

Chapter 2

The State of Science-Based Regulation and Genetically Modified Crops

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2.1 Introduction

Mankind's relationship with risk has changed in a multitude of ways and degrees over the millennia. While the likelihood of being attacked, killed and eaten by a wild animal has dramatically decreased, the probability of being killed in an automobile accident has increased. Life expectancies at the dawn of the twentieth century in Europe ranged from the mid-30s to the high 40s but by the close of the century, life expectancies had risen to the mid-70s for men and low 80s for women (Kinsella 1992). Clearly, the nature of the risks that humans face has changed over time and so have the incidences of life-threatening risks. At the beginning to the twenty-first century, mankind has mitigated many risks that have previously been life threatening, especially when it comes to food and food security.

This mitigation has been more successful in industrialized nations than developing ones, but even in developing nations risks are being successfully addressed. For example, in the centuries past, millions and millions of people in the world died from a disease simply known as “consumption” or, more colorfully, galloping consumption. Today this disease is known as tuberculosis and, in the industrial world, it has been virtually eradicated. In Canada, for example, the risk of dying from tuberculosis reached a high of 7% of all deaths in 1926 (when death from other infectious diseases was 5% of all deaths) and, by 1990, deaths from any infectious disease contributed less than 1% of all deaths (Canadian Lung Association 2004). The developing world is also making significant progress in reducing this risk of

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death, with the World Health Organization reporting that tuberculosis incidences have fallen globally in several years and that the mortality rate has fallen by 41 % since 1990 (World Health Organization 2012).

While the actual risks and the magnitude of them change over time, total human exposure to risks is relatively constant. Exposure to a specific risk or even a class of risks may appear and then increase or wane over time, but the overall exposure to risk stays relatively constant through the ages as other risks appear and are addressed. So, for example, while exposure to risk in areas of food safety, nuclear contamination and climate change may be increasing, the risks of exposure to global warfare, starvation and enslavement have greatly decreased. Returning to the tuberculosis example, as the risk of tuberculosis has waned, global concerns about overall infectious disease risks are once again growing because of the effect that climate change may be having on the habitat of disease pathogens. One example of this is the recent rapid spread of the West Nile virus in North America.

Nevertheless, although the actual level of risk has stayed about the same, the perceived magnitude of risks in modern societies has risen to previously unimaginable levels. More often than not, it is our perception of exposure to risks that has grown rather than the actual risks. The risk of living in modern, industrial, and largely urban societies directly parallels the risks experienced in the societies of our grandparents and even that of their grandparents. Whilst the variety of risks that members of modern societies are exposed to are certainly larger, the absolute incidence of risk may not be substantially changed. Technological advances throughout the past century have, for example, introduced the risk of death due to airplane travel. While this risk is not trivial, it is actually lower than risks posed by many historical or traditional forms of transportation.

The pace of change of the variety of risks we face, however, has increased rapidly over the past century and is expected to continue into the future in response to technological and scientific advances. For example, within the past decade, the fields of computers, robotics and genetics have combined to dramatically affect human reproduction, agricultural biotechnology and nanotechnology. Technological innovations in these areas have allowed genetic modification of crop varieties; arguably the most important and successful innovation in the modern history of agriculture.

One fundamental unchanged factor when responding to risk is the need for a governance strategy adapted to the ever-changing nature of risk. Risk governance strategies are inevitably diverse, both in their objectives and their implementation. This chapter offers insights into the governance challenge by examining the development of risk assessment frameworks that have manifested themselves within and around the technology of agricultural biotechnology and the role that science-based regulation plays in biotechnology regulation. As will be seen, the original risk assessment frameworks were developed to respond to risks to human health posed by factors such as chemicals and human, plant and animal pathogens, matters which are particularly amenable to scientific assessment. That approach continues to be used by many nations today, particularly North America.

2.2 Origins of the Risk Analysis Framework

Regulations have been used to address innovation for practically as long as there have been innovations. Building codes, labor laws and unions, all in part, owe their origins to methods of dealing with innovation. Aspects of all of these social features can be related to improvements in economies, environments, and/or health. Given our ancestral history of coping with the innovation of the day and the resulting impacts on societies, it is no wonder that modern society is increasingly fixated on the mitigation of and, to a large extent, the eradication of risk. It is this latter concept of the eradication of risk that creates multiple challenges in modern societies as opponents of a particular innovation will argue that the innovation should have zero risk if it is to be commercialized. The problem they ignore is the technology that the innovation is replacing, or at least competing with, frequently, has a higher degree of risk associated with it. Further, in today's marketplace, no scientist or manufacturer will declare that any product is 100% safe, because there is always a degree of risk associated with every product that is purchased, be it for entertainment (a television), communication (a cell phone) or to eat (a tomato).

