the public as to what is an acceptable risk.[136]

The CFIA website provides a general overview of the process used for risk analysis of foodstuffs including novel foods.[137] Calling its approach to regulation of agricultural products "safety-based," the Office of Biotechnology, a department within the CFIA, identifies four activities involved in the process:
(1) determining whether a risk assessment is required – a risk assessment is required if the product definition and the evaluation of the product fall under the guidelines which require full assessment;

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[135] Canadian Food Inspection Agency, Office of Biotechnology, "Biotechnology, Agriculture and Regulation" (February 2001) CFIA website, *supra* note 62, at .../sci/biotech/reg/bare.shtml.
[136] This issue will be explored in Chapter 5.
[137] Canadian Food Inspection Agency, Office of Biotechnology, "The Safety-Based Approach to Regulation of Agricultural Products" (February 2001) CFIA website, *supra* note 62, at .../sci/biotech/reg/regage.shtml.

(2) risk assessment – potential risks are identified and assessed, based on information and scientific data provided by the proponent and, if necessary, additional product testing;
(3) risk management – the imposition of conditions on use in order to minimize identified risks; and
(4) regulation – "sets criteria for the monitoring of safety, quality, labelling, purity and potency of the product."

This risk assessment process is very similar to the risk analysis framework set out in Chapter 1, which is derived from Codex Alimentarius. As under the Codex risk analysis framework, the approach of Canadian regulators begins with a scientific risk assessment to determine the nature of a particular hazard and the level of that hazard. The risk management step is the determination of how to deal with the risks identified – here it is described as both risk management and regulation, via the imposition of conditions and subsequent monitoring. The risk communication aspect of the risk analysis process outlined in Chapter 1 occurs throughout the process, by way of the communication between the proponent and the government agency, by the release of government decision documents, and by way of regulatory requirements including labelling.

The following is a more detailed discussion of the way Health Canada carries out the three steps of the risk analysis process.

(a) Risk Assessment

Health Canada currently requires a risk assessment if a novel food was derived through a new production method, such as genetic modification, if such a method has not been used on that particular food in Canada before.[138] An assessment is also required if a novel food has a composition that is in any way different from its traditional counterpart. Thus the public can be assured that all GM foods are at least subjected to a scientific risk assessment.

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[138] *Ibid.*

However, as noted by the Royal Society, Health Canada rarely does any direct testing of these products, relying instead on research provided by the proponent of a product and on the principle of "substantial equivalence," which holds that if a GM food is substantially the same as its traditional counterpart, detailed testing of its toxicity and allergenicity, and so on, is not necessary. The principle of substantial equivalence is described in the Guidelines as follows:

> A guiding principle in the safety assessment will be comparison of molecular, compositional and nutritional data for the modified organism to those of its traditional counterpart, where such exists. It is expected that once substantial equivalence to an existing food product can be established, no additional safety testing would be required. Where similarity or degree of equivalence cannot be established, a more extensive safety assessment may be necessary. It is recognized that availability of compositional data for traditional foods is often limited and may be unavailable for new products. Thus, there is a need to develop international databases on the composition of traditional foodstuffs to serve as a basis for comparison.[139]
>
> [emphasis added]

As there is little guidance in the Act and Regulations as to how the risk assessment should be conducted, the Guidelines provide the only concrete reference point for determining how Health Canada makes its decision. The Guidelines state:

> The safety assessment of whole foods derived from genetically modified microorganisms, plants and animals is more complex than evaluation of single chemical food constituents or designed chemical mixtures. In assessing the safety of whole foods, knowledge of the previous use as a food, the level of complexity of the whole food, and the breadth of the modification will be determining factors in establishing information requirements for the evaluation. Where appropriate, the basis for the safety assessments will be comparison of the molecular, compositional, toxicological and nutritional data for the modified organism to those of its traditional counterpart. In cases where the genetic modification is well defined, with specific effects, the safety

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[139] Health Canada Guidelines, *supra* note 35, at 5.

> assessment may be limited to information provided on the development and production of the modified organism and a comparison of the composition of the modified product to the unmodified product. For poorly characterized changes, or cases in which a genetically modified organism is determined to be significantly different from its traditional counterpart, a more comprehensive review may be required for the novel product. This review may include a toxicological and nutritional assessment of the product, including a combination of *in vitro* and *in vivo* tests applied on a product-specific basis. Where there are potential concerns related to the allergenicity of the novel food product, the Food Directorate should be consulted to determine the approach to be taken in order to mitigate any concerns.
>
> In all cases, the degree of exposure to the modified organism or its metabolic products will be an important factor in determining the extent of the data required for a meaningful safety assessment.
> ...
>
> Initial assessments will necessarily be on a case-by-case basis. It may be possible, once sufficient experience is gained, to design more explicit criteria that may preclude the need for the detailed evaluation of specific products.[140]
>
> [emphasis added]

The Guidelines then summarize the types of information that a proponent must provide to Health Canada. However, the Guidelines are fairly general and state that "not all information requirements outlined below may be appropriate to all cases." The Guidelines emphasize the need for proponents to consult with the Food Directorate in order to "reach agreement on what information is appropriate to the evaluation of the safety of the product."[141]

Because the legislative and regulatory framework is vague, it is somewhat lacking in transparency with respect to the scientific methodology used at the risk assessment stage of the risk analysis. In an apparent effort to improve the transparency of the process, Health Canada has made use of its website to post decision documents summarizing the risk assessments of almost all of the GM foods approved to date.

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[140] *Ibid.* at 4-5.
[141] *Ibid.* at 7.

The decision documents generally identify the type of protein produced by the transgene introduced into the genetically modified plant, and the source of the transgene. They also summarize the likely dietary exposure to humans of the food, nutritional and toxicological information and the likelihood of a human toxin or food allergen being present in the genetically modified food. They give no detail as to the studies undertaken that lead to these conclusions, although they do provide a general summary of the nature of those studies. As an example, the review of toxicology of an insect-protected corn states:

> The lack of acute toxicity in animal studies and lack of homology to known protein toxins suggest that any MON 863 CRY3Bb1.11098 protein present in food product derived from the novel corn variety would not exhibit toxic activity. The unlikelihood of the MON 863 CRY3Bb1.11098 protein being a potential food allergen or toxin is indicated by its lack of homology to known protein allergens or toxins, and its rapid digestion in the stomach. Data demonstrating that the concentration of CRY3Bb1.11098 protein in the edible grain was very low relative to total plant protein, and that it was degraded during typical baking processes, adds support to the conclusion that CRY3Bb1.11098 protein expressed in corn event MON 863 is unlikely to be a mammalian toxin or food allergen.[142] [emphasis added]

This review would be based on data supplied by the proponent. Although there is some detail provided as to the interpretation of the data, and the type of data relied on in the risk assessment, the nature of the studies conducted to obtain the data is not clear. This information is insufficient to allow other scientists to replicate the experiments and obtain the same (or different) data, ruling out the possibility of independent peer review of the risk assessment. Nonetheless, Health Canada reached the conclusion that this particular corn is "as safe and nutritious as current commercial corn varieties."[143]

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[142] Health Canada website, *supra* note 99, at www.hc-sc.gc.ca/food/aliment/mh-dm/ofb/bba/nfi-ani/e re: insect protected corn line MON 863, developed by Monsanto and approved by Health Canada in March 2003. It should be noted that Health Canada and the CFIA have increased the number of decision documents posted on their websites, and the amount of detail provided in the decision documents, as part of their response to the recommendations of the Royal Society of Canada and CBAC. The decision document cited is one of the more recent, and therefore more detailed.

[143] *Ibid.*

(b) Risk Management

Risk management tools could include banning, limits on production or use, and labelling.[144] To date, no conditions have been set on any GM foods approved for use in Canada.[145] Health Canada takes the position that its testing is extremely rigorous and that proponents generally do not submit new products for approval unless they are confident that they will meet the criteria. Accordingly, once the safety assessment has been completed, there is no need for any risk management steps to be taken.

The Guidelines state that "the application of genetic modification does not inherently increase or decrease the risk associated with an organism."[146] Nonetheless, the guidelines go on to acknowledge that there is the possibility of unexpected toxicity or allergenicity arising from the process of genetic modification.[147] Granted, even conventional foods are not absolutely safe,[148] but the Royal Society report and Health Canada's aforementioned caveat acknowledge that the GM process itself creates the possibility of these unintended effects that are potential risk factors.

As this thesis is geared to the issue of labelling, the point to emphasize at this stage is that Health Canada does not require any specific labelling of genetically modified foods under the Act or the Regulations. There are suggestions on the Health Canada website, however, that labelling would be required in certain circumstances. The website states that there are guidelines on labelling products derived through genetic engineering that require special labelling where safety concerns such as allergenicity and compositional or nutritional

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[144] See the Novel Foods Regulation at Section 3.2.
[145] Health Canada website, *supra* note 99, at www.hc-sc.gc.ca/food/aliment/mh-dm/ofb/bba/nfi-ani/e.
[146] Health Canada Guidelines, *supra* note 35, at 4.
[147] *Ibid.*
[148] Benda, for example, argues that the risks of GM foods are no greater than those of conventional foods and that any possible unintended toxins or allergens should be dealt with as potential risks of the particular product: *supra* note 16, at 402-405. The problem with this view is that the unintended toxins or allergens that might need to be considered would not occur in the traditional variety of that particular food, and would only arise in the GM variety.

changes are identified.[149] However, no such guidelines could be found. Nor are these requirements apparent in the Regulations.

Further, the website states that a different common name must be used to describe a product that has a different composition.[150] However, this is not really a new requirement specific to GM foods. The existing regulations on ingredient labelling and common names require that ingredients be labelled according to their common names.[151] It would be difficult to argue that a GM food with a different composition could be identified by the name of its traditional counterpart. The problem with the lack of labelling requirements is that the scientific risk assessment undertaken by proponents, and relied upon by regulators, may not be sufficiently rigorous to identify all compositional changes in a GM food.[152]

It is significant that a voluntary labelling standard has been developed, but not by Health Canada.[153] The standard was developed by the Canadian General Standards Board in consultation with a variety of stakeholders and regulators, in an effort to establish parameters for any claims that producers of GM or non-GM foods may make. The standard is a positive step in aiding consumer choice; however, this thesis argues that Health Canada and the CFIA should require mandatory labelling, both as a risk management step and because full consumer choice can only be achieved through mandatory identification of GM foods.

(c) Risk Communication

Health Canada and the CFIA have both made an effort to address the concerns that many have expressed about genetically modified foods. Information on the websites of both agencies assures the public that a process is in place to ensure that products of biotechnology

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[149] Health Canada website, *supra* note 99, (2003) at www.hc-sc.gc.ca/food/aliment/mh-dm/ofb/bba/nfi-ani/e_faq/3.html#5.
[150] *Ibid.*
[151] See Section 3.1.2(c).
[152] See discussion *infra*, at section 4.2.
[153] Canadian General Standards Board, *supra* note 66.

are thoroughly assessed for safety and effectiveness, in terms of their impacts both on the environment and on human health. According to one document:

> The Canadian Food Inspection Agency focuses its assessments on the characteristics of the final product. The philosophy of the regulatory framework is that genetically engineered organisms are not fundamentally different from traditionally bred organisms and can be assessed using well-defined and understood principles of risk assessment. Each new product is therefore evaluated on its own merits and characteristics, while at the same time the processes used to develop the organisms are carefully considered. Because of the precise nature of the new techniques of biotechnology, we may in fact have more knowledge about genetically engineered organisms than about those that occur naturally.[154]

This webpage provides information about the benefits of biotechnology and a very basic overview of how genetic modifications to an organism are accomplished. While it acknowledges that some people have expressed concern about these products, which has led to its processes for risk assessment, it does not acknowledge that any of those concerns may be well-founded. Indeed, the information appears to be designed to ask Canadians to accept that the foods are rigorously tested and therefore safe when they reach the market.

The CFIA and Health Canada websites seem to be focused on the benefits of biotechnology and on assuring people that the risk assessment review process is thorough and results in the safest possible food supply. However, the websites lack full, or indeed any, information on potential hazards of GM foods such as the presence of bacterial or viral gene markers on cloned DNA, the possibility of allergic responses to proteins produced by genes from organisms that have never before been a human foodstuff, or the possibility of interactions between the transgenes and the natural genes.[155]

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[154] Canadian Food Inspection Agency, Office of Biotechnology, "Concerns and Issues About Biotechnology" (January 2001) CFIA website, *supra* note 62, at .../sci/biotech/gen/issuse.shtml.
[155] See section 4.2.2, *infra*.

The Office of Biotechnology website addresses certain specific issues of concern, for example, the issue of allergenicity.[156] According to this webpage, any GM food must undergo Health Canada's assessment for safety, which includes explicit consideration of the potential allergenicity of the novel food. This assessment is made by "looking at the history of both the host and donor organisms and the modification that has been undertaken."

