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Food security and the evaluation of risk

Stuart J. Smyth [a], Peter W.B. Phillips [b], William A. Kerr [a,*]

[a] Department of Bioresource Policy, Business and Economics, University of Saskatchewan, 51 Campus Drive, Saskatoon, Canada S7N 5A8
[b] Johnson-Shoyama Graduate School of Public Policy, University of Saskatchewan, 101 Diefenbaker Place, Saskatoon, Canada S7N 5B8

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ABSTRACT

Achieving global food security over the next 40 years will require sustained increases in agricultural productivity. This will require increased investment in agricultural R&D. If there are systemic reasons why agricultural R&D is inhibited, they warrant investigation. New products and technologies require regulatory approval if they are to be commercialized. Approval, or not, is based on risk assessment with only those products that pass the risk assessment contributing to productivity improvements. If the likelihood of meeting the acceptable risk threshold is reduced, investment in R&D will be negatively impacted. This paper investigates the changing methods of risk assessment for agricultural products and notes a deterioration in the likelihood that risk assessment exercises will be completed successfully. Genetically modified products are used as an example. The changing nature of risk assessments is found to be inhibiting international market access, reducing trade and, hence, making investments in productivity enhancing technologies in agriculture less interesting. Achieving future food security goals will be more difficult.

1. Introduction

There are hundreds of millions of people that currently do not enjoy an acceptable level of food security. Furthermore, there are serious challenges involved in feeding more than 9 billion by 2050 (Beddington, 2010; Evans, 2009). FAO's Deputy Director-General suggested that "agricultural production needs to increase by 70% worldwide, and by almost 100% in developing countries, in order to meet growing food demand" (Tutwiler, 2011).

As global populations expand, ensuring that enough food is available and affordable requires that productivity in food production keeps pace. Otherwise there will be more individuals chasing ever scarcer food – leading to higher prices, lower availability and food insecurity for some. Ultimately if the Malthusian Trap is to be avoided, agricultural productivity must increase (Alston et al., 2009). Meanwhile, there is considerable evidence of serious underinvestment in agricultural R&D over recent decades (Alston et al., 2009; James et al., 2008). Even if investment could be increased to eventually backfill the current shortfall, there are considerable lags – often in the 25-year plus range – between when investments are made and productivity increases are fully manifest (Alston, 2010).

Many reasons exist for underinvestment in agricultural research, including governments' fiscal difficulties (Gaisford et al., 2001); the inability to capture full benefits (Alston, 2002); misaligned incentives (Malla and Gray, 2005); resistance to technological change (Haggui et al., 2006); poor intellectual property protection (Cardwell and Kerr, 2008); high costs in identifying and acquiring existing intellectual property (Smyth and Gray, 2011); and long and costly regulatory processes for new technologies (Smyth et al., 2004).

One further factor that can negatively impact investments in productivity-enhancing technologies is the risk assessment process. Prior to commercial production, products must be judged to pose a sufficiently low degree of risk to be acceptable to society (Phillips et al., 2006). Over the last 20 years the process of risk assessment has been evolving and diverging geographically. The major spur for the diverging treatment has been agricultural biotechnology (agbiotech). The rift over agbiotech is often portrayed as a disagreement between the EU and the US and, while they have been major champions of the divergent approaches to risk, the rift has global implications for investments in agricultural technologies and food security (Isaac and Kerr, 2007a; Barrows et al, 2014).

An increase in the likelihood that a new product or process will not be considered safe enough to be commercialized will reduce the appetite – both public and private – to make the required investment (Smyth et al., 2014). The higher the probability of failing to reach an acceptable level of risk, the smaller the expected benefits will appear to be and less investment will be made (Kerr and Yampoin, 2000; Gaisford et al., 2002, 2007). Similarly, if part of a market has a reduced likelihood of achieving an acceptable level of risk, the expected benefits are reduced

* Corresponding author.
E-mail addresses: stuart.smyth@usask.ca (S.J. Smyth), peter.phillips@usask.ca (P.W.B. Phillips), william.kerr@usask.ca (W.A. Kerr).

