

## How Low Can You Go? The Consequences of Zero Tolerance

Jill E. Hobbs, William A. Kerr, and Stuart J. Smyth

University of Saskatchewan, Canada

Establishing tolerance levels for the presence of unwanted materials that may inadvertently become co-mingled with products that are acceptable in markets is a problem for regulators that requires arbitrary *lines in the sand* to be drawn. While the degree of tolerance is ultimately an arbitrary value—because the full information necessary to make a non-arbitrary decision is never forthcoming—decision making can be informed by theory, existing information, and where gaps in information lie. Where tolerances have been established that do not appear to have been informed, they should be re-examined if for no other reason than they may impose unnecessary costs on society. Zero tolerance has been imposed by regulators in a number of jurisdictions for unwanted materials that could co-mingle with products acceptable in the market. One such case is the European Union's (EU) policy of zero tolerance for co-mingling of unapproved genetically modified (GM) materials with agri-food products. This article uses two case studies related to the regulation of GM materials in the EU to examine the implications of zero tolerance. While the topic of the regulation of modern biotechnology has been the subject of much debate in the EU and globally, there appears to be little discussion of zero tolerance. Given that zero tolerance imposes considerable externalities on non-EU agri-food sectors as well as in the EU itself, it may be time to re-examine zero tolerance in an informed way.

**Key words:** food safety, genetic modification, international trade, supply chains, zero tolerance.

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### Introduction

A fond memory while touring a whisky distillery in Scotland many years ago was of the tour guide—a fascinating crusty old character who had worked at the distillery for years—expounding upon the virtues of this particular brand of scotch: how its distinct taste and unrivaled quality were derived from the locally-sourced barley, the dense smoky peat fire used to dry the barley, and above all the unique pristine highland water piped to the distillery daily from a lake high above in the hills. Our mouths were watering. This special highland water, he said, was the secret behind this, the 'verra best' of Scottish whiskies. At this point a member of our tour group timidly raised a hand and asked "But... but, what happens if you find a dead sheep floating in the lake?" Fixing her with a gimlet eye, the tour guide replies: "Weeel, wull jus' fish it oot!"

The distillery guide exhibited, in his quaint way, a good deal of what we call *common sense*. The person asking the question was looking for a more dramatic answer—possibly throwing out all of the distillery's production for the period the sheep was in the water or shutting down the distillery, draining the lake, and waiting for it to refill, then testing the water again before

resuming production. For the most part, common sense has characterized the regulation of undesirable attributes found in foods, whether they be rodent feces, pharmaceuticals in beef, pesticide residues on fruit, other seeds in certified wheat varieties, or pebbles in grain shipments. Even, it seems, sheep in lakes (provided that you fish them out). The presence of undesirable attributes and the need to establish tolerance levels—officially or notionally—is a problem that is common to all food products to some degree. All tolerance levels are arbitrary *lines in the sand*<sup>1</sup> but are arrived at through an assessment of the hazards, risks, and costs associated with alternative potential tolerance levels—a common-sense solution. Arriving at the common-sense consensus is a process that is undertaken with differing degrees of formality. There are a number of examples from the recent past where tolerance levels have been established at zero (e.g., such as California banning the use of certain pesticides for agricultural production; Cash, Sunding, Swoboda, & Zilberman, 2003). Zero tolerance has also been specified in certain circumstances for the pres-

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1. This is because the information required to make a fully informed decision is never complete.

ence of genetically modified (GM) materials in food products by the European Union (EU). While there is vast literature on the issues surrounding the regulation of GM products in the EU and elsewhere (Smyth, Phillips, & Castle, 2014), there is a dearth of discussion on the specific issue of tolerance levels set at zero. This article uses a cost-of-regulation lens to examine the issue of establishing tolerance levels and, while it does not rule out the possibility that zero tolerance is a *common-sense* solution, it suggests that it cannot be presumed to be the case. Given that zero tolerance leads to international trade disruptions (Viju, Yeung, & Kerr, 2011b), poses considerable challenges for supply chains (Ryan & Smyth, 2012), and over the long run inhibits technological advancement (Smyth, Kerr, & Phillips, 2011), it may be time to revisit the policy.

The article draws upon economic and political economy arguments to explore issues such as the waning role of science in determining risks in some jurisdictions; the implications for monitoring, certification, and liability within supply chains; and the market access and international trade policy implications of zero tolerance standards. These concepts are illustrated through a discussion of two recent examples of the application of zero tolerance standards for GM material in international food markets: the discovery in 2009 of trace amounts of a deregistered variety of Canadian flax in bakery goods in Germany leading to the closure of the EU market to Canadian flaxseed, and the September 2011 decision by the Court of Justice of the EU to classify pollen as a food ingredient.

A cost-based model to examine the question of appropriate tolerance levels is developed in what follows. The article then argues that the willingness of some jurisdictions to limit the role of science in determining risk has, in part, allowed the push toward zero-tolerance standards. The article concludes with a discussion of zero-tolerance standards examined through the lens of the two case studies alluded to above. The implications for supply chains and international trade are outlined.

### The Costs of Co-Mingling

What level of tolerance imposes the least cost? Under what configuration of costs will zero be the superior outcome? Individual countries approach this problem differently, both with respect to the attribute in question, as well as comparatively across countries. Olsen, Gecan, Ziobro, and Bryce (2001) found that non-zero tolerance levels have been established for a wide range of attri-

butes that present hazards (e.g., drug residues, rodent excrement) or diminish product quality in other ways (weed seed, unborn chicks in eggs). In a limited number of cases, tolerance levels have been established at zero—the above mentioned state-level tolerances for chemical residues in the United States and the presence of GM materials that have not been approved by EU authorities. The latter is a particular problem for shipments of foreign-origin agricultural products destined for the EU<sup>2</sup> but also applies to some EU member states' co-existence regimes. The observations in this article are derived from EU cases of zero tolerance, but the approach can be applied to other instances where a zero-tolerance standard has been put in place.