The CFIA website addresses the issue of public involvement in the process of regulating novel foods in a document entitled "Public Input and Access to Information about Biotechnology."[157] This document describes public involvement as follows:

> The departments responsible for regulating agricultural products of biotechnology have all involved stakeholders in the development of guidelines and regulations. Since 1988 there have been many general consultations on the regulation of agricultural products of biotechnology. These consultations have included workshops, multistakeholder meetings, and distribution of draft documents for comment. In addition, there have been extensive commodity specific consultations on technical and scientific matters.
>
> It has been important to involve and obtain the input of members of the public during the development of the regulatory framework, since it would be impractical to accommodate public input into regulatory decisions on a product by product basis.
>
> While the public is not directly involved in individual product registration decisions, CFIA prepares "decision documents" whenever regulatory decisions are made. These decision documents are made available to the public in hard copy and on the Internet. These decision documents explain in detail what was reviewed in order to make the decision, and why certain conclusions were reached. The CFIA encourages public feedback on these documents in order to continually improve their quality and usefulness to Canadians.

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[156] Canadian Food Inspection Agency, Office of Biotechnology "Allergens" (May 1998) CFIA website, *supra* note 62, at .../ppc/biotech/safsal/allerge.shtml.
[157] (April, 1997) CFIA website, *supra* note 62,.../ppc/biotech/gen/publice.shtml.

As discussed above,[158] decision documents show that, in a safety assessment, Health Canada relies on information provided by the proponent to determine whether there are any differences in composition or nutritional characteristics between the novel variety of a food and the traditional varieties.[159] However, the design of the experiments undertaken and the actual data and information provided by the proponent are not made public.[160]

4.2 Critique of the Risk Assessment of GM Foods in Canada

It is the regulators who must decide the practical answers to questions of risk and make the decisions on how to regulate genetically modified foods.[161] But it is the scientists who conduct the risk assessment and provide the raw material for regulatory decision-making – both in terms of the available data as to health risks, and as to the composition of GM foods. Regulators must consider the scientific data in order to decide whether the introduction of GM foods into the marketplace raises issues under either of the policy goals of the food regulation system – safety and certainty. The key questions with respect to the regulation of GM foods are whether they pose significant or unacceptable risks, and whether GM varieties of foods are, in fact, substantially equivalent to the traditionally-bred varieties – that is, from the perspective of consumers getting the product they wish to purchase.

With respect to the safety goal, regulators cannot promise zero risk. The reality is that, even if the testing is done, there will inevitably be some risk involved in ingesting GM foods. This is particularly true for people who may have an allergy or sensitivity, which in some cases may not be known until they encounter a food modified with genes from a novel organism. But there is debate as to what must be done in the risk assessment process to assure consumers that the risk is as low as can reasonably be expected.

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[158] Section 4.1.2(a).
[159] Health Canada website, supra note 99, at www.hc-sc.gc.ca/food/aliment/mh-dm/ofb/bba/nfi-ani/e.
[160] Royal Society of Canada, *supra* note 2, at 36.
[161] The risk management and risk communication steps of risk analysis, which are considered in more detail in Chapters 5 and 6, along with a more theoretical consideration of risk assessment.

In response to criticisms[162] regarding its risk assessment process,[163] Health Canada has asserted that the majority of food products that have been approved so far involve the introduction of one or two novel proteins. Further, the assessment includes a comprehensive characterization of the modified plant at the molecular level and of the composition of the food itself. In this way the components which are different in the GM food from its traditional counterpart are identified and are subjected to intense scrutiny on their own. The document also states that the reliance on molecular homology[164] in determining toxicity is sufficient and that "[t]he use of more animals in extensive (long term) testing would not provide additional assurances with respect to safety and would result in the unnecessary sacrifice of laboratory animals." Finally, Health Canada argues that its risk assessment method is endorsed by numerous experts and used by "regulatory agencies around the world in countries such as the European Union, Australia, New Zealand, Japan and the United States."

4.2.1 Risk Assessment Methodology

The primary international source of methodology for risk analysis of foodstuffs is the Codex Alimentarius Commission ("Codex"). [165] The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*[166] (the "Codex Guidelines") specifically incorporate the Codex *Principles for the Risk Analysis of Foods*

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[162] The specific criticisms are addressed *infra*, in Section 4.2.2.

[163] Health Canada, "A Bureau of Food Policy Integration (Food Directorate) Response to: Food Safety of GM Crops in Canada: toxicity and allergenicity" (January 2000) Health Canada website, supra note 99, at www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/health_canada_response_gmo.html. Page numbers are not given for the quotations in this paragraph as the document is very brief.

[164]This term essentially means that compounds are not considered to be toxins if they do not show structural or other similarity at the molecular level to known toxins. See discussion *infra* at section 4.2.2.

[165] Health Canada states that it uses FAO/WHO and OECD standards: Health Canada website, *supra* note 99, at www.hc-sc.gc.ca/food/aliment/mh-dm/ofb/bba/nfi-ani/e_faq_2.html. Given that Codex is a body developed by FAO/WHO, this is effectively an endorsement of Codex standards.

[166] Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, CAC/GL 45-2003 – these are specific to recombinant plants. There are similar guidelines for other broad categories of organisms, for example micro-organisms.

Derived from Modern Biotechnology[167] (the "Principles"). The Principles are intended to provide "a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology."

The Codex Guidelines and Principles are lengthy, and in many ways they support the approach taken by Health Canada. Some key sections of the Principles are interesting to compare to that approach, and accordingly are quoted here at length:

> 10. Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.
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> ...
>
> 12. A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of quantity that would withstand scientific peer review.
>
> ...
>
> 14. Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Data should be assessed using appropriate science-based risk assessment methods.
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> ...

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[167] Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003.

> 22. Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.
> [emphasis added]

The Principles also incorporate the *Working Principles for Risk Analysis* used by Codex.[168] The latter principles include similar statements regarding openness and transparency at all phases of the risk analysis process. They also recommend "a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment...". Moreover, they recommend a transparent process for the selection of experts conducting risk assessments, and a selection based on their "expertise, experience, and their independence with regard to the interests involved." A public declaration of potential conflicts of interest is also recommended. Further, "Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner."

These comments on the transparency of the system are clearly applicable to the practice of Health Canada of relying on data from proponents of GM foods rather than conducting their studies. As well, the lack of peer review of the data because of a lack of disclosure is an issue raised by the Royal Society in its report.[169] However, concerns have been raised not just about the fact that proponents are conducting the risk assessments and supplying the data, but also about the nature of the experiments done and whether they are sufficient to allow regulators to make an informed decision as to the level of risk and the appropriate regulatory response.

The Codex Guidelines recognize that the assessment of the safety of whole foods, such as GM foods, is considerably different from the assessment of individual constituents. That is, the safety of GM corn cannot scientifically be determined in the same way as the safety of a

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[168] Codex, *supra* note 13.
[169] Royal Society of Canada, *supra* note 2, at 211-215.

particular ingredient, such as a preservative. The latter can be isolated, whereas a whole food is complex and often naturally contains substances that would ordinarily be considered toxic.[170] This is why the concept of substantial equivalence is recommended. However, the Codex Guidelines state:

> 13. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.
>
> ...
>
> 15. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.
>
> 16. Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant-DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.

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[170] E.g. arsenic – see discussion at section 3.1.2(a).

> 17. The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. ...
>
> [emphasis added]

The Codex Guidelines set out detailed descriptions of the types of data, both qualitative and quantitative, that should be considered in the risk assessment. The Health Canada Guidelines appear, at least from the perspective of a layperson, to be substantially similar. Indeed, any analysis of the scientific considerations will not draw many non-scientists into a debate, because we tend to think that we won't be able to understand the science and therefore should leave it to the experts. However, there are, not surprisingly, different opinions among the experts as to whether the concept of substantial equivalence is a satisfactory method of determining risk.

4.2.2 Criticism of the Risk Assessment Process

The reliance of risk analysis scientists on assumptions[171] underlies a key area of disagreement among those who argue whether current methods of risk assessment are adequate. This concern is reflected in several papers written by members of the group GE Alert, made up of scientists dedicated to publicizing what they see as the risks inherent in genetic engineering. One such paper, by Ann Clark, a crop production physiologist, analyzes

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[171] See discussion *infra*, at section 5.1.

the methodology used by Health Canada in assessing the toxicity and allergenicity of new GM foods.[172] While a detailed discussion of the science involved in risk assessment is beyond the scope of this thesis, it is worth noting that the paper suggests that there is disagreement among scientists as to the nature and extent of studies that ought to be done before the risk assessor or risk manager can draw a conclusion as to the risks associated with GM foods.

One of the primary concerns expressed in Clark's paper as to the risk assessments relied on by Health Canada is the following: if there is no structural or chemical homology between new proteins in the modified food and proteins which are known to be toxic or allergenic, it is assumed that the new protein does not have either of these properties. In other words, if it doesn't look like a known toxin or allergen, it isn't one. Actual testing to determine the absence of toxicity or allergenicity is, in the majority of cases, not done.[173]

As well, Clark questions the decision of the regulators to restrict their consideration to the target protein alone, i.e. the new protein produced by the GM plant as a result of the insertion of a transgene. Individual genes provide the coding necessary for an organism to produce specific proteins; however, it is generally accepted that there is not necessarily a one gene-one protein relationship, but there may in fact be interactions among the genes themselves that could produce unanticipated effects.[174] As Clark points out,

> ... restricting consideration to only the target protein(s) assumes that the only factor which distinguishes transgenic from conventional crops is the target protein(s) coded for by the transgenes themselves. Theoretical as well as empirical evidence suggests that this is an unsound assumption ... .[175]

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[172] Clark, E. Ann, on behalf of GE Alert, "Food Safety of GM Crops in Canada: toxicity and allergenicity" (2000) GE Alert website at www.canadians.org/ge-alert/clark-foodsafety.pdf.
[173] See discussion of "substantial equivalence" at section 4.2.1.
[174] Royal Society of Canada, *supra* note 2, at 184-185.
[175] Clark, *supra* note 172.

A third major concern noted in the paper is the lack of any trials to examine the issue of long-term exposure from chronic consumption of GM foods. The author points out that the acute toxicity data that have been collected cannot predict chronic risks. In conclusion, Clark states that "... extrapolating the safety of single purified proteins to entire crops, or results of acute testing to chronic risk, is unwarranted." She suggests that the process for testing the safety of GM foods in Canada should be reassessed at a fundamental level.

These concerns are also reflected in the Royal Society of Canada Report. The Royal Society discusses the origins of substantial equivalence as a concept within the conventional breeding process.[176] The Report notes that substantial equivalence is currently used as a decision threshold, which, according to the authors, is not justifiable:

> Both in Canada and elsewhere, therefore, "substantial equivalence" is currently employed as an explicit rule stating the conditions under which it can be assumed that a new crop poses no more risk than a counterpart that is already considered safe. It represents one of the early criteria to be met in the regulatory decision trees. ... If a plant or food is judged to be substantially equivalent to one present in the Canadian diet, passage of this step in the decision tree spells success for its approval. Conceptual and practical implementation of "substantial equivalence" is thus the most critical element in the current approval process.
>
> ...
>
> In summary, the Panel has identified two different uses of the concept of "substantial equivalence":
>
> 1. A GM organism is "substantially equivalent" if, on the basis of reasoning analogous to that used in the assessment of varieties derived through conventional breeding, it is assumed that no changes have been introduced into the organism other than those directly attributable to the novel gene. If the latter are demonstrated to be harmless, the GM organism is predicted to have no greater adverse impact upon health or environment than its traditional counterpart. We refer to this interpretation as the *decision threshold* interpretation.
> 2. A GM organism is "substantially equivalent" if rigorous scientific analysis establishes that, despite all changes introduced into the organism as a result of the introduction of novel genes, the organism poses no more risk

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[176] Royal Society of Canada, *supra* note 2, at 177 et seq.

> to health or to the environment than does it conventional counterpart. We refer to this interpretation as the *safety standard* interpretation.
>
> The Expert Panel accepts the validity of the concept when used in the "safety standard" interpretation. We have grave reservations about its validity when employed in the "decision threshold" interpretation.
>
> In the Panel's view, the use of "substantial equivalence" as a decision tool within the regulatory process would appear to demand a careful assessment of safety impacts associated with any "novel trait" being considered for deployment in a new transgenic variety. If the presence of the novel trait can be rigorously demonstrated to be harmless (or the harm does not surpass a certain agreed-upon threshold) in the tested genetic/environmental context, the new genotype can be considered to be as safe as the original variety from which it was derived during the genetic engineering process. The question then becomes one of defining "rigorous demonstration" and its implementation.[177]

The Royal Society goes on to consider whether it is justifiable to predict simple, linear results from a particular genetic modification. Given the complexity of biological systems, the Report suggests that changes are likely to be affected by numerous factors, including the genetic background of the original organism, the new organism and the environmental pressures acting upon the new organism. Accordingly, the expression of a novel gene can lead to unanticipated changes, which should be tracked and assessed for significance of risk. In the end, the Royal Society recommends that testing for the potential for new transgenic organisms to cause harm to the environment or to human health should be rigorous and should replace the current regulatory reliance on "substantial equivalence" as a decision threshold.

4.3 Conclusion

In general, the risk analysis process for genetically modified foods in Canada is well-structured in that it follow international standards, incorporates scientific risk assessment and

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[177] *Ibid.* at 182-183.

makes available to regulators effective risk management and risk communication tools. However, concerns have been raised by a variety of detractors who argue that GM foods are not subjected to sufficiently rigorous scientific assessment, that there is too much reliance on the data of proponents, and that there is a general lack of transparency and failure to effectively communicate to the public the data relied upon in reaching the conclusion that the GM foods that have been approved do not pose significant or unacceptable risks to consumers.