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(Gaisford et al., 2001). All of this inhibits investment in R&D, reducing the rate of technological change just when it is most needed to ensure food security (Smyth et al., 2011). While agbiotech has been the major force behind changes in risk evaluation, this paper tries to make a broader point: once new methods of risk assessment are accepted there is an increased chance that they will be applied to other agricultural innovations, which could jeopardize efforts to address food security. We will use many examples from biotech, but these are just examples – the objective of the paper is not to focus on GM-policy in the EU. Rather, future food security requires we look at all the impediments to higher agricultural productivity, one of which is the risk assessment process facing new technologies.

2. International scope of science-based risk assessment

International risk management strategies have been grounded in science to ensure that risk assessments (and their processes) are not used to distort trade. While no international institution has the mandate to govern biotechnology, there are several with the mandate to govern risks related to agriculture. Four international institutions have staked claims to regulating the food safety and environmental health of products developed from biotechnology. Science-based governance underpins these institutions: the World Trade Organization (WTO); the Codex Alimentarius Commission (Codex); The World Organization for Animal Health (OIE); and the Secretariat of the International Plant Protection Convention (IPPC).

The WTO does not establish regulations governing agbiotech, but it does adjudicate disputes. A nation that enacts a regulation that contravenes the standards of Codex, the OIE or the IPPC can be subject to a WTO member filing a claim that the standard is an unfair trade barrier. 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 to protect the environment or human, animal and plant health. The SPS specifies that: (1) standards which conform to international (i.e. Codex, OIE, IPPC) norms are consistent with the SPS; (2) standards that are in excess of international standards or where no international agreement exists must be based on scientific principles and the completion of a scientific risk assessment.

If, for example, an International Standard for Phytosanitary Measures (ISPM) established by the IPPC allows for a trade barrier, then every member country of the WTO is allowed to implement this standard without fear of challenge. If a WTO member implements a standard that contravenes the internationally-agreed standards, then that country may be accused of using a disguised trade barrier. Countries may have higher standards than those of an international organization, but only if there is a scientific justification and a risk assessment that satisfies SPS commitments.

The IPPC is a treaty that protects natural flora, cultivated plants and plant products from the spread of pathogens through international trade. It provides a forum for cooperation and technical harmonization. Regulating genetically modified (GM) crops has been addressed though several ISPMs. The IPPC's most important role in trade policy is through the SPS Agreement which accepts the IPPC standards as the basis for evaluating WTO disputes. National measures based on IPPC standards are not open to a WTO challenge.

Codex develops international standards for processed foods including additives, potential contaminants, hygiene, labeling requirements and the scientific procedures used for sampling and analysis. Upon a standard being adopted at Codex, countries are encouraged to incorporate it into domestic rules, but countries may unilaterally impose more stringent food safety regulations, provided the different standards are scientifically justifiable. Codex standards are acknowledged in the SPS and Technical Barriers to Trade (TBT) Agreements of the WTO. There has been significant effort to develop a standard for the labeling of food products derived from biotechnology. The Codex Committee on Food Labeling, after nearly 20 years, in 2012 adopted the principles for a risk analysis of foods derived from biotechnology. It established that labeling is an appropriate strategy for managing identifiable risks. Codex stresses that any risk analysis of biotechnology-derived foods has to be science-based and that any assessment not address “environmental, ethical, moral and socio-economic aspects” (Codex, 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.

In addition to these international institutions, the Organisation for Economic Cooperation and Development (OECD) has, since 1995, actively assisted in the international harmonization of regulatory requirements, standards and policies related to biotechnology. The OECD has worked toward more transparency to facilitate trade in agbiotech products. It develops Consensus Documents that set out the biology of crops, introduced traits, or gene products to provide a common basis for various national regulatory assessments of agri-food products derived from biotechnology. These Consensus Documents contain the technical knowledge that is utilized in the risk assessment of agbiotech products. These mutually recognized documents are increasingly embedded in national regulations.

Risk evaluation systems in modern market economies have been scientifically-based processes that combine the identification and characterization of hazards with assessments of exposure to characterize risk (FAO, 2012; Powell, 2000; Lammerding and Paoli, 1997). The practice is that governments establish a risk threshold that rejects new products with unacceptable risks but allow those with acceptable impacts (Jackson, 2014; Ryan, 2014; Beckmann et al., 2014).