Identification of the least-cost level of co-mingling can be informed by the economic approach of decision-making at the margin. The least-cost optimum will be where marginal benefits arising from a specified non-zero level of co-mingling equals the marginal cost associated with the same positive level of co-mingling.<sup>3</sup> For clarity of exposition, the model is developed using a total-cost approach following Hobbs and Kerr (1999). The total cost of any specified level of co-mingling is the sum of two costs: 1) the potential impact cost of GM material that has not been approved in the EU being found in the food system, and 2) the costs associated with reducing the threat of co-mingling. The total cost approach can be illustrated using Figure 1. The degree of co-mingling—from 0 to 100%—constitutes the horizontal axis. The impact costs of unapproved GM products being in the food system are illustrated by curve UU and rise as the degree of co-mingling increases. The costs associated with lowering the risk of co-mingling—mitigation costs—are depicted in curve MM. These costs are expected to rise as the degree of co-mingling moves toward zero.

2. *The terms often applied to the existence of trace amounts of unapproved GM material in non-GM (conventional) or approved GM shipments are low-level presence (LLP) or adventitious presence (AP). LLP pertains to finding a GM variety that has not been approved for commercial release by the European Commission but has been approved in the exporting country. AP pertains to a case where the unwanted variety has not been approved for commercial production in any jurisdiction.*
3. *This cost-based model abstracts from discussions of societal welfare. Models formally incorporating social welfare in the context of GM regulation have been developed by Lapan and Moschini (2007) and Giannakas, Kalaitzandonakes, Magnier, and Mattas (2011).*

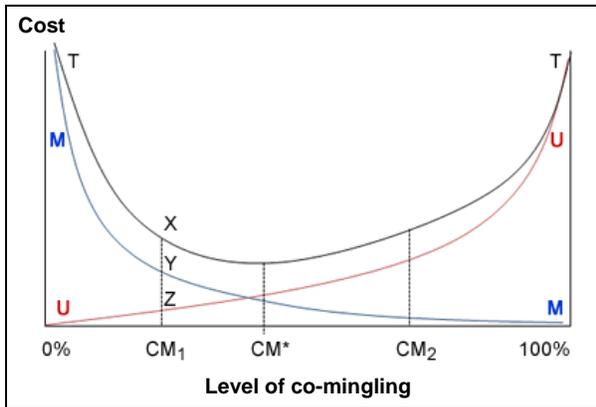


Figure 1. Determining the socially optimal level of allowable co-mingling.

Thus, at any level of co-mingling the total cost is the sum of the impact costs and the mitigation costs. Total cost is illustrated by curve TT. As an example, at co-mingling level  $CM_1$  mitigation costs are the vertical distance  $CM_1$ -Y and impact costs equal  $CM_1$ -Z. Total cost at  $CM_1$  is the sum of  $CM_1$ -Y and  $CM_1$ -Z or vertical distance  $CM_1$ -X.

The cost-minimizing level of co-mingling is at  $CM^*$ , where TT is at its lowest value. At points to the left of  $CM^*$  (e.g.,  $CM_1$ ) there is a reduction in the impact costs associated with co-mingling; however, this reduction is not sufficient to offset the additional mitigation costs required to achieve level  $CM_1$ , thus yielding a higher total cost than at  $CM^*$ . To the right of  $CM^*$ —say  $CM_2$ —while mitigation costs decline due to less effort being made to reduce the degree of co-mingling, this is not sufficient to offset the additional impact costs. Total costs at level of co-mingling  $CM_2$  exceed those at  $CM^*$ .

Zero tolerance—moving the degree of co-mingling to the left-hand axis—is not optimal. Only in a case where the UU curve intersects the vertical axis at a point which is above the MM curve (illustrated in Figure 2) would zero tolerance be the optimal level of co-mingling. In this case, the impact costs exceed the mitigation costs for every level of co-mingling.<sup>4</sup> As suggested above, many tolerance levels that have been established for undesirable potential attributes of food products are at non-zero levels and represent common-sense approximations to  $CM^*$  in Figure 1.<sup>5</sup> While the model allows for a zero-tolerance decision to be optimal, it would seem prudent that such decisions be made within the model's framework.<sup>6</sup>

4. On the cost axis, distance 0 to A exceeds distance 0 to B.

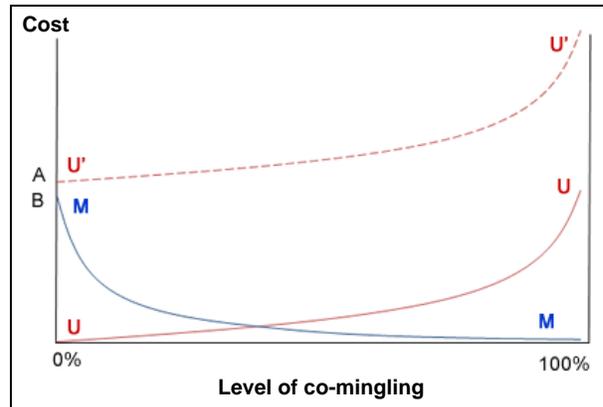


Figure 2. When zero tolerance is socially optimal.

The particular configurations that the UU and MM curves take will be influenced by a number of factors. The UU (impact cost) curve will be defined by the value society assigns to avoiding GM products that have not been approved to be part of the food basket. The MM curve depends on the costs associated with limiting co-mingling. In addition, operationalizing zero itself depends on the available detection technology. In other words, while the concept of zero may be an absolute, the ability to achieve zero depends on the ability to detect co-mingling. If a dead sheep sank quickly to the bottom of a dark Scottish lake and no one knew it was there, there would be no opportunity to “fish it out.”

