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Regulatory barriers to international scientific innovation: approving new biotechnology in North America

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Abstract

The regulation of science often differs among countries and leads to a divergence that can create barriers to research, knowledge transfer and product trade. Many types of scientific research are mobile activities that be done in a number of countries for a comparable cost. With technology development firms facing comparable development costs regardless of location, it is well understood that location decisions are driven by the time and monetary costs of compliance with regulatory systems. In this article we show the compatibility of a country's regulatory system with foreign regulatory systems can also impact the viability of research investment. We argue there may be considerable economic gain from bilateral, and eventually multinational, agreements to adopt a harmonized or shared regulatory process. This is particularly germane for the United States and Canada which are already in a free trade agreement.

Keywords: agricultural biotechnology; biosafety; harmonization; NAFTA; regulation; scientific-based innovation

Introduction

Global population is expected to rise to a total of nine billion by 2050, thus adding more than two billion new mouths to feed. Even maintaining, much less improving, global food security in the coming decades is dependent upon ensuring that food production technology and food products can be made available to those most in need. Meeting future food security goals faces major obstacles. One of the most important is that regulatory frameworks are becoming more complex and difficult to navigate for technology developers, increasing the cost and time it takes to receive commercialization approvals. Contentious technologies such as agricultural biotechnology are particularly prone to the problems associated with regulatory divergence (Gaisford *et al.* 2007, Hobbs *et al.* 2014). If global food security is truly going to be advanced, regulatory solutions are required.

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Canada and the United States have very integrated economies. To enhance this cross-border trade, Canada and the United States negotiated the Canada–United States Trade Agreement (CUSTA) in 1988 and the Canada–United States–Mexico North American Free Trade Agreement (NAFTA) in 1994. The objectives were to remove trade barriers and harmonize regulations. While efforts to move toward harmonization are important and have had sporadic success, it is largely absent when it comes to regulating new plant varieties. Considerable harmonization potential exists, which would reduce both the time and costs associated with variety approvals. If these two interconnected countries are unable to establish a joint plant regulatory framework, there is scant hope that other geographically distant nations will be able to accomplish this objective. If there is to be a substantial global effort made to address looming food security challenges, making biosafety regulations more efficient must be an early and central element.

In a globalizing economy, market access for technologies has become a concern for international agribusiness. The increase in global commerce and trade over the last 20–30 years has created the present-day scenario, at least for agriculture, where the efficiency of a domestic regulatory system is now a crucial part of a multinational firm's investment strategy. Regulatory efficiency is such an important factor that the greatest competition for research and development (R&D) project investment is not gaining an advantage over other multinational firms, but rather over domestic subsidiaries of their own firm. For example, Brazil's regulatory approval time for new biotechnology crop varieties is shorter than that of Canada. Hence, the Brazilian subsidiary of a multinational firm would have a stronger investment proposal for developing the new variety than would the corresponding Canadian subsidiary.

In November 2011, the Government of Canada released a report from the Regulatory Cooperation Council (RCC; Government of Canada 2011). The RCC was formed early in 2011 under the Perimeter Security and Economic Competitiveness agreement between Canada and the United States. The objective was to, where possible, simplify and align regulatory approaches. Two specific areas identified in the Joint Action Plan were food safety systems and biotechnology. Key priorities to be dealt with regarding food were the mutual recognition of food safety systems and developing common approaches to food safety requirements and policies. Priority areas for biotechnology were identified as: (1) a joint review process to deal with asynchronous approvals; and (2) a common policy for dealing with the low-level presence of unapproved products. While this initiative sounds well intentioned, it is only one of a number of initiatives aimed at regulatory harmonization in the agri-food sector which have, for the most part, come to naught. While the use of biotechnology in agriculture has a number of facets that are contentious (Gaisford *et al.* 2001), including the degree to which large multinational agribusiness firms own the intellectual property rights to both processes and genetic material (Perdikis *et al.* 2004, Kerr and Isaac 2005), these do not appear to have tempered governments' willingness to seek regulatory harmonization in North America.

