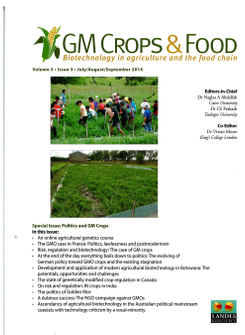

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Risk, regulation and biotechnology: The case of GM crops

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Keywords: food security, GM crops, politicization of risk, risk assessment, science-based regulation

Abbreviations: BSE, bovine spongiform encephalopathy; CPB, Cartagena Protocol on Biosafety; EFSA, European Food Safety Authority; eNGOs, environmental non-governmental organizations; EU, European Union; FAO, Food and Agriculture Organization; GM, genetically modified; GMOs, genetically modified organisms; LLP, low level presence; RAF, risk analysis framework; USDA, United States Department of Agriculture; WTO, World Trade Organization

The global regulation of products of biotechnology is increasingly divided. Regulatory decisions for genetically modified (GM) crops in North America are predictable and efficient, with numerous countries in Latin and South America, Australia and Asia following this lead. While it might have been possible to argue that Europe's regulations were at one time based on real concerns about minimizing risks and ensuring health and safety, it is increasingly apparent that the entire European Union (EU) regulatory system for GM crops and foods is now driven by political agendas. Countries within the EU are at odds with each other as some have commercial production of GM crops, while others refuse to even develop regulations that could provide for the commercial release of GM crops. This divide in regulatory decision-making is affecting international grain trade, creating challenges for feeding an increasing global population.

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 decreased dramatically, the probability of being killed in an automobile accident has increased. Life expectancies at the dawn of the 20th 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 and low 80s.[1] Clearly, the nature of risks that humans face has changed over time, but so too has the incidence of life threatening risks. At the beginning to the 21st century, mankind has mitigated many risks that have previously been life threatening, especially when it comes to food and food security.

Not since the 'Dirty 30s' and World War II have industrialized nations been forced to manage the challenges created by food shortages. Food rationing and soup kitchen lines are but high school history lessons today. As the level of food security increased in the post war period, attention was increasingly focused on the safety of foods being consumed. Scientific advances in testing provided the opportunity to detect the presence of unsafe bacteria, foreign matter and other contaminants and adulterants. The ability to test for undesirable attributes associated with consuming a particular food product made it possible to determine safe consumption thresholds. Risks regarding food consumption were quantified and this greatly aided in the ability to improve the safety of the food products. By 1979, a uniform risk analysis framework (RAF) had been developed that could be applied to a wide variety of consumable products.[2]

As the safety of food products increased over recent decades, the ability to test for those consumers that may suffer from adverse reactions to particular food products or ingredients has greatly increased. Testing allows for increasingly refined sub-sets of the population to be assessed for their exposure and response to a particular substance. For example, the ability to test young children for their potential to have adverse reactions to nuts, especially peanuts, has increased. The benefits of these scientific advances in risk analysis are substantial in further reducing harmful effects from food consumption. However, correlation is not always possible between what is scientifically defined as a risk that could affect the products safe consumption and a risk that registers with government politicians requiring regulatory action.

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The concern is that as risk is increasingly being politicized, especially within the European Union (EU), the risks to consumers of consuming unsafe products will increase. Certainly the potential to reject safe products has increased as is witnessed by the rejection of genetically modified (GM) food products. Risk assessment of food products borders on rejecting science-based risk assessment as a way of determining what foods are safe to consume, resulting in some consumers facing food safety risks that their ancestors did hundreds of years ago.

