The Impact of Asynchronous Approvals for Biotech Crops on Agricultural Sustainability, Trade, and Innovation

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Introduction

In this brief report, the authors outline the main economic effects of the observed asynchrony in approvals for biotech-improved crops from regulatory systems in countries that are major global commodity exporters and importers.

In this brief report, the authors outline the main economic effects of the observed asynchrony in approvals for biotech-improved crops from regulatory systems in countries that are major global commodity exporters and importers. The purpose here is not to evaluate the quality or functionality of any national regulatory approval system. Rather, current scholarly research and knowledge regarding the impact of asynchronous regulatory approvals on global agricultural innovation, production, trade, and consumption are reviewed. Initially the work of scientists from a range of academic disciplines who use a variety of modeling and analytical techniques to approach this general question is described. The next section includes a detailed discussion of the question at hand and why it is so important to producers and consumers worldwide. This is followed by a description of concrete research results in several relevant areas, including the effects on trade, downstream industries, the adoption of biotechnology innovations, biotech investment and R&D (research and development), crop breeding, and farm income. There is also a discussion of proposed policies that could decrease regulatory asynchrony and its impacts on the global agricultural economy. In the final sections, the authors identify some areas for future research and summarize their findings.

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The Issue

Biotech crops limit yield losses from pests, free up labor, decrease the use of sprays on insect-resistant crops, and rein in increases in food prices.

The year 2016 was the 21st year that crops improved through modern biotechnology (biotech crops) have been produced and sold on agricultural markets.[1] Biotech crops possess enhanced insect resistance, herbicide tolerance, and other useful traits, so their adoption by agricultural producers around the world has been swift. Since 1996, two billion cumulative hectares of biotech soybeans, maize, cotton, canola, sugar beets, and other crops have been grown in more than 30 countries, with 180 million hectares cultivated in 2015 alone (James 2015). Data from the U.S. Department of Agriculture (USDA) show that global soybean output expanded 150% and corn output grew 85% in the two decades since biotech crops were introduced.[2]

Biotech crops limit yield losses from pests (Brookes and Barfoot 2015; Klümper and Qaim 2014); free up labor, resulting in additional earning opportunities for farmers (Fernandez-Cornejo, Hendricks, and Mishra 2005; Subramanian and Qaim 2010); decrease the use of sprays on insect-resistant crops, benefitting the health of farmers, especially in less-developed countries (Huang et al. 2005); and, through a growing crop supply, rein in increases in food prices (Alston, Kalaitzandonakes, and Kruse 2014). Economists have estimated the annual social benefits from biotech crops to be in the billions of dollars and broadly shared among innovators, crop producers, processors, downstream producers, and consumers in both importing and exporting countries (Alston, Kalaitzandonakes, and Kruse 2014; Brookes and Barfoot 2015; Carpenter 2010; Falck-Zepeda, Traxler, and Nelson 2000; Klümper and Qaim 2014; Konduru, Kruse, and Kalaitzandonakes 2008; Qaim 2009; Sobolevsky, Moschini, and Lapan 2005).

Crops produced through modern biotechnology are strictly regulated, and regulatory approaches differ across countries.

Crops produced through modern biotechnology are strictly regulated, and regulatory approaches differ across countries. In countries with biotech regulatory systems, it is illegal to produce or import biotech crops for human food, livestock feed, or industrial processing purposes unless their specific transformation events[3] have been reviewed and approved by regulatory authorities.[4] Governments regulate biotechnology and its products in an attempt to minimize any potential environmental and animal or human health risks that new biotech events might present.[5] The associated regulations involve administrative, compliance, and other social costs that must also be taken into account both by the crop developers and the society as a whole (Kalaitzandonakes, Alston, and Bradford 2007).

Developers must anticipate future market conditions and trade but, ultimately, have no control over where grain produced from their seeds is marketed.

In order to comply with regulations, developers must submit thorough application dossiers to the competent authorities in every country where they might want to sell seeds with a new biotech trait or where they anticipate grain produced from these seeds may be exported. Developers must therefore anticipate future market conditions and trade but, ultimately, have no control over where grain produced from their seeds is marketed. Gaining regulatory approval for a new event requires several years of extensive testing, data collection, and regulatory review (Kalaitzandonakes, Alston, and Bradford 2006; Prado et al. 2014).