Traditional assessment theory suggests that risk is a combination of exposure and hazard; that is the level of adverse effects of the agent on other organisms (NRC, 1983). This can be expressed as

$$\text{Risk}^{\text{scientific}} = \text{Hazard} \times \text{Exposure}$$

Scientists use this formula to evaluate whether initial research should proceed or be halted, providing the scientific basis for evaluations. If an assessment's level of risk was determined to be higher than what was accepted as scientifically safe, government agencies would not approve the technology or product. While the hazard would appear to be 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.

There has been significant effort put into understanding the divergence between objectively assessed risks (the original science-based model) and socially constructed risks. Sandman (1994) believes that the original formula underestimated the perceived level of risk because it ignored the public response to a risk, which he termed ‘outrage’. He argues that regulators should use the following formula for understanding consumer perceptions of risk:

$$\text{Risk}^{\text{socially constructed}} = \text{Hazard} \times \text{Outrage}$$

Sandman (1994) suggests that public concern is focused on whether the risk is acceptable rather than on the scientifically perceived incidence of that risk. While the model accommodates areas where outrage dominates, it does not fully account for the interaction between expert and public opinion on matters related to exposure.

Perhaps a better risk analysis framework is one that incorporates three independent elements, that is, hazard identification and characterization, exposure assessment and consumer/citizen

Table 1
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

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 could vary widely, at times muting concerns and raising tolerance for risky outcomes and at other times dramatically raising the bar for market entry.

Ultimately, risk assessment ought to be designed to make socially optimal decisions – that is accepting safe products and rejecting unsafe products. As with any human system, there is potential for error, especially when considering a new class of products where empirical evidence is scarce. While the system should be designed to avoid making Type 1 errors (accepting false positives), that is, accepting something that is not safe, it has to be mindful of the trap of making Type 2 errors (accepting false negatives), unnecessarily and wastefully rejecting safe products and activities (Table 1). 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 the loss of all of the attendant benefits that could flow from them. Social amplification of risk raises the potential of making a Type 2 error, thereby diminishing the flow of new and innovative products. Such Type 2 errors in the agricultural industry can have dire effects on the efforts to enhance productivity in aid of achieving food security.

Thus, there is a pressing need to consider the appropriate role for science and society in the evaluation of risks associated with technological improvements.

3. The politicization of risk

Science-based regulations underpin international organizations and agreements. While not perfect, science-based regulation has fostered frameworks that provide consistent and repeatable decisions to parties involved in, among other things, international trade (Wozniak and McHughen, 2013; Smyth et al., 2014). While disagreements arise, developed countries have traditionally respected the rationale of grounding the regulation of trade in agricultural products in science. Strong evidence of this is the acceptance by consensus of the WTO SPS Agreement in 1994 (Isaac, 2007).

Starting with commercialization of GM crops in the mid-1990s, there has been an effort by some countries to move away from science-based risk assessments (Smyth and Falck-Zepeda, 2013; Falck-Zepeda et al., 2013; Ludlow et al., 2014). The Cartagena Protocol on Biosafety (CPB) represents one ongoing effort to provide a comprehensive international structure to ensure the protection of biodiversity and to facilitate consideration of non-scientific concerns. The CPB was negotiated specifically to deal with trade in the products of biotechnology, providing one set of rules for transboundary movements of GM organisms intended for food or environmental release. It provides a forum for expressing concerns about biotechnology and to justify national laws addressing potential harms to environment, human health or other forms of loss.

In general, socio-economic assessments provide useful information about the potential impacts of new technologies, but do not contribute to reducing or minimizing the technology's scientific risks. In the case of GM crops, this information may include socio-economic impacts at the farmer, household, industry and trade levels. Furthermore, socio-economic assessments include non-pecuniary and indirect impact considerations, including the effect of lower health risks arising from reductions in pesticide use or shifts to less toxic active ingredients, market size, possibilities for tracking and tracing, implications for biodiversity, the need for specific regulations in areas close to important ecological zones and changes in farm labor organization (Ludlow et al., 2014). Nevertheless, the results of a socio-economic assessment can almost always be expected to be controversial and may vary depending on the choice of methods, baseline data used, spatial and time focus and even the research team conducting the analysis.