Trends in Risk

The risk evaluation systems operating in most industrialized countries are generally scientifically-based processes that combine the identification and characterization of hazards with assessments of exposure to characterize risk. In essence, they objectively assess the probabilistic outcomes of discrete adverse events, for the most part abstracting from issues related to risk management. The practice is that governments establish a risk threshold for products or classes of products that reject new products with unacceptable risks but allow those with acceptable impacts to enter the market.[3]

Risk assessment is defined by the Food and Agriculture Organization (FAO) as "a scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization[4]". Powell[5] offers an elaboration of the system by combining the US National Academy of Sciences—National Research Council model of risk assessment with observations of Lammerding and Paoli.[6] 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, including the conditions where the pathogen survives, grows, causes infection and dies. As such, this stage often involves epidemiological and surveillance data, scientific studies and regulatory validation. These macro results need to be scaled to subpopulations 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., immunosuppressed, old, young). The combination of hazard identification and characterization provides a theoretically supported rationale for a causal relationship between exposure and response. In contrast, exposure assessment is the determination of the extent of human exposure before or after application of regulatory controls. This includes a description of the pathways through which a pathogen 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 pathogen. Finally, risk characterization entails describing the nature and often the magnitude of human risk, including aspects of uncertainty. This is the stage, where the hazard, exposure and variability of the results are combined to estimate the potential risk of a new product.

Traditional risk assessment theory suggests that risk is a combined measurement of the degree of exposure multiplied by the hazard, that is the level of adverse effects of the agent on other organisms.[7] This can be expressed as:

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

Scientists have used this formula to evaluate whether initial research findings should proceed or be halted. If the assessment was conducted and the level of risk was determined to be higher than was scientifically safe, then government agencies would not approve the technology or product for release. While 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. Hence, it is not unreasonable to expect to see different levels of risk accepted in different circumstances. The final decision is based on the public policy of the country which determines the acceptable or tolerable level of risk.

Economists argue that in a rational world where scientific judgments reign, one would expect that risk thresholds would be comparable across all socially mediated activities and that governments would thereby standardize risks. This is empirically testable. If we had a common standard of acceptable risk, one would expect that the cost-benefit ratio of different risk analysis decisions would be equal. That is, the implicit valuation of life would tend to be clustered or the same across all products and categories of risky activities. Of course, the reality of this is much different. In fact, public policies implicitly weigh some risks higher than others, with the result that the implicit public valuation of life varies widely across different categories. Tengs et al., *ex post* analysis of public investments in risk management suggests that we have a far from rational system (**Table 1**).[8]

Governments in North America and Europe are willing to spend extremely large amounts to save a human life from some risks (i.e., $20 billion for benzene emissions) while in other circumstances even token amounts of investment are foregone (i.e., less than $100 per life saved from seat belt use).[8]

Many use this set of results, which can be repeated in other markets, to question whether we really have an objective risk analysis framework. Experts are the greatest sceptics. Naturally, experts have a different view about the level of risk associated with a new product or technology than will the general public. This is due to their relationship between the substance that could potentially cause a risk and their ability to harmfully interact with that substance. As a result, experts are often confused by consumer reactions to new products and technologies. Scientists understand that thresholds exist for many undesirable attributes and that consumption of extremely low levels of these attributes can be seen as safe. It is possible, however, to identify factors that influence the divergence between expert assessment and public concerns. Many have pointed out that our willingness to accept risk varies widely depending on the types of risk—voluntary or

Table 1. The Price of Life

Cost of saving one year of one person's life, 1993$US	
Passing laws to make seat belt use mandatory	69
Sickle cell anemia screening for Black new-borns	240
Mammography for women aged 65 and over	810
Giving advice on stopping smoking to people who smoke more than one pack a day	2,000
Putting men aged 30 on a low cholesterol diet	9,800
Regular leisure time physical activity, such as jogging for men aged 35 and over	19,000
Making pedestrians and cyclists more visible	38,000
Installing air-bags (rather than manual lap belts) in cars	73,000
Installing arsenic emission standards at glass manufacturing plants	120,000
Setting radiation emission standards for nuclear power plants	51,000,000
Installing benzene emission control at rubber tire manufacturing plants	20,000,000,000

involuntary, familiar or exotic, predictable or random. Voluntary, familiar and predictable risks—such as car accidents and heart attacks—often generate little public concern, which works to mute the perceived risk and can lead to under-investment in assessing or managing that risk. In contrast, involuntary, exotic and random risk—such as the prospect of being infected by Creutzfeldt-Jakob Disease from BSE infected cows—can generate outrage, amplifying the perceived risk and leading to over-investment in assessing or managing that risk.