Each country has its own procedures and capabilities for assessing the dossiers and its own timetable for doing so.

Each country has its own procedures and capabilities for assessing the dossiers and its own timetable for doing so. As such, the time required to review and approve new biotech events varies significantly from one country to another (Kalaitzandonakes, Alston, and Bradford 2006). It is generally expected that the efficiency of national regulatory systems improves with experience. Despite the evidence regarding the safety and performance of biotech crops that has been accumulated worldwide over the last 20 years, however, regulatory review times for new biotech events have increased in key jurisdictions (Smart, Blum, and Wesseler 2016), and approvals have

[1] Modern biotechnology means the application of the following: (1) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or (2) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (CODEX 2009).

[2] See USDA production, supply, and distribution database (USDA–FAS n.d.).

[3] The term “event” is used to characterize “the unique DNA recombination event that took place in one plant cell, which was then used to generate entire transgenic plants” (http://www.gmo-compass.org/eng/glossary/163.event.html).

[4] Nearly 200 separate biotech events in 29 crops have thus far been approved by various regulatory authorities in one or more of 40 different countries that have regulatory systems governing the cultivation and/or importation and use of biotech crops (ISAAA 2016). A number of other countries are in the process of developing their own regulatory apparatus.

[5] See, for instance, *Foods Derived from Modern Biotechnology* (Codex 2009) or the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 2000).

become more asynchronous in recent years (de Faria and Wieck 2014; Kalaitzandonakes, Kaufman, and Miller 2014a; Kalaitzandonakes et al. 2016; Stein and Rodríguez-Cerezo 2010a,b).

On a few occasions, regulatory asynchrony has led to a situation in which new biotech crops have been approved and commercialized in some key markets although still being unauthorized for use in others.

On a few occasions, regulatory asynchrony has led to a situation in which new biotech crops have been approved and commercialized in some key markets although still being unauthorized for use in others (e.g., Redick, Galey, and Feitshans 2015). Most countries have "zero tolerance" for unapproved biotech events—that is, they prohibit even incidental or unintended importation in any amount until the national authorities have granted full authorization.

Asynchrony in regulatory approvals between importing and exporting countries puts large volumes of trade worth billions of dollars at risk.

Asynchrony in regulatory approvals between importing and exporting countries puts large volumes of trade worth billions of dollars at risk.[6] The primary risk under such asynchrony that small amounts of grain with biotech events approved in an exporting country but not in an importing one, known as low-level presence (LLP), may be contained in an international shipment of agricultural commodities. Such an occurrence would not be exceptional. Given the structure of modern commodity handling systems, small amounts of foreign material (e.g., weed seeds, seeds of other grains, stones, etc.) are inevitably present in all traded commodity lots and are managed through commercial tolerances. Most countries, however, maintain a zero tolerance policy for unapproved biotech events; any measurable presence is treated as a violation. Under zero tolerance, then, LLP incidents can lead to trade disruption and, ultimately, trade distortions.

There have been a few well documented, major LLP incidents, but there are far more LLP incidents for which few details are available.[7] In 2006 U.S. corn gluten feed (CGF) shipments arriving in Europe were found to contain Herculex (DAS 59122-7) maize, despite coordinated efforts to segregate supplies in the United States and the European Union (EU) (Kalaitzandonakes 2011; USDA–FAS 2011). In 2009 traces of Triffid flax, a biotech variety that was approved in the United States and Canada, were detected in European bakery products containing flaxseed (Viju, Yeung, and Kerr 2014).[8] In the fall of 2009, several shipments of soybeans from the United States were quarantined in European ports when dust from asynchronously approved biotech maize was detected in these shipments (USDA–FAS 2010; Wager and McHughen 2010). The largest disruption due to asynchrony occurred during 2013–2014, when the presence of MIR 162 maize, approved for cultivation in the United States but still unapproved for importation in China, was detected in maize and distillers dried grains (DDGS) shipments from the United States (USDA–FAS 2014). With many new events in the development pipeline, the potential for LLP can only increase in the future (Parisi, Tillie, and Rodríguez-Cerezo 2016). Indeed, the potential for sustained regulatory asynchrony and chronic trade disruptions in the future is magnified by the tendency of major importers—the European Union, China, and several other Asian countries—to adopt approval systems that are not synchronized with those of key exporting countries—Argentina, Brazil, Canada, and the United States.

