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The Economic Impacts of Asynchronous Authorizations and Low Level Presence: An Overview

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Abstract

This paper discusses the potential economic impacts of asynchronous authorizations and low level presence (LLP) of biotech events not yet authorized in the importing country in agricultural commodities and foods traded in international markets. In this context, the paper provides an overview of key economic factors that may be taken into account when alternative LLP policies are being considered. Available empirical evidence suggests that the economic impacts of regulatory asynchronicity and LLP can be significant, highlighting the need for effective national LLP policies.

1. Introduction

Modern biotechnology has been used to improve the productivity and quality of crops for more than 30 years. Unlike most other genetic methods of crop improvement, however, modern biotechnology and biotech crops are strictly regulated for food and environmental safety. To date, more than 120 biotech events and 24 biotech crops have passed the regulatory hurdle in various countries and many of them have been commercialized in the last fifteen years.

The adoption of most commercialized biotech crops by agricultural producers around the world has been swift. Since 1996, over one billion cumulative hectares of biotech soybeans, maize, cotton, canola, sugar beets, and other crops have been grown around the world, with 148 million hectares cultivated in 2010 alone (James 2010). Economists have estimated the annual social benefits from biotech crops to be in the billions of dollars and broadly shared among the developers of the new crops, agricultural producers, handlers and processors, as well as consumers in both exporting and importing countries (Brooks et al., 2010; Carpenter 2010; Falk-Zepeda et al. 2000; Konduru et al. 2008; Qaim, 2009; Sobolevsky et al. 2005).

Because major agricultural producing and exporting countries have led their adoption, biotech crops represent a substantial share of some key agricultural commodities (maize, soybeans, cotton, and canola) which are broadly traded in international markets. Their trade has not always been uneventful, however, as in few occasions small amounts of unauthorized biotech crops have been found in the food supply chain and, in some cases, have led to trade disruptions (Carter and Smith 2005; Li et al., 2010; Lin et al. 2003; Schmitz et al. 2004, 2005).

There are four different types of unauthorized biotech events that may be found in the food/feed supply:

1. Biotech events (e.g. Starlink maize) that have received regulatory approval for some uses (e.g. feed) but not for others (e.g. food);[1]
2. Biotech events that have been approved for all possible uses (e.g. DAS 59122-7 maize) in one or more countries (e.g. US, Japan, S. Korea) but not yet in others (e.g. European Union), a case of asynchronous approvals;
3. Experimental events contained in laboratories, greenhouses or field trials which are found unexpectedly in the commercial food/feed supply chain (e.g. Bt 10 maize, Prodigene maize, Liberty Link rice, Event 32 maize, Bt rice, FP 967 flax). Typically, such events have not yet received regulatory approval in any country;
4. Biotech events that have been reviewed and have received time-limited regulatory approvals which may have expired.[2]

The term “Low Level Presence” or LLP has been adopted to describe the accidental presence of small amounts of biotech events that have undergone full safety assessment and have received regulatory approval for all possible uses in one or more countries but are still unauthorized in others due to regulatory asynchronicity or expiration of their approvals (i.e. cases 2 and d above).

Alerts about the chance of structural asynchronicity and the potential for growing incidence of LLP have been issued by industry, governments, and academics in recent years as the biotech pipeline moving towards or awaiting regulatory approval has expanded while regulatory approvals across

1 Since the Starlink incidence, “split market” registration has been avoided both by applicants and regulators.

2 Biotech firms have active stewardship programs intended to remove products with expired registrations from the market and minimize the chance of their presence in the food/feed supply chain.

different countries have become less synchronized (Krueger and Buanec 2008; EC DG AGRI 2007; Backus et al. 2008; Stein and Rodriguez-Cerezo, 2010a and 2010b).

In order to actively evaluate and manage any potential food/feed safety or environmental risks from the LLP of unauthorized biotech events, some countries have developed national LLP policies which they can implement when the need arises. The US and Japan, for instance, have clarified the steps their regulatory agencies would take in the face of a LLP incidence. International organizations have also sought to facilitate the development of national LLP policies.

In 2008, the Codex Alimentarius Task Force on Foods Derived from Biotechnology provided an international guidance for food safety assessment of biotech events authorized as safe for food and feed in one or more countries, including in the country of cultivation, but not yet in the country of import. Such guidelines are detailed in The Annex on Food Safety Assessment in Situations of Low-level Presence (LLP) of Recombinant-DNA Plant Material in Food. The Annex foresees that importing countries can undertake an abbreviated risk assessment in instances of LLP of products that have been fully authorized in the country of export in a manner consistent with Codex risk assessment guidelines. If appropriate, import countries may then declare the unauthorized event "safe for food and feed at low levels" while they wait for the full regulatory review to be completed.

Parallel efforts to develop guidelines for an expedited environmental risk assessment have also been advanced by an OECD working group in the last few years. Such guidelines are meant to complement the Codex Annex (which is focused on food/feed safety) and seek to propose an expedited technical review for the environmental risk assessment of LLP in seeds and commodities that can function biologically as seeds.[3]

While the Codex Annex pertains to abbreviated risk assessment procedures, it does not specify the exact levels of acceptable LLP and does not explicitly consider the potential economic implications of alternative LLP policies. The objective of this paper is to review key economic factors that may be taken into account when national risk management policies and specific LLP levels are being considered.