This article explores the potential for, and practicality of, integrating the plant variety approval regulations of Canada and the United States. The next section develops the theoretical case for regulatory harmonization and outlines the costs associated with its absence. The third section outlines harmonization initiatives that are enshrined in NAFTA, but which have proved largely ineffective. The fourth section explores the record of harmonization, including where some success has been achieved. The fifth section discusses the implications of the absence of regulatory harmonization. Suggestions for how harmonization might be facilitated and concluding comments are then offered.

Regulatory harmonization and implications of failure to harmonize

Theory of regulation harmonization

Product evaluation and regulation underpins the smooth operation of most markets. New products are typically screened for potential adverse effects. In Canada, plants with novel (genetic) traits are tested and screened for adverse impacts on the environment, human health and animal health. In the United States, genetically modified (GM) crops undergo similar testing and regulation.

The absence of new product regulation could result in substantial harm. In the short run, consumers or the environment would bear the brunt of the costs. Over time, the nature of the harm would mean reduced demand for the product. In most cases, the costs related to the absence of regulation would be well beyond those associated with the innovator introducing the product, should also include the impact on the market demand for similar products, and could spill over into public health care and ongoing environmental costs, depending on the hazard.

The knowledge created from product testing is non-rival, meaning that once created it can be used again and again without further development costs or depletion, suggesting considerable economies of scale in its application. For instance, if a soybean variety is tested for allergenicity, this knowledge can apply to the first ton sold and the 10 millionth ton sold. Much of the knowledge could, in principle, also be applied across jurisdictions.

Scale economies originate in the fixed costs associated with: (1) product testing; and (2) regulatory approval (review of the tests, etc.). The average social cost of regulation is F/Q (fixed costs over quantity). Scale matters!

Regulatory requirements vary considerably, depending on the nature of the innovation and the conditions in the jurisdiction, including: physical environment, human health impacts, consumer tastes, income levels, risk preferences, cultural differences, hysteresis and institutional rigidity.

Nearly all governments choose to spend public resources and to impose private costs to regulate new product introductions. Costly regulation is justified on the basis of market failure. In the absence of regulation, private firms have little incentive to consider, for example, environmental externalities. In the case of food production, regulation plays an important role in limiting adverse health impacts and addressing asymmetric information.

In the absence of regulation, potentially harmful products can enter the food supply. When consumers become aware of a risk, they will avoid consumption and market demand will suffer. For example, in the 1990s when aflatoxin was discovered in some pistachios in Germany, demand declined 25 per cent and remained low for several years after the issue was addressed. In addition to market impacts, unregulated product can impose costs through health care expenditures.

Figure 1 illustrates the impact of product regulation. Assume a firm is introducing a new differentiated product that has a marginal cost of production, MC . In the absence of regulation, the demand for the product is D_0 , and there is very limited scope for commercialization. The government imposes a requirement for product testing, which has a total fixed cost equal to the shaded area; the corresponding average per-unit cost incurred by firms to bring their operations into regulatory compliance is $ACRC$. The demand shifts out to D' as consumers have improved information. The imperfectly competitive firm sets price P , earning a producer surplus over and above the regulatory cost, and consumers gain an area of consumer surplus below the demand D' and above price P .

In designing a welfare-maximizing regulatory system, policy makers would consider the net surplus in Figure 1, minus public expenditures and any external environmental impacts.

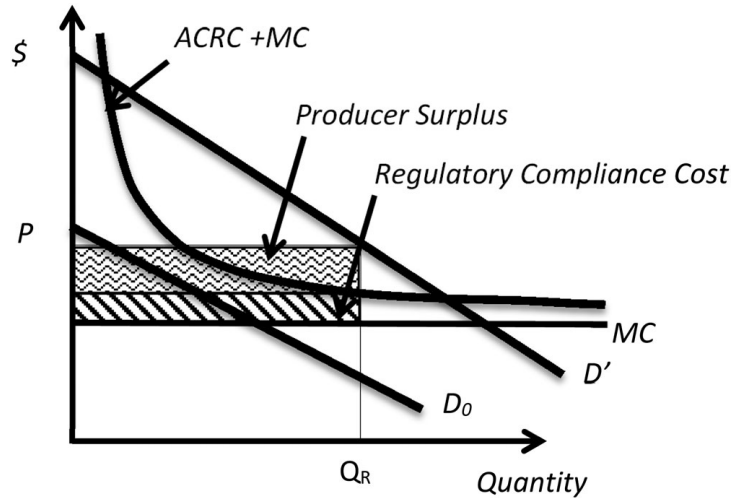


Figure 1. The economic impact of product regulation.
 Notes: P = price; Q_R = regulated quantity; D_0 = initial demand; D' = increased demand; MC = marginal cost; ACRC = average cost of regulatory compliance.