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The Impacts of Asynchronous Approvals and LLP Incidents

Trade and Export Markets

The most immediate effects of LLP incidents caused by asynchronous approvals fall directly on the trading parties. Shippers experience substantial economic losses, including increased shipping costs (demurrage charges) if unloading of vessels is delayed as well as lower revenues if shipments must be diverted to secondary markets. In extreme cases, they may lose the value of the entire shipment if local authorities decide the product must be destroyed. Their trading partners, grain traders, and processors in the importing country likewise incur greater costs from cancelled contracts, purchases of more expensive substitute goods, or shortages if no suitable substitutes are readily available. The impact of any LLP incident then propagates quickly across the international agrifood supply chains (Kalaitzandonakes 2011).

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[6] Trade impacts can be significant because biotech crops are very broadly traded. Data from the USDA indicate that global imports of cotton and soybeans are equal to about a third of global production. Approximately 12% of corn produced in the world is also traded internationally.

[7] In 2013 the Food and Agriculture Organization of the United Nations surveyed member countries on LLP incidence, and 35% of the respondents indicated they had experienced such events. Respondents indicated that most incidents led to trade disruptions, with shipments of grain being blocked by importing countries and destroyed or returned to the country of origin (see FAO [2014] for details).

[8] It should be noted, however, that there is no specific marker for Triffid and the levels detected were statistically indistinguishable from zero (Booker and Lamb 2012), so it's possible the detections were false positives.

The specific impacts of such trade disruptions are unique to each LLP incident, but their general characteristics have been described in several ex ante impact assessment studies.

The specific impacts of such trade disruptions are unique to each LLP incident, but their general characteristics have been described in several ex ante impact assessment studies. Three such studies used global spatial equilibrium models to represent international trade patterns and examine the effects of LLP-driven trade disruptions on international commodity markets. Kalaitzandonakes, Kaufman, and Miller (2014a) examined the potential effects of a disruption in the maize trade due to LLP between Mexico and its trading partners in the Americas, including the United States. They estimated a maize price increase of 9–20% on the Mexican market, depending on the extent of the disruption and global supply conditions in the year of analysis. Kalaitzandonakes and colleagues (2016) analyzed the potential effects of LLP and disruption in maize trade between South Korea and major exporting countries. This study indicated a 7.5% increase in the price of maize in South Korea, which could be exacerbated by other potential supply shocks. Kalaitzandonakes, Kaufman, and Miller (2014b) investigated the potential effects of LLP and trade disruption in soybeans between the EU and its main suppliers—the United States, Brazil, and Argentina. If only trade with the United States was suspended, the availability of alternative supplies kept prices essentially unchanged. If soybean trade with all three major suppliers were to be stopped due to regulatory asynchrony and LLP, soybean and soybean meal prices in Europe would roughly triple due to the lack of ready alternative supplies.

In all these studies, increased prices in importing countries resulted in decreased demand, diminished trade, and social welfare losses.

In all these studies, increased prices in importing countries resulted in decreased demand, diminished trade, and social welfare losses. Producers in exporting countries suffered generally smaller losses due to lower prices as they attempted to dispose of their excess supply on world markets. The impact on importers and exporters in the rest of the world varied, some seeing lower prices and some higher, depending on available sources of supply, transportation costs, and other factors. In another study of interest, the EU Directorate General for Agriculture used a partial equilibrium model to analyze the potential effects of an interruption of soybean imports from Argentina, Brazil, and the United States due to asynchronous approvals in the EU. If trade only with the United States was stopped, the availability of supplies from the other soybean-producing countries kept price effects negligible. If trade with both Argentina and the United States was suspended for two years due to LLP, their model indicated a 3.3 MMT (million metric tons) supply shortfall, with prices increasing by 22.8%. In their worst-case scenario, trade with all three countries was halted. Here EU feed supplies were reduced by 25.7 MMT because of the lack of soy inputs, causing an increase in feed expenditures of more than 600%. The study authors caution that this scenario exceeded the technical limits of their model and the magnitude of the estimated price increase might not be reliable (DG AGRI 2007).