The impact costs, of necessity, will have to include a number of factors where considerable risk or uncertainty may exist. In the case of GM material, these risks and uncertainties relate to human, animal, and plant

5. As with many theoretical outcomes derived using the marginal approach in economics, it is not expected that decision makers explicitly maximize using the applicable marginal measures, but rather approximate the results of those decision rules in whatever means they use to arrive at a decision. For example, it is not believed that decision makers in business actually set marginal cost equal to marginal revenue—concepts from economics—when choosing their level of output. Instead, they are believed to approximate the decision when they determine their output levels. Firms do not even attempt to collect and generate information on marginal costs and marginal revenues. Of course, businesses use a range of information to assist their decision makers. In a similar fashion, regulators can be seen as arriving at common-sense tolerance levels.
6. It might also be prudent for regulators to revisit decisions to set tolerances at zero that were made in the absence of the framework outlined in the model.

health and effects on the environment (Gaisford, Hobbs, Kerr, Perdakis, & Plunkett, 2001). The issue of how to regulate GM material has, and continues to be, a contentious issue globally where no consensus exists and where there is considerable regulatory divergence internationally (Phillips & Kerr, 2002). Concerns pertaining to human health and adverse environmental consequences of GM material among some EU environmentalists and consumers are well known (Costa-Font, Gil, & Traill, 2008; Hoban, 1998; Hobbs & Plunkett, 1999; Zechendorf, 1998). The broader GM debate is not the focus of this article. Any regulatory regime, however, must deal with the long-term uncertainties pertaining to human, animal, and plant health and the environment. Unapproved GM material will carry some risk to health and the environment, as do many other undesirable attributes that may be present in food. However, to date this risk would appear to be slim: Nicola, Manzo, Versonesi, and Rosellini (2013) recently assessed more than 1,700 peer-reviewed articles, finding no scientifically verifiable concerns.

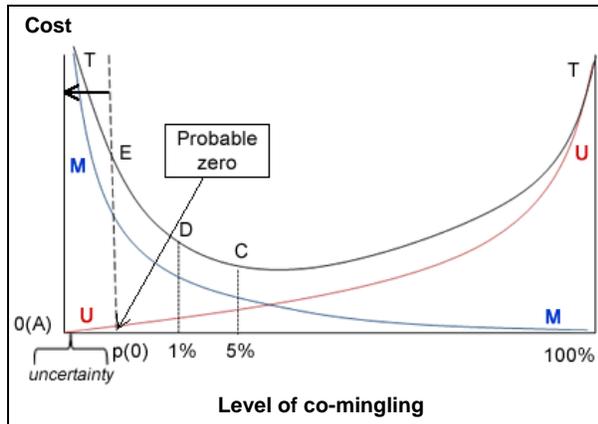
Ethical concerns also define undesirable attributes in foods for some consumers (Isaac, 2007b). In some cases consumers wish to eschew the consumption of GM products entirely. This preference is embodied in *consumers' right to know* irrespective of any evaluation of risk. This will factor into impact costs depending on the weight that regulators assign to these concerns. The European Commission has given this perspective considerable weight, leading to a regulatory divergence with North America, to the extent that the approaches can be viewed formally as alternatives—a *scientific rationality* approach in North America and a *social rationality approach* in the EU (Isaac, 2002). In many ways, the latter paved the way for the reduced role of science in determining risk, as discussed in the next section.

To reduce the incidence of co-mingling requires the expenditure of resources. Given the long, multi-actor and complex nature of most modern agri-food supply chains, multiple interventions are likely required. These interventions include segregation of supply chains, including in some cases segregation on farms, in processing facilities, in transportation, and in distribution. Once segregated, the identity of the separate products must be preserved as the product moves through the supply chain (i.e., no opportunity for the undesirable attribute to co-mingle—or re-mingle—with the product without the undesirable attribute). As tolerances are reduced, some markets may have to be forgone. The changes to the “way things are done” will extend

throughout the supply chain (Hobbs, Kerr, & Phillips, 2001; Huygen, Veeman, & Lerohl, 2003; Vandeburg, Fulton, Dooley, & Preckel, 2000) and in how the various actors in the supply chain interact with each other (e.g., increased vertical integration; Hobbs & Kerr, 2003). In some cases a product may have to be destroyed when it cannot be cleaned to within tolerance levels. As tolerance levels become more stringent—a move to the left along the MM curve in Figure 1—costs can be expected to rise more sharply. For example, Huygen et al. (2003) found that costs increased substantially if co-mingling thresholds for marketing Canadian wheat were reduced from 5% to 0.1% of co-mingling.

While scientific progress is often seen as the engine driving increased productivity, the reality is that improvements in science can cut both ways. For example, GM crops have been adopted widely and moved into the food supply chain (a process that began in the 1990s in some jurisdictions) with no apparent increase in food safety risks and adverse environmental consequences. After more than 15 years of production, some GM crops have become well established both in agricultural production and in peoples' diets. The results of this *experiment writ large* suggest—at least to those who champion science-based regulation—that science has brought increased production, lower-priced consumption, and expanding international trade.

At the same time as science has been enhancing productivity, improvements to science have also increased the efficacy of detection and testing. In effect, this has meant that the detection of smaller and smaller degrees of co-mingling is technologically and economically feasible. One of the challenges regarding testing technology has been the inability to distinguish between identification of foreign matter and false positives. Advances in the field in the past few years have dropped the rate of false positives to a level that is once again acceptable. Thus, zero tolerance may be a moving target whose trajectory leads to ever-rising costs associated with achieving the tolerance level for international shipments. While the problem of increased detection due to scientific progress can be true for any undesirable attribute, it has had considerable consequences for GM products because zero tolerance has been specified (as opposed to some degree of non-zero tolerance that is less costly to achieve). In Figure 3, as the tolerance level declines from 5% to 1%, total costs increase—from C to D. If zero is set as the tolerance level then the mitigation costs rise as there is a movement to the left along the MM curve and thus the TT curve. Total cost moves further away from the minimum. With a low level of ability



**Figure 3. Moving goalposts: The scientific uncertainty of zero.**

to detect and test for undesirable attributes, probable zero is to the right of the left-hand axis, say, at point  $p(0)$  yielding a total cost of E.

Scientific improvements can radically alter the accuracy and costs associated with detection. The breakthrough of X-ray technology radically altered the ability to detect broken bones and lung cancer. Ultrasound technology dramatically increased the ability to detect problems in fetuses. Hence, at any moment in time, zero is not an absolute but a probability defined by the state of science in testing. Such a point is illustrated in Figure 3 using a dashed line to indicate the achievable axis. If scientific knowledge regarding detection and testing improves, the axis moves to the left. As a result, mitigation costs increase for those involved in supply chains and total costs for society move further from the least-cost point. These increases in costs may not be what were envisioned by policy makers when they initially established the zero-tolerance policy in consultation with various stakeholders. The area between any probable zero and absolute zero is the realm of uncertainty—uncertainty over where probable zero may lie in the future and uncertainty over the costs associated with achieving any new probable zero in the future. The uncertainty applies to both those involved in the affected supply chains and policy makers charged with designing regulations for the benefit of society.