Recently there has been significant effort put into understanding the divergence between objectively assessed risks (the old science-based model) and what many call socially constructed risks. Sandman believes the old formula under estimated the actual level of risk because it ignored the public response to a risk, which he termed 'outrage'.[9] He argues that regulators should instead use the following formula for understanding consumer perceptions of risk:

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

Sandman advocates that public concern is focused on whether the risk is acceptable rather than on the scientifically perceived incidence of that risk. While 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 is one that incorporates all elements of the perspectives, that is, hazard identification and characterization, exposure assessment and consumer/citizen response, or outrage. Thus:

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

Hazard and exposure would be included in the scientifically derived measure of risk, but the outrage factor would be normalized at 1.0. **Table 2** shows illustrative outrage factors calculated by converting the implicit value of life calculations from (**Table 1**) into indices using different social values of a life ($100,000, $200,000 and $300,000).[10]

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 empirical evidence. While the system is and should be designed to avoid making Type 1 errors, that is, accepting something that is not safe, it has to be mindful of the trap of making Type 2 errors, rejecting safe products and activities (**Table 3**). While we can tally up the cost of Type 1 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 significantly raises the potential of making a Type 2 error, thereby diminishing the flow of new and innovative products and progress in a science-based economy.

Thus, there is a pressing need to consider the appropriate role for science and society in the evaluation of new risks imposed by transformative technologies, in this case by the introduction of biotechnology in the agri-food system.

The Politicization of Risk

Science-based regulations provide the underpinnings of international organizations, agencies and agreements and have done so for decades. While not perfect, science-based regulations have established frameworks that provide consistent and repeatable decisions to those parties involved in the international trade of agricultural products. While disagreements have arisen, been addressed and resolved, developed countries have traditionally respected the rational for grounding the regulation of

Table 2. Illustrative Outrage Factors Based on Implicit Value of a Life

If social value of a life saved is:	**$100,000**	**$200,000**	**$300,000**
Then outrage factor for risk would be:	*Index where 1.0 = normal*		
Passing laws to make seat belt use mandatory	0.07	0.03	0.02
Sickle cell anemia screening for Black new-borns	0.24	0.12	0.08
Mammography for women aged 65 and over	0.81	0.41	0.27
Giving advice on stopping smoking to people who smoke more than one pack a day	2.00	1.00	0.67
Putting men aged 30 on a low cholesterol diet	9.80	4.90	3.27
Regular leisure time physical activity, such as jogging for men aged 35 and over	19.00	9.50	6.33
Making pedestrians and cyclists more visible	38.00	19.00	12.67
Installing air-bags (rather than manual lap belts) in cars	73.00	36.50	24.33
Installing arsenic emission standards at glass manufacturing plants	120.00	60.00	40.00
Setting radiation emission standards for nuclear power plants	51,000	25,500	17,000
Installing benzene emission control at rubber tire manufacturing plants	2×10^7	1×10^7	6.67×10^6

Table 3. The Typology of Errors

Decision	**Product is safe**	**Product is unsafe**
Accept as safe	Correct	Type 1 error
Reject as unsafe	Type 2 error	Correct

international trade in agricultural products in science. It is posited here that the creation of the European Food Safety Authority (EFSA) has dramatically altered the EU's adherence to science-based risk assessment and product approvals, encouraging movement toward socio-economic-based regulation of agricultural products and, hence, the politicization of risk. The establishment of EFSA resulted in a decoupling of the risk assessment and product approval processes within the EU. EFSA conducts the risk assessment using science-based methodologies and provides a report of their assessment to the European Commission. However, the product approval process resides with committees of the European Commission, resulting in the politicization of risk.