Several studies have examined the economic impacts of LLP using computable general equilibrium models, often based on the Global Trade Analysis Project.

Several studies have examined the economic impacts of LLP using computable general equilibrium (CGE) models, often based on the Global Trade Analysis Project (GTAP). Henseler and colleagues (2013) used a combination of the GTAP and partial equilibrium models to model the effects of a trade ban by the EU on soybeans and soy meal, due to asynchronous approvals, from its major suppliers—Argentina, Brazil, and the United States. Net soybean imports to the EU were found to decrease by more than a third, whereas prices of soybeans and soybean meal both increased by 30%. Also using a GTAP model, Huang and Yang (2011) examined disruptions in the soybean trade due to asynchronous approvals in China. If imports of soybeans to China were cut by only 10%, they projected an 18% increase in the price of soybeans in China, with a decrease in social welfare of $191 million. The 10% drop in imports would translate into decreases in exports of just more than 3.5% for the United States and Brazil and 6.8% for Argentina, with cuts in production of 1–2% in all three countries.

Experience from actual LLP incidents illustrates the potential scope and durability of ensuing trade disruptions.

All above ex ante impact analyses estimate the economic impacts of potential trade disruptions during a single year. Experience from actual LLP incidents, however, illustrates the potential scope and durability of ensuing trade disruptions. After Herculex (DAS 59122-7) maize was detected in CGF shipments to the EU, monthly CGF trade between the United States and the EU dropped from 200,000–250,000 metric tons per month to near zero for much of the next two years (Kalaitzandonakes 2011). Data from the Food and Agriculture Organization of the United Nations further demonstrates that the U.S.-EU CGF trade has not been restored to its historical levels in more recent years, except in the case of Ireland. Similarly, data from the Canadian Grain Commission indicate that Canadian exports of flax continue to be less than half of what they were before the 2009 LLP incident despite continuing testing and stewardship efforts. It will require more time to fully assess the impact of the 2013–2014 MIR 162 incident in China. After the detection of MIR 162 maize, Chinese authorities rejected more than 1.25 million metric tons of corn and DDGS shipments that were diverted to other destinations or destroyed during 2014.[9] Since that time, U.S. DDGS exports to China have recovered but U.S. maize exports to China have all but ceased. Domestic supply conditions, imports of substitute feedstuffs (sorghum), and other factors may have contributed to such reductions.

Ex post impact assessment studies have arrived at conclusions that are consistent with these empirical observations. De Faria and Wieck (2015) analyzed the relationship of known regulatory asynchronies and historical trade patterns in world cotton, maize, and soybean markets. They found evidence that greater asynchronies between pairs of countries were associated with smaller trade volume.

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Grain Supply Chain and Downstream Industries

The bilateral trade disruptions that follow any LLP incident mean that importing countries experience import supply shortages in the affected commodities and need to find alternate sources and substitute goods. Indeed, all of the economic impact assessment studies discussed above indicate that the severity of the impact is largely determined by the scope and duration of the trade disruption and the availability of alternative supplies and suppliers of substitute commodities.

The impact assessment studies summarized in the previous section have also gone into varying degrees of detail in examining the effects on downstream grain and oilseed processors, livestock producers, and consumers. In all cases they found decreased supplies, higher prices, and lower producer and consumer welfare. For instance, the EU DG AGRI study calculated that EU pork and poultry sectors would be hardest hit in the worst-case scenario, where trade with all major suppliers was cut off, seeing pork production fall 35% and poultry production fall 44% (DG AGRI 2007). A more recent report commissioned by DG AGRI found smaller effects from the structural loss of all suppliers, with the different meat sectors seeing production decreases of 3–5%. This study, however, assumed ready availability of substitute supplies (Nowicki et al. 2010). In another relevant study, Philippidis (2010) used a GTAP CGE model to investigate the effects of a possible EU trade disruption from regulatory asynchrony and LLP on Spanish livestock markets and found that the pork and poultry sectors in Spain would experience declines in production by as much as 35% and consumer price increases as high as 56%.