### The Reduced Role of Science and Zero Tolerance

It is well documented that the EU has struggled with the World Trade Organization (WTO) Uruguay Round commitments it made in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) to having

science as the arbitrator of trade rules dealing with sanitary and phytosanitary measures (Isaac, 2007a). One of the main reasons for this difficulty with its commitments is the rise of new protectionists in the form of consumer groups, environmental groups, and others in civil society—as opposed to traditional producer-based protectionist interests (Kerr, 2004a). The WTO has no mechanism to allow member states to respond directly to the requests for protection from these groups and, as a result, the SPS has become the channel by which protection is extended; this has meant that the EU has had to re-interpret its SPS commitments (Kerr, 2010; Smyth, Phillips, & Kerr, 2009). Internationally, the EU strategy regarding SPS issues has had three major thrusts: 1) ignore WTO Panel rulings and accept retaliation from trading partners—as is its right under the WTO (Kerr & Hobbs, 2005); 2) put trade-restricting measures in place that may be controversial and await a challenge at the WTO; if a challenge comes, use all possible procedural avenues to delay (Viju et al., 2011b), and; (3) attempt to move the regulation of trade in products of biotechnology out of the SPS agreement into a separate multilateral environmental agreement—the Biosafety Protocol (Hobbs, Hobbs, & Kerr, 2005; Holtby, Kerr, & Hobbs, 2007). Behind the cover of these international initiatives, domestic procedures were constructed in ways in which science simply informed decisions but the ultimate decision-making power resided in the political sphere (Viju et al., 2011b). In this situation, zero tolerance became an acceptable criterion. Institutionally, the European Food Safety Authority (EFSA) became the major implementing body for the zero-tolerance policy on unapproved GM material.<sup>7</sup>

International regulation of sanitary and phytosanitary threats has been based on the principle of scientific-based justification for many decades; for example, the international organization dealing with animal diseases—the Office International des Epizootics (OIE)—was established in the 1920s.<sup>8</sup> The recognition of science-based regulation was formally enshrined in the SPS agreement that was part of the 1994 Uruguay

7. *The EFSA also assesses applications for licensing new GM products. It does these assessments on a scientific basis. Its recommendations are then passed on to the political realm where decisions on allowing GM products into the market and for release into the environment are made. This is an entirely different role for the EFSA than enforcing a zero-tolerance policy.*

8. *It has been renamed The World Organization for Animal Health but has kept its long-standing acronym OIE.*

Round agreements. As with any international agreement, there have been disagreements over interpretation, but in general there has been widespread international support for a science-based system. It is posited here, however, that the creation of its new regulatory regime for GM material in 2003 has dramatically altered the European Union's adherence to science-based regulations, encouraging instead a movement towards socio-economic-based regulation of agricultural products.

Faced with considerable controversy around the potential effects of GM products on the environment and long-term human health, the EU suspended approval of new GM products in June 1999. Market entry was also denied to foreign-origin GM products. This *de facto* moratorium on GM products was ultimately ruled by a WTO disputes panel in 2006 as being in contravention of international commitments. In the wake of the WTO judgement on its previous moratorium, the EU claimed that the new regulatory regime that had been put in place in 2003 would be WTO compliant, but it needed time to make the necessary adjustments (Viju et al., 2011b). Under its new regulatory regime, the European Commission called for the development of coexistence frameworks by each of the EU countries—frameworks that would allow farmers growing conventional (and particularly organic) crops to not be negatively impacted by the growing of GM-crops.<sup>9</sup> Until the new regulatory regime was put in place in 2003, the regulation of experimental research and field trials for new GM products was handled by individual Member States and was science-based.

Smyth, Khachatourians, and Phillips (2002) identify two instances where seed varieties in Europe were found to contain trace amounts of GM varieties. The first was in Switzerland, and thus not within the EU, but is illustrative of a non-zero-tolerance—*common sense*—approach to regulation. In May 1999, the Swiss Department of Agriculture announced that two Pioneer Hi-Bred non-GM corn varieties, imported and distributed by Eric Schweizer Samen AG, had been found to contain trace amounts of GM varieties. Based on polymerase chain reaction (PCR) tests, the level of co-mingling ranged from 0.1% to 0.5% (Fürst, 2002). Pioneer Hi-Bred 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 burned or controlled with herbicides. The importing firm agreed to pay compensation of 700 Swiss francs per hectare.

In a second incident, which took place in 2000, oilseed rape seed imported into the EU by the crop breeder Advanta was found to be co-mingled with unapproved GM material at the 0.4% level (Bijman, 2001). Advanta quickly determined that the co-mingling was caused by genes migrating from an adjacent 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 prevented the harvested crop from entering EU food supply chains. In Britain, more than 15,000 hectares were planted and had to be destroyed. Compensation was paid by Advanta (Bijman, 2001).

An additional case of undesirable material arose in 2002 when Aventis CropScience advised the British government that GM material was present in oilseed rape seed being used in field trials in Great Britain (Scottish Government, 2002). In ongoing monitoring by the Scottish Agricultural College, co-mingling of 2.8% was found. The crop was harvested and subsequently destroyed.

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

The above are examples of co-mingling or the detection of low-level presence (LLP) of GM material in other international 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

9. There are no EU-wide coexistence regulations. The European Commission makes recommendations, but the Member States can ignore them if they wish.

countries where GM events occurred, the incidents were addressed in a common-sense way and resolved without the closure of borders and the suspension of international trade—political interference appears to have been minimal. As will be shown below, since the establishment of the new EU GM regulatory regime in 2003 the environment has become much more restrictive.

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 announcement from the EU on August 20, 2006, that under its 2003 GM regulations it would no longer accept rice shipments from the United States (Li, Wailes, McKenzie, & Thomsen, 2010). As is noted by Kershen (2009), despite a 14-month investigation by the US Department of Agriculture (USDA) into how this co-mingling occurred (costing more than US\$1 million), no conclusive explanation exists.