2. Regulatory Approvals of Biotech Crops, Asynchronicity and Chance for LLP

To fully appreciate the role of regulatory asynchronicity as a potential cause of LLP and understand its potential economic impacts, one must be mindful of certain nuances in the regulatory oversight of new biotech crops as well as in the workings of the global agricultural commodity trade system. Regulatory reviews and approvals for the cultivation and marketing of biotech crops are country-specific. Hence, at some point in the R&D cycle, biotech crop developers must decide in which countries they choose

3 The relevant OECD project is entitled "Environmental Risk/Safety Assessment and Use of Information in Situations of Low Level Presence of Transgenic Plant Material in Seed and Commodities." Its purpose and scope is to provide an aid to risk assessors and regulators regarding LLP; including information acquisition and use (where to access appropriate information) and to facilitate environmental risk assessment in a situation of LLP in seed and/or commodities of transgenic plant material that has received approval in at least one country but has not received approval or authorization in the country of import. It only relates to LLP situations in the environment. This project covers commercial seed used intentionally for planting and commodities (e.g. grains and oilseeds) that may be unintentionally released into the environment during handling and transport or possibly used for planting but was intended for food, feed or processing.

to seek regulatory approval for their products (Kalaitzandonakes, et al., 2006). In this context, they must consider not only the countries where the cultivation of the new biotech crops could take place (requiring regulatory approval for cultivation) but also the countries where the consumption might ultimately occur (requiring regulatory approval for importation and use). Biotech crop developers must also consider the sequence of regulatory submissions in order to conform to different countries' regulatory requirements and duration of their authorization processes. This requires a reliance on the statutory timelines for approvals in those countries, which often are not met, leading to delays in expected timelines for approvals. Finally, they must account for the incremental regulatory costs implied by wider-ranging regulatory applications as well as the potential foregone revenue streams if timely approvals cannot be secured in one or more of the major crop markets.[4] Given the large and expanding agricultural commodity trade flows across the globe, these considerations have become increasingly complex.

Currently, 33 countries[5] have regulatory systems that handle submissions seeking regulatory approval for the cultivation and/or importation and use of new biotech crops while a number of other countries are in the process of developing theirs. There are, however, significant differences in the regulatory procedures used by different countries including the amount of time required to complete them (Kalaitzandonakes et al., 2006). At one extreme the US, Canada, Japan and some other countries have continued to review and approve new biotech crops, at variable but similar speeds. At the other extreme, the European Union (EU) and some other countries have been slow and unpredictable in reviewing and approving new biotech crops. Indeed, the EU stopped considering petitions for regulatory approvals in 2001 and began reviewing regulatory dossiers in 2004 again only after mandatory labeling laws and full traceability of biotech foods and feeds along the EU supply chain were implemented. This *de facto* moratorium on regulatory approvals of new biotech crops prompted the filing of a WTO complaint by the US, Argentina and Canada in 2003. Yet even today when the EU has continued to review and approve new biotech crops, the review process has, on average, taken almost twice as long as in the US (EC DG AGRI 2007; FEFAC 2007; Stein and Rodriguez-Cerezo, 2010a).[6]

Significant discrepancies in the amount of time required to review and approve new biotech crops can lead to "asynchronous approvals." Under such conditions, new biotech crops are cultivated and marketed for food and feed in some countries but remain unauthorized in others. This asynchronicity can become a particularly difficult problem for broadly traded commodities.

3. Asynchronicity, LLP, and Potential Trade Disruptions

Synchronicity in the regulatory approvals of any two countries generally would imply that their trade can continue to flow in its usual ways supported by an agricultural commodity trade system that is renowned for its operational efficiency. The commodity trade system has been built over decades and depends on an expansive network of interlinked firms and infrastructure used in the production, storage, processing and distribution of agricultural commodities and processed foods and feeds.

A typical commodity grain supply chain is illustrated in figure 1. Grains may be used as food, livestock

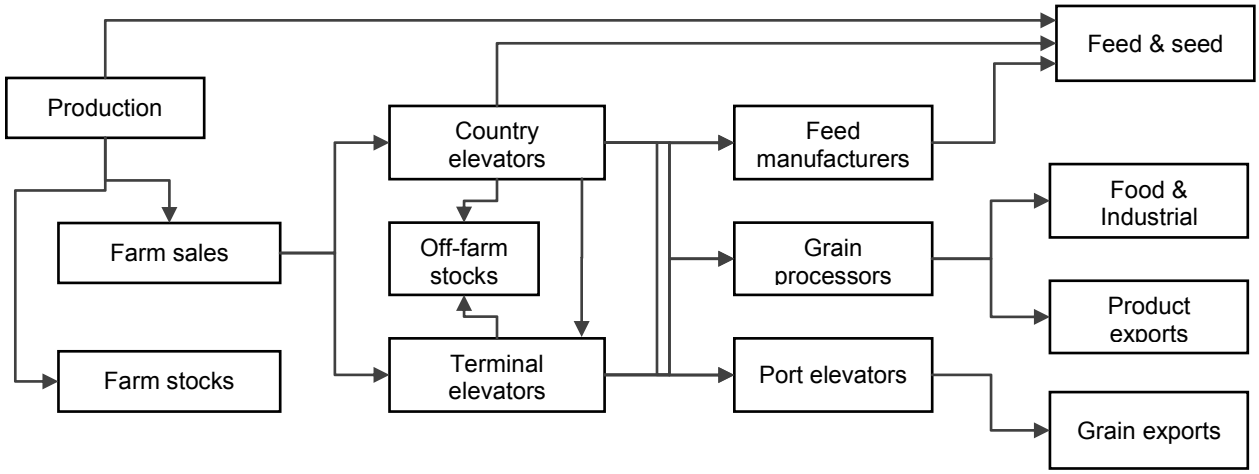
4 Biotech firms have adopted stewardship programs that seek to minimize market and trade disruptions from asynchronicity and LLP by committing to refrain from the commercialization of new biotech crops until regulatory approvals have been secured in all major crop markets with functioning regulatory systems (e.g. see http://www.croplife.org/prod_launch_stewardship)