Disagreement among scientists with regard to the methodology of the risk assessment process is not the only dispute. There is also a great difference of opinion between scientists and members of the public, those expected to assume the risk, as to which risks are significant and unacceptable. This difference of opinion undermines the effectiveness of the entire risk analysis process. The results of the risk assessment are inevitably affected by the assumptions and methodology of the scientists carrying it out. Accordingly, the conclusions of the scientific risk assessment, as to the level of risk, will impact upon the decision of the risk regulator as to whether the risk is acceptable and whether it is appropriate to impose particular risk management strategies. Further, assumptions that lead to a determination of lower risk can result in less effective risk communication, as risk regulators will not view the risk as being significant or unacceptable enough to warrant the step of risk communication measures such as mandatory labelling.

The ways in which the risk analysis process can be undermined by its methodology are considered in more detail in the next chapter. Chapter 5 provides an overview of the theoretical underpinnings of risk assessment, risk management and risk communication. The various perspectives considered will then be used to address arguments for and against the proposition that the best risk management solution to the problems identified in the risk assessment and risk communication processes is to institute mandatory labelling of GM foods and ingredients.

Chapter 5 – Theories of Risk Analysis

5.0 Introduction

The previous chapters have shown that it is impossible to eliminate all risks from our food supply, and that the regulatory goals of safety and certainty can only be achieved through the risk analysis process. The aim must be to minimize risk and to permit consumer choice to the greatest extent possible, with some regard for economic considerations. And given that Canada is a democratic society, there must be some regard for the views of the public when judging whether the regulatory goals are being achieved.

The process of risk analysis should begin, as discussed in Chapter 4, with the assessment of risk at the scientific level, followed by risk management decision-making by regulators. This is the process contemplated in the Novel Foods Regulation.[178] The third phase of risk analysis, which in fact occurs throughout the process, is effective risk communication. This is vital to gaining public acceptance for risk management decisions.

Labelling, the focus of this thesis, can be seen as a risk management step and as a risk communication step, both in furtherance of the safety goal. It is a means of providing consumers with the information necessary to make their own risk management decisions when they cannot or do not wish to rely on the decisions made by risk regulators. It also serves the certainty goal by providing consumers with information regarding those food attributes which they cannot see or are otherwise unable to judge for themselves.[179]

It must be recalled that the overall goal of the risk analysis process, with respect to the regulation of food, is to ensure the safety of consumers to the greatest degree that regulators can reasonably achieve. A necessary step in the risk analysis process is to make a risk

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[178] See section 3.2 and 4.1.1.
[179] This will be elaborated upon in Chapter 6.

management decision. Should the food in question be marketed freely, should it be banned outright, or should other regulatory steps, such as labelling, be applied? Given that there are some risks, or at least potential risks, inherent in foods produced by genetic modification, and that consumers may not be satisfied with the conclusions of risk assessors that a particular GM food does not pose a significant risk, it would seem that some risk management steps ought to be taken.

It would be difficult to argue that an outright ban on genetically modified products is warranted, nor is it within the scope of this thesis to make such an argument. Indeed, it would seem that there are many potential benefits of GM foods that should not be ignored, and might not be realized should a ban be implemented. Further, the risks of genetically modified foods are most likely risks only to susceptible individuals – for example, the possibility of increased allergenicity. Labelling is a compromise solution. It is both an effective risk communication technique and an effective risk management response by regulators to the potential risks of GM foods, yet does nothing to prevent producers and consumers from realizing the potential benefits.

However, there is not universal consensus that mandatory labelling is an effective middle ground in the dispute between proponents and detractors of GM foods. Accordingly, it is necessary to consider the various arguments for and against labelling before concluding that it is, in fact, an effective response in the circumstances. However, before considering those arguments, this chapter will review theories of risk analysis, and particularly risk communication, in an effort to develop an analytical framework for analyzing the pro and con arguments regarding labelling.

In practice, risk analysis with respect to GM foods in Canada is subject to common risk communication problems. Regulators and scientists tend to focus on the statistical estimates of risk in deciding what is acceptable. The public, on the other hand, is least accepting of risks which are uncontrollable, involuntary, catastrophic, and carry unclear benefits or

impose an inequitable distribution of risks and benefits, even when those risks are very unlikely to occur.[180]

Members of the public also believe that scientists and regulators don't pay attention to their concerns. As one risk communication expert describes this tension:

> Scientists and managers who study risk for a living are consistently irritated that the public seems to worry about the "wrong" risks, which is often true when mortality statistics are used as the standard. But rather than see this as a perceptual distortion on the part of the public, it is more useful and accurate to see it as an oversimplification on the part of the scientists and managers.
>
> In other words, the concept of risk means a lot more than mortality statistics. Let us take the classic definition of risk – how many people are how likely to incur how much damage if we do X – and call that "hazard." Hazard is what risk assessments are designed to estimate. Now, let us call everything else that goes into lay people's risk perceptions "outrage." Outrage is everything that is relevant about a risk except how likely it is to be harmful.
> ...
>
> Here, then, is the fundamental premise of my argument: Expert risk assessments ignore outrage and focus on hazard, but citizen risk assessments are more a product of outrage than of hazard. That is, we consistently underestimate the hazard of risks that are low-outrage and overestimate the hazard of risks that are high-outrage. We do this because we care about outrage.[181]

So the tensions in the process of risk regulation are that of the ostensibly objective, scientific method of risk assessment used by the regulators versus the public perception of risk, a perception considered by some to be deeply flawed.[182] However, a strong argument can be made that, in a democracy, individuals ought to be able to decide which risks they are willing

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[180] Covello, Vincent T. et al., "Principles and Guidelines for Improving Risk Communication" in Covello, *supra* note 60, 3 at 14.
[181] Sandman, Peter M., "Hazard versus Outrage in the Public Perception of Risk" in Covello, *supra* note 60, 45 at 45-46.
[182] See, for example, Benda, *supra* note 16, at 229.

to assume, no matter how small, and whether those risks are worth the benefits. Objectively, there is a distinction between risks that people take for their own benefit, such as driving their own vehicles, and risks which bring benefits primarily to others, such as toxic pollution from a nearby chemical plant. While the chemical plant may generate employment and products that are generally beneficial to society, the individuals living near the plant may not experience any direct benefit and yet carry a disproportionate level of risk. Moreover, they have no choice in the matter, but are forced to assume the risk.

The public attitude toward GM foods is a good illustration of this disjunction between those who will reap the benefits and those who are burdened with the risks. Without disputing that GM technology may offer great benefits to farmers throughout the world, there are potential health risks for consumers.[183] Moreover, the benefits of genetically modified foods are, at least currently, not benefits to consumers.[184] It is arguable that the primary beneficiaries of the first wave of GM crops are agricultural biotechnology corporations. For example, one of the GM crops being grown in Canada now is Roundup Ready canola, which is resistant to the effects of the patented pesticide known as Roundup.[185] This provides a built-in tie between the seed and pesticide, both of which are manufactured by the same large biotechnology company.

It would appear, then, that the potential benefits of biotechnology will, at least at present, accrue primarily to producers and agriculture industry players, while the potential health risks will be borne by consumers. This shifting of the risks away from the recipient of the benefits is one of the key factors likely to push members of the public toward viewing a risk as less acceptable. In the case of unlabelled and unidentified GM foods, the risks are shifted to consumers, and yet they are not even aware that they have assumed them. Yet industry

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[183] See section 2.2.1.
[184] Royal Society of Canada, *supra* note 2, at 21.
[185] Benda, *supra* note 16, at 252.

has some seemingly valid objections to mandatory labelling, which are considered at the end of this chapter.[186]

To analyze these arguments, it is helpful to consider some theoretical perspectives on the three aspects of risk analysis – assessment, management and communication. Section 5.1 examines some of the inherent problems in a scientific risk assessment, which show that even science is not completely objective. Section 5.2 introduces a theory of risk management emanating from the law and economics school of legal theory. The conclusions of this theory dovetail with risk communication theory, which is reviewed in section 5.3. Section 5.4 provides a summary of the arguments made by industry that there are no safety-related reasons to label GM foods. Finally, section 5.5 applies the theory to the objections and draws conclusions as to whether labelling of GM foods should be mandated to help accomplish the safety and certainty goals of food regulation.

5.1 Theoretical Views on Risk Assessment

For a scientist to determine whether GM foods are "substantially equivalent" to traditional varieties, and whether they pose significant or unacceptable risks, scientific methods must be followed. But who should make the decision as to whether a risk is significant or unacceptable? Can proponents, scientists or the government decide for individuals whether the risk of a particular GM food is worth the benefits? Regulators and industry tend to argue that any regulation must be science-based. But science, despite its empirical methods and quantitative analysis, is practiced by humans and can never be completely objective.

There are a variety of empirical techniques used for assessing the risk associated with a product or activity, depending on its nature. Scientists in various disciplines, such as engineering, toxicology and statistics, have developed standard methodologies for

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[186] See section 5.4.

quantifying risk.[187] However, the task of scientifically assessing risk is becoming increasingly difficult, described as follows by Alvin Weinberg:

> When the concerns were obvious – like smog in Los Angeles – science could and did give unequivocal answers. For example, smog comes from liquid hydrocarbons, and the answer to smog lay in controlling emissions of these substances. The regulator's course was rather straightforward because the science upon which the regulator based his judgment was operating well within its power. But when the concern was subtle – How much cancer is caused by 10 percent of background radiation? – science was being asked a question that lay beyond its power to answer; the question was trans-scientific. Yet the regulator, by law, was expected to regulate, even though science could hardly help in the process. This is the regulator's dilemma.[188]

Weinberg's article describes the difficulties faced by scientists in trying to determine the probability of an extremely rare event. While the likelihood of fairly common events across a large population, such as motor vehicle accidents or deaths due to smoking, can be ascertained simply by dividing the number of occurrences by the population at risk, the likelihood of an event like a nuclear accident cannot be estimated. It is similarly difficult to make an estimate with any degree of scientific certainty as to the likelihood of developing cancer from exposure to a low level of a particular toxin. Weinberg argues that designers of technologies can strive for perfect safety, but when this cannot be achieved without unreasonable expense, the best that science can offer is the setting of a *de minimis* standard, which is in itself an approximation rather than a highly accurate determination.

Scientists have developed a variety of predictive modelling approaches to this problem, relying on such qualitative tools as analogies, indirect inferences and professional judgment in order to develop key assumptions and gather data on actual incidences of the event

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[187] Hattis, Dale, "Scientific Uncertainties and How They Affect Risk Communication" in Covello, *supra* note 60, 117 at 117.

[188] Weinberg, Alvin M., "Science and Its Limits: The Regulator's Dilemma" in National Academy of Engineering, *Hazards: Technology and Fairness* (Washington, D.C.: National Academy Press, 1986) 9 at 9.

occurring.[189] Then, to assess risk, they must follow a chain of causation through a complex series of steps, including regulations in place, transportation, consumption habits, and cellular processes of metabolism and repair, in order to determine the likelihood of a particular event resulting in harm to a given number of people exposed to it.

The article by Dale Hattis argues that the biases and value preferences of the scientist performing the risk assessment inevitably creep into the process of developing assumptions. Certain heuristics, or mental shortcuts based on assumptions, can also lead to the use of assumptions that are based on anecdotal rather than quantitative data.[190] It is rare that the scientist can claim total objectivity. In effect, the risk assessor is making value choices on the public's behalf by discounting certain scenarios or probabilities as unimportant to the assessment, or by placing a greater emphasis on other aspects of the risk.

An example of the risk assessor's value judgments would be a failure to take into account a person's socio-economic or employment circumstances in quantifying the risk of contracting a disease from exposure to second-hand cigarette smoke. Suppose that the risk assessor had always lived and worked in areas where smoking was not permitted, and, as a result, never became aware of co-workers who were smokers. Further, he had never been to a bingo hall, a bar, or any other venue where smoking is permitted. Accordingly, it did not occur to him to consider workers in such venues who would be exposed to unusually high amounts of second-hand smoke compared to other workers in environments where smoking is banned. The assumption would be that people are not exposed to second-hand smoke in the workplace, but only in certain social situations. Clearly, this assumption would skew the results of his risk assessment relative to anyone working in a smoke-filled environment, and would not produce an accurate assessment of that person's risk.

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[189] Hattis, *supra* note 187, at 117.
[190] See section 5.2, *infra*, on how heuristics can impact the risk judgments of members of the public.

Such assumptions allow inaccuracies to creep into a risk assessment, but they can also be compounded by a failure to communicate the assumptions to the risk manager. Hattis makes the following recommendation:

> In each case, I would suggest that the general criteria the analyst should apply would be those of relevance for foreseeable decisions the audience might wish to make based on the risk information. If it seems reasonably likely that more accurate information of a particular type or on a particular topic could influence the choice of risk control options, then the analyst should seek to provide that type of information as part of the analysis. If the analyst knows of a category of information that would have a good chance to influence choices (if it were available) but that cannot be provided, that fact should be disclosed. Otherwise the analysis in its incomplete form may be given more weight than it should in decision-making. In this way, the analyst can help avoid what Holdren accurately cites as a tendency to "confuse things that are countable with the things that count."[191]

Of course the difficulty with this idea of effective communication is that many of the assumptions and value-preferences in a risk assessment are based on biases held by or inherent in the thinking of the risk assessor. Accordingly, they are probably not consciously considered and so are not likely to be communicated.