More than 1,000 lawsuits have been launched against the developer of LL601, Bayer CropScience, as the courts rejected a class action lawsuit (Smyth, Endres, Redick, & Kershen, 2010). The authors note that some reports indicate that more than 6,000 lawsuits have been filed. The lawsuits seek compensation for ruined crops and for depressed international markets for rice exported from the United States. The German food producer, Rickmers Reismühle GMBH (Rickmers), sued two Arkansas defendants—the large grower cooperative Riceland Foods and the Producers Rice Mill—alleging that shipments to the company contained unapproved genetically engineered rice in breach of several contracts. Riceland Foods and the Producers Rice Mill turned to the developer of the rice variety, Bayer CropScience for an explanation, as well as compensation. In the spring of 2011, the court awarded Riceland Foods \$136.8 million.

In December 2009, the first of the producer cases were settled with the first two 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 \$750 million to settle all of the producer lawsuits related to the LL601 rice case. This settlement is based on the condition that at least 85% of the total rice acres planted between 2006 and 2010 are encompassed by the settlement (Endres & Johnson, 2011). This case was settled in 2011 and producers were compensated on a per-acre basis. The southern US states were the major exporters of long grain rice to Europe. Six years after the initial detection in the EU market, sales of US long grain rice have not

fully recovered. Current exports are less than one-third of previous levels (C. Carter, personal communication, 2012).

Smyth et al. (2010) discuss the implications for US-EU corn trade following the commercialization of Herculex corn. This GM corn variety was approved in the United States 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 United States to the EU to drop by 30-40%. What is interesting in this case is that Pioneer Hi-Bred submitted notification of import into the EU for Herculex I in 2000 (EuropaBio, 2006). By 2006, Herculex I had received approval for feed and food use, as well as for planting. The problem arose when Herculex (R) Rootworm varieties were detected in shipments coming from the United States. These varieties were ultimately approved by the EU in 2009. For the three-year period from 2006 to 2009, corn trade was disrupted.

Following the centralization of European regulatory authority for approvals of GM crops in the regulatory regime put in place in 2003, there has been a noticeable movement away from the use of science-based regulations dealing with GM products in general, but more specifically with the co-mingling of GM and non-GM products. As is noted in the March 2012 editorial of *Nature Biotechnology* (2012, p. 197), “[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.” The move away from science-based regulation as the underpinning of international trade to the use of socio-economic considerations in decision-making has increasingly incorporated the principles of the Biosafety Protocol into regulatory frameworks.

As is indicated above, thresholds exist for a variety of unsafe materials that are commonly found in not only food, but in the trade of agricultural products. Even while knowing that trade in agricultural products cannot function at 0%, 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; therefore the tolerance threshold was established at zero. The blanket moratorium on imports of unapproved GM material is not based on either scientific justifications or an assessment of risk. By 2011, this was proving

unworkable and so, in a move designed to provide assistance to the animal feed industry in the EU, a threshold of 0.1% was agreed upon for the detection of unapproved events in the EU that had been approved for production in a non-EU country—perhaps a move to a more *common-sense* tolerance threshold. The zero threshold, however, still applies to food imports, as the EU member states were not able to reach a consensus on this issue.

In the lead up to the establishment of the new regime for GM products in 2003, there was a degree of co-operation between firms found to be responsible for co-mingling and the regulators, and decisions were based on scientific information and assessments of risk. In some instances the compromised crop was allowed to be harvested and exported. In the wake of the new GM regulatory regime, EU borders immediately closed to imports of co-mingled products. The process was automatic with no account taken of risk. If science-based coexistence was allowed in the 1999-2003 moratorium period in Europe, why is it no longer feasible within the current regulatory regime? 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. A LLP event cannot be dealt with solely through a science-based decision process. Instead, there is a default to closing borders to international trade. With regulatory accountability residing in the political realm, there is a disconnect between regulators and affected supply chains.

With EFSA being accountable to the European Commission and the European Parliament, supply chains adversely affected by a LLP incident because of zero tolerance have no opportunity to hold the EU regulators accountable for their decisions (Wesseler & Kalaitzandonakes, 2011). 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 post-2003 EU regulatory regime appears to be aligning its regulatory rationale with the Biosafety Protocol and socio-economic considerations. As yet, no challenge has been mounted at the WTO by exporters. As illustrated by the model developed above, there are considerable costs associated with zero tolerance, while the benefits are difficult to discern—except those that may arise from the exercise of political precaution (Kerr, 2009).<sup>10</sup>

The two cases that follow are used to illustrate the costly outcomes that can arise from a policy of zero tol-

erance and raise questions about the objectives of the policy.

### Canadian GM Flax in the European Union

The zero-tolerance policy for unapproved GM material applies to co-mingled products originating outside the EU. If the threshold of zero is not met by import shipments, imports of the product are banned. Zero tolerance applies both to shipments where unapproved GM material is co-mingled with non-GM products and where unapproved GM material is co-mingled with approved GM crops. The co-mingling can be within a crop or across different crops (i.e., unapproved GM oilseed rape and non-GM wheat). The EU divides the types of co-mingling events that can occur into two categories: 1) *low level presence* (LLP), where GM material that has been approved in a non-EU jurisdiction but not approved in the EU is found co-mingled with a product cleared for import; and 2) *adventitious presence* (AP), where the GM material has not received approval in any jurisdiction—it is still in the experimental stage. Zero tolerance, however, applies to imports of products co-mingled with either type of GM material. As more and more GM crops are approved and adopted elsewhere in the world, LLP co-mingling events are becoming more common and will continue to increase as long as asynchronous approvals continue.

If LLP of unapproved GM material is detected in a shipment, emergency measures can be imposed on the co-mingled product under European Commission food safety Regulation 178/2002 (European Commission, n.d.). Emergency measures are broadly defined and include specific measures that must be undertaken, temporary import embargoes, or longer-term market closures. No scientific evidence is required. No risk assessment need be conducted. As a result, the emergency measures violate the SPS commitments of the EU under the SPS agreement. Under the SPS, such measures could be allowed for precautionary purposes if sufficient scientific information is deemed not to exist. In the case of zero-tolerance-based import refusals, no scientific information is assessed. In any case, the SPS requires that a country imposing trade measures in the name of precaution must actively seek out the missing

10. *Political precaution has been defined by Kerr (2004b, p.35) as arising “when politicians are being pressured to do something, or to be seen to be doing something, in the face of strongly expressed concerns by members of civil society even when risks are very low or largely speculative.”*

scientific information—which is not the case in the regulatory response to co-mingling in the EU (Viju et al., 2011a).