It is posited here that the experience with a WTO challenge under the SPS pertaining to an EU ban on imports of beef produced using growth hormones (Kerr and Hobbs, 2005) and domestic resistance to biotechnology (Perdikis, 2000; Hensen, 2001) dramatically altered the EU's adherence to science-based regulations, encouraging movement towards socio-economic-based regulation of agricultural products and, hence, the politicization of risk. While the change is scattered throughout EU legislation, it is best illustrated by the regulatory regime put in place to govern agbiotech in 2003 – after a moratorium on regulatory approvals instituted in 1999 (Viju et al., 2012). The new regime established the European Food Safety Authority (EFSA) along with political institutions – both of which must grant approval – resulting in a decoupling of risk assessment from product approval processes. EFSA conducts science-based risk assessments, however the product approval process is decided in European Commission institutions, resulting in the politicization of risk.

Between June 1999 and August 2003, the EU had a moratorium on the approval and import of GM products. During the moratorium, the regulation of GM crops in field trials and experimental plots was science-based and under the jurisdiction of individual Member States. This moratorium was ultimately found to violate WTO commitments (Isaac and Kerr, 2007b). In 2003, the EU implemented a new regulatory regime for GM crops and food products and, in the wake of the WTO judgement on its previous moratorium, claimed that the new regime would be WTO compliant, but it needed time to make the necessary adjustments (Viju et al., 2012). The EU Commission called for all member states to develop frameworks for coexistence whereby producers growing organic or conventional crops would not suffer economically from their crops comingling with GM products. Most states have developed coexistence legislation. However, seven member states have refused to do so, signaling their opposition to GM crops.

Smyth et al. (2002) identify instances where seed varieties in Europe were found to contain trace amounts of GM varieties prior to the 2003 regulatory system (Table 2). In 2000, Advanta imported breeder's canola seed from Canada that unknowingly contained 0.4% unapproved GM traits (Bijman, 2001). The acreage planted with this seed in most countries was insignificant, except Britain where over 15,000 hectares had to be destroyed. Advanta paid compensation in the millions of dollars (Bijman, 2001).

In 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 in field trials (Scottish Government, 2002). The discovery arose from a routine audit conducted by the Scottish Agricultural College. Given the crop was already well advanced, it was harvested and destroyed.

Trace amounts of GM canola were detected in Canadian mustard exports to the EU in 2003 (Western Producer, 2003). According to export standards, mustard exports are allowed to contain 1% canola and since 75% of the canola produced in Canada at that time was GM, comingling was not surprising. There is no information on what the European importers did with the mustard shipment.

Table 2
Pre-EFSA comingling detection.
Source: Bijman (2001), Scottish Government (2002), and Western Producer (2003).

Commodity	Yr.	Export country	Importer/ developer	Countries affect (size)	Percentage comingling	Result	Cost
Canola	2000	Canada	Advanta	Sweden (300 ha) Germany (300 ha) France (600 ha) UK (15,000 ha)	0.4%	France and Germany plowed under; Sweden harvested and exported; UK harvested and destroyed	US $M
Canola	2002	NA	Aventis	UK (field trials)	2.8%	Harvested and seed destroyed	NA
Mustard	2002	Canada	NA	EU	trace	NA	NA

NA – not available.

Table 3
Post-EFSA comingling detection.
Source: Endres and Johnson (2011), Smyth et al. (2010), Dayananda, 2011, and COCERAL (2010).

Commodity	Years	Export country	Import market	Import concern	Trade impact	Cost
Rice	2006–2011	USA	EU	Event unapproved in US and EU	EU border was closed to US rice exports	$890 million
Corn	2006–2009	USA	EU	Event not approved in EU	Corn gluten exports decreased 30–40%	NA
Flax	2009–2010	Canada	EU	Event not approved in EU	EU border closed for 3 months	$58 M in Canada and €39 in EU

NA – not available.

The above are examples of the detection of low-level presence (LLP) of GM material in other crops. 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 crop varieties that have not been approved. However, with science-based regulations underpinning the domestic regulatory systems of the countries where GM comingling was found, the incidents were addressed and resolved without the suspension of international trade. Political interference was minimal. As shown below, since the establishment of the new agbiotech regulatory regime the way risk is dealt with has been politicized.