5 EU 27 is counted as a single entity or "country" here.

6 Because of divergent policies as well as other factors, there are significant discrepancies in the number of new biotech events that have been approved by different countries. For instance, the US has approved 122, Japan 114, Canada 99 while the EU has approved 45 new biotech events.

feed, and fuel feedstock. For all these uses, every year the commodity chain must then balance supply and demand spatially (moving grains from surplus to deficit areas) and temporally (storing grains when they are plenty and drawing down stocks when grains are needed). As such, during harvest, grains are stored on the farm or in commercial storage (local/regional elevators) and stocks are then gradually sold to livestock producers, exporters, millers, processors and manufacturers at various locations over the course of the marketing year.

Figure 1: Typical Grain Commodity Supply Chain



Because grains are bulky and relatively expensive to transport and store while their final unit value is relatively low, commodity supply chains must control operational costs to make trade possible. Grades and minimum quality standards have been developed to enable the exchange between buyers and sellers in distant markets without visual inspection thereby limiting operational and transactions costs.

Maximizing operational efficiency and minimizing costs in the trade of commodity grains is critically dependent on aggregation. Grains from numerous farms and storage facilities are constantly mixed throughout the supply chain resulting in perfectly fungible and divisible product streams. This fungibility facilitates the efficient use of discrete storage, transport and processing assets and yields significant economies of scale.

Since aggregation and commingling of grains from various farms and storage facilities is on-going, grain dispersion of various origins throughout the commodity supply chains is expected. While there is limited knowledge of the rate and extent of such grain dispersion, recent empirical evidence suggests a pattern of broad spatial and temporal dispersion of grain at low levels throughout the supply chain, even from a very small acreage base (Kalaitzandonakes and Kaufman, 2011).

Under these circumstances, asynchronicity and the cultivation in an exporting country of biotech events which are unauthorized in any one of its importing partners implies that standard commodity practices in their bilateral trade would inevitably lead to LLP incidence. As a result, the standard commodity practices are no longer viable in their bilateral trade. Instead, authorized product flows must be segregated from unauthorized ones in the exporting country and only authorized product flows can be directed to the importing country. When such segregated trade is not feasible or is too costly, the bilateral trade between the two countries is suspended. The incremental costs associated with the use of segregated systems or with the disruption of trade define, in large part, the economic impacts of regulatory asynchronicity and LLP.

4. LLP policies and the Use of Tolerances

While governments can implement strategies that minimize the time lags between national and international authorizations so that asynchronicity is diminished, perfect synchronicity may not always be feasible. The capacity of regulatory agencies, the timeliness and completeness of dossier submissions by the applicants and other idiosyncratic factors may also affect the speed of regulatory reviews in different countries and hence their degree of regulatory asynchronicity. As such, the chance for LLP of unauthorized biotech events may be lessened but not eliminated. In addition to minimizing asynchronicity, a complementary national strategy may therefore involve the development of a pragmatic LLP policy, potentially, by adopting the Codex Annex, which can be invoked in the face of any LLP incidence.[7]

An abbreviated risk assessment would allow countries to evaluate whether there are health and/or environmental risks from the LLP of an unauthorized biotech event and an appropriate risk management strategy would allow them to minimize any negative commercial impacts of such LLP. In this context, the exact levels of acceptable LLP tolerances would need to be decided within individual countries.

Tolerances could conceivably be established for each LLP situation that may arise, or countries may opt for a fixed level that would apply to all LLP situations. In the context of an LLP incidence, tolerances have dual significance. First, tolerances determine the effective exposure of the human and animal population as well as of the environment to the unauthorized biotech event.[8] Tolerances would therefore be important if the abbreviated risk assessments identified potential risks. Second, tolerances determine the effectiveness and cost of segregated trade.

The setting of tolerances therefore implies a weighing of risk and economic considerations. Higher LLP tolerances can limit trade disruptions and associated economic costs but may be viable only when no significant food, feed or environmental safety concerns exist. Lower tolerances imply higher costs as segregation becomes more costly and trade disruption more likely. The systematic evaluation of the potential economic impacts of alternative LLP policies is therefore an important part of national LLP risk management strategies.

5. LLP, Segregation and the Role of Tolerances

In the face of a LLP incidence, authorized product flows must be segregated from unauthorized ones in the producing country and only authorized product flows can be directed to the importing country. In segregated supply chains a primary objective is to ensure the absence of unauthorized grains from all final products. This implies that unauthorized grain must be avoided at each and every part of the supply chain (figure 1). For this purpose, segregated supply chains use both prevention and remediation.