Genetically modified flax of Canadian origin was found in bakery goods in Germany and a Rapid Alert warning was issued across the EU on September 8, 2009. An import embargo against Canadian flax shipments swiftly followed. The unapproved co-mingled GM flax is a variety known as Triffid.<sup>11</sup> Flax seed is shipped to the EU where it is crushed for its oil, which is largely used in the industrial production of linoleum and paint. The meal that remains after the oil is extracted is used as feed for livestock. A very small proportion of flax seed imports are also part of human diets. Flax is shipped internationally in bulk with no segregation of flax that is used for direct human consumption.

GM Triffid flax was engineered for resistance to sulfonylurea herbicide, often found in soil after its use. Development began in the 1980s and after successful field trials, regulatory approval for human consumption was sought and received in both Canada and the United States.

In 1998, when Triffid received approval in Canada, genetic modification was becoming a major political issue in the EU. Given that the EU was the major market for Canadian flax, and the security of market access in the EU was in doubt, Triffid was voluntarily deregistered pre-emptively to keep the EU market open to Canadian flax exports (Viju et al., 2011a). The variety had not reached the stage of farmer adoption, as seed companies were still in the process of growing the first batches of commercial seed. In 2001 and after deregistration, these pre-commercial stocks of seed were destroyed. The existing germplasm was also destroyed. These measures were thought sufficient to eliminate all traces of Triffid. At the time, there was no way to test for the presence of Triffid in flax supply chains.

The science of testing has advanced over the decade since the 1990s. PCR or quantitative real-time PCR (qPCR) methods form the basis for modern testing for GM materials. While these methods have been around for a considerable period, their efficacy has steadily improved so that smaller and smaller levels of co-mingling can be detected. Specific tests are often developed in the private sector; in the case of Triffid, the test was devised by Genetic ID NA, Inc. of Germany. This test

was lodged with the EU Community Reference Laboratory (CRL). It is a specific test for detecting Triffid using real-time PCR. Testing began in July 2009. Triffid was found in bakery products across the EU—in all, more than 100 positive identifications were made. Canadian authorities began using the test in Canada and traces of Triffid were found throughout the domestic supply chain for flax. Amongst much speculation, no conclusive reason has been found to explain the origin of Triffid in the Canadian ecosystem (Viju et al., 2011a). Further testing identified the presence of Triffid flax in Brazil and Japan. The import ban imposed under zero tolerance imposed costs on the Canadian flax industry. The costs to EU industrial users of imported flax, which had no alternative sources of supply, have been estimated to have exceeded the costs borne by the Canadian industry (Dayananda, 2011; Viju et al., 2011a).

The imposition of the import ban on Triffid flax is a good example with which to delve into the costs and benefits of a blanket policy of zero tolerance for unapproved GM material. Triffid flax could have been in the EU food system for more than a decade. Co-mingling was endemic but there had been no reported human health problems. While the intent of the zero-tolerance policy is to keep GM materials such as Triffid from entering the EU market, the imposition of the import ban cannot achieve this objective *ex post*. The import ban may be able to prevent further imports of Triffid. The EU food system, however, now includes GM flax, albeit at trace levels. It is unlikely that it can be purged from the food system, and EU authorities do not seem to have attempted such a cleanup—nor have they banned human consumption of flax. The latter would be the only way to prevent consumers from eating co-mingled flax.

Flax could have been banned from the EU food system if there was a significant risk to human health. As the import ban was automatic under zero tolerance, no EU health assessment or risk analysis had ever been done on Triffid flax.<sup>12</sup> Health authorities have no basis upon which to decide whether flax should be banned from the EU market. If approval for Triffid were to be sought in the EU, then those making the approval application would have to supply scientific evidence and the EFSA would have a chance to evaluate it. This will never happen, however, because with the passage of

11. Officially it is CDC Triffid, named for the Crop Development Centre at the University of Saskatchewan in Canada where it was developed.

12. Of course, such an assessment had been done in both the United States and Canada where Triffid had been approved for human consumption.

time Triffid flax has become agronomically obsolete (Viju et al., 2011a). As new GM products continue to be developed, there may be a considerable number which are not suitable for the EU, either agronomically or to import for consumption. Thus, approval for this GM material will never be sought and, should it become co-mingled with conventional imports, those imports will face a ban similar to that imposed on conventional flax. International trade could be considerably disrupted. If co-mingled unapproved GM and non-GM flax remain in the EU food supply, is zero tolerance meaningful? With the import ban imposed without any examination of the scientific evidence and no achievable objective, the import ban simply looks like a disguised barrier to international trade. Preventing the use of such trade barriers is the reason for the existence of the SPS agreement.<sup>13</sup>

As suggested in the previous discussion of the model (Figure 3), probable zero can change when a zero-tolerance policy is in force. Improvements in the ability to monitor can have major impacts on society's costs. When Triffid was developed, there were no tests that could be used in its detection. At that point in time, zero was defined by Canada's declarations that Triffid was no longer part of the ecosystem. Canadian flax was accepted for import by the EU on the basis of these assurances. No human health issues arose in the EU. As there was no monitoring in Canada, there was no cost associated with achieving probable zero. The invention of the test moved probable zero considerably to the left in Figure 3. This increased the total cost of achieving the new probable zero, yet there was likely no improvement in human health. Hence, the cost of achieving zero increased considerably, but there was no increase in the benefits arising from the additional effort required.