Market size and the impact of regulation

Given the non-rival nature of the knowledge involved in the regulatory process, market size becomes very important for the average cost of regulatory approval. In a small country or market, the per-unit cost of regulatory compliance will be higher, which will reduce the producer surplus of the innovator, as shown when comparing markets of different size in Figure 2. As the same fixed costs are spread over a larger output in the large country, per-unit costs fall – shown by AC Reg. compliance. If the producer surplus is insufficient to cover the other fixed R&D costs of the firm, the product will not exist in smaller countries. For example, the limited size of the lentil market and the large costs associated with the regulation process for GM plants in Canada makes it prohibitively expensive to commercialize GM pulse varieties. Hence, in this case, the required research and the associated benefits do not exist.

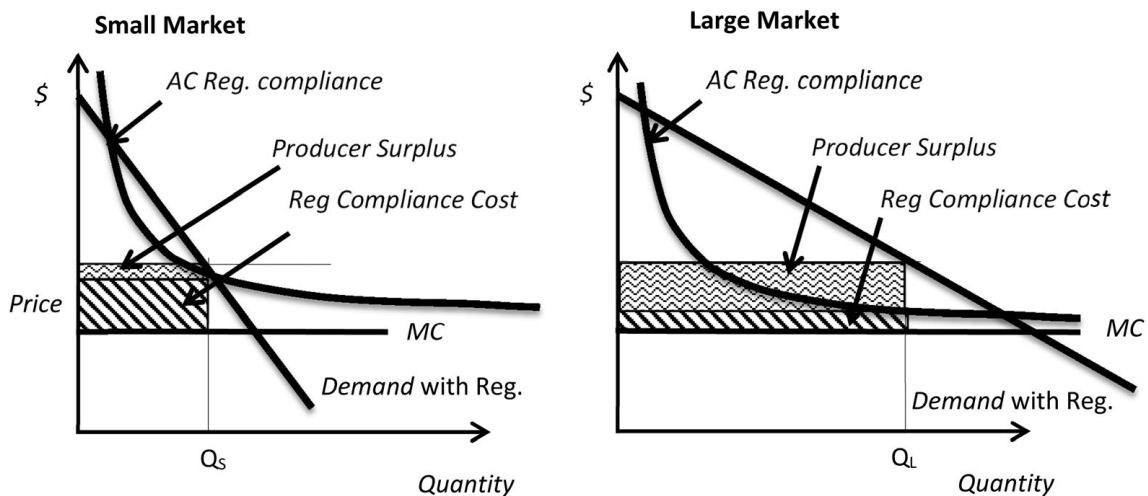


Figure 2. The impact of market size on the average cost of regulatory compliance.
 Notes: Q_S = quantity produced in small market; Q_L = quantity produced in large market; MC = marginal cost; AC = average cost.

This cost structure can also have a major impact on the location where a new product is introduced for production. In a situation where the fixed costs of regulation are similar, firms will have a very large incentive to introduce their product in the largest markets, where per-unit costs of regulation are lowest.

Regulatory harmonization

Harmonization will increase the market size for any given regulatory process. This will reduce average per unit regulatory costs and make the innovator indifferent in terms of location, assuming both markets could be accessed from either side of the border. However, if harmonization represents a new set of regulations and, hence, may be less reflective of the regulatory need of each country, the regulations can be less effective in one or both countries. If this is the case, the lower cost of regulatory compliance must be considered in the context of potential demand reduction or greater external costs associated with less-tailored regulations.

Regulatory harmonization is shown in Figure 3. The lower average cost of regulation increases the potential economic surplus, particularly for the smaller markets. With lower regulatory compliance costs, new products will face a lower economic threshold for entry, thereby increasing consumer surplus. The demand curve D'' reflects the case where the harmonized regulations are less reflective of smaller country needs. In this case, harmonization reduces consumer surplus. For example, this could reflect a situation where some consumers don't like GM foods but harmonized regulatory structures are accepted.