These concerns are noted by the Royal Society of Canada in its report. The Royal Society explicitly acknowledges that, even at the level of risk assessment, the issues are not entirely scientific.[192] The report notes that there are scientific disagreements about the types and degrees of risk to human health associated with GM foods. It also notes the existence of political disagreements about social and economic impacts and, further, religious, ethical and philosophical disagreements about the use of biotechnology. The report goes on to say that proponents of GM foods tend to argue that issues as to risk fall entirely into the first

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[191] Hattis, *supra* note 187, at 122. Note that Hattis uses the terms "analysis" and "analyst" to describe the scientific risk assessment process and the risk assessor.
[192] Royal Society of Canada, *supra* note 2, at 7 et seq.

category, that of scientific inquiry, and that the other two categories are aspects of the debate that do not involve actual risk assessment. However, the Royal Society report states:

> The Panel does not accept the common classification of the issues in the biotechnology debate because of its implication that the questions put to it in the Terms of Reference – having to do with the identification of potential risks to human, animal and environmental health – are purely questions of science. There is no doubt that questions about the potential hazards inherent in the products of agricultural biotechnology and the mechanisms for assessing the magnitude of the health risks they pose are primarily scientific, requiring the very best scientific methods and expertise for their resolution. But they are not purely scientific. It is now generally recognized in the scholarly literature on the nature of risk analysis that many aspects of the task of assessing the magnitude of technological risks and managing them within the limits of safety involve judgment and decisions that are not themselves strictly scientific.
> ...
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> They involve value judgments related to such issues as the appropriate way to handle uncertainties in scientific data and results, assignment of the burden of proof among stakeholders in risk issues, standards of proof, definition of the scope of the risk issue (e.g. should human error be considered part of the risk of the technology?), and, of course, the central issue, already noted, of what levels of risk should be considered "acceptable". Such "extra-scientific" judgments are inherent in any assessment of risk and in the judgments about the technological and social mechanisms for maintaining it within safe limits. Similar judgments are involved in any attempt to predict future scientific and technological developments, which are always at least partially dependent upon human choices and other undetermined variables.[193]

The Royal Society goes on to explain that these extra-scientific issues in risk assessment require expertise from the "normative" disciplines of law, philosophy and ethics, which is why the Panel included specialists in these areas in addition to members with scientific expertise, who form the vast majority of the panel. The Panel further notes that the term "safety" itself must involve a consideration of the acceptability of risks, which ventures into the socio-economic and philosophical areas:

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[193] *Ibid.* at 8. Note the discussion of burden of proof, an expression of the precautionary principle.

> ... Many experts argue that the "safety" (acceptability of the risks) of these technologies depends upon whether the risks, whatever they may be, are outweighed by the overriding benefits they achieve. This "risk-cost benefit" approach to safety is only one among many safety standards that can be invoked by risk regulators. It tends to function as a less restrictive standard of safety, insofar as it permits, in principle, any level of risk as long as there are off-setting benefits. There are many other types of standards commonly advocated as well, including various "threshold" standards, procedural standards, and even "zero-risk", which are usually more restrictive, or conservative.[194]

Accordingly, the idea that the assessment of risk is not a strictly scientific endeavour, or in other words, a strictly objective endeavour, is shared by at least some scientists with expertise in this area. This perspective is important to note because the primary argument of proponents against mandatory labelling is that the scientific risk assessment indicates that GM foods are "safe" and accordingly do not need to be labelled.[195]

5.2 A Theory of Risk Management

Cass Sunstein and Timur Kuran, in a recent paper, have developed a theory of risk management that begins with law and economics theory but draws on sociological and cognitive theory to help explain the behaviour of individuals with respect to information.[196] Sunstein is part of a movement within the law and economics school of legal theory that calls itself the "New Chicago School." While law and economics generally accepts the public choice theory of regulatory policy, viewing politics as a market, the New Chicago School identifies social norms as a profound influence on behaviour and therefore on the law. In this

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[194] *Ibid.* at 5. Note the use of the term "risk regulation" to describe the process of risk management.
[195] This argument is discussed in more detail in section 5.4.4.
[196] Sunstein, Cass R. and Timur Kuran, "Availability Cascades and Risk Regulation" (1999), 51 Stanford L. Rev. 683. Sunstein has further developed this theory in his book, *Risk and Reason: Safety, Law, and the Environment* (Cambridge, U.K.: Cambridge University Press, 2002). Note that Sunstein and Kuran use "risk regulation" to describe risk management.

context, Sunstein argues that social mechanisms impact risk regulators and influence the drafting of legislation. The results range from "inconsistent health regulations to mass anxiety about foods with no scientifically confirmed health hazards." He also argues that these mechanisms affect legislators, administrative agencies and courts in such a way as to help shape the law in this area.[197]

5.2.1 Availability Heuristics and Cascades

As discussed in section 5.1, scientists and risk assessors use certain mental shortcuts, known as heuristics, in the risk assessment process. Sunstein and Kuran also consider cognitive heuristics in their paper, but in the context of how members of the public use mental shortcuts to assess risks and reach conclusions that are often inaccurate from a scientific or statistical perspective.[198] While Hattis suggests that value judgments should not be made for people, Sunstein discusses how the availability heuristic causes people to misestimate actual risks and to base their own risk judgments on erroneous information that they have obtained from other laypeople, as opposed to objective, expert information.

The availability heuristic is an effect which causes people to associate the likelihood of a risk occurring with the ease with which they can bring to mind incidents of the risk occurring.[199] In other words, the more available the risk is to the mind, the greater the perception of risk. According to Sunstein and Kuran, individuals pass on this misperception to others who lack concrete scientific information on the actual probability of the risk, resulting in a cascade, or bandwagon effect. This cascade is known as an availability cascade because, as individuals pass on their misperception to others, more and more people can bring the risk easily to mind, causing them to believe that it is more likely to occur than other risks.

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[197] Sunstein and Kuran, *ibid.* at 685.
[198] *Ibid.*
[199] *Ibid.* at 685-687.

To illustrate this point, consider an example – an individual who has numerous friends and acquaintances who have experienced or have recounted stories of people who have experienced a particular form of cancer, such as a cancer of the lymph nodes. If these stories are related to the individual along with anecdotal information as to something that the victims of the cancer have in common, such as a common water source, these two facts may become associated in the individual's mind, such that the individual, and those telling the stories, infer a causal relationship between the water source and the cancer. In the absence of any scientific information to the contrary, these individuals may all develop a strong belief that the water causes the cancer, and that there is a high risk of developing cancer for anyone who uses this particular water source.

Of course, the scientific reality may be quite different. There may be some other common causal factor, or it may be simply coincidence. Nonetheless, a cascade will have occurred among all of the individuals who share this information, causing all of them to develop a misperception as to the risks associated with the water source in question. Further, the number of stories related to the individual will make the risk of that water source more prominent in his mind, or more available, causing him to perceive a heightened level of risk of developing cancer from exposure to a dangerous water source.

This example further illustrates one of the prime components of an availability cascade, as formulated by the authors – an informational cascade.[200] This occurs when a large group of people who lack expert information are willing to base their beliefs on the information they receive from other non-experts. A further component is a reputational cascade, made up of individuals who do not accept the popular view of the severity of the risk but who nonetheless manifest agreement with the popular sentiment in order to safeguard their social reputations.[201] This phenomenon is also referred to as preference falsification. In our example, certain individuals sharing the information about the lymph node cancer and the

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[200] *Ibid.*
[201] *Ibid.*

water source might not believe that there is a causal relationship between the two, but might nonetheless act as though they believe it in order to be accepted by the other individuals. In other words, peer pressure can influence not only people's opinions, but also their willingness to express contrary opinions.

The authors point out that availability cascades can have a positive impact on risk regulation, as they may bring a genuine concern to the forefront of public attention, and may even stimulate needed regulatory action.[202] So, in the example, if there really was a causal relationship between the water source and the lymph node cancer, the informational cascade would be likely to bring some public attention and pressure on regulators to address the problem. However, the thesis of the article is that cascades which are based on misinformation can be extremely harmful as they create the same pressure on regulators but without good reason. The regulators then bow to the pressure due to reputational concerns and falsify their own preferences, resulting in large expenditures for relatively small gains in terms of lives saved.[203]

Thus the outrage factor described above[204] may in fact lead to disproportionate regulatory responses when the outrage is based on inaccurate information. The authors provide several examples of public outrage that was out of proportion to the risk and that created anxiety and panic that may in fact have been more harmful than the impugned risk.[205] An example is the 1989 uproar over the alleged carcinogenic properties of Alar, a pesticide used on apples. Although the US Environmental Protection Agency determined that media reports of the risk had been greatly exaggerated, public panic was such that apples were shunned by the public, removed from stores and banned in many school lunchrooms. Finally Alar was withdrawn from the market. The obvious downside to the hysteria was a loss of some $125 million to the industry in six months, not to mention the loss of a nutritious fruit from the diets of

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[202] *Ibid.* at 688. The case of BSE, discussed *infra* at section 5.3, is a good example.
[203] *Ibid.*
[204] See section 5.0.
[205] *Ibid.* at 698-700.

millions of Americans.[206] Although Sunstein and Kuran acknowledge that public concern about safety issues can push government to recognize a risk that it would otherwise ignore, their emphasis is firmly on the economic costs of exaggerating risk that can result from the social impacts of communication about risk among members of the general public.

5.2.2 Social Impacts on Risk Management

The authors draw several conclusions from case studies and from sociological and cognitive science perspectives. First, they suggest that it is perfectly legitimate and, in fact, desirable for a democratic government to "question the private risk judgments and preferences that underlie people's public communications on matters relating to risks."[207] This view is justified by the probable existence of availability errors and preference falsification. The authors argue further that availability cascades aggravate the cognitive biases inherent in people's private risk judgments, leading to serious consequences for regulatory policy.[208] As a result, "public discourse on any given risk may produce scientifically unnecessary, ineffective, even counterproductive policies."[209] Finally, even though availability cascades eventually run their course, they can create a lasting belief over a wide segment of the population in an erroneous assessment of the risk in question.[210] This in turn results in uncoordinated law dealing with risk issues, both within nations and in the international community.[211]

These conclusions might appear to suggest that telling the public too much about risk issues is a bad idea. However, Sunstein and Kuran suggest that the solution is to ensure that accurate information reaches the public as soon as possible. The authors offer a series of

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[206] *Ibid.* at 688.
[207] *Ibid.* at 738.
[208] *Ibid.* at 741.
[209] *Ibid.* at 742.
[210] *Ibid.* at 743.
[211] *Ibid.* at 744-745.

suggestions for institutional reforms which would be likely to stem the tide of availability cascades before they reach a level at which the provision of more accurate information will not reverse the public attitude about the perceived risk. The goals cited by the authors in undertaking such reforms are to strengthen the role of science and to attain "comprehensive rationality" in risk regulation.[212] It should be noted that these goals are somewhat different from the goals of food regulation that have been identified in this thesis – safety and certainty.

5.2.3 Regulatory and Institutional Reforms

One of the reforms suggested by Sunstein and Kuran is to introduce product defamation legislation to prevent damage to industry by the spreading of false allegations and rumours about alleged dangers lurking in their products.[213] The authors acknowledge that such legislation would have to be balanced to prevent frivolous lawsuits being used to suppress information about genuine product hazards. To attenuate such dangers the authors suggest strict rules on costs and a clear demarcation between intentional falsehoods and legitimate expressions of "hyperbole, doubt and concern."

The authors next turn to reforms in the structure of government. Many of these ideas apply specifically to the US federal government with its division between the executive and the legislative branches of government. However, the ideas can be summarized as suggesting the institution of an administrative body to oversee risk management, based on a type of cost-benefit analysis and using peer review to verify the scientific information on which the body relies in making its risk management decisions.[214] Another important recommendation is the use of the world wide web to disseminate information widely and quickly and to allow people to draw their own conclusions on a risk issue. The authors argue that this would "help

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[212] *Ibid.* at 748.
[213] *Ibid.* at 749-751.
[214] *Ibid.* at 752-754.

individuals form their risk preferences and judgments more rationally than is currently possible."[215] Finally, the authors advocate that courts adopt a doctrine which requires regulators "to demonstrate that their policies on risk regulation would plausibly make things better rather than worse, taking account of all relevant variables."[216] This idea answers the authors' concern that many risk decisions end up worsening overall risk factors by putting too much money into the control of relatively small risks.

The thrust of this article is in preventing unreasonable regulatory responses to risks that are not significant or unacceptable. In other words, it is directed at ways for government to avoid public panic about risks that are more imaginary than real. However, the article makes two points that support mandatory labelling. One is that regulatory responses are appropriate where the risks are real. The risks of GM foods are certainly real, but there is scientific disagreement as to the degree of risk and the likelihood of occurrence. Therefore it is arguable that a reasonable regulatory response would be a middle ground response – not a total ban on GM foods nor unfettered distribution of them, but the provision of sufficient information to members of the public to allow them to choose whether to assume the risks.

The second point is that wide dissemination of accurate information is essential to avoiding availability cascades that result in widespread misinformation. Given the concerns raised by the Royal Society and others about the lack of transparency in Health Canada's risk assessment process,[217] Sunstein and Kuran's thesis supports opening up the data and other information on which the agency relies in making its decisions. Short of this, at least the labelling of GM foods would go some way to reassuring members of the public that they need not panic, because they are at least being informed of the nature of what they are consuming. Further support for labelling as an effective form of risk communication, and

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[215] *Ibid.* at 756.
[216] *Ibid.* at 759.
[217] *Supra* note 169.

therefore a good middle ground among the regulatory options that could be used to address the unknown risks of GM foods, can be found in risk communication theory.