In 2006, trace amounts of an unapproved GM rice variety were detected in US rice exports to the EU. The widespread presence of LL601 rice resulted in an EU announcement on August 20th, 2006, that it would no longer accept rice from the US (Li et al., 2010). The German food importer, Rickmers Reismüehle, sued two Arkansas defendants – the large grower co-operative Riceland Foods and the Producers Rice Mill – alleging that shipments to the company contained unapproved GM rice in breach of several contracts. The two defendants turned to the developer, Bayer CropScience, for an explanation, as well as compensation. In the spring of 2011, Riceland Foods was awarded US$136.8 million (Table 3).

Producer lawsuits against Bayer for ruined crops and depressed international rice export markets were launched and in December 2009, the first cases were settled. One farmer received US$1.95 million, while the second received US$53,000. In 2011, Bayer offered US$750 million to settle all producer lawsuits based on the condition that at least 85% of the total rice acres planted between 2006 and 2010 were to be encompassed by the settlement (Endres and Johnson, 2011). This offer was accepted. The EU market has still not fully reopened to US long grain rice exports, however, which are now less than one-third of previous levels. The liability costs and reduced sales associated with the closure of the EU market will undoubtedly feed into future investment decisions pertaining to GM crops.

Smyth et al. (2010) discuss US–EU corn trade following the commercialization of GM Herculex corn, which 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% (EuropaBio, 2006).

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 approval in Canada in 1997 but had not entered commercial production when it was removed from the market in 1999 due to EU concerns about importing GM flax. The variety was deregistered in 2001. By September 2009, flax trade between Canada and Europe was suspended, pending identification of the source and the implementation of a testing protocol that could provide assurance to European importers that Canadian flax would be free of GM flax. Shipments of Canadian flax to the EU were embargoed for a three-month period, resulting in an estimated loss of C$58 million (Dayananda, 2011). The protocol agreed between Canada and the EU entails an expensive multi-stage testing regime and Canadian flax exports have not recovered to previous levels (Hobbs et al., 2014). No research into new varieties of GM flax is currently underway in Canada.

Following the centralization of authority for approvals of GM crops in 2003, there has been a visibly noticeable movement away from the use of science-based regulations at the European Commission level when dealing with GM. As noted in the March, 2012 Editorial of *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 (Nature Biotechnology, 2012)." The EU has moved from science-based systems as the underpinning of domestic regulation and trade to the use of socio-economic considerations (SECs) in decision-making. The principles of the CPB have been increasingly incorporated into regulatory frameworks.

Thresholds exist for various unsafe materials commonly found in the trade of agricultural products. In spite of knowing that trade in agricultural products is greatly impeded at a tolerance level of zero percent, it was decided by the European Parliament in Directive 2001/18 that if any GM variety not approved for import was detected, its use would be illegal and, hence, the tolerance threshold was established at zero (European Parliament, 2001). By 2011, this strict regulatory threshold was proving unworkable and,

Table 4
Typology of food safety risks.
Source: Authors.

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)	Low	High	High	Low
GM foods	Low	High	High	High

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 GM material that had been approved for production in a non-EU country. Of course, this change was possible because the "outrage" factor is likely lower for animal feeds than for direct human consumption. The zero threshold still applies to food imports. Thus, it would appear that the thresholds are arbitrary and open to political influence.

Political manipulation of thresholds is particularly obvious for GM soybean imports. In 2009, the University of Wageningen (LEI, 2009) reported that if the EU was determined to source non-GM soybeans for animal feed, the cost of complying with the EU's 0.9% tolerance would raise the price of soybeans from €290/t to over €7700/t. The EU's solution was to allow GM soybeans for animal feed. The size of this challenge for the EU was quantified by a report that places the value of GM soybean imports at US$6.5 billion in 2013 (USDA, 2013). The report shows that the EU imports 70% of its soybean meal requirements and, of this, 80% are GM. It is evident that when it is financially advantageous for the EU to adjust regulations, they will do so.

Prior to 2003, when decisions were based upon scientific risk assessments, accountability between regulators and those impacted by LLP was quite proximate. In some pre-2003 LLP instances the affected crop was allowed to be harvested and exported. Post-2003, at the earliest detection of LLP, the EU has automatically closed its borders to the affected product. If science-based coexistence was allowed in the 1999–2003 moratorium period in the EU, why is it no longer feasible? 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. The default is closing borders.