While no studies exist for the cost of the potential opportunities forgone, which arise from a lack of harmonization in biotechnology approvals in North America, there is considerable empirical evidence from other sectors to suggest the costs are high (see, for example, Wilson and Otsuki 2003, Swinnen and Vandemoortele 2008, Disdier and Marette 2010, Keener et al. 2014). One of the reasons why such an *ex ante* empirical evaluation has not been undertaken is the difficulty in estimating the rate of technological improvement arising from the innovation process – the performance of which regulatory harmonization is expected to enhance in this case. Of course, given that private-sector firms own the intellectual property associated with agricultural biotechnology, part of the benefits will arise as increased profits of those firms and they have an interest in pushing for harmonization. In other facets of

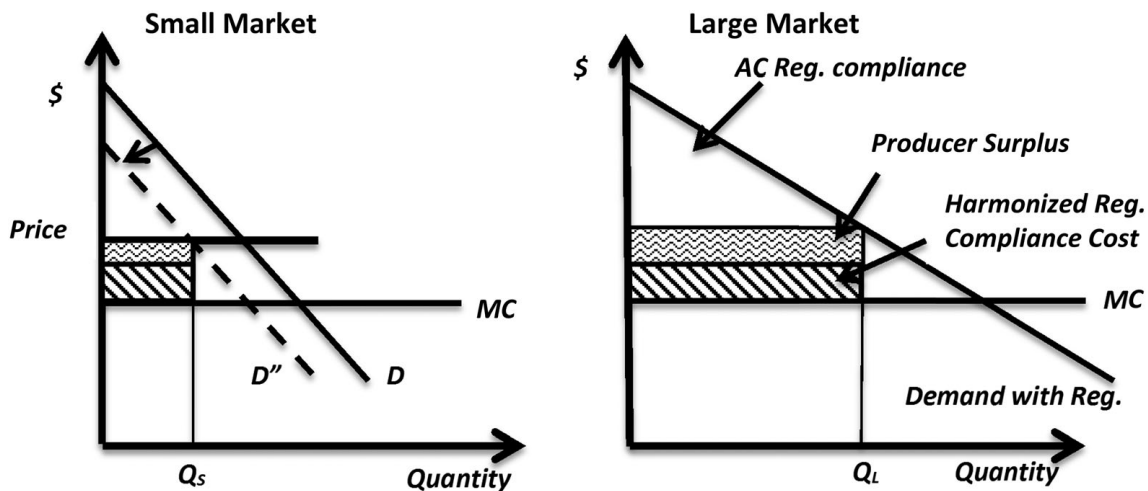


Figure 3. The impact of regulatory harmonization.

Notes: Q_S = quantity produced in small market; Q_L = quantity produced in large market; D = original demand curve; D'' = shifted demand curve; MC = marginal cost; AC = average cost.

biotechnology's use in agriculture, the increase in welfare arising from the technological improvement is shared between farmer users, consumers and the developers of the technology, with the latter receiving approximately 40 per cent of the benefit (Sobolevsky *et al.* 2005). In any case, governments appear to believe the costs of the forgone opportunities are sufficiently high to attempt to foster harmonization.

Attempts at regulatory harmonization in the NAFTA

Policy makers implicitly understand the case for regulatory harmonization. The negotiators of the CUSTA and NAFTA anticipated the need for institutional arrangements to address regulatory disharmony. Negotiators hoped these arrangements would mitigate the trade difficulties associated with independent regulatory development prior to the signing of the agreements and reduce the incidence of regulatory divergence in the future. This was specifically written into the NAFTA under Article 906: Compatibility and Equivalence (NAFTA 1994a).

Further, under Article 913, a Committee on Standards-Related Measures was to be created both to assist in harmonizing existing regulations and to foster regulatory harmonization subsequent to the NAFTA coming into force (NAFTA 1994b).