The costs calculated following actual LLP incidents largely agree with results of ex ante impact assessment studies. The disruption in the CGF trade between the United States and EU described above was estimated to have cost EU livestock producers as much as €1.6 billion (Stein and Rodríguez-Cerezo 2010b). Economists estimate the Triffid episode cost Canadian flax producers C$30 million and European food producers and consumers €39 million (Babuscio et al. 2016; Smyth 2014). Estimates of the economic impacts of the MIR 162 maize incident diverge for the moment (e.g., Fisher 2014; Han and Garcia 2016), but U.S. civil litigation by U.S. producers and grain traders against the trait developer, Syngenta, may add significantly to the direct commercial costs of the MIR 162 maize incident in China.[10]

Asynchronous approvals have further impacts by delaying the commercialization and adoption of new biotech events.

Adoption of Biotechnology in Developing and Developed Countries

Asynchronous approvals have further impacts by delaying the commercialization and adoption of new biotech events. Major biotech developers and seed firms voluntarily withhold new biotech events from commercial use until regulatory approvals are granted in all major import markets for the crop in which the event appears (Crop Life International 2015). These "stewardship programs" seem to have been at least partially successful in limiting LLP incidents, even as asynchrony has generally increased (de Faria and Wieck 2016).

Delayed commercialization of new biotech events imposes additional social costs by denying producers and consumers benefits from innovation.

Delayed commercialization of new biotech events imposes additional social costs by denying producers and consumers benefits from innovation. Kalaitzandonakes, Zahringer, and Kruse (2015) modeled the global cost of a three-year delay in the introduction of new herbicide-tolerant

[9] Reported by China's "Number One Business News" (SINA 2014).

[10] As reported by AgWeb (n.d.).

soybean cultivars due to regulatory asynchrony using a global partial equilibrium model. The delay resulted in increased weed control costs in several major producing and exporting countries and, in a few instances, a small amount of marginal land being removed from production. In turn, global soybean supplies were decreased and prices increased. As a result, the delayed commercialization of these new biotech events lessened the social benefits from their adoption by an estimated $20 billion over a ten-year period, roughly equally distributed between producers and consumers. Although not strictly related to asynchrony and LLP, a few other studies that have estimated the social costs from delayed or foregone biotech innovation in agriculture due to regulatory delays have also pointed to large social costs (Giddings, Atkinson, and Wu 2016; Wesseler and Zilberman 2014).

Some potentially profitable innovations may be neglected if regulatory delays and higher costs decrease the net present value of a prospective biotech innovation.

Agricultural Investment, Development, and Commercialization of New Products

The uncertainty imposed by regulatory delays arising from asynchrony can also divert investment in biotechnology R&D away from crops in which research effort could bring benefits to producers and consumers. Delays translate directly into higher costs in terms of additional testing and reporting requirements and lost revenue from delayed product launches. Cossey (2016) proposed that regulatory costs might have increased by 50% during 2005–2015. If accurate, these increases would add to the already-significant regulatory compliance costs for biotech approvals, which amount to tens of millions of U.S. dollars (Kalaitzandonakes, Alston, and Bradford 2007).

Some potentially profitable innovations may be neglected if regulatory delays and higher costs decrease the net present value of a prospective biotech innovation (Bradford, Alston, and Kalaitzandonakes 2006; Pray, Bengali, and Ramaswami 2005; Sachs 2016). Small market crops—especially subsistence crops in the developing world, but also specialty fruits and vegetables—are often only marginally profitable and may be disproportionately impacted by this condition (Pew 2007; Phillips 2013). This is supported by the predominance of large-scale field crops in recent biotech introductions, but even new events in major crops have lagged significantly behind projections (Cossey 2016). Regulatory delays and higher costs can also effectively shut out small, innovative firms from biotechnology R&D, leading to greater industry concentration (Phillips 2013; Sachs 2016; USDA–NIFA 2011).

Regulatory costs and delays may also discourage public sector developers who lack the financial and human resources to support the required sustained effort.

Crop Improvements and Plant Breeding

Although there is no published impact assessment work on the effects of regulatory asynchrony on crop improvements and plant breeding innovation, the same forces discussed above are expected to be at work. In the face of the considerable regulatory uncertainty, private sector breeders will tend to focus on crops with the greatest potential for generating returns on their investment, inclusive of regulatory costs and expected delays in commercialization. Other projects that might be economical under a more timely and less costly global regulatory system are likely to be left behind. Regulatory costs and delays may also discourage public sector developers who lack the financial and human resources to support the required sustained effort. The time and expense needed to navigate the regulatory system and gain approval represent resources that cannot be used in crop research.

