Asynchronous Approvals of GM Products, Price Inflation, and the Codex Annex: What Low Level Presence Policy for APEC Countries?

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Paper presented at the
International Agricultural Trade Research Consortium
Analytic Symposium
*"Confronting Food Price Inflation:
Implications for Agricultural Trade and Policies"*

June 22-23, 2009
Seattle, Washington

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Abstract

Genetically modified (GM) products are largely traded internationally in a commingled way. Despite the reluctance of their consumers, large western importers of maize, canola and soybeans, like Japan or the European Union have approved the imports of a number of key GM products. But with the acceleration in the release of new GM crop varieties in major commodity exporters (like the United States, Argentina, or Brazil), these and other importers are becoming concerned with delayed import authorizations and the increasing risk of temporary trade disruptions due to the adventitious presence of unapproved GM products conflicting with their zero percent tolerance for unapproved GM products. The consequence of such disruption is higher prices: importers either have to switch to less efficient GM suppliers or to non-GM suppliers to respond to their needs.
To address this issue, members of the Codex Alimentarius have recently adopted a guideline ("the Codex Annex") which proposes the use of a simplified risk assessment procedure for GM products approved at exporters but not yet at importers and potentially present in low levels in commodity shipments. However, this guideline does not specify what level of tolerance countries should apply and which products it should cover. In this paper, we model the economic effects of different implementation options of the Codex Annex. Using bilateral trade data and non-GM price premia, we apply our model to countries of the Asia Pacific Economic Cooperation (APEC), to assess the potential implementation cost of different options these countries should consider to avoid changing supplier and/or paying for non-GM in the presence of unapproved GM varieties in shipments.

Keywords: GM food, international trade, biosafety regulations, price inflation.

1. Introduction

Thirteen years after their introduction, the four main genetically modified (GM) products account for a significant trade volume of agricultural commodities. Although no official number is available, over 90% of traded soybeans are likely GM (exported from the largest GM producers), at least 50% of traded cotton, and maize, and a large portion of canola are also likely GM. Despite the reluctance of their consumers, large importers of maize and/or soybeans, like Japan or the European Union, have approved the imports of a few key GM products. Pushed by a rapid adoption in major producers of these commodities, GM products are now commonly traded.

But the growing adoption of the four major GM crops and the recent food price inflation crisis have increased the dependence of importers on exporters' adoption decisions. The increased price of food products has pushed towards even higher adoption of GM crops. Non-GM products have become more expensive pushing some importing companies to reconsider their non-GM policy. For instance, in 2008, Japanese and South Korean importing companies reluctantly started to import GM maize for use in certain food products, because of the large non-GM price premia in the market. In 2008, the Agricultural Directorate of the European Union published a report relating its dependence on the imports of authorized GM products for food and feed (EU Commission 2008). And executives from major European food companies, such as Nestle or Tesco, have publicly started to question their GM-free private standards, acting as a de facto ban of GM products on the retail shelves.

In this context, with increasing imports of the four GM products, and new types of GM events (crop/trait combination) being supplied to the market, the lengthy import authorizations procedures of certain countries have started to worry their domestic industries. Because most of these countries have a zero percent tolerance for unapproved GM events, and with GM products mixed up in the commodity supply chain, they fear that the trace presence of a new GM event in the exporting country not yet approved for import could result in shipment rejections and oblige them to find more expensive alternative, either from other GM exporters or from non-GM market suppliers, at least temporarily.

A few recent stories have shown the potential effect of trade disruption with a zero percent tolerance level. The de facto ban of US maize due to a moratorium on new GM varieties cost a lot to European importers. Although countries were still able to import the only GM maize variety approved from Argentina, in 2007, the approval of a new GM event in Argentina, and the limited export capacity from Ukraine, constrained the European industry to purchase the maize from Brazil with a reported premium of around Euro 50-70 per ton compared to US maize (Schumacher 2008). Similarly, the recent unwanted introduction of LL601 rice under confined field trial into the rice supply chain in the United States forced European and others to ban U.S rice, which cost approximately 3.5 to 7.5 million Euros per rice importer (Kettlitz 2008). [2]

Such happenings are only expected to multiply in the future. A report of the Directorate-General for Agriculture of the European Commission (EU Commission 2008) studied the effects of a two year import interruption due to asynchronous approval of a new GM soybean in USA, Argentina and Brazil, and found that it would increase feeding expenditures by 23% to 600% (with the three countries interrupting exports) and potentially have disastrous effect on the meat sector throughout the continent. Noting that Argentina and Brazil may slow the GM grain pipeline for fear of losing exports, they still consider such interruption as a distinct possibility given the difficulty of enforcing GMO seed bans in South America (and the possible escape from field trials) and the rise of China and other Asian countries as the new large customers for South America- resulting in the loss of market power of European buyers.