5.3 Risk Communication

As suggested by Sunstein and Kuran, too little information about risks can be more damaging than too much. Principles drawn from the field of risk communication lead to similar conclusions. To illustrate the dangers of too little risk communication, Powell and Leiss present a volume of case studies on risk communication gone wrong.[218]

Probably the most well-known example is the 1990s outbreak in the United Kingdom of bovine spongiform encephalopathy ("BSE"), more popularly known as mad cow disease. According to Powell and Leiss, risk communication experts, science has now established the likelihood of a connection between the appearance of BSE in a cow and the contraction of Creutzfeld-Jacob Disease ("CJD") in humans who have consumed meat from the diseased cow. Although the vector of the disease between cows and humans has not been conclusively identified, experts now agree that there is a connection. However, the government in the United Kingdom spent years telling the public that there was "no danger" in consuming British beef, despite the fact that they had some evidence that the two diseases might be connected.[219] The authors argue that the damage done to the beef industry in the United Kingdom in the wake of the scare about mad cow disease resulted largely from the failure of the government to reveal to the public that there was some scientific data indicating cause for concern.[220] This failure extended to a failure to effectively regulate the risk and resulted in a loss of trust on the part of the people in what their government was doing to protect them from a risk they considered unacceptable.

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[218] Powell, Douglas and Leiss, William, *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication* (Montreal & Kingston, McGill-Queen's University Press, 1997).
[219] *Ibid.* at 11.
[220] *Ibid.* at 3-16.

Powell and Leiss identify ten lessons to be taken from their examples of poor risk communication practice.[221] These can be summarized as follows:

1. A risk information vacuum is a primary factor in the social amplification of risk.
2. Regulators are responsible for effective risk communication.
3. Industry is responsible for effective risk communication.
4. If you are responsible, act early and often.
5. There is always more to a risk issue than what science says.
6. Always put the science in a policy context.
7. "Educating the public" about science is no substitute for good risk communication practice.
8. Banish "no risk" messages.
9. Risk messages should address directly the "contest of opinion" in society.
10. Communicating well has benefits for good risk management.

These ten lessons, and the discussion of Powell and Leiss regarding risk communication theory in general, can be summarized in terms of a few broad principles, which are arguably applicable throughout the risk analysis process. These principles are:

1. Industry and regulators must establish a relationship of trust with the public;
2. The availability of accurate information is critical to good risk communication; and
3. The risk assessment based on science must always be balanced with other policy considerations.

The following sections elaborate upon these three principles.

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[221] *Ibid.* at 214 et seq.

5.3.1 Principles of Risk Communication

(a) Trust

Perhaps the most important of these broad principles is trust. The public will not accept the risk message of a regulatory body or industry that it does not trust. As in law and politics, both regulators and industry must ensure that there is no appearance of collusion and no perception that the primary interest of the regulator is to smooth the path for industry at the expense of full risk analysis. As well, information must not be withheld – its later appearance will only undermine the trust relationship. The best way to establish trust is through a transparent process with plenty of consultation and feedback, and with a regulatory structure that emphasizes the independence of the regulators from any specific policy agenda.

Trust can be compromised if the employer of the scientist conducting the risk assessment is a proponent of the product whose risks are being assessed. The data of a scientist will be questioned if he receives funding from industry groups that stand to make large profits from favourable studies.[222]

Structural issues in the regulatory system may affect how much trust the public is willing to place in the government. There is also the issue of one branch of the government aiding in the development of technology (e.g. Industry Canada supporting biotechnological initiatives) and of the watchdogs (CFIA) falling within a government department whose mandate is industry-related (Agriculture Canada).

Both regulators and industry must take responsibility for establishing the necessary relationship of trust with the public. Often laypeople perceive that industry is driving the

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[222] As an aside, this argument can cut both ways. Data from scientists who question the industry research is often dismissed by proponents as unsound, even as "junk science."

technological agenda and that the role of government is simply to facilitate that development. So even when regulators provide the risk messages, the public may perceive that they are doing so more for the benefit of industry than for consumers. This perception can best be countered by early and frequent dissemination of accurate information, as discussed below.

(b) Availability of Information

Another broad principle, drawn from both the cognitive and social theory discussed in section 5.2 and from the principles of risk communication, is that a lack of accurate information creates significant barriers to public acceptance of government risk analysis. Powell and Leiss discuss the concept of risk information vacuums, which is not unlike Sunstein's theory on the absence of accurate information contributing to cascade effects. Powell and Leiss argue that there will always be a gap between the scientific understanding of risk and the public perception of risk, but that the greatest consequences for institutions and the public arise from what occurs in the gap when a public policy response is required:

> The risk information vacuum arises where, over a long period of time, those who are conducting the evolving scientific research and assessments for high-profile risks make no special effort to communicate the results being obtained regularly and effectively to the public. Instead, partial scientific information dribbles out here and there and is interpreted in apparently conflicting ways, mixed with people's fears. In this connection the main theses of our book are, first, that failure to implement good risk communication practices gives rise to a risk information vacuum; and second, that this failing can have grave and expensive consequences for those who are regarded as being responsible for protecting the public's interests.[223]

The linkages between Sunstein's conclusions and the principles of good risk communication are apparent in the following comment from Powell and Leiss on why a risk information vacuum creates risk management problems:

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[223] Powell and Leiss, *supra* note 218, at 30-31.

> Risk communication failures can initiate a cascade of events that exacerbate risk controversies and render risk issues difficult to manage. At the core of all risk issues there are problematic aspects – lack of timely information, uncertainties in the risk estimates, lack of trust, lack of credibility, complexity of the scientific descriptions, and so forth – which breed apprehensiveness, suspicion, and concern over personal safety among the public. In a risk information vacuum, this latent apprehensiveness, suspicion, and concern feeds upon itself and, in the absence of the dampening effect that good risk communication practices might supply, may be amplified to the point where credible and pertinent information makes no difference in the formation of popular opinion.[224]

(c) Science

Finally, one can detect a broad principle relating to the use of science in the formation of public policy. Like Sandman and Hattis,[225] Powell and Leiss argue that there is more to risk decisions than the science. Even very low risks are often rated by the public as unacceptable, such as deaths due to terrorism.[226] Regulators have a similar role to risk communicators in that they must bridge the gap between science and democratic concerns to formulate policy that is effective, can be applied well and is accessible to the public. This also relates to the idea that there should not be "no risk" messages and that the differences between scientific opinion and public opinion should be addressed directly.

To address these differences, regulators need to work at the provision of information that explains what scientific assessments are being done and how they are being done. The public should also be given opportunities to provide feedback and express concern over the way risk assessments are conducted. Some might argue for legislative requirements that risk assessment be done in a specific way, but this would probably be too inflexible and unresponsive to developments in the science of risk assessment over time. Regulators should

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[224] *Ibid.* at 214.
[225] Quoted above in sections 5.0 and 5.1 respectively.
[226] Covello, *supra* note 180.

be motivated to keep the public well-informed if for no other reason than to ensure that lobbyists do not begin campaigning for such legislative restrictions.

5.3.2 Application of the Principles to the Regulation of GM Foods

The Royal Society of Canada expresses strong concerns about several issues that are contemplated in the foregoing principles.[227] The Panel identifies, for example, the potential for regulatory conflict of interest, in that the government has official policies that endeavour both to support a viable biotechnology industry and to protect the public from potential health hazards. Further, the Panel is concerned that the test data submitted by proponents of new GM foods is kept confidential, as proprietary information, which makes it more difficult for the public to scrutinize the risk assessment decisions that are made. Further, the Panel supports the idea of arm's-length, peer review of the scientific assessments made by the proponents. Finally, the Panel decries the "co-opting of biotechnology science by commercial interest" which contributes to the "erosion of public confidence in the objectivity and independence of the science behind the regulation of food biotechnology."

The recommendations of the Panel in this regard include the following: that regulators be very careful to maintain an objective and neutral stance with respect to the risks and benefits of biotechnology; that public transparency of the scientific data upon which regulatory decisions are based be increased; that regular peer review of the risk assessments be implemented; and that the Canadian Biotechnology Advisory Commission review issues surrounding the increasing "domination of the public research agenda by private, commercial interests, and make recommendations for public policies that promote and protect fully independent research on the health and environmental risks of agricultural biotechnology."[228]

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[227] Royal Society of Canada, *supra* note 2, at 211 et seq.
[228] *Ibid.* at 218.

The above concerns would suggest that the principles of effective risk communication may not be adequately applied in the risk analysis process used by Canadian regulators with respect to GM food. The next section makes the argument that the system as it currently operates does not use effective risk communication practices and that all stakeholders would benefit from improvements in these practices.

5.4 Risk Analysis and the Arguments for and against Mandatory Labelling

Although this chapter, and this thesis in general, has considered perceived flaws in the risk assessment and risk management strategies of the CFIA and Health Canada, the focus of the thesis remains on the mandatory labelling of GM foods. Accordingly, no specific recommendations will be made with respect to the risk assessment step. It is noteworthy, though, that the risk assessment process inevitably includes some subjective elements, which adds to the argument that mandatory labelling ought to be imposed upon GM foods. Labelling is seen here as both a risk management step, in that it should be mandatory, and therefore managed by regulators, and a risk communication step. The justification for labelling as an aspect of risk management is the fact that concerns have been raised with respect to the risk assessment step, but not concerns that warrant a ban on GM products. It is also justifiable as a risk communication step, in keeping with the principles of trust, full information, and recognition that risk analysis should always consider values beyond scientific considerations.

As in any risk analysis, risk communication with all interested parties should be undertaken. The question is whether mandatory labelling is the best means of communicating the risks associated with GM foods. Health Canada has already implemented some risk communication strategies, including the release of decision documents. However, these general steps do not communicate the fact that a particular product contains GM ingredients. How can the risk associated with GM ingredients be communicated to consumers if they are not advised that the product they are purchasing contains such ingredients?

Proponents of GM foods would argue that the risk assessment process, being a review by Health Canada of data supplied by the proponents, is sufficient to assure regulators and the public that there are no risks associated with GM foods that are any greater than those associated with traditional varieties.[229] According to this line of reasoning, there are no risks that warrant the step of alerting consumers to the presence of GM foods in every individual product that contains them. Indeed, meeting the standards set by experts and international regulators, in particular the Codex Guidelines, supports the contention that the risk assessment process applied in Canada is sufficient to assure the public that GM foods are "safe."

But given the comments made by Clark, by Hattis, and by the Royal Society of Canada,[230] it would not be unreasonable for consumers to conclude that the assumptions in the scientific risk assessment process represent decisions about the safety of GM foods that were made by scientists on behalf of consumers, but without consulting them. As discussed, the public perception of risk is an important factor in successful risk regulation, as a lack of public acceptance can lead to serious consequences for industry, regulators and the general population. Therefore, all stakeholders should benefit if the transparency of the risk assessment process is improved by ensuring that uncertainties and judgments made in the risk assessment process are adequately communicated to the public.

Risk communication is not just about the communication of data, or the communication of the conclusion reached by regulators that a product is safe. It is about assuring consumers that regulators feel confident about the product, as do the proponents – so confident that they do not feel the need to keep secrets from the consumers. They are prepared to provide the consumers with all pertinent data, including the fact that there is some risk in these novel products, however remote, and allow consumers to decide if the risk is a concern to them.

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[229] Benda, supra note 16, at 402-405.
[230] In sections 4.2.2 and 5.1.

This recognizes the fact that those with food allergies may not be satisfied with assurances that GM products that have been approved have not been modified with genes from any known allergen, or that any new proteins or other compounds do not show structural similarities to any known allergens or toxins. People with severe allergies may prefer to avoid GM products altogether, because they do not feel there is any benefit to them, while the risk is high because no one can guarantee that an allergen won't appear in a food modified with genes from an organism that was not previously a part of the human food supply.

Effective risk communication, then, is about assuring people that proponents and regulators have nothing to hide. This is even more important where the structure of the regulatory system and the methods of risk analysis suggest that there may be conflicts of interest in that process.

Most risk regulation decisions, at least those of a day-to-day nature, are made by regulators without a great deal of public input. For example, when decisions are made as to the safe level of chemicals in water or food, regulators look at the objective data gathered by scientists, analyze it and determine the safe level.[231] However, many decisions require public input. When decisions are made as to overall policy, such as the desirability of nuclear power over more conventional sources of power, democratic ideals require that the public have a say.

It is clear that individual members of the public cannot, in practical terms, have direct involvement in all of the risk regulation decisions made by the CFIA and Health Canada. This is where the importance of risk communication comes to the forefront. The public may be more comfortable with risk decisions being made for them if they at least understand or

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[231] Note that per the conclusions of Hattis as discussed in section 5.1 and Clark in section 4.2.2, even the data used to determine safe levels could be considered not entirely objective, as they are undoubtedly arrived at after a series of assumptions have been made. For example, assumptions would be made as to the size and weight of a typical person consuming the water and as to their exposure to the same chemicals from other sources.

have access to knowledge about how risk decisions are made. According to Powell and Leiss, the primary goal of risk communication is to break down the barriers to communication between risk assessment experts, who speak the language of science and deal with uncertainties, and the public, most of whom hold fundamentally different ideas about what makes risk significant or unacceptable.[232]

There are no legislative or regulatory requirements for particular risk communication practises in this area. However, it is submitted that regulators need to establish effective risk communication practises in order to assure the public that their health is being effectively safeguarded without undermining truly beneficial technological developments. The goals of risk regulation should be to protect members of the public from risks beyond their knowledge and, to the greatest extent possible, to allow them to decide for themselves what level of risk is acceptable and whether the potential benefits warrant taking that risk.