Regulatory asynchrony may also be disruptive in the development of cultivars with multiple, or stacked, biotech traits.

Regulatory asynchrony may also be disruptive in the development of cultivars with multiple, or stacked, biotech traits (Prado et al. 2014).[11] These are usually developed through conventional crossing and selective breeding of existing varieties with approved events. Countries differ in their approach to approving these cultivars—in some cases stacked events with previously approved individual events are treated as known quantities, whereas others require full regulatory review as if stacking renders them completely novel. This differential regulatory approach may also increase confusion among plant breeders working to combine approved genetic engineering events through conventional breeding.

[11] Stacked events come in two types. In some cases, multiple biotech traits that are important to producers (e.g., herbicide tolerance and insect resistance) may be combined in one crop cultivar. In other instances, multiple events of the same trait can be combined. For instance, tolerance of multiple herbicides offers more effective weed control and can greatly delay the emergence of resistant weeds.

On- and Off-Farm Income

The specific impacts of regulatory asynchrony and LLP for on- and off-farm income require further detailed examination.

Impacts on farm income and off-farm earnings are complex and variable and have not been studied except in few instances and in limited ways.[12] Effects on income and its distribution from LLP incidents, trade disruptions, and delayed innovation may vary from country to country and across the supply chain. Generally, crop producers in exporting countries as well as producers in downstream industries in both exporting and importing countries would tend to suffer losses when LLP incidents occur and when biotech innovations are delayed. Crop producers in disrupted import markets may temporarily gain. Although such general effects are expected to hold, the specific impacts of regulatory asynchrony and LLP for on- and off-farm income require further detailed examination.

Possible Solutions for Asynchronous Approvals and LLP

Given the significant and multifaceted impacts of regulatory asynchrony and LLP on the global economy, the issue has attracted significant attention and alternative policy solutions have been proposed.

Given the significant and multifaceted impacts of regulatory asynchrony and LLP on the global economy, the issue has attracted significant attention and alternative policy solutions have been proposed. Indeed, key international organizations have sought to facilitate the development of LLP policies. In 2008 the Codex Alimentarius Task Force on Foods Derived from Modern Biotechnology provided guidance for an abbreviated food-safety assessment of biotech events already authorized in one or more countries. These are detailed in Annex 3 to the basic Codex guidance document for foods derived from modern biotechnology (Codex Alimentarius Commission 2008). Through such abbreviated reviews, if appropriate, importing countries may provisionally declare the unauthorized event "safe for food and feed at low levels" until a full regulatory review is conducted. The Philippines was the first country to consider adoption of the Codex Annex as an LLP management policy (Demeke and Perry 2014).

Another LLP policy alternative that has been proposed is the establishment of nonzero commercial tolerances for asynchronous events that are present at low levels in the agrifood supply chain (GAABT 2015). Commercial tolerances and thresholds have been in use for many other nonstandard materials in agricultural commodities for more than a century (Hill 1990). They recognize the fact that complete or near absence of nonstandard material is impossible to achieve and prohibitively expensive to attempt in view of the nature of the production and marketing of farm products (Hobbs, Kerr, and Smyth 2014). Several countries have considered specific LLP commercial tolerances for biotech-derived material, with Canada and Colombia having the most advanced deliberations on this issue (Tranberg and Lukie 2016). In September 2016, Canada released a new LLP policy model for discussion of "Managing Low Level Presence of Genetically Modified Crops in Imported Grain, Food, and Feed."[13]

It is worth emphasizing that all such policy proposals simply recognize the potential negative impacts of asynchrony and LLP and seek to limit them.

Recognition of safety assessments and regulatory approvals of trading partners have also been proposed as possible solutions to regulatory asynchrony (Demeke and Perry 2014; Ramessar et al. 2008). Vietnam is the first country to implement such a policy through national legislation (Gruère 2016).