Between June 1999 and August 2003, the EU had a moratorium on the approval and import of GM crops and food products. This moratorium was ultimately ruled by the WTO to be in violation of international commitments in 2006.[11] In 2003, the EU implemented a new regulatory regime for GM crops and food products and, in the wake of the WTO judgment on its previous moratorium, claimed that the new regime would be WTO compliant, but it needed time to make the necessary adjustments.[12] By 2004, under its new regulatory regime, the EU Commission called for all member states to begin developing frameworks for coexistence whereby agricultural producers growing organic or conventional crops would not suffer economically from their crops comingling with GM products. During the moratorium, the regulation of GM crops in field trials and experimental research plots was science-based and remained under the jurisdiction of individual EU Member States.

Smyth et al., identify 2 instances where seed varieties in Europe were found to contain trace amounts of GM varieties.[13] In May 1999, the Swiss Department of Agriculture announced that 2 Pioneer Hi-Bred non-GM corn varieties, imported and distributed by Eric Schweizer Samen, had been found to contain trace amounts of GM varieties. Based on polymerase chain reaction tests, the level of comingling ranged from 0.1% to 0.5%.[14] Pioneer had distributed enough seed to plant an estimated 400 hectares, of which about half had been seeded at the time of detection. The GM traits that were identified were not approved for import or commercial release in Switzerland. As a result, the fields that were planted were burnt or controlled with herbicides. The importer agreed to pay compensation of 700 Swiss francs per hectare.

The second incident, in the spring of 2000, was a breeders shipment of canola seed imported by Advanta into Europe containing 0.4% unapproved GM traits.[15] Advanta quickly determined that the unexpected presence of GM canola was caused by gene flow from GM foundation seeds that had been planted in a neighboring field. Canadian seed growers had followed isolation rules but the genes still moved into the conventional foundation seed. The total acreage planted with this seed in most countries (except Britain) was insignificant with Sweden and Germany each having 300 hectares and France having 600 hectares. The affected countries faced a cost in dealing with this incident. France ordered all 600 ha to be ploughed down and Sweden allowed the canola to be harvested but prohibited the canola from entering the domestic or wider EU market. In Britain, over 15,000 hectares were planted and had to be destroyed. As a result of this, Advanta had to pay compensation in the millions of dollars.[15]

In August 2002, the United Kingdom's Department for Environment, Food and Rural Affairs announced that they had been advised by Aventis CropScience of some impurities in canola seed that was being used for Farm Scale Evaluation field trials in England and Scotland.[16] The initial discovery arose from a routine audit conducted by the Scottish Agricultural College where the level of comingling was 2.8%. Given the crop was well advanced at the time of the discovery, it was harvested and the resulting seed destroyed.

Trace amounts of GM canola were detected in Canadian mustard exports to the EU in March 2003.[17] A mustard shipment in late 2002 was tested and found to contain trace amounts of GM material. Since there were no GM mustard varieties in Canada at that time (and none exist at present), the importers conducted further tests and determined that the trace amounts of GM material were GM canola. According to export standards, mustard exports are allowed to contain 1% canola and since 75% of the canola produced in Canada at the time was GM, it was not surprising that trace amounts would comingle. There is no information on what the European importers did with the mustard shipment.

The above are examples of comingling or the detection of low-level presence (LLP) of GM material in other crop shipments. The international trade of bulk agricultural commodities never has, and realistically cannot, function with zero-tolerance as the threshold, such as is currently required in EU regulations pertaining to GM crops that have not been approved. However, with science-based regulations underpinning the domestic regulatory systems of the countries where GM comingling occurred, the incidents were addressed and resolved, without the closure of borders and the suspension of international trade—political interference was minimal. As is shown below, since the EU decided to decouple risk assessment from product approval, the approval process for GM crops in the EU has become purely politicized.