Over time, the framework for understanding and responding to risk in relation to innovation became increasingly codified. This was, especially, the case following the technological innovations of the post-war years (Phillips et al. 2006). It was during this period that regulators developed a structured format for risk analysis as a regulatory response to public policy problems.

This process officially became part of government regulation with the American National Research Council's 1983 report to the United States federal government. This report has become known as the Redbook on the Risk Analysis Framework (RAF). The report identifies the Council's mission as "a search for the institutional mechanisms that best foster a constructive partnership between science and government, mechanisms to ensure that government regulation rests on the best available scientific data and judgments in the unavoidable collision of the contending interests that accompany most important regulatory decisions" (National Research Council 1983, p. 1). While this is a broadly interpreted objective, the mandate was more focused in that it sought to "examine whether alterations in *institutional arrangements or procedures*, particularly the organizational separation of risk assessment from regulatory decision-making and the use of uniform guidelines for inferring risk from available scientific information, can improve federal risk assessment activities [original emphasis]" (National Research Council 1983, p. 17). This process was done within the scope of examining the possible risks of cancer from exposure to the increased use of chemicals in the environment.

The RAF Redbook definitions have become the cornerstone for modern RAFs. The Redbook defines risk assessment as "the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations" (National Research Council 1983, p. 3). Risk management is defined as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data

and with social, economic, and political concerns to reach a decision” (National Research Council 1983).

Most risk assessments comprise some or all of the following aspects: hazard identification, dose–response assessment, exposure assessment, and risk characterization. Hazard identification determines if the element in question is causally linked, or not linked, to known health effects. Dose–response assessment determines the relationship between the magnitude of the exposure and the probability of detrimental health effects. Exposure assessment determines the extent of human exposure prior to the onset of detrimental health effects. Finally, risk characterization describes the nature and magnitude of the risk, such as low, high, or uncertain.

The development of the RAF based on these factors was derived from a variety of the US federal risk assessment guidelines developed by numerous federal regulatory agencies or institutions dating back to the early 1960s. Some of these guidelines met with greater success than others. In the late 1970s, efforts were undertaken by the Interagency Regulatory Liaison Group (IRLG) to reduce inconsistencies and duplication among the various federal agencies while working to improve coordination (National Research Council 1983). In 1979, the IRLG developed guidelines for carcinogens that were adopted by the President’s Regulatory Council. These guidelines were used as a starting point for the development of the RAF under the premise that if structured properly, uniform guidelines should be used for risk assessment by all federal agencies. The report of the IRLG served to develop the uniform risk analysis framework, which has gone on to be widely adapted and adopted. The next section examines how the RAF has evolved over the past 30 years.

2.3 Advancement of the Risk Analysis Framework

The risk evaluation systems operating in most developed Organisation for Economic Co-operation and Development (OECD) member countries generally are scientifically based processes that combine the identification and characterization of hazards with assessments of exposure to evaluate risk. In essence, they purport to objectively assess the probabilistic outcomes of discrete adverse events, abstracting from issues related to risk management or risk communication. In practice, governments establish a risk threshold for products or classes of products, allowing those with acceptable impacts to enter the market and prohibiting new products with unacceptable risks. Over time, the ability to accurately and reliably test for the presence of adventitious materials in food products has dropped from the detection of parts-per-million to parts-per-billion.

The Food and Agriculture Organization (FAO) of the United Nations defines risk assessment as a scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, and risk characterization (Food and Agriculture Organization 2012). Powell (2000) offers an elaboration of the system by combining the United States NRC model of risk assessment with the observations of Lammerding and Paoli (1998). In this model, hazard identification

is the determination of whether a particular element in the food system is, or is not, causally linked to particular health effects. This includes determining the link between disease and the presence of the food pathogen, as well as the conditions where the pathogen survives, grows, causes infection, and dies. As such, this stage often involves epidemiological and surveillance data, challenge testing, and scientific studies. These macro results need to be scaled to sub-populations in society. Exposure assessment, sometimes called dose–response assessment, involves determining the relation between the magnitude of exposure and the probability of occurrence of the health effects in question. Therefore, by necessity, a range of responses in the population to a pathogen must be examined. This often involves examining sub-groups of consumers that might be most at risk (e.g., old, young, and immunosuppressed). The combination of hazard identification and characterization provides a theoretically supported rationale for a causal relationship between exposure and response.