Triffid flax may have been in the EU market for a decade and its presence did not result in any identifiable environmental or human health issues. Hence, the original system for ensuring zero was at least adequate from society's perspective. There is no evidence that when stricter testing methods were put in place that the impact costs of having unapproved GM flax present in the market were reduced in any substantive way (i.e., that the UU curve in Figure 3 declined as probable zero moved to the left). Of course, the mitigation costs faced by par-

ticipants in the flax supply chain in both the EU and Canada increased significantly (i.e., the MM curve increased considerably as probable zero moved to the left). Improvements in scientific knowledge over time will inevitably lead to improvements in detection methods. In effect, probable zero is at any particular moment in time defined by the state of science. As a result, the cost of achieving probable zero can increase considerably without any discussion of the desirability of the change. There is no chance to ask the question: is the increase in costs associated with the achievement of the new probable zero justified by the benefits that will arise? An assessment may well produce an affirmative answer, but with zero tolerance as the stated objective no assessment need take place. Detection technology alone will drive the achievement of the policy objective. This is a phenomenon that needs to be considered by those setting zero-tolerance policies.

Policy-making is further removed from the consequences of a zero-tolerance threshold when the pace of improvements in detection is driven by the private sector. Private firms base the decision to devise new tests on whether the new test is expected to be profitable. The test developed for Triffid was first used in the EU and subsequently in Canada, Brazil, and Japan among other countries. A second and improved test for Triffid was eventually put on the market (Viju et al., 2011a). Thus, probable zero is defined by private-sector decisions pertaining to profitability expectations and totally divorced from the costs imposed on supply chains in meeting the new level of stringency.

As the import ban on co-mingling of unapproved GM material covers co-mingling of both the same crop and other crops, and unapproved GM crops are being produced in foreign markets, the only way to ensure that zero-tolerance standards are met is for the EU to not accept any agri-food imports. If the EU is not willing to eschew all agri-food imports—and at the moment it is not—then standards must be established for exporters. Zero must be operationalized. In the wake of the discovery of Triffid flax in the EU and the ban on imports of Canadian flax, a bilateral Protocol was developed between the Canadian flax industry and the European Commission—the Directorate for Health and Consumer Affairs (DG SANCO). The Flax Council of Canada acted for the Canadian industry.<sup>14</sup> The Protocol sets out the sampling and testing regime that must be put in place along the entire Canadian supply chain. If the standards in the Protocol are met by a shipment of flax destined for the EU, then the current EU interpretation of zero is deemed to be met. Viju et al. (2011a) indicates

13. *Of course, this would not prevent the imposition of short-term import bans until the scientific evidence can be examined—a common-sense precaution—but it is incumbent on the country imposing such a temporary ban to actively engage in acquiring the information (Isaac, 2007a). Under zero tolerance there is no need for the EFSA to seek any information.*

that a maximum co-mingling of 0.01% provides an acceptable level of risk. This level approximates what can be detected given the current detection technology. At this level of testing a great deal of commercial risk remains as it has proven difficult for the firms involved in the flax supply chain to ensure their shipments pass the tests. In other words, even with the best efforts to identify and segregate conventional flax destined for the EU, shipments still often fail. Costs are incurred, but market access remains elusive and unpredictable.

After approximately 5,000 tests had been conducted between the acceptance of the Protocol and the spring of 2010, endemic co-mingling was found throughout the entire Canadian flax supply chain, but at very low levels (Stephens, 2010; Vakulabharanam, 2011). Thus, there is a non-zero amount of unapproved GM material in shipments cleared for import into the EU—probable zero is not absolute zero.

The original Protocol developed in 2009 proved too risky for Canadian exporters. This was because testing once the shipment had been loaded on ships destined for the EU was mandated. This meant that whether a shipment would be acceptable in the EU could not be determined prior to the ship leaving port. As a result, some shipments were refused entry to the EU and quarantined at Belgian ports. This is a very expensive point in the supply chain for import refusals to be imposed as new buyers must be found, demurrage and storage paid for, and the costs of shipping-on assumed. Alternatively, the costs of destroying the shipment are the responsibility of the exporter. As a result, in March 2010 the Protocol was altered so that the final test would take place prior to loading ships for transatlantic movement (Hall, 2011). If the shipment is refused at that point, it is much less costly to find alternative buyers either in North America or offshore.

According to the Protocol, sampling of flax seeds is required at three points. The first is at the point where flax enters the supply chain from farms—at country elevators where grain is collected and then loaded on trains for shipment to port. Samples are taken again prior to loading railcars. The contents of up to five rail cars can make up one sample. As suggested above, the final tests are taken after rail shipments and prior to loading ships—at terminal elevators. These final tests are taken

by employees of the Canadian Grain Commission (CGC). If at any of these testing points a positive result is obtained—GM co-mingling at unacceptable levels—then the load of flax will be shifted to a non-EU destination. At the ports, the CGC makes sure that no loads that are above the threshold (test positive) are loaded on ships destined for EU ports. Officials from the CGC provide a Letter of Analysis for those receiving shipments in the EU (Viju et al., 2011a).

Sampling is the mechanism that underlies testing. Due to sampling, however, there will be errors. This means that the sample may not represent the actual composition of the shipment. Hence, due to sampling error some shipments that should be refused are cleared for entry into the EU. This result would seem to be at odds with the official threshold of zero. While there have been considerable improvements devised for raising the efficacy of testing regimes, the testing regimes actually specified represent decisions that are inherently arbitrary. The specification of testing regimes can have considerable cost implications—as the case of testing before or after ships are loaded illustrates. While questions related to testing will arise for any threshold that is specified, when absolute zero is specified as the official objective it cannot be achieved because there will always be errors. If an alternative common-sense threshold were to be specified, sampling errors could be taken into account.

The experience with Triffid flax suggests it might be time to revisit zero tolerance. It is an overly simplistic public policy. The policy goal is ultimately unachievable and the policy outcome is determined by exogenous factors such as the science of detection, the expected profitability of developing tests, and the sampling method chosen. The costs to society of zero tolerance may increase considerably without any assessment by policy makers regarding its desirability.

### **Pollen Judged to Be a Food Ingredient in the EU**

On September 6, 2011, the Court of Justice of the European Union (ECJ) ruled that pollen found in honey constituted a foodstuff (ECJ, 2011). This judgement, which on first glance would appear to represent rather arcane hair-splitting regarding a minor agricultural crop, in fact may have major implications for agriculture on a global basis.