Prevention of admixtures requires re-engineering of the standard production, storage, processing and distribution processes in commodity supply chains. In fact, segregated supply chains must often reach beyond the farm to ensure the purity of planting seeds. A variety of interventions that seek to prevent admixtures in segregated supply chains can be used, including:

- Use of stringent field management practices in seed and farm production, such as geographic and temporal isolation of production, minimum allowable distances between fields, buffers, border

7 In early 2009, the Philippines became the first country to adopt the guidelines in the Codex Annex for incidence of LLP of unauthorized biotech events.

8 Risk assessments during full approvals of biotech events assume 100% exposure over long periods of time.

rows and other physical barriers that can reduce the incidence of cross-pollination from neighbouring crops, as well as control of volunteer plants in production fields (e.g. Bullock and Desquilbet, 2002; Devos et al., 2005; Kalaitzandonakes and Magnier, 2004).

- Meticulous cleaning of farm, transport, storage and processing equipment as well as use of dedicated equipment and facilities to minimize the chance of admixtures and inadvertent commingling with unauthorized grain during planting, harvest, shipping, storing and conditioning, processing and manufacturing (e.g. Bullock and Desquilbet, 2002; Kalaitzandonakes et al, 2001; Kalaitzandonakes and Kaufman, 2006; Wilson and Dahl, 2005, Pelaez et al. 2010.)

In addition to prevention, segregated supply chains use remediation when admixtures occur despite preventive measures. Through repeated testing they seek to identify accidental admixtures thereby isolating unauthorized grain before entering the segregated stream or redirecting comingled lots back to the commodity supply chain. Testing can occur at different parts of the supply chain, but most frequently, when there is a change in the custody of the grain.

To be effective, testing must not greatly interfere with the operational efficiency of the supply chains; it must not lead to erroneous results (false positives or false negatives); it must discourage cheating; and it must be cost-effective. In all cases, there are trade-offs between testing costs and risks from sampling and analytical uncertainty (Kalaitzandonakes, 2006) and these factors are taken into account when firms design their strategies and decide where to test, how much to test and what test to use (Wilson and Dahl, 2006; Konduru et al., 2009).

Changes in supply chain operations to prevent admixtures as well as testing and remediation involve additional costs. There are both direct and indirect segregation costs (Kalaitzandonakes et al., 2001). Direct segregation costs are payable costs and result from the re-engineering of operations (e.g. extra labour for equipment cleaning during planting, harvest, storage and processing; extra capital for dedicated equipment, etc.); additional coordination and control (e.g. contracting costs, testing costs, third party certification fees, etc.); and liabilities from product failures (e.g. demurrage costs, costs of product recalls, costs of dispute resolution, etc.). Indirect segregation costs are non-payable and result from efficiency losses caused by underutilization of production, storage and transportation assets as well as foregone profits (Kalaitzandonakes et al., 2001; Bullock and Desquilbet, 2002).

Segregation costs are not fixed. They can vary significantly from one part of the supply chain to the other (Borchgrave et al., 2003); across commodities;[9] with the physical configuration of the supply chain (Kalaitzandonakes et al., 2001, Bullock and Desquilbet, 2002, Wilson and Dahl, 2005); across regions; and over time.[10] A number of factors can therefore influence their relative size. The most significant driver of segregation costs and the overall chance of success of segregated systems for unauthorized biotech events, however, is the tolerance level set for LLP.

Segregation costs increase as tolerances decrease. The rigor with which segregation procedures are designed and implemented depends mostly on the allowable "margin of error" which is defined by the LLP tolerance. For segregated supply chains with low LLP tolerances, strict measures designed to

9 Commodities differ in their production systems, supply chains, and end uses. Because of idiosyncrasies, segregation costs can vary substantially across commodities. For instance, while outcrossing control may require expensive measures in the production of cross-pollinating maize, it is a minor issue for self-pollinating soybeans. Similarly, testing costs might be significantly higher in non-GM maize programs than in soybean ones due to the greater amount of events that one must test for.

10 Variation in input and commodity prices alone can lead to significant spatial and temporal variations in segregation costs. For instance, large swings in commodity and input prices imply significant changes in the opportunity costs associated with foregone yields and efficiency losses in the production of segregated grains.

prevent even traces must be put in place. Low tolerances also mean additional testing and increased product failures (Bullock and Desquilbet, 2002; Kalaitzandonakes and Magnier, 2004). Beyond certain levels, as tolerances diminish, segregation costs increase exponentially (Kalaitzandonakes and Magnier, 2004, 2006).

LLP and Zero Tolerance

Under a zero tolerance policy for LLP, trade of the relevant commodity between the two countries will likely cease (Kalaitzandonakes and Kaufman, 2011; Magnier et al., 2009; Toepfer Internal, 2008, FEFAC, DEFRA) as perfect segregation of authorized and unauthorized biotech events cannot be consistently achieved.[11] Under zero tolerance there are also higher failure risks and costs. Failure risks correspond to the chance that segregated supplies considered free of unauthorized biotech events test positive at some part of the supply chain. Costs from such a product failure would likely be manageable as long as the failure occurs within the borders of the exporting country. Non-conforming supplies can be redirected to the commodity supply chain with a significant salvage value still in place. If the product failure were to occur at the point of import or beyond, however, failure costs would quickly mount. Because of legal liabilities and significant multiplier effects, economic losses from such failures tend to be disproportionately high relative to the value of the delivery.[12]

The expected outcome of increased failure risks and costs is immediate suspension of segregation and trade (Kalaitzandonakes and Kaufman, 2011; Magnier et al., 2009; Toepfer International, 2008). Importing and exporting firms engaged in such trade are expected to act rationally and avoid potential damages that are disproportionally higher to the potential profits from such transactions. This type of market behavior can be readily observed in the few instances when failure risks and costs increased in the presence of unauthorized biotech events that could not be effectively kept away from export markets, like in the illustrative case study that follows. Foregone trade must be then made up from alternative suppliers, increased domestic production, or use of close substitute products.