In 2006, trace amounts of an unapproved GM event were detected in US rice exports to the EU. The widespread presence of what has subsequently become known as LL601 rice resulted in an EU announcement on August 20th, 2006, that it would no longer accept rice shipments from the US.[18] As is noted by Kershen, after a 14-month USDA investigation as to how this comingling occurred, costing over US$1 million, no conclusive explanation exists.[19]

Over 1,000 lawsuits have been launched against the developer of LL601, Bayer CropScience, as the court rejected a class action lawsuit.[20] The authors note that some reports indicate that over 6,000 lawsuits have been filed. The lawsuits seek compensation for ruined crops and for depressed international markets for rice exported from the US. The German food producer, Rickmers Reismüehle, sued 2 Arkansas defendants—the large grower cooperative Riceland Foods and the Producers Rice Mill—alleging that shipments to the company contained unapproved GM rice in breach of several contracts. Riceland Foods and the Producers Rice Mill turned to the developer of the rice variety for an explanation, as well as compensation. In the spring of 2011, Riceland Foods was awarded US$136.8 million.

In December 2009, the first of the producer cases to be settled was decided with the first 2 farmers receiving settlements. One farmer received an award of US$1.95 million, while the second received US$53,000. In the summer of 2011, Bayer offered US$750 million to settle all producer lawsuits related to the LL601 rice case. This settlement was based on the condition that at least 85% of the total rice acres planted between 2006 and 2010 would be encompassed by the settlement.[21] Producers were to be compensated on a per acre basis. This offer was accepted by the affected rice producers. Six years after the initial detection the EU market has still not fully reopened to US long grain rice exports with current exports being less than one-third of previous levels.

Smyth et al.,[2] discuss the trade implications in US-EU corn trade following the commercialization of Herculex corn. This GM corn was approved in the US, but not in the EU and in spite of testing prior to export, trace amounts were discovered in the EU. The detection of this variety of corn, released by Pioneer Hi-Bred in 2006 caused corn gluten feed exports from the US to the EU to drop by 30–40%. What is interesting in this case is that Pioneer submitted notification of import into the EU for Herculex I in 2000.[22] By 2006, Herculex I had received approval for feed and food use, as well as planting. The problem arose when Herculex (R) Rootworm varieties were detected in shipments coming from the US. These varieties were ultimately approved by the EU in 2009. For the 2006 to 2009 period, corn trade was disrupted.

In September 2009, the EU's Rapid Alert System for Food and Feed announced the detection of GM flax in food products in Germany. GM flax received variety approval in Canada in 1997 and the seed was multiplied from 1997–99, but had not entered commercial production when it was removed from the market in 1999 due to EU concerns about importing GM flax for industrial application. The variety was deregistered in 2001. GM flax never received variety approval in Europe, hence the problem. By the end of September, Canadian flax in Europe was in quarantine and flax trade between Canada and Europe was suspended, pending identification of the source of comingling and the implementation of testing protocol that could provide assurance to European importers that Canadian flax exports would be free of GM flax. Testing of 26,000 flax samples in Canada revealed that 0.05% of samples have tested positive.[23] The European border to Canadian flax was closed for a 3-month period, at the height of Canada's flax export season, resulting in an estimated market loss of C$58 million.[24]

Following the EU centralization of regulatory authority for approvals of GM crops with EFSA, there has been a visibly noticeable movement away from reliance on their science-based regulations at the European Commission level in dealing with GM products in general, but more specifically with the comingling of GM and non-GM products. As is noted in an Editorial in *Nature Biotechnology*, "[i]n Europe, since the mid-1980s, regulators have shifted from evidence-based risk assessments to implementation of rules that specifically discriminate against transgenic products and emphasize the precautionary principle".[25] The EU has moved from science-based regulation as the underpinning of international trade to the use of socio-economic considerations in decision-

making, by increasingly incorporating the principles of the Cartagena Protocol on Biosafety (CPB) into regulatory frameworks and especially into the product approval process. EFSA's science-based risk assessment of GM crop variety applications have been increasingly rejected by the politics within the European Commission.

As indicated above, thresholds exist for a variety of unsafe materials commonly found not only in food, but in the trade of agricultural products. Even while knowing that trade in agricultural products cannot function at zero percent, it was decided by the European Parliament in Directive 2001/18 that if any GM variety was detected in agricultural product imports, or found growing in the EU, and if the variety was not approved for import or feed production, its use would be illegal and therefore the tolerance threshold was established at zero.[26] By 2011, this was proving unworkable and so in a move designed to provide assistance to the European animal feed industry, a threshold of 0.1% was agreed upon for the detection of unapproved events that had been approved for production in a non-EU country. The zero threshold still applies to food imports as the EU member states were not able to reach a consensus on this.