This brings us back to mandatory labelling as the best risk communication solution, and the best risk management solution, to ensure that the safety and certainty goals of food regulation in Canada are being fulfilled. There are several arguments involving the risk analysis system that can be used to support or oppose mandatory labelling. The primary arguments are summarized below.

5.4.1 Conflicts of Interest in the Risk Assessment Process

The oft-repeated claims of proponents are that GM foods have been judged safe by regulators. But even scientists are concerned about the fact that regulators have arrived at those conclusions almost exclusively by reviewing data provided by scientists employed by

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[232] Powell and Leiss, *supra* note 218, at 29.

the proponents of GM foods.[233] Most objective observers would agree that this appears to be a case of the proverbial fox guarding the hen house.

Further, the CFIA and Health Canada websites make much of the potential benefits of GM foods without devoting much space to the potential risks.[234] This creates the impression that studies which don't agree with industry data are not given equal treatment but rather refuted. For example, Health Canada's response to the paper by Clark questions her methods.[235] It should also be noted that the paper by Clark[236] raises concerns about the fact that the studies on which Health Canada relies are not published in any recognized medical journal, which indicates that peer review, a necessary element for the publication of a scientific study, is currently not undertaken with the data provided by industry. This concern is echoed by the Royal Society.[237]

The reliance on data that is not peer-reviewed and is provided by scientists with a vested interest in the approval of the product raises the appearance of a conflict of interest. Part of the problem may be a lack of research being done at public institutions to challenge or validate the data collected by industry.[238] The new trend toward privatization of public scientific research is a matter of great concern to many scientists. There has been a growing collaboration between private sector biotechnology corporations and publicly funded research institutions. As a result, the private sector has an ever-increasing level of control over what research will be conducted. The need for increased market share often drives the research agenda. Long-term research, for example on the chronic effects of a GM food, is often reduced.[239]

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[233] Royal Society of Canada, *supra* note 2, at 214-215; Canadian Biotechnology Advisory Committee, *supra* note 43, at 19-22.
[234] Various documents, CFIA website, *supra* note 62.
[235] *Supra* note 163.
[236] *Supra* note 172.
[237] Supra note 2, at 211 et seq.
[238] This is another concern raised by the Royal Society of Canada, *ibid.* at 215 et seq.
[239] Busch, *supra* note 35, at 208-212.

For regulators to assess the risk associated with a product, whether the product should be made available, and whether it needs to carry any warning on the label, they must have access to appropriate testing data. In the interests of regulatory transparency, the data should be obtained from independent sources that do not stand to benefit from the marketing of the product. Without suggesting that there is any dishonesty on the part of scientists who conduct these tests, it is nonetheless fair to question how they go about assessing the products, what assumptions they make in the process and how much testing they conclude must be done in order to satisfy themselves that the product is safe.

If the system will not, or cannot, be structured in a way that reflects these concerns and removes all possible conflicts of interest, this is an argument in favour of mandatory labelling. What better way is there to address this problem than to allow consumers to make the decisions for themselves? This is only possible if GM foods are required to be labelled in some way so that they can be identified by consumers as products of genetic modification.

5.4.2 Scientific Flaws in the Risk Assessment Process

The Clark paper[240] further criticizes the fact that the decision documents made available to the public by Health Canada do not provide sufficient detail on how risk assessments are conducted. Certainly some assumptions are identified, such as the reliance on structural homology to identify potential toxins, but may not be justifiable if Clark's criticisms are widely accepted.

Further, it appears that the risk assessment procedure is based on an assumption that transgenes will only produce certain proteins in the novel food and that only those proteins need be examined.[241] Moreover, there is an assumption that those proteins are safe if they

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[240] *Supra* note 172.
[241] See discussion in section 4.2.2.

are not homologous to any known toxin or allergen. Finally, there is an assumption that if the proteins and, by extension, the foods are found not to be toxic or allergenic on an acute scale, there is no concern about the potential for long-term harmful effects. There is certainly evidence that these assumptions are not necessarily warranted.[242]

Again, the argument is that the risk assessment process is not adequate, so consumers must be advised when they are purchasing GM foods, by way of labels, so that they can choose for themselves whether to assume the risks.

5.4.3 Cost/Benefit Analysis

Once the science can be considered complete and reliable, risk regulators must consider not only the scientific data but also the other reasonable concerns of individuals who will be exposed to the risk. If regulators are evaluating risk on the basis of a cost/benefit analysis, they should consider such questions as whether the risks and benefits are fairly distributed, or perhaps borne by completely different parties. In the end, regulators must recognize, and in fact are usually the first to admit, that no matter how thorough the science, they cannot guarantee zero risk and they should not claim that they can do so.

Moreover, when regulators come to a conclusion as to whether a risk is acceptable, they tend to forget that any risk assessment or risk management decision is subject to some bias on the part of the assessor or regulator, simply because these decision-makers are human beings. Accordingly, there must be allowance made for consumers to make their own decisions as to whether the risk is worth taking. They cannot make this decision if they are not even aware that they are taking the risk because they are unaware that they are consuming the product in question. Therefore effective risk communication is essential.

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[242] Royal Society of Canada, *supra* note 2, at 48, 61 and 184-185.

5.4.4 Implication of Undue Risk

One of the arguments against mandatory labelling is that a GM label would be viewed by consumers as a warning and discourage people from buying the product. In a paper on the American regulatory scheme and the resistance to mandatory labelling, Michael Whittaker discusses consumer perceptions of the risks of GM foods and points out that the primary policy goal in the introduction of food labelling requirements is to ensure the "communication of essential information to enable consumers to choose foods more wisely."[243] He states that labelling of GM foods is a tool which should be used to educate consumers as to the risks and benefits of these foods.

Whittaker acknowledges that the average consumer is likely to overreact to the level of risk inherent in GM foods, but asserts that consumer confidence in biotechnologies such as genetic modification will in fact be increased through open communication and prudent education.[244] Whittaker also points out that consumer skepticism is growing and could best be eased by providing labelling and full information. Without this, he argues, there is a real risk that the benefits of GM technologies could be lost. Again, effective risk communication is beneficial not only to consumers but, in the long run, producers as well.

In another article, Lara Beth Winn considers the concerns of biotech food producers that labelling will trigger consumer fear and will cause consumers to avoid their products for unsound reasons.[245] She suggests, like Whittaker, that labelling could be seen as an opportunity to provide more detailed information to consumers and to educate the public as to the relative safety of these products. She argues, quite persuasively, that consumer fear

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[243] Whittaker, *supra* note 37, at 1223.
[244] *Ibid.* at 1224.
[245] Winn, L.B., "Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks used by FDA and Food Producers?" (1999) 54 Food & Drug L.J. 667 at 682-683.

does not justify the decision not to require labels, and says that the burden of any negative reaction should fall on the industry. She concludes the issue by saying:

> It is in the best interest of manufacturers to convince consumers of the value of their products. This generally is how the market works; manufacturers develop a product and convince consumers to buy that product. The correct response, therefore, to a negative reaction to special labelling, is not for FDA to withhold labelling requirements. Instead, the correct response is to make manufacturers responsible for educating consumers, allaying their fears, and instilling their confidence in biotech food.[246]

It is clearly arguable that proponents would in fact benefit as much as consumers from the provision of adequate information by way of mandatory labelling. Any concern among the segment of the population that is worried about the risks of GM foods would become the responsibility of those individuals.

Nonetheless, there is an argument to be made that a mandatory label appearing in the form of a warning label would create the impression that the risks of GM foods are significant. To address this concern, this thesis will recommend that mandatory labelling be addressed in the context of ingredient labelling for pre-packaged foods, which are the primary foods containing GM ingredients at this time.

5.5 Conclusion

The theoretical perspectives on risk analysis confirm that it is vital for risk assessors and risk managers to communicate effectively with each other and with those who will bear the risks. This is not only to protect those subjected to the risks, in this case consumers, but also to protect producers and regulators from misperception of the actual risks. In the case of risk communication via labelling, the goal of allowing consumers to choose food products based

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[246] *Ibid.* at 683.

on attributes that they are unable to judge without further information allows the market to decide which products the consumers are willing to accept; in other words, which risks they are willing to bear. Thus the principle of full information to consumers in a free market supports mandatory labelling.

Labelling also addresses the concerns brought up with respect to the clash between scientific risk assessment and risk analysis that incorporates value judgments and other factors considered important by consumers. In other words, if consumers do not consider the benefits of GM food to outweigh what they perceive the risks to be, labelling allows them the option of choosing not to consume GM foods. From the point of view of proponents of GM foods, there are ample opportunities to communicate their views as to why their GM products are "safe" and beneficial.

Further, labelling addresses the three principles of risk communication summarized above in section 5.3. Labelling of GM foods is an exercise in increasing transparency in the regulation of these products; it is an effort to acknowledge that science is not the only consideration in risk assessment and risk management; and it is an attempt to provide more information. Finally, publicly acknowledging that foods are genetically modified is likely to have a positive effect on the trust level of consumers.

It is submitted, therefore, that the principles of effective risk analysis are a sound basis for achieving both the safety and certainty goals of food regulation. Further, the arguments against labelling in the context of risk analysis principles are not particularly persuasive. However, proponents also make economic arguments against the imposition of mandatory labelling. Chapter 6 summarizes theoretical perspectives on the economic aspects of labelling, and then considers the economic arguments for and against mandatory labelling.

Chapter 6 – Labelling Theory and Economic Issues

6.0 Introduction

The policy goals of food regulation have been an important consideration throughout this thesis. As several commentators have noted, the purpose of regulation is to protect the public interest. The public interest is, of course, multifaceted and includes not just the interests of consumers but also the economic interests of food manufacturers and producers. However, as described in section 3.0, the labelling of food products is governed by the *Food and Drugs Act*, which falls primarily under the aegis of Health Canada. Moreover, the policy goals of the legislation are to protect the public health and to prevent consumer deception – safety and certainty. Arguably one government agency cannot protect these aspects of the public interest and also be charged with the promotion of foods that may carry some risk.[247] So there can be no doubt that the purpose of regulating the sale of food and, more specifically, the sale of novel foods, is to protect consumers' health and their right to obtain the products that they are led to believe they are purchasing.

However, the public policy goals of promoting the economic interests of food producers are not necessarily in conflict with the goals of protecting the public interest in safety and certainty. In a democratic country with a free market economic system that is regulated to the extent necessary to correct for market failure and to protect the public interest, other values support these same regulatory aims. A democracy requires that the public be generally satisfied with the regulatory efforts of its government, a goal largely achieved by way of a transparent regulatory process. A free market economy requires that the market be permitted to regulate economic affairs to the greatest extent possible. However, it is not possible for consumers to decide whether products will be successful if those same consumers are not aware of the characteristics of the products they are purchasing. Full

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[247] Royal Society of Canada, *supra* note 2, at 211 et seq.

information is necessary for a free market to operate efficiently.[248] In other words, for consumer choice to be the regulator of the market, consumers must be able to choose. Finally, openness and transparency on the part of both regulators and food producers will likely result in greater public acceptance of the product and the methods of risk analysis used by producers and regulators – a desirable goal for all parties.

The safety and certainty goals of food regulation in Canada were established in Chapter 3 of this thesis. Chapter 4 demonstrated how regulators seek to achieve these goals in practice. Through this analysis, it has become clear that protecting consumer safety is a risk management exercise, as there can be no absolute guarantee of safety. Chapter 5 demonstrated that the safety goal can best be achieved through good risk management and effective risk communication, particularly in the form of mandatory labelling of GM foods. Risk communication also addresses the certainty goal by ensuring that consumers have full information and can obtain the products with the characteristics that are important to them, in light of their own risk choices.

In this chapter, analysis from the theoretical perspective of law and economics will further demonstrate that the certainty goal can be achieved only through effective communication of information regarding the hidden attributes of a food product. It will be argued that mandatory labelling of GM foods, through the regulatory framework already established in Canada, is the best and most practical means of achieving the certainty goal from an economic perspective, without unduly compromising the economic interests of proponents of GM foods.

The chapter begins with a review of labelling theory, which is based in economic theory. It then draws arguments from this perspective that support mandatory labelling, and considers these against the economic arguments that oppose mandatory labelling.

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[248] Caswell, Julie A., *Uses of Food Labelling Regulations*, OECD Working Papers, Vol. 5, No. 100 (Paris: OECD, 1997).

6.1 Labelling Theory

The principles and examples discussed in the foregoing sections demonstrate the necessity for the provision of full information to consumers. This thesis argues that without mandatory labelling of GM foods, consumers cannot receive full information.

Critics of mandatory labelling argue that such a system would shift both the burden and the expense to those who wish to avoid GM foods, as labelling of all GM foods and ingredients would necessitate the segregation of GM varieties right from the crop stage of food production. However, many other types of regulation are just as onerous for producers. To determine whether there are economic arguments in favour of mandatory labelling of GM foods, therefore, it is helpful to consider the factors that are considered by regulators in developing labelling policy. From an economic perspective, the measures that ought to be considered are determined primarily by their practical effect and by the significance of their costs and the likely benefits of their imposition.