6. Essential Elements of Economic Impact Analysis for LLP Policies

To evaluate the potential economic impact of alternative LLP policies, governments might begin to examine the economic effect of asynchronicity and zero tolerance by calculating the incremental costs implied by trade disruptions against the norm of well-functioning international commodity trade. This represents a “worst case” scenario for the potential economic impacts of LLP. Governments might also evaluate the economic implications of alternative LLP policies and tolerances by calculating the incremental costs of suitable segregated systems.

Incremental Costs from Trade Disruptions

Since LLP can affect a country’s trade with various countries and commodities and over separate periods of time differently, such variation must be taken into account.

Extent of asynchronicity, duration of LLP and trade disruptions: The extent of asynchronicity in the authorizations of new biotech events between a particular importing country and various exporting countries determines the potential scope of trade disruptions that could be experienced by the

11 In the face of an LLP incidence, the importing country might also choose to ban imports from the exporting country altogether but zero tolerance in LLP would tend to result in the same commercial outcome – no trade.

12 For examples of failure costs from importation of grains containing unapproved events in the EU see Backus et al., 2008; Brooks, 2008; CIAAA, 2007; FEFAC 2008

importing country. At any given point in time, the extent of asynchronicity may be examined by evaluating:

- the number of events that are authorized for production in exporting countries but remain unauthorized in the import country of interest;
- the level of adoption and use of such new biotech events in various exporting countries;
- the time lags between authorizations in various exporting countries and the importing country of interest;
- the commodities whose trade might be affected by LLP (including considerations of potential cross commodity effects).

Case Study: Zero Tolerance and LLP in US-EU Trade of Maize Gluten Feed

In 2006, roughly 1% of the total US maize area was planted with Herculex maize (DAS 59122-7 Herculex Rootworm) which was approved in the US, Japan, Korea and elsewhere but not in the EU. In anticipation of possible trade disruptions, US seed producers, farm organizations, processors and EU importers jointly developed a plan to keep EU maize gluten feed imports free of the unapproved event. The plan called for coordinated deliveries of Herculex maize to dedicated storage facilities in the US and broad based testing of barges destined for export markets. Barges that tested positive were to be diverted to the domestic market or other export markets where Herculex was approved.

Despite the small level of adoption and efforts to manage and segregate product flows, almost half of all sampled barges tested positive for traces of DAS 59122-7. Specifically, a total of 2079 protein tests were taken, of which 1134 were positive (54.5%). For 188 of the barges that tested positive, PCR tests were also performed. For 134 of those tests, the content of the unapproved event could not be quantified (due to harsh conditions in production and drying of the gluten feed) while for 54 the amount of the unapproved event averaged 2.6%.

Figure 2 Impact of unapproved GMOs on EU maize gluten feed trade with the US, in MT.

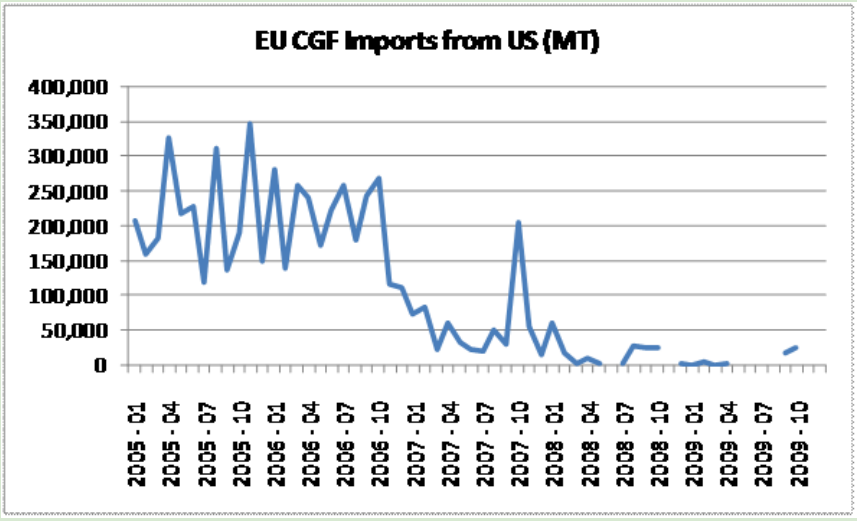


Figure 2 illustrates the EU monthly imports of maize gluten feed from the US over the 2005-2009 period. The immediate impact of the unsuccessful segregation and zero tolerance for the unauthorized biotech event on maize gluten feed trade is readily apparent. Monthly exports of US maize gluten feed abruptly declined upon recognition that the segregation system could not fully prevent LLP. Imports restarted briefly following the EU approval of DAS 59122-7 in September of 2007 with "old crop" gluten feed imports from the US but stopped once again as harvest of the "new crop" that included two new unauthorized biotech events – MIR 604 and MON88017 – picked up in the fall of 2007.