With most companies operating only in domestic markets and EFSA being open to countermand by the European Commission and the European Parliament, those adversely affected by an LLP incident have no opportunity to hold EU regulators accountable. None of the earlier GM 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 rationale with the CPB and SECs. SECs are subject to political manipulation. Based on the recent LLP detections and the EU's response to these issues, risk assessment within the EU can now be viewed as politicized.

4. Socio-economic regulatory frameworks

Socio-economic assessments of genetically modified organisms (GMOs) have become a controversial issue under the CPB. They clearly represent a movement away from science-based risk assessments (Falck-Zepeda, 2009). Under the Protocol, parties may include SECs in decisions regarding imports. Some argue that the Protocol limits the scope of SECs to factors affecting biodiversity with an emphasis on local and indigenous communities. Nevertheless, many countries are, or have, considered inclusion of SECs in their legislation. As technological change always creates winners and losers, it will always be possible to identify potential negative socio-economic consequences (Leger et al., 1999). Article 26 provides the opportunity for including a socio-economic assessment in national biosafety regulations:

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. (Secretariat of the Convention on Biological Diversity, 2000).

Concerns have been raised that SECs will become a mandatory part of approval processes and further complicate the new GM-crop approvals. This will be a particular problem if the SECs are not bounded by the realm of conservation and sustainable use of biological diversity.

Over the past 20 years, risk analysis has, in some jurisdictions and in relation to some specific items, progressively moved away from science-based assessment. Regulations are no longer solely concerned with the scientific 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 regulatory function expressed as a two stage process whereby the scientific risk hurdle might be cleared

$$Risk^{scientific} = Hazard \times Exposure$$

But, subsequently, there is a second stage of political risk assessment, which is isolated from the scientific evidence and deliberations

$$Risk^{political} = Outrage \times Unsubstantiated\ information \times eNGO\ Pressure$$

The two systems are fundamentally not connected, and in some ways do not even overlap conceptually or practically, as a different array of government actors engages in the political risk assessment. Government decisions will be impacted by the presence of social outrage from society, which can easily be influenced by hearsay, allegations and innuendoes that can come from

environmental non-governmental organizations (eNGOs). According to Isaac (2007, p. 288)

… risks are defined to include speculative risks which lack experience, data, a causal-consequence mechanism and an accepted analytical method for assessment; they are logical possibilities – irrefutable and untestable. Typically, such risks would have no standing within a science-based framework. Under the … approach science only informs the decision and 'other legitimate factors' are also weighted.

The various formulas for assessing risk can be compared in terms of their response to a series of food safety concerns (Table 4).

Politicization of risk jeopardizes increased food security by allowing political influence to regulate (and delay or reject) safe new products or technologies (i.e., a Type 2 error), while drawing attention and resources away from identified, substantiated and remediable food safety and environmental risks. This trend in risk assessment is actually amplifying the potential for Type 1 errors, not so much that unsafe foods are being approved, but rather that products and technologies that are less safe than they might otherwise be are not subject to increased regulatory scrutiny. For example, food products that have been well documented in the health science literature as having been identified for concern given the presence of high cholesterol, sugar or sodium receive some political encouragement to improve or to better label the health problems associated with consumption, but foods that truly present safety concerns rank quite low in terms of political food safety priority.

As outlined above, trace amounts of GM flax were detected the EU. The political risk associated with this unauthorized material was clearly substantial and the EU banned flax imports from Canada for a three-month period, ultimately costing C$80 million in Canada and the EU. This was a product approved for 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 what was initially reported as organic cucumbers contaminated with *E. coli*. (World Health Organization, 2011). The political risk from the death of consumers from unsafe organic food in the EU was perceived as being low, while the political risk from virtually undetectable trace amounts of GM flax which had been judged as having a sufficiently low risk when a science-based assessment was used – albeit in different political jurisdictions – was subject to massive regulatory intervention.

This politicization reduces the expected returns from investing in technological improvements in agriculture – and, hence, threatens the achievement of future food security goals. Quantifying the degree to which the politicization of risk has inhibited investments in biotechnology is not likely possible because it would require information on the decisions of biotechnology companies – 'what would have been' scenarios. There is, however, considerable evidence that investments are being inhibited. Important advances such as GM wheat have been shelved due to expected difficulties with political risk assessments in the EU, even in the face of evidence that GM wheat would probably receive approval under a scientific risk assessment (Furtan et al., 2005). Wilson (2014) provides estimates for the US of forgone benefits from the failure to pursue the development of GM-wheat – approximately $500 million per year. In a survey of studies pertaining to GM crops, Frisvold and Reeves (2014) found a paucity of studies of the effects of constraints on the development of, and trade in, GM products on levels of investment.