Prior to the establishment of EFSA, accountability between regulators and those impacted by LLP was quite proximate, where decisions were based upon scientific risk assessments. In some pre-EFSA LLP instances the affected crop was allowed to be harvested and exported. Post-EFSA, at the earliest detection of LLP, the EU has automatically closed its borders to imports of the affected product. If science-based coexistence was allowed in the 1999–2003 moratorium period in the EU, why is it no longer feasible in the post-EFSA period? The answer appears to be that risk in the EU context is no longer about science-based assessment, but is now a political accountability issue and no one within the European Commission system for approving GM crops and food products, wants to take responsibility for allowing an LLP event to be dealt with through a solely science-based decision process and now, instead, defaults to closing borders to international trade. With regulatory accountability residing with the Commission, there is a disconnection between regulators and those affected. The detection of GM flax in Europe is estimated to have cost the European flax industry €39 million and over 600 jobs were lost.[27]

With companies and producers being domestically based and coexistence and LLP policies being the mandate of the European Commission and the European Parliament, those adversely affected by an LLP incident have virtually no opportunity to hold regulators accountable for their decisions. None of the above GM canola LLP incidents had been approved for import or production within the EU, yet science-based regulation allowed these situations to be addressed while international commerce continued. The EU is clearly aligning its regulatory rational with the Cartagena Protocol on Biosafety (CPB) and socio-economic considerations. Risk assessment and product approvals within socio-economic consideration-based regulatory systems is subject to political manipulation. Based on the recent LLP detections and the EU's response to these issues, risk assessment and GM product approval within the EU can now be viewed as politicized.

Socio-economic Regulatory Frameworks

Socio-economic assessments of genetically modified organisms (GMOs) have become a controversial issue under the Cartagena Protocol on Biosafety to the Convention on Biological Conservation.[28] The objective of the Protocol is to contribute to ensuring an adequate level of protection in the safe transfer, handling and use of "living modified organisms resulting from modern biotechnology" that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health and specifically focusing on transboundary movements (Article 1 of the Protocol).[29]

Under the protocol, parties may also include socio-economic considerations in reaching decisions on imports, including the planting of GMOs. Some authors, such as Jaffe argue that the Protocol limits the scope of socio-economic assessments to those factors affecting biodiversity with an emphasis on those affecting local and indigenous communities.[30] Nevertheless, even if the scope of the Protocol is limited, many countries are, or have, considered inclusion of socio-economic aspects in their national legislation. While Article 26 provides the opportunity for including a socio-economic assessment in national biosafety regulations, international concern has been raised that socio-economic assessments will become a mandatory part of approval processes and further complicate the approval of new crops.[29]

Article 26 of the Cartagena Protocol on Biosafety

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Socio-economic regulations move risk assessment even further away from scientifically quantifiable measurement. Over the past 20 y, risk assessment has, in some jurisdictions and in relation to some specific items, progressively moved away from science-based assessment (e.g., Norway, the Netherlands, Mexico, Thailand, Egypt).[31] Socio-economic regulations are no longer concerned with the scientifically quantifiable aspects of risk, such as hazard or exposure, rather, they now involve issues such as ethics, labor impacts and consumer choice. The politicization of risk creates a function that can be expressed by:

$$\text{RISK}^{\text{political}} = \text{OUTRAGE} \times \text{UNSUBSTANTIATED INFORMATION} \times \text{eNGO PRESSURE.}$$