Structure of trade and redistribution of trade flows: Since there are many importers and exporters that trade agricultural commodities in international markets, redistribution of trade flows can occur in response to bilateral trade disruptions. Such trade redistribution, though possible, may also be costly. Important factors that determine the incremental costs that might be incurred by the importer include:

- differential freight costs;
- differential prices charged by various exporters;
- differential tariffs;
- incremental costs implied by alternative imports of inferior quality.

Redistribution of trade might also be constrained at times. A number of factors influence the overall "tightness" of international commodity markets and, hence, the ease of trade redistribution as well as the level of incremental costs, including:

- the proportion of the commodity traded in international markets relative to its overall use;
- the importance of exporters and the importer experiencing asynchronicity in authorizations (their market shares);
- the market structure and nature of competition in the commodity markets;
- the presence or absence of relevant institutions that can influence transaction and switching costs (e.g. types of contracts, etc).

Duration of trade disruptions: Trade disruptions from asynchronicity and LLP can be either short or long term in nature. Short term disruptions are likely to be more abrupt since possible adjustments are limited (e.g. trade redistribution, use of existing stocks, and use of less desirable substitute products) but less costly due to their limited duration. Long term disruptions may be less abrupt as possible adjustments over time become more plentiful (e.g. broader redistribution in the trade of the relevant commodities, domestic and international changes in the supply of authorized commodities, trade substitution of restricted commodities for finished or semi-finished products, and broader spectrum product substitution). However, long term trade disruptions are likely to also be more costly due to their lengthy duration. The greater the price elasticity in the market, the lower the incremental costs will tend to be. Hence the price elasticity and the extent of substitutability in the market are important considerations.

Timing of trade disruptions: Because of the seasonal nature of commodity production in various countries, the timing of trade disruptions due to asynchronicity and LLP can significantly influence the economic impact on a particular importer. Hence, the timing of relevant disruptions and their seasonal impact on suppliers and prices must be taken into account.

Incremental Costs in Downstream Industries

The economic impacts of trade disruptions from asynchronicity and LLP in relevant commodity markets can also extend into downstream industries and can be significant. Relevant impacts might include:

- reduced economic activity for first handlers and importers;
- reduced processing activity in domestic processing industries;
- reduced feed milling and/or food manufacturing activity due to increased costs and/or limited availability of ingredients;
- reduced domestic production of livestock, meats and/or processed food products due to increased ingredient costs, reduced demand due to higher prices, and/or increased imports of final food products;
- increased consumer prices for various food products.

It is therefore possible that trade disruptions from LLP can affect not only the overall economic welfare of consumers but also the competitiveness and structure of various downstream industries as well as the level of employment in these industries. Some of the incremental costs, however, may be net transfers between groups (e.g. livestock producers, processors and consumers in the importing country may be net losers while grain producers may be net gainers). Hence, such redistributions must be accounted for.

The Economics of Alternative LLP Policies and Tolerances

Adoption of LLP policies involving accelerated reviews and alternative LLP tolerances can help minimize or eliminate trade disruptions. LLP tolerances can facilitate the use of segregation programs so that trade can continue even in the presence of LLP. Incremental costs associated with the segregation programs can affect both the patterns and levels of trade and, as discussed above, higher LLP tolerances imply greater flexibility, lower chance of failure and lower segregation costs. At the same time, even small variations in LLP tolerances might result in significant differences in costs, especially as tolerances are set at increasingly lower levels. Hence the economic impacts of different LLP policies (and tolerances) must be separately evaluated.

For each LLP tolerance, a number of factors shape the cost effectiveness of segregation programs, including:

- the production location and share of authorized or conventional grain in various exporting countries;
- the logistical infrastructure in exporting countries, its configuration and its capacity to segregate at different tolerance levels;
- the optimal testing programs and relevant supply chain practices used in exporting countries;
- the market structure and nature of competition along the supply chains in exporting and importing countries;
- the segregation unit costs for different tolerance levels and commodities.

Evaluation of the potential incremental costs and available supplies through segregated programs under different LLP tolerances then allows estimation of the overall economic impacts in commodities and downstream industries along the lines described in the previous two subsections. Comparisons of the overall economic impacts with and without LLP allowances define the economic impacts of alternative LLP tolerances.

7. Empirical Evidence on the Economic Impact of LLP

There are two sets of recent studies that have empirically estimated the economic impacts from the presence of unauthorized biotech events in the agrifood supply chain. The first set includes *ex ante* studies that calculate the potential economic impacts of LLP under presumed asynchronicity, zero tolerance and disruptions in the global trade of key commodities and related sectors (DG AGRI EU Commission 2007; Kalaitzandonakes et al., 2011; Pérez-Domínguez and Jongeneel, 2011; Philippides 2010). These studies use partial or general computable equilibrium (CGE) models to represent global commodity trade and, as discussed above, their results should be viewed as worst case scenarios. The second set includes *ex post* studies that estimate the economic impacts of specific incidents, such as the discoveries of Starlink maize and the Liberty Link rice. Many of these studies use partial equilibrium or time series analyses and focus on individual commodity markets that are affected most directly by the incidence of unauthorized events (Carter and Smith 2005; Li et al., 2010; Lin et al. 2003; Schmitz et al. 2004, 2005). A few others examine the economic impacts of specific incidents on downstream industries, mostly through personal interviews of supply chain participants and case studies (Brookes 2008; DEFRA, 2010).