While not a direct issue for food security, Canadian GM flax was deregistered in both Canada and the US in response to politicized risk assessment in the EU (Ryan and Smyth, 2012). Meanwhile, a number of major developers of agricultural technology have moved their R&D operations out of the EU – disruptions that slow the pace of technological advancement. In January 2012, BASF announced that it was moving its research division from Europe to the US due to the lack of timeliness in regulatory decisions (BASF, 2012). In part, this decision arose because it took 13 years to receive approval for a GM potato variety (BASF, 2010). Further, in July 2013 Monsanto announced that it was scaling back research investments within the EU and abandoning existing GM crop variety submissions (Cressey, 2013). There is no doubt that biotechnology is a divisive subject in the EU – and one politicians have struggled with for two decades (Anderson et al., 2004; Levidow, 2014; Viju et al., 2012). Widespread consumer acceptance of GM technology in the EU cannot be expected in the near future. Nevertheless, the policies put in place to govern and regulate agbiotech could be constructed in ways that do not impose extensive externalities on the global food system. Redefining risk assessment of technologies to include socio-economic concerns as well as scientific risks imposes large externalities on those considering productivity enhancing technologies. It may be that policy makers may wish to deny a technology, but a retreat from science-based risk assessments needs to be considered very carefully given the negative externalities it imposes.

One of the major externalities is that developing countries also fail to adopt GM technologies due to perceived political risk in the EU and the potential that it would threaten their export markets (Smyth et al., 2013). As a result, it reduces the incentive for agricultural technology firms in developed countries to undertake R&D into tropical and other crops specifically suited to their environment (Paarlberg, 2002; Graff et al., 2009). While significant increases in trade in agricultural products will be required to reach food security goals by mid-century, increases in agricultural productivity must also make a major contribution. In a globalized economy, the impact of differences in how risk is dealt with can have wide-ranging detrimental impacts on technological progress.

5. Conclusions

In its attempts to deal primarily, but not exclusively, with the GM issue, the EU is attempting to broaden the way risk is defined to include a host of socio-economic factors. Given that all new technologies will create some economic losers, redefining risk assessment will make seeking approval for new technologies less predictable and transparent. This, in turn, will alter the incentives to invest in new technologies needed to meet future food security goals. While the GM issue has been the driving force behind the moves to alter risk assessment, once the new method of risk assessment becomes part of accepted international procedures (just as the science-based "risk assessment framework" (RAF) did previously), it can be applied to any new technology. This is a different issue than the EU simply refusing to approve GM-crops – which also alters the incentives to invest and has been written about previously. The politicization of risk does not deliver either safer food or technological improvements.

Science-based risk assessments have been successful in denying the commercialization of unsafe foods while politicized risk assessments continue to rule that consuming GM foods is a danger to one's health or the environment. If this regulatory divergence meant only that consumers in some rich countries have fewer food choices, the making of this kind of Type 2 error would not be a particular focus for concern. The EU has also made the granting of the most preferred market access for the products of developing countries under its Generalized System of Preference (GSP-plus) program contingent on accession to the CPB – meaning that the non-scientific risk assessment methods are spread to developing countries that may most need productivity enhancing innovations (Ansong, 2013). Given the long term negative impacts on technological improvement in a period when concerns regarding future

food security are high, a re-assessment of politicized risk seems prudent.

While the focus of this paper has been on one particular agricultural technology – transgenic modification – the real danger lies in the potential acceptance of politicized risk more generally. Once it is applied to one technology and accepted as a guiding principle, it can be extended to other technologies. New technologies will always have their doubters and detractors. They inevitably create potential 'losers' who have a vested interest in having a technology denied. While future food security may not be dependent on fully exploiting the potential of agbiotech, it does depend on technological advancement. Formally allowing non-scientific factors to enter into risk assessments gives process legitimacy to some factors that are normally relegated to political pandering to protectionist vested interests.

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