6.1.1 Methods of Food Regulation

An OECD working paper provides a useful discussion of the economic considerations behind regulatory labelling requirements.[249] There are numerous ways in which government can regulate the production and sale of food products. Production or processing standards[250] may be in place from primary production on farms through factory processing and packaging. Standards for retail display may also be used. These methods control certain attributes of food products, many of which cannot be judged by the consumer at the time of purchase or, indeed, at any time. Few of us are able to detect the ingredients in a loaf of bread by inspection. Where hidden product attributes like ingredients are not subject to enforced

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[249] Caswell, *supra* note 248, at 7.
[250] For example, the standards considered in section 3.1.2(b).

quality standards, the primary method of communicating those product attributes to consumers is by way of labels on the product. These attributes include not only ingredients, but also nutritional content and even, in some cases, process attributes such as irradiation of the product or the use or non-use of pesticides in the growing of a food crop.

Another possibility is for government to allow the market to regulate those food attributes that can be valued by consumers. That is, consumers can make a choice to pay a certain amount for certain food attributes. Certain consumers are willing to pay a premium for an organic label, for a variety of reasons. It could be that they value a reduction in their overall consumption of pesticide residues. Perhaps they place a high value on choosing products with minimal impact on the environment. Or perhaps they consume animal products but are prepared to pay more to ensure that the animals suffer as little as possible. It is clear, however, that consumers would be unable to make these choices if the producers were prevented from labelling their products as organic and were not able to define what that term means. Where full information is provided, consumers (the market) will set the price that producers can charge for products which are produced or processed in the desired way.

Nonetheless, it is impractical if not impossible for government to regulate all of the hidden attributes of foods. In analyzing the types of attributes that are or should be subject to some level of regulation, Caswell groups various food product attributes into categories that can be paraphrased as follows:

(1) food safety attributes, which include such things as natural toxins, pesticide residues and the presence of pathogens;
(2) nutrition attributes;
(3) value attributes, including taste and purity;
(4) package attributes, which include labelling; and

(5) process attributes, which include environmental impact, pesticide use, animal welfare, worker safety and biotechnology.[251]

It should be noted that category (5) places biotechnology, which includes genetic modification, in the same group as attributes which have no impact on the individual consumer. However, given the conclusion drawn in this thesis that genetic modification is a risk characteristic, GM should be considered a food safety attribute and given priority over other types of attributes for inclusion on labels.[252]

Regardless of the categorization of genetic modification as a food attribute, it is undeniable that the provision of information is necessary to allow the market to regulate food quality attributes that are hidden from consumers. Genetic modification, just like ingredients and irradiation, is such a hidden attribute. The most obvious method of ensuring that food producers disclose hidden attributes is by way of mandatory labelling. However, the decision as to what attributes must be disclosed should be made only after considering the potential impact of both disclosure and non-disclosure. The Caswell paper summarizes the functions of labelling and some of the drawbacks, both of which are discussed in the next section in general and in light of the specific issues relating to mandatory labelling of GM foods.

6.1.2 Labelling Considerations

Food labels fulfill several functions, all of which generally support the argument that mandatory labelling is a useful regulatory measure to ensure that consumers obtain full information about the foods they buy. Several of the functions noted in the Caswell paper[253] show that labelling helps fulfill the certainty goal of food regulation and also, indirectly, the

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[251] Caswell, *supra* note 248, at 6.
[252] See discussion of genetic modification as a risk characteristic in section 4.0 and at note 124.
[253] Caswell, *supra* note 248, at 11-14.

safety goal. On the certainty side, the most important of these functions is as a direct aid to consumers in making purchase decisions. As discussed above, consumers cannot make decisions about products based on food safety attributes, or risk characteristics, if they are not given information about those attributes. Another equally important function of labelling is to reassure the public that regulators are monitoring the important quality attributes of our food supply – a point already noted in the discussion of effective risk communication.

Caswell also discusses the somewhat unexpected third party effects of labelling, such as the significant influence that labelling requirements can have on product design. For example, when producers were required to start listing ingredients on their packaging, many manufacturers of cookies and crackers stopped using lard. Labelling tends to influence advertising as well, which expands the opportunities for consumers to obtain information about the quality attributes of the product. Further, labelling requirements provide some definition of public values and may open a forum for discussion among consumers, and may also help to educate consumers. These functions show that labelling can also help fulfill the safety goal by helping to make food products safer from a health perspective and by helping consumers make their own nutritional and other health decisions regarding the foods they choose to consume.

Labelling regulations also help to achieve safety and certainty in the food supply by requiring the mandatory disclosure of certain information and by ensuring that claims made are not deceptive.[254] Mandatory disclosure is typically required of negative attributes – an example is the requirement that cigarette manufacturers disclose the health effects of their product in labels on the package. There are also prohibitions on making claims that products meet certain standards if those standards are not met, such as products being fat-free or GM-free.[255]

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[254] *Ibid.* at 14; for example, nutrition labelling, *supra* note 96.

[255] One of the positive effects of the voluntary standard now in place is that it establishes a standard for the percentage content of GM ingredients that is allowable when a label claims that a product is GM free: Canadian General Standards Board, supra note 66.

Despite the numerous positive effects of labelling, Caswell notes some considerations that militate against using it too widely.[256] First, the effectiveness of labelling information is dampened by the fact that consumers devote limited time to using label information, and will not use any information that is too complex. Further, labels have a disproportionate ability to reach different demographic groups – that is, not everyone pays attention to labels. Considering these facts and the limited amount of space available on a label, producers want to use a maximum of label space to market their product – in other words, to promote those aspects of the product that are seen as positive and likely to induce consumers to purchase it.

As a result, regulators must decide which attributes are most important when deciding what must go on the label. Most would undoubtedly agree that, where consumers want disclosure of more attributes than a food producer can reasonably be expected to disclose by way of the label, mandatory labelling should be imposed for the most important attributes first, which must be the food safety attributes, also described in this thesis as risk characteristics.

Labelling therefore creates the perception, probably accurately, that certain food quality attributes are important precisely because they are on the label.[257] In other words, if GM ingredients are identified as such on labels, consumers are likely to form the impression that the disclosure amounts to a warning of significant risk. This raises another consideration brought up in the Caswell paper – the idea of commercial free speech.[258] As noted above, food producers prefer to use labels as much for the purpose of promotion of the product as possible. Labels can affect the competitive positions of similar products, and producers are naturally concerned that labelling which creates the impression of elevated risk will put their products at a competitive disadvantage.

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[256] Caswell, *supra* note 248 at 10-11.
[257] *Ibid.* at 13.
[258] *Ibid.* at 10-11.

Finally, Caswell notes that strict labelling regulations can have significant economic costs for government and food producers.[259] When governments set labelling requirements, they must ensure that the infrastructure is in place to support testing and enforcement or certification of products, which can be an expensive prospect. For producers, regulations may quickly become out-of-date and make it difficult for new products with new processes or production methods to be introduced. They may also stifle competition in and development of private markets for quality attributes.

Despite these potential negative impacts, the foregoing discussion provides an economic argument in favour of mandatory labelling to provide consumers with information on various food quality attributes, most importantly those related to food safety and risk characteristics. In fact, labelling is a type of regulation that can reduce the need for other, more intrusive regulatory measures. As Caswell states:

> Governments use food labelling regulations to shape 1) consumers' knowledge, purchasing patterns, and use practices and 2) manufacturers' product offerings and marketing practices. Labelling can complement other forms of regulation such as process and performance standards. Countries may also be interested in the potential for labelling regulation to substitute for other types of regulation. The idea is that mandated improvements in the information available to consumers can allow private markets for quality to develop that will obviate the need for regulations such as process or performance standards.[260]

In the context of GM foods, the considerations for proponents are obvious. If government ultimately feels sufficient public pressure to impose further regulatory measures on the sale of GM foods, as Canadian regulators did in the case of irradiation, the least intrusive and most flexible of the measures available is labelling. The imposition of process standards would be considerably more onerous than the pre-market notification process; requirements

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[259] *Ibid.* at 16-18.
[260] *Ibid.* at 19.

for more scientific scrutiny prior to approval or for post-market monitoring would also be more onerous. Nonetheless, proponents raise several economic arguments against mandatory labelling, which are considered in the next section.

6.2 Economic Arguments for and against Mandatory Labelling

In the context of fulfilling the safety goal of food regulation, this thesis has argued that substantial equivalence is not an appropriate measure for declaring that there are no risks in the consumption of GM foods, or that the risks are not significant enough to warrant disclosure to consumers of the presence of GM ingredients in food products. For the certainty goal, the question is whether GM foods are significantly different from their traditional counterparts. Is the certainty question answered by arguing that GM foods are "substantially equivalent" to their natural counterparts, and therefore there is no deception when they are not identified as genetically modified?

There are numerous indications from the CFIA and Health Canada that there are, in fact, differences between GM foods and their natural predecessors. The introduction of the Novel Foods Regulation, the fact that it requires the submission of considerable data, and the regulators' admission that GM foods cannot be described as risk-free, all indicate that there are significant differences. What no one would argue is that these products are different at the process level, and while some would suggest that foods should be judged strictly on their composition and not on the method of production, the detailed standards related to processing and labelling of irradiated foods demonstrate that some foods are regulated according to the way they are processed.[261] Whether they *should* be regulated in this way is another question.

To answer the question of whether GM foods are different enough from natural varieties to amount to deception when they are not identified as such, it is helpful to recall that the certainty goal of food regulation arises from the longstanding legal tradition of protecting the

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[261] See section 2.1.3.

rights of consumers to obtain the product they believe they are purchasing, whether it is food or any other item.[262] It is also useful to reiterate the purposes of ingredient labelling, the mandated use of common names and other principles of food labelling mandated by the Food and Drug Regulations.[263] Ingredients identified in ingredient lists must be identified by their common names, and certain chemical modifications of particular types of molecules, such as fats and proteins, and their source, dictate a change in the common name used – for example, hydrogenated fats or vegetable protein. These requirements fulfill both the safety goal, in ensuring that consumers can identify ingredients that concern them due to specific health risks, and the certainty goal in allowing consumers to choose foods with ingredients that they wish to consume, and to avoid those that they do not wish to consume.[264]

There is certainly evidence of public demand for mandatory labelling of GM foods in Canada.[265] Winn argues that consumer desire to know about the presence of GM ingredients in foods is sufficient reason to conclude that a failure on the part of producers to disclose their presence amounts to deception:

> ... one could argue that consumers are being misled or deceived in the absence of information about genetic engineering, because the primary reason such information is not disclosed by producers is their fear that consumers will shy away from their products. With information disclosure and consumer deception prevention at the heart of common or usual name requirements, it is reasonable to conclude that new genetic material is a characterizing component of biotech food.[266]

Fundamentally, it seems clear that a demand by consumers to be advised of GM ingredients in the foods they purchase is like any other contractual provision – consumers are entitled to

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[262] See discussion at section 3.0.
[263] See discussion at section 3.1.2(c).
[264] This argument is also made by Winn, *supra* note 245, at 673, as follows: "the primary purpose of a common or usual name is to assure consumers that they are purchasing and eating exactly what they think they are ...".
[265] Lang, *supra* note 15, re: recent polling information showing that Canadians want mandatory identification of genetically modified food.
[266] Winn, *supra* note 245, at 674.

obtain the product they believe they are purchasing. If consumers wish to know about certain attributes of a product that the producer does not wish to disclose, the consumer can refuse to purchase the item. However, when the item is food and the attribute is genetic modification, which the consumer cannot possibly discern without labelling, the consumer is left with no choice as to whether to purchase GM foods or not purchase them. In other words, if consumers want to know the information, particularly when the information relates to a risk characteristic, failure to provide that information amounts to deception.[267]

In any event, it is arguable that GM foods are different enough to warrant labelling in order to avoid deceiving consumers as to what they are purchasing, particularly where there is a growing desire on the part of those consumers to make their own choices when it comes to purchasing these foods. The only arguments against the provision of this information are economic ones, most of which can be easily addressed. The economic arguments for and against mandatory GM labelling, considering the costs and benefits for both producers and consumers, can be broken into a few categories and are discussed in the following sections.

6.2.1 Cost Implications of Segregation and Labelling

One of the chief problems identified by opponents of mandatory labelling is the difficulty of segregating GM crops from their traditional counterparts and ensuring that no GM products creep in. The difficulty of identifying GM foods, and thus enforcing the labelling requirement, is also cited. However, this argument has the appearance of a smokescreen. Wheat can be segregated according to its grade. Products that are highly allergenic can be segregated. Moreover, as pointed out in Chapter 1, producers of GM foods will be only too happy to segregate their products once they have engineered foods with benefits for

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[267] An example of this reasoning is the U.S. Food and Drug Administration's conclusion that irradiated foods should be identified as such because of consumer demands for that information. The FDA stated that information is important if consumers think the information is important, and if the omission of the information from the label may be misleading to consumers: Winn, *supra* note 245, at 670.

consumers, and will probably use litigation to prevent anyone from slipping these GM foods into their products without paying the appropriate licensing fees.[268]

Whittaker points out that technology already exists to detect the presence of GM foods in very small quantities. [269] He argues that, although segregation and labelling of GM foods will be expensive, the cost will simply be passed on to the consumers who are demanding the information. He suggests that the costs can be minimized by bringing in a uniform standard for labelling and avoiding a prolonged battle leading into a painful harmonization effort. Whittaker concludes that labelling is scientifically justifiable, given the existence of risks, and that labelling is necessary to develop public confidence in food biotechnologies.[270]

6.2.2 Practical Limits on Labelling

Others say that not everything in our food can be identified on the label.[271] It is true that there are all sorts of substances that make their way into food, including highly undesirable material. The tolerances in the Food and Drug Regulations allow for the presence of small quantities of such material without the disclosure on the food label. But the fact that we cannot guarantee all food as pristine is not a reason to refuse to label products that are made up of a significant proportion of GM ingredients. There can be tolerances for these items just as easily as for anything else.