Ex Ante **Impact Assessment Studies:** One of the first *ex ante* studies was contributed by the DG AGRI of the EU Commission in 2007. The study assumed that asynchronicity would lead to trade disruptions in the EU soybean market for two years and through a partial equilibrium model it calculated the potential economic impact on the EU feed and livestock markets. Three scenarios of soybean/meal trade interruptions were examined by sequentially eliminating imports from one, two and all three major soybean exporters (the USA, Argentina and Brazil). The results suggested that loss of trade from one of these key exporters (the US) would have limited economic impact on the EU because of the modest bilateral trade flow and the capacity of the EU to substitute lost imports from other sources. However, when trade from two or all three key exporters was interrupted, feed expenditures in the EU were found to rise from 22.8% to more than 600%. In the short run, the pork and poultry sectors sustained substantial reductions in production and exports while imports increased. The competitiveness of other livestock sectors was also affected, though somewhat less than that of poultry and pigs. Losses in the competitiveness of the EU livestock sector were found to have important implications for agricultural incomes and employment, considerable secondary effects on downstream sectors, and significant increases in the meat prices paid by European consumers.

Philippidis (2010) analyzed the impact of trade disruptions caused by asynchronous approvals on the EU maize and soybean markets using the computable general equilibrium model GTAP. Philippidis assumed that asynchronicity resulted in bilateral trade disruptions and examined several scenarios involving the loss of one, two or three major exporters to the EU (Argentina, Brazil and the USA). The impact from the loss of trade with all three key suppliers was found to cause a 500% increase in feed costs in the EU market. The surge in feed costs was, in turn, estimated to cause a 34% contraction in the EU poultry and pork production and smaller ones in cattle, sheep and milk production. Due to reductions in production and parallel price increases, EU poultry and pork exports were found to decline between 40% and 50% while meat imports from Brazil, the US and other countries increased, eroding the competitiveness of the EU livestock industry.

Kalaitzandonakes et al. (2011) also investigated the potential consequences of LLP and related trade disruptions in the EU maize and soybean sectors using spatial equilibrium models. As in previous studies, the worst case scenarios examined reflect circumstances where EU trade with major exporters of maize and soybeans is disrupted. In the case of maize, such trade disruptions were found to result in a 11.5 MMT reduction of EU maize imports, a large part of which was made up through increased supply in the EU as well as reduction in EU maize exports to other countries. EU maize prices were found to increase, on average, by 23%. The impacts on the EU soybean, soy meal and soy oil markets were more significant. EU imports of soybeans experienced a net reduction of over 7 MMT and the net supply of soy meal in the EU market declined by more than 19 MMT. As a result, the EU soybean price increased by 220%, while the price of soy meal increased by 211% and the price of soy oil by 202%. Prices for all major exporters were found to decline by 7-53%.

Pérez-Domínguez and Jongeneel (2011) also examined the potential economic impact of trade disruptions in the EU maize and soybean market using the multi-country, multi-sector partial equilibrium model, CAPRI. Pérez-Domínguez and Jongeneel analyzed in detail potential changes in livestock feed rations and the potential substitution of imported maize and soybeans for other oilseeds and crops. Their impact analysis showed that, given sufficient time, there is scope for partial replacement of soybeans in livestock feed rations as well as for expansion in the cultivation of substitute oilseeds (mostly rapeseed) and cereals in the EU. Because of such substitution and changes in feed rations, the economic effects on EU livestock producers were found to be more moderate, though still substantial. Furthermore, due to border protection measures against less expensive imports, it was also found that EU livestock producers could pass a significant part of the cost increases they faced on to European consumers. In the worst case scenario considered, such additional consumer expenditures in the EU-27 were estimated at €10.5 billion annually.

The singular focus of these *ex ante* impact assessment studies on the EU and the possibility of trade disruptions due to regulatory asynchronicity and LLP has been motivated by Europe's heavy reliance on imported soybeans as a primary source of protein for its livestock sector, its significant position in international soybean and maize markets, and its slow regulatory approval process. Indeed, the possibility of trade disruptions between the EU and all major soybean exporters is far from removed. Historically, South American exporters like Brazil and Argentina had maintained synchronicity with the EU to minimize potential LLP occurrences by slowing their regulatory approval process. In recent years, however, they have shifted away from such policy reviewing and approving new biotech events with much higher frequency.[13] Despite the exclusive focus on the EU and the variety of modeling techniques, however, these empirical studies provide consistent evidence of significant economic losses, declining sectoral competitiveness, production, and employment as well as steep increases in consumer prices and expenditures from broad trade disruptions caused by LLP. They also provide insight on the conditioning effects of substitution and the time required to adjust.

Ex Post **Impact Assessment Studies:** In one of the first *ex post* economic impact assessment studies, Lin et al. (2003) calculated the supply disruption of US exports to Japan and S. Korea prompted by the discovery of Starlink maize. They found that up to 3.2 MMT of maize were affected and concluded that, for a limited period of time, there were price differentials of 4-6% between Starlink-free and commodity maize in the US.

Carter and Smith (2007) used time series analysis and also calculated the market effects of Starlink maize in the US. Carter and Smith estimated that the discovery of Starlink maize in the US and export food supply led to a 6.8% discount in the US maize price which lasted for at least a year.