Exposure assessment, in contrast, is the determination of the extent of human exposure both in the absence of and, with the application of, post-release regulatory controls. This includes a description of the pathways through which a hazard is introduced, distributed, and challenged in the production, distribution, and consumption of food. In short, it is assigning a probability to the event based on extensive situational analysis of how the food system operates and how it would relate to a hazard. Finally, risk characterization entails describing the nature and often the magnitude of human risk, including aspects of uncertainty. As such, this is the final stage of the analysis where the hazard, exposure, and variability of the results are combined to estimate the potential risk of a new or transformed product.

Traditional risk assessment theory (Isaac 2002) suggests that risk is a combined measurement of the degree of exposure multiplied by the hazard, which is the level of adverse effects of the agent on other organisms. This can be expressed by the following formula:

$$\text{RISK scientific} = \text{HAZARD} \times \text{EXPOSURE}.$$

Science has used this formula to evaluate whether initial research findings should proceed or be halted. If the assessment revealed a level of risk higher than was scientifically safe, then government agencies would not approve the technology or product for commercial release. Although the hazard would appear to be quite objectively derived through risk assessment by the global scientific community, the acceptable levels and the estimated relative level of risk for a product could vary widely between intended uses (e.g., countries or markets). It is not unreasonable to expect to see different levels of risk accepted in different circumstances.

There has been significant effort put into understanding the divergence between the old model of objectively assessed risks and what many are calling socially constructed risks. Sandman (1994) believes the old formula underestimated the actual level of risk because it ignored the public response to a risk, which he termed outrage. He argues that regulators should instead use the following formula for understanding consumer perceptions of risk:

$$\text{RISK socially constructed} = \text{HAZARD} \times \text{OUTRAGE}.$$

Sandman argues that public concern is focused on whether the risk is acceptable rather than on the scientifically perceived incidence of that risk. Although that model accommodates areas where outrage dominates, it does not fully account for the interaction between expert opinion on exposure and public concerns.

Perhaps a better configuration of the risk analysis framework for new technologies is one that incorporates all elements of the perspectives, that is, hazard identification and characterization, exposure assessment and consumer/citizen response, or outrage. Thus:

$$\text{RISK modern} = \text{HAZARD} \times \text{EXPOSURE} \times \text{OUTRAGE}.$$

Hazard and exposure would be as elucidated in the scientifically derived measure of risk, but the outrage factor would be a socially derived measure (Phillips et al. 2006). When outrage factors are very high (or very low), industry, non-government organizations (NGOs) and international agencies and organizations may either take suitable actions to position themselves to exploit those divergences or they may seek to ameliorate the divergences through lobbying or engagement in public processes.

Ultimately, the risk assessment system ought to be designed to make the right decisions—that is accepting safe products and rejecting unsafe products. As with any human system there is potential for error, especially when a new class of products is being considered where there is no accepted body of empirical evidence. Although the system is, and should be, designed to avoid making Type I errors—that is accepting something that is not safe—it has to be mindful of the trap of making Type II errors—that is rejecting safe products and activities. While we can tally up the cost of Type I errors in lost lives or damaged ecosystems, we cannot convincingly estimate the cost of foregone opportunities and all of the attendant benefits that could flow from them. The difficulty is that social amplification of risk (reflected in high outrage factors) significantly raises the potential of making a Type II error, thereby diminishing the flow of new and innovative products and progress in a knowledge-based economy. In one sense, risk amplification increases the probability that a Pareto potential improvement—net welfare enhancement—in our production system might not be realized because of the uncertainties of how the market might respond. Fear, in and of itself, can raise the potential and cost of Type II errors.

This underlying set of overlapping and, at times, conflicting processes and objectives provides the baseline against which new products or technologies are assessed. Deviations from expectations, especially those reflecting an outrage factor, provide the basis for legal, political and socio-economic discussions about liabilities and compensation. Moreover, if the degree of outrage is not included explicitly in the risk analysis, when there is a Type I error, the liability may be even higher due to punitive damages.

2.4 International Governance of Risk

Safety, especially as it relates to the safety of food and agricultural commodities, has a history of being subject to manipulations (Smyth et al. 2009, 2011). The improper use of sanitary and phytosanitary measures as the rationale for restricting trade in agricultural products is difficult for those countries, or firms, adversely affected to document and substantiate. Therefore, such measures are attractive to governments seeking to protect national interests. The ability of individual governments to manipulate sanitary and phytosanitary standards to serve the interests of particular segments of domestic agricultural markets created an international agricultural trade market that was fraught with frustration and uncertainty. Throughout the course of the twentieth century, numerous international institutions sought to harmonize the standards pertaining to international trade in agricultural products to ensure a more “level” playing field. At present, there are five different international institutions that stake a claim to coordinating and regulating the food and environmental/health safety of biotechnologically developed bioproducts, foods and crops. Table 2.1 provides a summary of these institutions. While many of these institutions and agreements have a broader range of mandates, for relevant purposes, only those that relate to agricultural biotechnology will be discussed.