The concern of Europe has extended to other countries, to the point of becoming an international issue. On the one hand, importers are keen to keep their import authorization procedures for new GM products with a 0% tolerance level. On the other hand, market realities push them to worry about the cost of

[2] LL601 GM rice was under trial when it entered the marketing chain and was therefore unapproved for consumption, but it was subsequently approved for consumption by U.S. authorities, so it is different from other noted cases. In this paper we focus solely on products approved at exporters and not yet approved at importers.

keeping lengthy approval procedures and 0% tolerance for products approved by exporters, especially if these products are only present in minimal quantities in shipments.

Beyond supply delivery problems, asynchronous approvals create new market constraints that increase the volatility of commodity prices and likely contribute to the overall inflation in food prices. Restricting imports of new GM products in certain countries encourages market differentiation, limiting sources for all importers, and therefore creating long term pressure on prices. The multiplication of new GM events may also increase demand for non-GM, thereby encouraging the abandonment of some potentially higher productivity GM crops. At a time of persisting high food prices, and risks of increased protectionism, the impact of any further increase in price and/or reduced production would only accelerate price pressure on non-regulating importers, particularly those countries already suffering from food price inflation.

To respond to this issue, in July 2008, the WHO/FAO Codex Alimentarius Commission adopted an amendment in annex to its standard on GM food assessment,[3] which elicits a new set of simplified risk assessment guidelines on the temporary approval for the low level presence of GM products approved by the exporter but not yet approved by importers (Codex Alimentarius Commission 2008, Korves 2008). These new simplify guidelines, commonly called the "Codex Annex", aim to encourage countries to adopt simplified and more rapid procedure for any new GM event to be approved temporarily at low levels in commodity shipments while waiting for full approval. At the same time, the Codex Annex encourages the setting up of new data sharing mechanism on the testing and approval of new GM products, to facilitate information exchange between exporters and import regulators.

The adoption of this new guideline is a clear signal of the international consensus on the increasing importance of GM traces in international trade and the need to find practical regulatory mechanisms to respond to this reality. The standard was rapidly adopted by consensus by the over 160 members of the Codex Alimentarius, despite dramatic country differences on many aspects related to the regulation of GM food. In comparison, discussions at the Codex Alimentarius Committee on Food Labeling on the issue of GM food labeling remain completely blocked 16 years after it was first introduced, because of seemingly irreconcilable differences across member countries.

In principle, the Codex Annex satisfies exporters and importers. The United States Government was reportedly appreciative of this new optional flexibility in trade practices. The European Union accepted the standard conditional on the setting up of an information sharing mechanism that they hope will help them conserve their 0% tolerance and increase the efficiency of their system (ITCSD 2007). Other countries, notably in the developing world, that tend to follow Codex rules as reference for their food standards, may use this regulatory option to avoid trading high prices for what they may consider low safety standards.

Still, even if it provides new guidance, the Codex Annex leaves a lot of room to countries with regard to implementation options. First, it considers different categories of products: processed products, grains whose GM part is small in final consumption goods, and whole produce, like fruits or vegetables, without specifying whether the rule should apply to each category in a similar manner. Second, and more critically, the Annex does not define what "low level presence" means. It leaves the discretion to countries to define what may be considered low level presence (LLP). Such a lack of focus may reflect

[3] See appendix for the full text of the Annex.

political realities given differences in importer preferences on the complex issue of GM regulations. But it also opens a wide range of possible options that will ultimately determine whether the procedure will be useful, feasible, and able to fulfill its goals of accommodating safety concerns and marketing realities.

Although a number of studies have been published on import regulations of GM food (e.g., Bernauer 2003, Carter and Gruere 2006), GM free private standards (Gruere and Sengupta 2009, Knight et al. 2008), and exporters' challenges (e.g., Nielsen et al. 2001, Paarlberg 2002, Gruere et al. 2009), the issue of asynchronous approval has not been examined as such in a thorough manner in the literature. The EU Commission report remains the most complete evidence on this matter, but it relates specifically to the assessment of the consequences of asynchronous approvals of soybean or maize in the EU. It still provides a first overview of the problematic. The issue is complex; it involves regulatory differences, bilateral trade specificities, timing of approval and trade, efficiency of testing and stochastic presence of GM in imports, enforcement, and known and unknown risks.