Schmitz et al. (2004) estimated the market impacts of the reduced demand for U.S. maize caused by the Starlink LLP event in 2000. For their analysis, they used a partial equilibrium model which accounted for the conditioning effects of the Loan Deficiency Payment (LDP) program enjoyed by US farmers. Schmitz et al. concluded that the reduction in Japanese maize demand alone would have reduced the average price received by U.S. maize producers in 2000 by 2.5-4% if LDP payments did not partially offset the market impact. However, after adjusting for LDP payments, the average price received by U.S. maize producers dropped by less than 1%. In aggregate, this translated into a loss in revenue for US maize farmers of $48-$78 million.

Following the discovery of Liberty Link rice in the US export supply chain, Li et al. (2010) used time series analysis to evaluate the impacts of the incidence on the US and Thai rice prices. Li et al. estimated US prices to decline by 17% within two weeks of the discovery and to return to normal levels within 2 months. Li et al. found no impact on Thai rice prices.

Existing *ex post* studies have therefore focused on the economic impacts of trade disruptions from the discovery of unauthorized events on the exporters of a single commodity and in specific markets. As such, they are more limited in scope than the *ex ante* studies. At the same time they provide more detailed market accounts on the workings and the economic impacts of such trade disruptions and useful insights on the conditioning effects of their duration.

In all, both *ex ante* and *ex post* empirical studies provide evidence on the relative size of the potential and actual economic impacts from trade disruptions caused by LLP of asynchronously approved or unauthorized biotech events,[14] the distribution of such economic impacts among producers, value

13 Brazil, for instance, had approved just two new biotech events until 2007 but has approved 25 new biotech events in the last four years.

14 Empirical evidence on the economics of segregated trade under alternative LLP tolerances, however, is not as plentiful.

adding sectors and consumers; and the influence of conditioning factors such as the duration and extent of trade disruptions, the role of agricultural and trade policies, and others. They also illustrate the variety of alternative empirical approaches that may be used to calculate actual and potential economic impacts from LLP. Taken together, existing empirical studies clarify that the economic impacts of LLP can be significant, even when a small number of trading countries and commodities are involved. As such, they imply that minimizing asynchronicity and adopting LLP policies which can effectively deal with incidents of LLP when they occur could yield large economic benefits.

8. Concluding Comments

In the context of any policy discussion on regulatory asynchronicity and LLP, it is important to reflect on some key emerging trends, including: (a) the fast expanding pipeline of novel biotech events; (b) the fast-expanding biotech acreage and the growing number of countries that raise them; (c) the expanding number of biotech crops being grown and traded; (d) the expanding share of biotech crops in international commodity trade; and (e) the increasing number of countries with nascent and inexperienced regulatory programs that will be called on to manage a large number of regulatory submissions for new biotech crops in the coming years. Under these circumstances, incidents of regulatory asynchronicity and LLP in some parts of the food/feed supply chain are almost inevitable and these trends speak to the need for significant coordination in the international regulatory system in order to avert systemic and widespread trade disruptions.

Individual countries would be well served by adopting preemptive policies that minimize the lags in their regulatory reviews as well as complementary LLP policies with abbreviated regulatory reviews and practical LLP tolerances in order to minimize any food/feed and environmental safety risks and costly disruptions of trade. Guidelines for abbreviated food/feed safety reviews are already provided by the Codex Annex and guidelines for abbreviated environmental safety assessments are being considered by an OECD working group. In addition to technical guidelines, international organizations and national governments are also developing systems for sharing of information, data and experiences through actual case studies.

The small but growing empirical literature on the potential and actual economic impacts of LLP incidents suggests that governments should actively seek to understand the economic implications of alternative LLP policies. This paper has provided a brief overview of the key economic factors that may be taken into account when alternative LLP policies are being considered. Because of the multitude of these factors and their complex interrelationships, however, practical examination of their significance in any national context is expected to be a good deal more involved that could be described here. National case studies, like the companion IPC analyses on China, Vietnam and Latin America, help clarify the relative size of the economic impacts of LLP, the key factors that shape them, as well as the diversity of analytical methods that can be usefully employed.

It is important to note here that certain potential economic impacts from LLP have been ignored in this paper (and in the previous literature) because of the analytical complexity they imply. The analysis described above implicitly assumes that the adoption of new biotech crops in exporting countries is largely exogenous and unaffected by their degree of authorization in importing countries. The level of research and development (R&D) and the rate of biotech innovation have also been assumed independent of regulatory progress. In reality, there is most likely a dynamic interplay between the rate of biotech innovation, the adoption of new biotech crops and the progress in regulatory approvals across different countries. In such a case, in addition to the direct costs associated with trade disruptions, unaccounted indirect economic effects might include foregone benefits from unrealized innovation and productivity gains. Potential environmental impacts have also not been discussed in any length.

Trade disruptions and import substitution could involve shifts to alternative production activities with potential impacts on land, water, and energy use as well as on greenhouse gas emissions.

The emphasis of this overview paper has been on the potential economic loss associated with the LLP of unauthorized biotech events. It is recognized that governments must balance safety considerations, the potential economic costs of trade disruptions, and, perhaps, other sociopolitical objectives (e.g. innovation, employment, industry competitiveness, and environmental sustainability) when devising their LLP policies. The underlying process by which the various objectives and interests are balanced has not been examined here. Conceptual models where LLP tolerances might be derived in a way that maximizes social welfare (e.g. Gruere, 2009, and Magnier et al., 2009) may be possible and could help clarify the tradeoffs between economic impacts and other social objectives.

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