In agriculture, a Committee on Agricultural Trade (Article 706) was established that was to put in place a Working Group on Agricultural Grading and Marketing Standards. Under Article 722 a Committee on Sanitary and Phytosanitary Measures was also mandated, as well as working groups for: (1) Animal Health; (2) Dairy, Fruits, Vegetables, and Processed Foods; (3) Fish and Fisheries Product Inspection; (4) Food Additives and Contaminants; (5) Labeling, Packaging, and Standards; (6) Meat, Poultry, and Egg Inspection; (7) Pesticides; (8) Plant Health, Seeds, and Fertilizers; and (9) Veterinary Drugs and Feeds. The NAFTA preceded the commercial use of agricultural biotechnology by a decade so no specific reference to reducing regulatory divergence in their approvals was included – although the work of the Committee on Sanitary and Phytosanitary Measures could be applicable.

Clearly, those negotiating NAFTA were aware of the potential for regulatory insularity to be disruptive, and took considerable and detailed care to ensure that institutional arrangements existed to reduce the potential for discord.

While institutions can be put in place, they may fail to operate as intended. While deficiencies in the NAFTA institutions pertaining to regulatory harmonization have not been at the forefront of the debates surrounding NAFTA's efficacy, the issue has been raised a number of times (Gillis *et al.* 1985, Kerr, 1992, Hayes and Kerr, 1997). The NAFTA committees have, for the most part, simply become forums to talk and talk without any mechanism to bring closure to an issue (Green *et al.* 2005, Kerr 2006).

The one exception appears to be the Technical Working Group on Pesticides (TWGP). The TWGP was established in 1996 under provisions on sanitary and phytosanitary regulations to “serve as a focal point for addressing pesticide issues arising in the context of liberalized trade among the NAFTA countries” (Health Canada 2015). The key objectives were: sharing information, undertaking collaborative scientific work, forging common data requirements, collaborating on risk assessment or compliance methods, carrying out joint reviews and developing common NAFTA or international standards (Health Canada 2015).

The TWGP is comprised of officials from all three countries that have regulatory expertise in pesticides. Representation is from the Canadian Pest Management Regulatory Agency (part of Health Canada), the Environmental Protection Agency (EPA)'s Office of Pesticide Program in the United States and the Mexican Ministries of Health and Agri-foods, Aquaculture and Fisheries.

The working group's initial period, 1997–2002, was predominantly occupied with establishing baselines for further collaboration. This involved garnering three-party agreement on

principles and practices, and existing standards and regulations, and clearly defining which products were approved for use in each market. Two reports exist, one examining the work of the TWGP from 2003–2008 and the other a 2008–2013 strategic plan (NAFTA–TWGP 2009a, 2009b). The assessment document reports that a vision statement was developed for the TWGP’s work: “Canada, the United States and Mexico are striving to make the North American region a world model for common approaches to pesticide regulation and free trade in pesticides and food” (NAFTA–TWGP 2009a, p. 1). The TWGP report defines three objectives that the assessment is conducted against: (1) full North American collaboration in pesticide regulation, including re-assessment; (2) equal and timely access to new pest management tools; and (3) robust stakeholder participation (NAFTA–TWGP 2009a).

Much of the 2003–2008 efforts were directed toward re-evaluation and re-registration of existing pesticides. Prior to this period the time that approvals were valid varied. As a result of the TWGP efforts, it was standardized at 15 years for all pesticides, after which each pesticide must be re-reviewed and re-approved. Considerable work was also done to harmonize maximum pesticide residue limits.

Simultaneous three-country registration of new active ingredients was encouraged. This resulted in the review assessment work being apportioned among the three nations with the results being shared and peer reviewed. This approach proved successful as, by 2005, two new active ingredients were approved in 14 and 16 months – record approval times (NAFTA–TWGP 2009a). This has institutional implications as the shared review processes “resulted in increased levels of shared scientific knowledge and in increased understanding of each country’s risk assessment and risk management processes. Consequently, governments have gained trust in their counter-part’s regulatory decision-making” (NAFTA–TWGP 2009a, p. 6). Industry stakeholders suggested that the joint review and work-sharing process should be a model for international regulatory collaborations.