McHughen suggests that it would be ridiculous to set tolerances for the levels of GM materials present in foods. [272] This leads to another common argument against labelling – that it is impossible to guarantee that products are GM-free. This being the case, proponents

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[268] As in *Monsanto Canada Inc. v. Schmeiser*, [2004] S.C.J. No. 29.
[269] Whittaker, *supra* note 37, at 1240-1241.
[270] *Ibid.* at 1242.
[271] McHughen, *supra* note 5, at 211-213.
[272] *Ibid.* at 213-217.

suggest that it is an onerous task to develop standards and tolerances, as well as a testing protocol, to ensure that products containing GM ingredients are labelled accurately.

Whittaker discusses various standards that might be employed to determine at what level of GM content labelling will be required.[273] Labelling might be appropriate, for example, when foods are modified to contain proteins not previously found in food (even in minute quantities); when they are modified to contain proteins new to that particular food; or when foods are modified to contain a higher or lower concentration of a protein naturally found in a food. In Canada, the voluntary labelling standard is set at a 5% margin of error, which may be lowered as technology to detect GM ingredients improves, on a product which claims to be free of GM ingredients.[274]

Winn summarizes possible distinctions between biotech foods which should be labelled and those which may not need labelling, much as Whittaker does. She argues that a decision could be made, on one of several possible criteria, and that any difficulty inherent in such a decision is not sufficient reason to avoid labelling.[275] As for the economic costs involved, Winn suggests that many biotech foods need to be segregated anyway. Genetically modified tomatoes that ripen on the vine, for example, have to be picked with different equipment and must be treated differently in shipping than traditional tomatoes which are still hard when picked. Crops which produce their own insecticide must be grown separately from traditional crops or the benefit of the insecticide in reducing the need to apply chemical pesticides will be lost.[276]

Both Winn and Whittaker suggest that it would be economically better for producers in the long run if consumers know what they are buying and if the producers used labelling as an opportunity to educate the public about the benefits of their product. Accordingly, the

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[273] Whittaker, *supra* note 37, at 1235-1241.
[274] Canadian General Standards Board, *supra* note 66.
[275] Winn, *supra* note 245, at 685.
[276] *Ibid.* at 685-686.

arguments against labelling on the grounds of the practical limitations of implementing and enforcing a mandatory labelling system are not well-supported.

6.2.3 Regulation of Process vs. Product

It is difficult to discern from the Regulations any particular approach to labelling that would render GM foods exempt from a labelling requirement. Some proponents of GM foods argue that they should not be labelled because they are distinct only in terms of process considerations.[277] The basis of the argument that process considerations do not warrant a label is unclear, but it seems to be phrased either as an argument that we don't traditionally regulate by process so we shouldn't, or that the process itself does not raise safety issues and nothing should be subject to mandatory labelling that does not raise such issues.

With respect to the first argument, however weak it may be, it is clear that process is already a consideration in labelling and in setting standards. Moreover, the terms used to identify chemically modified foods would indicate that a food that is somehow different from the naturally occurring version of that food should be identified as such.[278] If process is regulated and subject to standards, why would it not be subject to labelling requirements?

With respect to the safety argument, this has already been thoroughly canvassed in Chapter 5. However, another argument that brings process into the arena of labelling is the concern about philosophical, ethical and religious issues raised by the Royal Society in its report.[279] Few people would argue the right of individuals to avoid certain foods on religious or philosophical grounds, such as the Jewish prohibition on consuming pork or the ethical concerns of vegetarians. However, how can we answer the question of whether a food derived from plants is no longer appropriate for these individuals to consume if the plant has

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[277] McHughen, *supra* note 5, at 145-146; Benda, *supra* note 16.
[278] Compare to this to the discussion regarding ingredients in section 3.1.2 (c).
[279] Royal Society of Canada, *supra* note 2, at 6-7.

been modified with a pig gene? As the Royal Society concludes, the resolution of this quandary cannot be based on scientific, objective standards that tell us genes are the same across all living organisms. This is a problem that people who choose their food on the basis of religious or philosophical principles must resolve for themselves. There is no way for them to do this without segregation and labelling of GM foods.

On this point, there is clearly a clash between the interests of producers and the interests of consumers. Given that the system of food regulation in Canada is geared to protecting the safety and certainty of the food supply for the benefit of consumers, it is clear that the interests of consumers ought to take priority where the clash is simply a philosophical question of whether we ought to regulate process.

6.2.4 Labelling as a Competitive Disadvantage

Finally, producers of GM products argue that placing a label on the product is likely to create the impression that it is somehow a safety attribute, which is unfair given that the products have been judged safe by regulators. The producers claim that such a label would be unnecessary and misleading.[280] Further, it puts products which do, or simply may, contain GMs at a potential competitive disadvantage.

This argument can be answered in several ways. First, this thesis has concluded that genetic modification of food is a risk characteristic and therefore ought to be disclosed by consumers. Producers are free as always to provide consumers with direct information regarding the safety of their products. Second, the voluntary standard allows for a margin of error, which ought to be included in a mandatory standard to ensure that products that "may contain" a GM ingredient do not have to be labelled unless there is an unusual safety concern, such as a greater than usual risk of allergenicity in that product. Finally, mandatory labelling does not have to take the form of a warning label. Incorporating the term "GM"

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[280] Caswell, *supra* note 248, at 13.

into the common name for genetically modified ingredients would allow the information to be available on the label to all consumers who are interested in it, without drawing such attention to the GM content that disinterested consumers are unreasonably alarmed.

6.3 Conclusion

Government is always faced with the dilemma of determining when to step in and regulate a new product, and what type of regulatory measures to impose. In the case of GM foods, there are strong feelings on both sides of the debate, and some voices calling for extreme measures such as a total ban or minimal regulation. Those who prefer minimal regulation of products typically argue that the market should regulate new products and determine their success or failure – yet the market cannot regulate the success or failure of GM foods because consumers do not know that they are purchasing GM foods unless they are identified.

What, then, should government consider in setting its policies with respect to labelling? According to Caswell, one of the first things a government should look at is how the market is currently functioning with respect to the regulation of the quality attribute in question. For example, there may be voluntary programs in place, or companies may simply provide label information on their own initiative. In the case of GM foods in Canada, voluntary labelling has recently been instituted, but it is too soon to know how the voluntary standards will affect the market.

The certainty goal of food regulation requires government regulators to take all reasonable and necessary steps to protect consumers from deception. The argument that novel foods are in fact no different from the traditional varieties has been refuted, and the potential risks of GM foods render them different from the perspective of the consumer. Once it has been established that there is some risk, or even potential risk, in a GM product that is not present in the traditional variety, it cannot be argued that the product is the same. For the market to

regulate these novel foods and determine whether or not they will be successful and acceptable to consumers, consumers must be able to make a conscious choice whether or not to purchase them.

Given the public concern about GM foods and the possibility of unintended effects, it is clearly arguable that genetic modification is an attribute that should be identified on food labels for the same reasons as irradiated foods and potential allergens. However, proponents of GM foods have advanced several economic arguments against mandatory labelling, all of which can be addressed by using the voluntary standard published by the Canadian General Standards Board in conjunction with the existing regulations regarding common names and ingredient labelling to provide the information that consumers seek without causing undue disadvantage to producers of GM foods.

The bottom line is that GM foods should be treated like any other innovative product. It is up to the producers and manufacturers to market it and, in the process, convince consumers that it is something they will like. They will have to do so eventually in any event, when they try to sell products based on genetic changes that, finally, offer some direct benefits to consumers.

Chapter 7 – Conclusion

Should the Canadian government legislate a labelling requirement for GM foods? There is no doubt that there are some potential health issues with respect to GM foods, particularly for individuals who are prone to allergic reactions. More importantly, unanticipated effects might not appear on a short-term basis, and the failure to segregate and label GM foods makes it impossible to track effects of a long-term nature, or even unexpected allergic reactions. On the basis of protecting the health of consumers, the federal government has the ability and, in fact, a duty to require food producers to advise consumers if the food products they consume contain GM ingredients.

Can the federal government legislate a mandatory labelling requirement with respect to GM foods? There are issues of constitutional jurisdiction, but certainly it can do so for reasons related to health and safety. If labelling requirements could be imposed on irradiated foods without any evidence of particular safety concerns, such requirements could clearly be imposed on GM foods. Moreover, there are sufficient comments from CBAC, the Royal Society of Canada and other scientists, including those at Health Canada and CFIA, identifying the potential health risks of GM foods, that it is unlikely that a labelling initiative would be challenged on constitutional grounds.

As set out in this thesis, there are many reasons to impose mandatory labelling of GM foods, not the least of which is the fact that consumers are demanding it. Moreover, much work has already been done toward the development of a voluntary standard with a margin of error that is generous to producers but also protective of consumers. Finally, the framework for ingredient labelling for common names already exists in the Food and Drug Regulations and can easily be adapted to include new common names for GM ingredients. Instead of having just "vegetable protein", the list of common names could include such names as "GM vegetable protein."

The only real economic cost of mandatory labelling to producers would be the need to segregate GM crops and produce. However, given the proprietary nature of GM seeds and the fact that new GM crops are expected on the market that will benefit consumers directly, proponents have an interest in keeping their products segregated from the mainstream. Further, the next generation of GM products are likely to be based on much more complex modifications that will raise more safety issues and will likely raise more regulatory concerns. Bringing in a system of mandatory labelling at this time would pave the way for a less onerous regulatory structure than might otherwise be imposed on these new products. It would also do a great deal to enhance the public trust in both the regulators and the proponents of GM foods, thus improving the likelihood of public acceptance of new GM products.

The establishment of trust, as discussed in Chapter 5, is critical to consumer acceptance. And, as argued in Chapter 6, consumer acceptance is critical to meeting the goals of safety and certainty in the food supply. Pursuant to the ideas from risk communication, the social and cognitive studies of Sunstein and Kuran discussed in section 5.2, and the concerns about scientific risk assessment brought up by Clark and Hattis,[281] this thesis proposes the following general recommendations to risk managers in Canada:

(1) Trust must be established by ensuring that there is no conflict of interest or apparent conflict of interest caused by regulators owing duties to both proponents and consumers.

(2) Risk assessment decisions must be based on scientific data which are peer-reviewed and which rely on assumptions as little as possible. Assumptions must be clearly identified and justified. Wherever possible, data should be reviewed by independent bodies.

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[281] See sections 4.2.2 and 5.1, respectively.

(3) While scientific data is important, regulators must listen to public concerns about other factors, such as fairness in the distribution of benefits and risks. These factors should be taken into account in the decision-making process.

(4) Regulators must effectively communicate the results of their risk assessment decisions to the public, along with the methods used and the justification for those methods. Information must be accurate and must be forthcoming early and often.

(5) Regulators must banish "no risk" messages and must acknowledge the fundamental conflict in the risk assessment process between scientific perceptions and public perceptions of risk. This acknowledgment must include an admission that no risk assessment is truly objective and that individuals must make their own risk assessments based on the information provided to them.

It is submitted that mandatory labelling would address most of these issues. Even if there are ongoing concerns with the scientific risk assessment process, labelling allows consumers to make their own risk management decisions. Further, consumers who are trusted by regulators and proponents to make sound risk management decisions for themselves are that much more likely to trust the risk management efforts being made by regulators and proponents. Consumers, and the public in general, want to have some sense of control over their own lives, and few things are more important for them to control than the nature of the food they eat.

As several authors have pointed out, it is not chance that takes us down a particular technological path. The transformation of society by biotechnology is coming about because of a series of decisions that are being made at many levels. The very core of the democratic process is that citizens should have the opportunity to have a say in the policy directions that our society takes. Citizens cannot exercise this fundamental right with respect to biotechnology if they are not given adequate information about how the technologies are

developed and where these technologies appear to be taking us. It is the responsibility of industry to provide full and fair information, while it is up to government to allow the public to make their own decisions about the role that biotechnology will occupy in their lives.

Biotechnology is, to a large extent, an exercise in reductionism – in reducing all of life to a complex code that is in the process of being broken. Perhaps it is because of this reductionist philosophy that so many scientists feel there is no room in their work for philosophical, social and ethical considerations. These "non-scientific values" are, after all, an expression of what it means to be human – more than just the sum of our parts, more than walking vessels for the DNA molecules which help to make us who we are. Ethics are the means we have developed to govern our relationships with one another in a civilized way. If we really were just DNA carriers and nothing more, it wouldn't really matter how we interact – all that would matter is that the most genetically fit individuals win the human race. But somewhere deep down, in that human part of the brain that can't be described in molecular terms, we know that there is more to us than that.

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