The WTO does not, and has not, established regulations governing trade in products of biotechnology, but it does adjudicate international trade disputes, based upon the standards established by three standards setting organizations: *Codex Alimentarius* Commission (Codex); the Office International des Epizooties (OIE), which is now known as The World Organization for Animal Health, and the International Plant Protection Convention (IPPC). A nation that enacts a regulation or standard that contravenes the standards of any of Codex, the OIE or the IPPC, can be subject to any other WTO member nation filing a claim that argues that the regulation or standard is an unfair barrier to trade and, therefore, seeks compensation for lost trade opportunities. The Agreement on Sanitary and Phytosanitary Measures (SPS) of the WTO establishes the use of science as the decision-making criteria for justifying barriers to trade for the protection of the environment or human, animal and plant health. The SPS Agreement allows for the adoption or enforcement of measures necessary to protect the environment or human, animal or plant life or health. However, criteria are specified as to the application of any such measures. The SPS specifies that: (1) any measure(s) should not discriminate between countries; (2) standards which conform to international standards developed by international organizations (i.e. Codex, OIE, IPPC) are presumed to be consistent with the obligations outlined in the SPS Agreement; (3) standards that are in excess of established international standards or where no international agreement exists must be based on scientific principles and the completion of a risk assessment; and (4) measures shall not constitute a disguised restriction on international trade.

Codex, the OIE and the IPPC provide the technical standards framework for the SPS. If an International Standard for Phytosanitary Measures (ISPM) established by the IPPC allows for a trade barrier, then every member country of the WTO is

Table 2.1 International institutions regulating biotechnology. (Source: Adapted from Buckingham and Phillips 2001; updated by authors)

Institution	Date	Coverage	Member states	DSM	Orientation
World Trade Organization	1947	Trade in all goods and most services	159	Binding	Establish rules for transparency and dispute settlement through TBT and SPS agreements
International Plant Protection Convention	1952	Pests and pathogens of plants and plant products	178	Non-binding, sets WTO standards via SPS S.3.4	International standards for plant measures involving quarantines
Organisation for Economic Co-operation and Development	1961	Harmonization of regulatory requirements, standards and policies	34	None	Consensus documents; special commissions and events to seek common ground
Codex	1962	Food labeling and safety standards	185	Non-binding, sets WTO standards via SPS S.3.4	International standards to provide guidance for the food industry and protection for consumer health
Cartagena Protocol on Biosafety	2003	Transboundary movements of GMOs	166	None	Treaty creates rules for the transboundary movement of GMOs

TBT technical barriers to trade, *SPS* sanitary and phytosanitary, *DSM* dispute settlement mechanism, *GMOs* genetically modified organisms

allowed to implement this standard into their domestic regulatory framework without fear of challenge. If a WTO member country implements a regulatory standard that contravenes the IPPC standards, then that country may be accused of using a trade barrier in a case brought to the WTO by any other member country. Countries may have higher standards than the IPPC but only if there is a scientific justification and a risk assessment that satisfies SPS commitments.

The IPPC is a multilateral treaty that seeks to protect natural flora, cultivated plants and plant products from the spread of pathogens through international trade. Through collaboration between regional and national plant protection organizations, it provides a forum for international cooperation, dialogue, harmonization and technical exchange of plant information. The IPPC has addressed the regulation of biotechnology and genetically modified (GM) crops through several of the ISPMs.

To determine the relationship between socio-economic considerations (SECs) and the IPPC, one must look to the International Standards for Phytosanitary Measures (IPSMs). There are 24 different ISPMs, none of which provide an allowance

for SECs. However, ISPM No. 5, Supplement No. 2 provides guidelines relevant to understanding the potential economic importance and the related terms of reference for environmental considerations. Economically unacceptable impacts and/or environmental damage relating to the unintended introduction of a plant pest are compensable. Three criteria are required to be documented before economic compensation from plant pests can be sought: first, the potential for the plant pest to be introduced; second, the potential for the pest to spread; and third, the potential for harmful impacts on crops (lower yield or quality), the environment (damage to ecosystems, habitats or species) and other values (tourism or recreational activities). Based on the definition of economic damage provided by ISPM No. 5 of the IPPC and therefore as part of the SPS Agreement of the WTO, any country that incorporates SECs into their domestic regulatory system that do not address risk reduction of the environment or human, plant or animal health, should know that this will be deemed a barrier to trade and said country should expect to have a disputes case brought to the WTO to have this barrier removed.