The NAFTA–TWGP planning document identified a set of common objectives for 2008–2013 (NAFTA–TWGP 2009b). The objectives are to improve the coordination and cooperation in the pesticide review process and to further harmonize the regulatory frameworks. Unfortunately, no review is available for the most recent five years. The TWGP experience suggests that progress toward harmonization is possible through cooperation among regulatory regimes.

Despite the apparent success of the TWGP, regulatory harmonization has remained elusive in North America despite the efforts of those involved in the design of the NAFTA. The reasons why regulatory harmonization is not forthcoming are complex. In the case of trade barriers such as tariffs, the implementation of an agreement’s provisions remain with the ministry that is responsible for trade and trade negotiations. Thus, removal of tariffs on agreed schedules is never an implementation issue. In the case of regulatory barriers, removal is unlikely to be under the control of the trade ministry. Domestic-oriented ministries have their own priorities, agendas and stakeholders. While, at some level, their agreement would have been obtained by the trade negotiators, this does not mean that implementing commitments in trade agreements is a priority. Removal of such barriers often requires that something else must be put in place, necessitating changes to established routines and resources to develop new protocols and undertake more costly activities. If the existing system is operating satisfactorily, there may be little enthusiasm to undertake the agreed changes, and certainly not expeditiously. If the changes require consultations and negotiations with the trading partner, then these can be used strategically for delay (Hayes and Kerr 1997).

When moves toward harmonization of sanitary and phytosanitary regulations are included in trade agreements, other institutional impediments and bureaucratic vested interests may also arise. This is because sanitary and phytosanitary procedures can often have serious human, animal or plant health ramifications. Further, it is a sensitive policy area. There is almost nothing that can

be more devastating to a government's reputation, and an individual politician's career, than a major food safety incident that takes place on their watch. Hence, politicians have been particularly reluctant to relinquish sovereignty in this area of public policy (Kerr 2009). Consider the case of two countries, A and B, whose regulatory processes in the area of, for example, food safety differ in important aspects. Harmonization can follow three paths. Country A can harmonize with Country B's existing regulations; Country B can harmonize with Country A's existing regulations; or the two countries can agree to cooperate in devising new regulations. From the perspective of the regulators and politicians, it would be preferable if the other country reconstituted its regulatory processes because this would require no changes to their existing system and no additional resources. All of the costs of harmonization would be borne by the other country. Thus, in negotiations on harmonization, there are vested interests in negotiating hard to obtain the result that leads to harmonization with one's existing system – and there is nothing to gain from compromising. Negotiations are likely to be protracted with little incentive to conclude them.

If pushed by policy makers to compromise, the vested interests in the regulatory system can always appeal to civil society that they are being forced to *lower food safety standards, endangering the public due to pressure from trade partners*. This is the type of story that opposition parties can use to considerable advantage and which those in government wish to avoid.¹

The egocentric nature of regulatory regimes, and personnel, can also lead to resistance to harmonization to existing alternative or newly devised standards. For sanitary and phytosanitary regulations, as the science underlying procedures develops, they become considered the *best practice*. It is unlikely that those responsible for any science-based system will admit that an alternative system is superior – if it were, responsible regulators would adopt the *superior* system. Thus, when regulatory regimes develop separately, those administering them tend to think theirs is the *best system*. Hence, there is a bias toward believing that harmonization should lead to a convergence to their superior system. When faced with pressure to harmonize to other standards, it raises awkward questions as to why *best practices* are not already being applied domestically. Were the regulators not doing their jobs and not doing their best to provide safe food? This egocentricity means that those responsible for food safety genuinely believe they have the best system, and a feeling that they would be remiss if they agree to move to alternative standards.

The upshot is that there is likely to be considerable resistance to harmonization by existing regulatory personnel (Sawyer *et al.* 2009). There may also be direct vested interests resistant to changes mandated by trade agreements. One of the changes mandated in the CUSTA was the removal of border inspections for red meat (Kerr *et al.* 1986). The American government border inspectors were faced with job losses (or relocation), and private firms that owned the border inspection stations were faced with their facilities no longer being needed, threatening their investments. Together, they were able to considerably delay their closure (Kerr 1992).