It is worth emphasizing that all such policy proposals simply recognize the potential negative impacts of asynchrony and LLP and seek to limit them. Ideally, each country's biotech regulations would apply the principles set forth in the World Trade Organization's SPS agreement (WTO 1994): being science based, proportional to risk, nondiscriminatory, and applied in a predictable and timely manner in order to ensure that all market participants benefit. Although it is broadly recognized that few countries have biotechnology regulatory systems that are entirely faithful to these principles, the disparity among countries in the measures imposed to ensure the safety of biotech crops and the degree of risk they present has grown ever wider over the last two decades (Giddings and Chassy 2009). An expanding biotech pipeline and an increasing recognition of the great economic and social costs associated with regulatory asynchrony and LLP seem to demand

[12] For instance, Kalaitzandonakes and colleagues (2016) modeled the changes in Korean livestock markets from LLP and potential trade disruptions in the maize trade of the country. They found that even a small (7%) feed price increase, when passed on to consumers, shifted demand from domestic beef to largely imported pork and poultry, significantly decreasing the income of Korean beef producers as a result of the trade disruption.

[13] See Agriculture and Agri-Food Canada (n.d.).

renewed attention to the principles of science-based, proportional, and nondiscriminatory regulation.

Further Studies Needed

More research is needed into the decision-making process of biotech developers, in both the public and the private sectors, in order to clarify the impacts of regulatory asynchrony on their calculus for which projects to proceed with and which to abandon.

As the above discussion shows, the bulk of research on this topic concerns the impact of asynchrony on market outcomes. These are expressed in terms of changes in prices and quantities in production, trade, use of agricultural commodities by downstream producers, and ultimately consumer spending and welfare. These are the areas most amenable to economic modeling, which are based on plentiful data and require the least speculative assumptions. Although it would seem that the effect on family income, both on- and off-farm, as well as the income of firms in other affected sectors would fall into this category as well, relatively little work has been done in these areas and additional research could shed some light on the effects of regulatory asynchrony and LLP on farm and other firm incomes.

More research is also needed into the decision-making process of biotech developers, in both the public and the private sectors, in order to clarify the impacts of regulatory asynchrony on their calculus for which projects to proceed with and which to abandon. This is likely a very challenging branch of inquiry because both the data and the processes are rather inaccessible, but it could yield very valuable insights. Intermediate delays of existing innovations and long-term distortions in the incentives to invest in the development of new technologies and crops are likely to have sustained impacts and large welfare implications.

Conclusion

Because of significant differences in the institutional arrangements, regulatory procedures, administrative capacity, and attitudes toward biotech crops, the amount of time required to complete the review of new biotech events varies significantly from one country to another.

Because of significant differences in the institutional arrangements, regulatory procedures, administrative capacity, and attitudes toward biotech crops, the amount of time required to complete the review of new biotech events varies significantly from one country to another. This has led to asynchrony in the approval of new biotech crops in countries around the world, which has increased over the last ten years. Coupled with a nearly universal policy of zero tolerance for unapproved events, the stage has been set for chronic and disruptive LLP incidents. Experience with recent LLP incidents has affirmed that they can cause abrupt, large-scale trade disruptions, sustained changes in international trade patterns, and significant economic losses that are borne by both importers and exporters. There is also some evidence that regulatory asynchrony and LLP can cause delays in the implementation of existing innovations and hinder the development of future ones. Such impacts are generally less immediately apparent but potentially far more costly and sustained.

This report has identified research priorities in which the existing literature has the greatest gaps and additional information would be most meaningful.

Alternative policy interventions have been proposed for some time, chief among them the establishment of nonzero LLP tolerances, the use of accelerated risk assessments based on the Codex Annex, and mutual recognition of safety assessments or approvals by trading partners. Recently, Canada and Vietnam began to adopt some of these policies and other countries are considering alternatives. Still, much is unknown about the extent of the short- and long-term impacts of regulatory asynchrony and LLP as well as the relative effectiveness of alternative policy instruments that may manage them. Timely research could therefore inform policymaking and improve the design of policy instruments at this stage. This report has identified research priorities in which the existing literature has the greatest gaps and additional information would be most meaningful (including the impacts of asynchrony and LLP on crop improvements, on- and off-farm income, and other indicators of social welfare). It has also argued that as long as the current situation persists, agricultural biotechnology will be prevented from delivering the full range of promised benefits of improved standard of living and food security.

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