Table 4. Typology of Food Safety Risks

Food safety issue	RISK ^{scientific}	RISK $^{socially\ constructed}$	RISK ^{modern}	RISK ^{political}
High cholesterol foods	High	Moderate	Moderate	Low–moderate
Foods high in sugar	High	Moderate	Moderate–high	Moderate
High sodium foods	Moderate	Low	Moderate	Low
Decomposing snail in beverage bottle	Low–high	High	High	Low
Dead frog in package of frozen vegetables	Low–moderate	High	High	Low
E-coli in hamburgers	High	Low	Moderate	Low
Salmonella	High	Low	Moderate	Low
Mycotoxins	High	Moderate	High–moderate	Low
Filth and extraneous materials (insect fragments, stones, twigs, rodent manure)	High	High	High	Low
GM foods	Low	High	High	High

Governments will be impacted in their decision-making capacity by the presence of social outrage from society, which in turn, is a factor of hearsay, allegations and innuendoes promoted by environmental non-governmental organizations (eNGOs). The various formulas for assessing risk can be thus compared in terms of their response to a series of food safety concerns (**Table 4**).

The politicization of risk jeopardizes the movement toward increased food safety by utilizing political influence to regulate (and reject) safe products, Type 2 errors, while drawing attention and resources away from identified and substantiated food safety risks. This concerning trend in risk assessment and regulation of food products is moving toward Type 1 errors, not so much that unsafe foods are being approved, but rather that foods that are less safe than they might otherwise be are not subject to increased regulatory (i.e., food safety) scrutiny. Food products that have been well documented in the health science literature as identifying that concerns are present regarding the high cholesterol, sugar or sodium of the product, receive some political encouragement to improve these products or to better label the health problems associated with consumption, but foods that truly have safety concerns rank quite low in terms of political food safety priority.

Food products that occasionally contain undesirable attributes such as beer with the decomposed remains of a snail in the bottle[32] or the presence of fumonisins in corn-based food products[33] receive low priority under a politicized risk assessment. The presence of a dead remains in food products is certainly revolting enough to consider if one had sipped the beer or eaten some of the vegetables and the outrage of this is correspondingly high and increased food safety scrutiny has ensured that these risks are minimized, but at a political level, there is simply not the impetus to rationalize this as being a leading health/food safety concern.

In September 2009, trace amounts of GM flax were detected in flax exported from Canada to the EU. The GM trait was not approved in the EU and so there was a zero tolerance threshold. The political risk of this was monumental as the EU closed the border for GM flax imported from Canada for a 3-month period, ultimately costing C$80 million in Canada and the EU. This was all over a product that had been approved for safe food consumption in both Canada and the US. To juxtapose this, in Europe from May to July 2011, over 50 people died from the consumption of organic cucumbers contaminated with *E. coli*.[34] Shockingly, the political risk from the death of consumers from unsafe organic food in the EU was non-existent, while the political risk from virtually undetectable trace amount of safe GM flax received massive regulatory scrutiny.

Conclusions

Millions, if not hundreds of millions, of our ancestors have died from the consumption of unsafe food. Over time, science-based food safety testing and detection mechanisms were developed and implemented to improve the quality of consumed food, minimizing the risk of consuming unsafe food products. Of course, no system functions at 100% safety and occasionally consumers unfortunately die from the food they eat. The present reality is that consumers die from eating unsafe food, not GM food.

Risk assessments have become increasing discerning in their ability to identify greater sub-sets of the general population that might be at risk from any innovation undergoing regulatory scrutiny. Of course, the cost of preventing a death in the smaller subsets increases substantially. This has grown to the point that in the case of regulating GM food products, an inordinate sum of money has been spent regulating these products in some jurisdictions with no identifiable corresponding increase in either food risks or food safety. Science-based risk assessments have proven that GM foods are safe to consume, while politicized risk continue advocating that consuming GM foods is a danger to one's health.

Political interference with risk assessments will jeopardize food safety in that unsafe food products (i.e., *E. coli*

contaminated organic food) will be allowed onto store shelves, constituting Type 1 errors, while safe food products (i.e., GM food products) are being rejected, Type 2 errors. The objective of food safety regulatory frameworks should be the provision of safe, healthy and nutritious foods. The politicization of risk is a frustrating deviation from such an objective.

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