The problems associated with achieving change in large organizations are not only those arising in trade agreements (Todnem By 2005). While there is no shortage of prescriptions for successful implementation and management of change (Paton and McCalman 2008, Hayes 2014), the problem with the NAFTA stemmed largely from an absence of a trilateral organization from which leadership on the issue could stem (Gill 2002). Once the agreement was signed, there was no institutional source for leadership on implementation among the array of domestic ministries and departments that would have to be involved (Kerr 2006).

Challenges for Canada–United States regulatory harmonization in biotechnology

Regulatory approaches to GM crops differ between Canada and the United States. This results in duplication of effort and delays that are costly – meaning the benefits outlined above remain opportunities forgone.

Canada created a distinct regulatory category for plants with novel traits (PNTs), which can include plants developed by number of breeding technologies. Thus far, all crop varieties developed using GM methods have been classified as PNTs by the Canadian Food Inspection Agency (CFIA; Smyth and McHughen 2008). The United States regulates all GM crops through the combined efforts of the United States Department of Agriculture (USDA), the EPA and the Food and Drug Administration (FDA) (Smyth and McHughen 2008). Both countries regulate the product that is created, but not the process to create it. Each approach to the regulation of the products of biotechnology is unique.

As mentioned above, in 2011, the RCC was established with the objective of aligning regulatory approaches. Both food safety and biotechnology are highlighted as key areas for the RCC. There is some activity pertaining to food safety, but none for biotechnology.

Action on improving food safety has focused on common approaches and testing, meat and poultry equivalence, and certification requirements and meat processing (Government of Canada 2015). While there is no evidence of efforts directed at the harmonization of plant regulations, there is evidence of work on crop protection, in particular pesticides. It is quite possible that the NAFTA–TWGP process was not meeting the needs of the two governments and industry, and they sought to facilitate the process using the RCC. The RCC activities concerning crop protection products indicate diligent attempts to improve the joint submission process for pesticides, develop joint guidelines and address obstacles to joint registration. It would appear that both Canada and the United States are now concentrating their efforts on the harmonization and, indeed, integration of pesticide regulations within the RCC process, largely replacing efforts previously undertaken by the NAFTA–TWGP.

While the opportunities forgone and additional costs associated with asynchronous approvals of pesticides may be more immediate than those associated with biotechnology, the costs of delays in garnering approvals for improvements to biotechnology may be much larger over the long run. This is because the benefits of biotechnology are likely to be much larger. Given the apparent interest of both the United States and Canada in dealing with approvals of advances in biotechnology, the question becomes: what will it take to ensure that a serious attempt is made to harmonize evaluation and approval processes?

Preferential trade agreements have differing records on harmonization. As suggested above, the NAFTA has not been particularly effective in removing technical barriers to trade and fostering regulatory harmonization. In contrast, the European Union has been very effective in its endeavors in these areas – although, ironically, not in the area of agricultural biotechnology. The European Union has a very different governance structure than the NAFTA does.

In Canada–United States relations, there is no formal supranational body to foster a bilateral agenda (Kerr 2002). The United States, in particular, is suspicious of supranational institutions largely because of concerns with the limits on sovereignty that they might impose. If one compares, for example, the NAFTA with the European Union, the most striking difference is the absence of the equivalent of the European Commission. The Commission is comprised of commissioners appointed by the member states' governments. Once appointed, however, the individual commissioners are expected to take a European Union perspective rather than to be an advocate for the government that appointed them. Commissioners “speak for Europe.” No one in the NAFTA system is expected to “speak for North America” – one is either an American, a Canadian or a Mexican. All those that work in the Commission also “speak for Europe.” This means that at almost any meeting, conference, policy forum or media event, there is someone there to provide a European Union-wide perspective.

The European Commission is also exclusively charged with devising European Union-wide policy proposals. Even if the proposals are rejected by the European Union's Council of Ministers or the European Parliament, it means that proposals with such a perspective must be considered.

In the NAFTA, there is no institution that plays this role. Instead, everything must be proposed and negotiated by advocates of the individual countries. This is not to suggest that either the United States or Canada give up sovereignty in relation to ensuring food safety and the environment and acting in a precautionary way. Instead, it is suggested as a means to re-align incentives to be less antipathetic to harmonization.