This paper aims to provide a first policy analysis of asynchronous approval and applications of the Codex Annex. The objectives of the paper are 1) to identify the main parameters of choice for policymakers and 2) to assess the likely economic consequences of different regulatory options. A simple analytical framework is developed and applied to the case of countries of the Asia Pacific Economic Cooperation (APEC) using past bilateral trade flow data, to provide indicative effects of potential trade disruption due to the LLP of unapproved GM in imported shipments of maize or soybeans.

Because this is a first study, a number of caveats apply. First, we do not provide a market model of the effects at this stage. This means that our estimates should be considered only relevant in the short run and are likely to be biased especially in the long run.[4] Second, we do make a number of critical assumptions, explained in the model, such as the perfect enforcement of the regulations, and the use of non-GM as alternative to unapproved GM. Due to these assumptions, the results of the applications should not be considered as precise estimates but rather benchmark values of what could happen.

The remaining part of the paper is organized in four sections. First an analytical model is developed using a specific importer as benchmark to identify the main policy constraints and variables. Second, we apply our model to the case of countries member of the APEC. Third, we briefly discuss harmonization issues, and we close the papers with a few conclusions.

2. The case of an importer

Let us assume, that at time t_0, a country A is importing product X from a GM producing country B. At time t_1, a new GM variety of X is approved in country B, but not yet in A. B is also a country where GM commodities are mixed in the system. In the absence of approval, until time t_2, A has to find another version of the good, which we assume to be a non-GM version, either in country B or another country to satisfy its need. For simplicity we assume that he has to purchase a non-GM good at a higher price than the GM mixed commodity he was previously purchasing from B. Assume a linear inverse excess demand for X in country A, $p=aQ+b$, $(a<0)$. We also assume that the probability of a safety outbreak is well

[4] Still, since the issue is related to short term rejection of shipments, the time horizon may not matter too much.

defined as N(σ, ν). Lastly, we assume perfect enforcement as a benchmark (enforcement issues are discussed in the conclusions).

Country A makes his decision according to a social welfare function that includes consumer and taxpayer welfare W:

$$W= w+ (b-p)/Q - \sigma DQ – CI(Q)$$

Where: w= basic welfare derived from good consumption, b = demand parameter, p= expected price, Q= quantity, σ= expected probability of damage per unit, D= damage, CI= cost of implementation.

This expression can be decomposed into three components: first, the Marshallian consumer surplus, traditionally defined; second, the expected damage from importing a possibly unsafe good; and third the public costs of a regulation. These three terms will be extended in more details below.

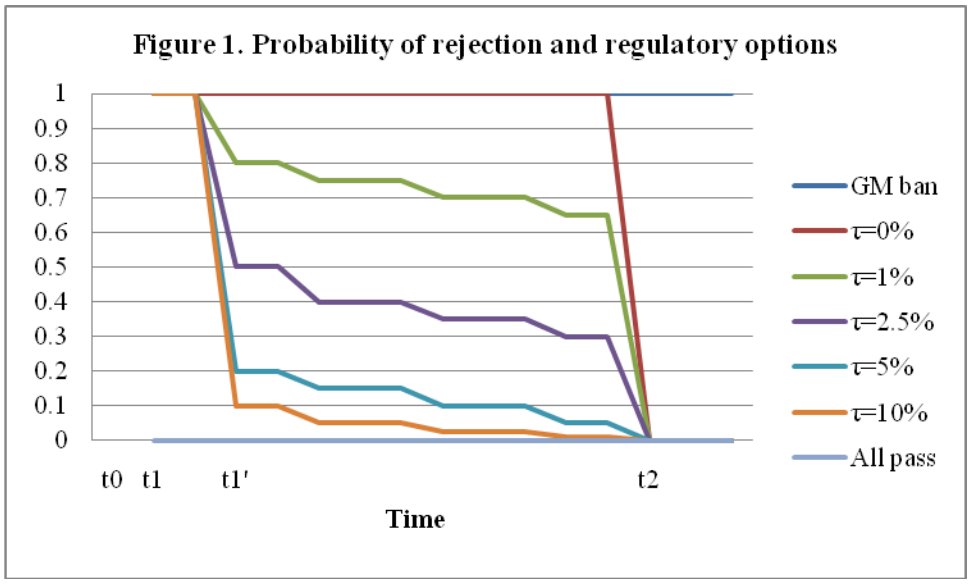
Most of the parameters depend on the regulatory choice. For simplicity, we will assume four possible regulatory scenarios for country A: i) Ban of GM, ii) 0 percent low level presence (LLP), iii) τ percent tolerance to LLP ($0< \tau <100$) , iv) Let everything pass ($\tau =100$). We separate scenarios with zero or 100 percent tolerance to single out the effect of implementing a LLP policy.

a. Consumer surplus

The consumer surplus is derived from the linear demand and assuming a perfectly elastic supply (price taker importer). The expression is not subject to regulatory change but the prices of the imported good will vary according to the regulation.