Codex develops international food standards that identify a processed food product and its essential composition and quality factors, identifies additives and potential contaminants, sets hygiene requirements, provides labeling requirements and establishes the scientific procedures used to sample and analyze the product. Jackson and Jansen (2010) provide a detailed discussion of the science-based risk assessment process for food safety and its relationship to WTO dispute cases. It commonly takes in excess of six years to develop a Codex standard. Upon a Codex standard being adopted, each member country is encouraged to incorporate it into any relevant domestic rules and legislation but they may unilaterally impose more stringent food safety regulations for consumer protection, provided the different standards are scientifically justifiable. Codex plays an important role in the agri-food trade because its standards, guidelines and recommendations are acknowledged in the SPS and TBT Agreements of the WTO. There are currently no Codex standards in place for products of biotechnology; however, there has been significant effort on behalf of Codex to develop a standard for the labeling of food products derived from biotechnology. The Codex Committee on Food Labeling was tasked in 1993 to initiate work on the development of a standard on the labeling of GM-derived foods and for nearly 20 years the Committee's efforts were gridlocked. However, in 2011 the USA relented on its opposition to the labeling of GM food products and, in 2012, Codex adopted the principles for a risk analysis of foods derived from biotechnology, which establishes that if a risk is identified, labeling is an appropriate management strategy. Codex stresses that any risk analysis of biotechnology derived foods has to be science-based and that these principles do not address "environmental, ethical, moral and socio-economic aspects..." (Codex Alimentarius Commission 2012, p. 1). It is important to note that this is a Codex principle on risk analysis of foods derived from biotechnology and not the standard on the labeling of GM foods that the Committee was tasked with 20 years ago.

The OECD has actively assisted in the harmonization of international regulatory requirements, standards and policies related to biotechnology, beginning in 1995. The OECD has undertaken a number of projects aimed at making regulatory

processes more transparent and efficient, to facilitate trade in the products derived from biotechnology and to provide an information exchange and dialogue with non-OECD countries. The OECD leads efforts to develop Consensus Documents that set out the biology of the crop plant, introduced trait or gene product and to provide a common base to be used in the regulatory assessment of an agricultural or food product derived from biotechnology. These Consensus Documents focus on the biology of the organism, containing the technical knowledge that is utilized in risk assessment of products derived from biotechnology, that are becoming embedded in the regulatory frameworks for Member States and are to be mutually recognized by other Member States.

The Cartagena Protocol on Biosafety (CPB) is representative of recent efforts to provide a comprehensive international structure to ensure the protection of biodiversity and to facilitate considerations of non-scientific concerns, so-called SECs. The CPB is a new international institution negotiated specifically to deal with trade in the products of biotechnology. The CPB, which was concluded in Montreal in 2000 and came into effect in 2003, provides rules for the trans-boundary movements of LMOs intended for environmental release and those destined for the food chain. The CPB only applies to the nations that have ratified the agreement, and the challenge of using the CPB to govern production and trade of GM crops is that many of the leading producers of GM crops are not signatories to the CPB, let alone having plans to ratify the agreement. None of Argentina, Canada or the USA is signatory to the CPB and these three countries represent three of the top five producers of GM crops (James 2011). This creates considerable challenges for the CPB.

As illustrated by the above discussion, most of the international institutions that hold a stake in the governance of products of biotechnology have existed for 50 years or greater and use regulations and principles to respond to risks that science can measure and assess. The recent CPB takes a different approach. That approach has been led by the efforts of numerous European nations and can be seen as a means of reducing global reliance on the WTO as the dominant institution that governs biotechnology products and trade. To a large extent, it has been the CPB that has created the impetus for the development and incorporation of concerns that science has not (and perhaps cannot) measured and assessed (the so-called SECS) into domestic regulatory frameworks for GM crops. This international divergence of regulatory strategies, with Europe following a socio-economic/precautionary principle-based approach which is discussed further in the next chapter, versus the science-based approach utilized in nations such as those in North America, has created a trans-Atlantic gap in the international governance of products from biotechnology. Many African nations have opted to follow the regulatory path of the European Union and its open aversion to agricultural biotechnology, while many South and Latin American countries are choosing to base their GM crop regulations on science. There have been many costs to this trans-Atlantic gap as illustrated by the January 2012 announcement by BASF that it was moving its research division from Europe to the USA due to the delays in regulatory decisions in Europe (BASF 2012). The increased polarization of attitudes towards the regulation of biotechnol-

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