Moving forward with regulatory harmonization for biotechnology

One is unlikely to be able to create an equivalent of the European Commission in North America, but it should be possible to create a non-partisan bilateral agency to advocate for harmonization of approval processes for biotechnology. The TWGP was a step along that road. It should be a permanent organization with representatives appointed by the two governments, but independent and mandated with taking a “North American” approach. It should be given the responsibility to actively develop proposals for harmonization and to put them on the public agenda of the RCC (or some other institution). The individual governments would have to approve the proposals, and would retain sovereignty in this important area of public policy, but at least there would be independent proposals being put forward. If proposals for harmonization are developed and approved, then there is something to which the bureaucracy can be held accountable – unlike the vague commitments for them to negotiate harmonization that were, for example, included in the NAFTA.

When biotechnology was a new technology and considerable uncertainty surrounded its efficacy and potential externalities, it is probably not surprising that regulatory regimes evolved independently. Existing institutions had to be adapted to deal with the new transformative technology or new ones created (Phillips and Kerr 2002). Multinational harmonization of biotechnology regulation has not been achieved – and may well be diverging (Kerr 2014). In the case of the United States and Canada, the experiences with agricultural biotechnology have, however, been similar. Even with diverging regulatory regimes, there were both early approvals and relatively rapid adoption of the technology. Given both the rapid uptake by farmers and the widespread use of the major biotechnology crops in processed food, there has also been consumption on a grand scale. Given 20 years of consumption without any evidence of harm to human health, both regulatory regimes appear to be working well. The experience is similar for environmental concerns. Vigilance, of course, is still required. It does suggest, however, that the costs and forgone benefits of separate regulatory regimes may no longer be justified. Either existing regime would do for both the United States or Canada; or a new common regime. Presumably, this could be determined by a non-partisan institution established to propose harmonized regulations. Given the relative size of the economies, harmonizing to the American regulatory regime would likely be less costly due to lower switching costs. Canada, however, would bear the harmonization costs. It would also have to ensure it retained sovereignty in cases where regulatory harmonization was not seen as being in its interests.

A new approach to regulatory harmonization for agricultural biotechnology in North America appears worthy of serious consideration. Before that can happen, institutional innovation may be required. If a non-partisan institution can be agreed upon, then harmonization proposals can be developed from a North American perspective, with the governments charged with dealing seriously with the proposals.

When technologies are new and potentially transformative, it is probably not surprising that governments regulate independently (Phillips and Kerr 2002, Kerr 2014). That there are opportunities forgone due to absence of harmonization is well known and exists in the technology’s early stages as well as later in its development. These costs, however, are considered acceptable given uncertainties surrounding new technologies.

As time passes and more information is acquired, the uncertainty gives way to a comfortable degree of transparency regarding the effects of the technology. Alternative regulatory structures can provide similar comfort levels. At that stage, the costs associated with divergent regulatory regimes gain more prominence as other concerns regarding the technology fade. Lack of harmonization can no longer be justified.

This would appear to be the stage approvals of new agricultural biotechnologies in the United States and Canada have reached. There is considerable comfort with the technology and no glaring examples of the benefits of regulatory independence. Yet there appears to be little movement toward harmonization despite the large costs imposed. This suggests that institutional innovation may be necessary to overcome political inertia and vested interests in the regulatory system.

Given the need to increase the pace at which agricultural productivity improves due to global food security challenges, regulatory harmonization within North America – a major developer of the technology – would represent one important step toward meeting those challenges. Successful institutional innovation might also provide a model for multilateral harmonization efforts that can assist in achieving much-needed increases in global agricultural productivity.

Disclosure statement

No potential conflict of interest was reported by the authors.

Note

1. One example might be Japan's policy response to mad cow disease, where the policy put in place to reassure the public was to test every domestic animal for the disease. This mandatory testing of all animals was also applied to imports of beef. The disease cannot, however, be detected in animals less than 30 months of age – so Japan's trading partners do not test animals less than 30 months old. The countries that export beef to Japan have pushed back against this *non-scientific* import regulation. Japan, however, has not relaxed the regulation because its politicians would be vulnerable to criticism that they were bowing to foreign political pressure and putting domestic consumers at risk (Loppacher and Kerr 2005).

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