In particular, the variable p can be defined as the expected price, and depends on the probability of rejection of shipments (π) defined as: $p= \pi\ p_n + (1- \pi)\ p_g$, where p_n is the price of pure non-GM counterpart and p_g the price of the GM/mixed good (originally the price of the good).

The probability of rejection depends on the tolerance level τ and on the timing of approval at exporter and importer. Indeed there is more chance that a shipment will be rejected at a low tolerance level than at a high tolerance level. And assuming some adjustment time, the system will improve overtime, so the probability of rejection should decrease. Figure 1 shows a likely schedule of rejection probabilities under different regulatory options.



Source: Author

In this figure, we note the timing of four key events:

- t_0: time of production approval in B,
- t_1: export,
- t_1': LLP approval,
- t_2: import approval

As shown in the figure, a GM ban naturally translates into a 100% rejection at anytime. A zero percent LLP policy, like in Europe, also results in a 100% rejection rate, but only until approval is granted. A no-policy approach lets everything go, therefore meaning a 0% rejection rate. And a LLP policy with a non-zero tolerance level, is an intermediate approach, and results in a non-zero, non-one probability of rejection. The level of rejection depends on the tolerance level, the lower the tolerance level, the higher the likely rejection. For instance, there is a 2% tolerance level on waste in grain shipments, and getting a lower level is considered challenging and costly for traders to achieve if the GM event is representing a non-negligible share of production. The schedule in Figure 1 also shows a decline in rejection probability overtime to demonstrate the fact that adjustment can occur.

Although Figure 1 presents relatively high rejection rate that may not completely realistic, another interpretation would be to understand these rejection rates as the unwillingness of a large portion of traders to even try exporting mixed GM shipment to the targeted country, because of the likelihood of rejection. What matters is that the expected price is a weighted average of GM and non-GM.

Figure 1 also shows that the timing is critical, because if t_1 nears t_2 there is no significant trade irruption. The extent to which there is asynchronicity in approval matters. So does the delay to approve a new GM event for LLP. Furthermore, if the Codex Annex is applied, a simplified procedure is used, but this procedure will only be effective if it is conducted quickly and if it is effectively faster than the full approval procedure.[5] Taking this in consideration, there are three key timing related parameters:
$\Delta t_1 = t_1' - t_1$: delay for LLP approval,
$\Delta t_2 = t_2 - t_1$: delay for full approval,

[5] A regulatory expert recently noted that the differences between the complete and simplified procedures were not very different. If so the effectiveness of a rapid system would be based on the implementation specifics: the review of data may be quicker or less detailed, and conducted by only a few people to accelerate the process.

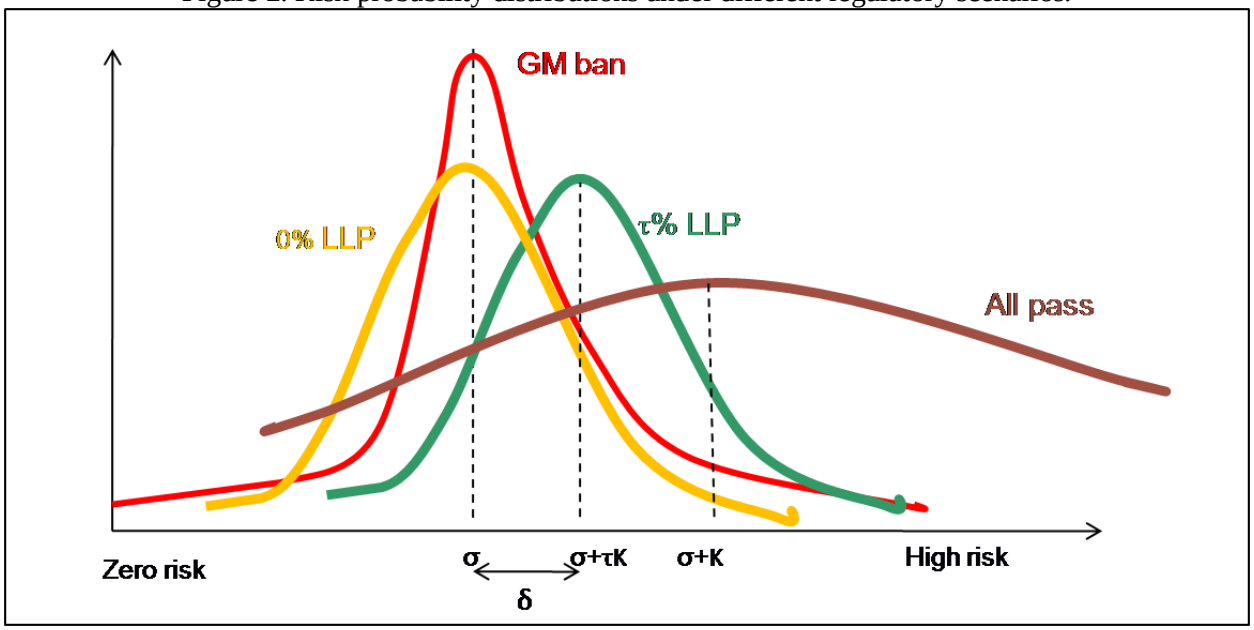
$\Delta t_3 = \Delta t_2 - \Delta t_1$: difference in speed between the simplified and full procedure.
These three parameters can already be singled out as relevant to policy discussions.