While the acceptance of GM products has long been a contentious issue in the EU (Perdikis, 2000), it has never been EU policy to ban the use of the technology

14. Agencies of the Canadian government were also involved, including Agriculture and Agri-Food Canada (AAFC), Foreign Affairs and International Trade Canada, and the Canadian Food Inspection Agency (CFIA).

or the importation of GM products on a permanent basis (Viju et al., 2011b)—although this is clearly the objective of some interest groups in the EU (Holtby et al., 2007). Devising an operational mechanism for approving such contentious products proved to be very difficult and the process for obtaining approvals is long and not always linear (Viju et al., 2011b). The major elements of the EU policy for GM approvals were put in place in 2003, although they have remained a work in progress. The first product to work its way successfully through the revised EU-level approval process—BASF's Amylopectin ('Amflora') potato—only received cultivation approval from the European Commission on March 15, 2010 based on an application made in February 2005. The achievement of an approval for cultivation, however, is extremely important as asynchronous approvals of GM products have become major international problems. Approvals for imports of GM products that will not be cultivated have been easier to achieve, but the approval process is still sufficiently slow that approvals are asynchronous internationally. As approvals were continuing apace in the major GM-accepting countries but not in the EU, international trade flows were disrupted, adoption of GM crops was inhibited (particularly in Africa where countries feared losing access to the EU market), and investment in new GM crops was reduced (Smyth et al., 2011). As time has passed, more and more GM crops are being approved in some jurisdictions but not in others, increasing the problems associated with asynchronous approvals.

An EU approval for the Amflora potato was taken as a positive signal that, while approvals were not yet synchronized, that approvals would now take place on approximately the same time frame—given that the scientific criteria in, for example, the United States and the EU are based on the same process (Isaac, 2007a). Further, the approval was taken to be evidence that, while an approval could be denied in the EU on a political basis, the veto would not be used in a *carte blanche* fashion. The approval process, however, is very demanding and costly for firms that wish to seek it.

The EU has a zero-tolerance policy for unapproved GM products. It also has a co-existence policy for the planting of GM crops whereby conventional and organic crops, including honey, should not suffer co-mingling from GM crops. This is operationalized by buffer zones that normally are defined in meters (e.g., 150 meters for GM corn). With pollen being judged to be an ingredient of food, and given that traces of pollen cannot be removed from honey, honey producers will be unable to sell their product unless the GM-crop from which the

pollen was derived has been approved for human consumption within the EU.<sup>15</sup> This applies equally to foreign producers of honey and domestic producers of honey in the EU. As only GM crops that have been approved for human consumption and cultivation can be grown in the EU, this should not be a particular problem for honey producers in the EU. The EU, however, is not self-sufficient in honey; imports constitute approximately 40% of its consumption. To a considerable degree, these imports have come from countries such as Canada, Brazil, and Argentina that have generally accepted the use of biotechnology. They are approving increasing numbers of GM products and the rate at which approval is sought for new GM products is expected to accelerate. Unless the GM crops that the bees visit have been approved for consumption in the EU, under zero tolerance honey containing traces of GM pollen cannot be sold in the EU. In some cases, the developers of GM crops suitable for cultivation in honey-exporting countries may never seek regulatory approval in the EU, even only for importation.

Further, EU honey producers wishing to sell their product as organic would be denied their designation because organic products must be GM-free. Under the co-existence regulations of some EU states, such producers would be entitled for compensation from the grower of the GM crop visited by the bees. Thus, given the roaming range of bees, to ensure no co-mingling, the required buffer zones have been estimated to range from 3 to 10 km surrounding a hive. In effect, this could prevent the planting of any approved GM crop. As beekeeping is a low entry-cost activity, it is also ideally suited to exploitation by those wishing to prevent the planting of GM crops.

Thus, the knock-on effect of zero tolerance in the pollen case is likely to lead to trade disruptions and inhibit the growing of approved GM crops in the EU.<sup>16</sup> This was not the intent of the zero-tolerance policy. The cost to society of zero tolerance in this case is likely to be much higher than the least-cost alternative level of tolerance.

## Conclusions and Policy Implications

Although the potential for trade challenges exists, external factors are unlikely to greatly influence EU policy. Any real change will require a change in domestic policy in the EU. Policy makers, in theory at least, should

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15. It is important that new applications for approvals of GM crops also explicitly seek approval for pollen.

be interested in policies that can lead to outcomes that impose reasonable costs on society. It seems clear that zero tolerance in the case of GM products cannot lead to minimum cost outcomes except under exceptional circumstances—a corner solution. Given the theoretical cost analysis, at the very least, a corner solution should not be presumed. Instead, a case by case examination is suggested. The case studies illustrate the degree to which the current EU policy of zero tolerance yields outcomes that are more costly to society than common sense might bring forth. The results suggest that EU policy makers might wish to revisit their system for regulating GM products. As increasing numbers of GM products are approved and produced commercially around the world, the societal costs of outcomes based on zero tolerance will increase, international trade will be evermore disrupted, and supply chains forced to spend more and more resources to satisfy rising levels of stringency as the science of detection improves. As suggested by the vignette that started this article, a dose of common sense in decision making can reduce the likelihood that policies will be based on doctrinaire rules yielding results that are far costlier than need be. The real question is not ‘how low can you go?’ but rather ‘how low should you go?’

Adam Smith, writing in 1776, would have well understood how a zero-tolerance policy arose:

The laws concerning corn may everywhere be compared to the laws concerning religion. The people feel themselves so much interested in what relates either to their subsistence in this life, or to their happiness in a life to come, that government must yield to their prejudices, and, in order to preserve the public tranquillity, establish that system which they approve of. It is upon this account, perhaps, that we so seldom find a reasonable system established with regard to either

of those two capital objects [emphasis added] (1776, p. 580).

After almost 240 years, one would have hoped that most common-sense approaches to food policy would have prevailed.

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16. *The European Commission is attempting to reduce the effect of the ECJ ruling through the use of a technicality whereby pollen would be classified as a constituent rather than an ingredient in honey. While ingredients of food must be labeled under zero tolerance, constituents only have to be labeled if they exceed thresholds that pollen is unlikely to ever reach. This would allow producers to escape having to label their honey as GM. This proposal by the European Commission is currently working its way through the EU legislative process. While this may appear to represent a creative way around the problem of zero tolerance, it also highlights the absence of common sense in implementing a zero-tolerance policy in the first place.*

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