b. Risk avoidance

The second factor that affects welfare relates to safety. The goal of biosafety regulations for imported consumption goods for food, feed or processing, is to limit risks for consumers. It is the most difficult factor to quantify without looking at a case by case basis.

In our analysis we model risk using an exposure and damage framework. Because of uncertainties we assume that the exposure is modeled as a probability distribution of potential damage per unit consumed. Figure 2 shows our interpretation of risk probabilities under different regulations.

Figure 2. Risk probability distributions under different regulatory scenarios.



Source: author.

We assume that regulations affect both the mean and variance of the probability distribution of risks, but they do not completely eliminate risks. A GM ban does provide some certainty as to food risks but do not eliminate risk (enforcement could leave some uncertainty, but more generally any food item is associated with nonzero inherent risks). A 0% LLP policy results in the short run in the same result as a ban, but in the long run, assuming the regulation works, slightly increases uncertainty about the consumption risk. This translates into a larger variance in Figure 2. A nonzero percent tolerance level is modeled as a shift in mean probability of risks compared to 0%, but we assume that the variance remains the same (at least at rates under 10%). This shift reflects the perceived possible risk associated with importing trace levels of a still unapproved GM product. Lastly, no import policy does shift the mean and largely increase uncertainties about the perceived safety of imported products.

In this figure we see that the shift, modeled as δ. K is the crucial determinant of the risk increase with a change in tolerance levels LLP for unapproved GM. K can be seen as the maximum expected risk increase from non-GM to 100% GM. The shift parameter K will depend on the type of product (processed vs. fresh), the intended use of the product (animal feed versus human consumption), and on the perceived

value of the exporter's regulatory framework. If a country has a strong trust in the exporter's regulations, it will not fear new unknown risk with LLP in shipments at a nonzero rate. If, however, the exporter's regulatory body is not credible, the importer will fear any possible intrusion of non approved GM material. Generally speaking, if some of the developed country exporters have advanced regulation in place, they differ relatively significantly. Furthermore, some developing countries that export GM do not have fully functional/enforced regulatory systems.

c. Cost of implementation

The cost of implementation is defined as: $CI(Q) = (C_1(\tau)\, S(\tau) + C_2)\, Q$, where $C_1(\tau)\, S(\tau)$ corresponds to the total testing costs, and C_2 the equipment and inspectors. Both components are considered variable costs because they depend on total quantity imported. The first term depends on the tolerance level, as it is generally assumed that: $C_1(\tau<1\%) > C_1(1\%<\tau<5\%) > C_1(\tau > 5\%)$, given detection level requirements. $S(\tau)$, defined as the sampling factor, is directly dependent on the tolerance level: $S(\tau) = N^* (1-\tau)$, where N is the maximum sample test size in a cargo and τ is expressed as a fraction. A high tolerance level does not require as large a sample. As illustration, Table 1 shows the number of beans that could be GM in various shipment sizes that contain 0.01% GM. Trying to find a few beans in a bushel is a different exercise than in a vessel of 50000 tons. A negative test at exporter does not guarantee a negative test at the import site.

Table 1. Number of GM soybeans in various shipments.

Unit	Number of trucks	Number of bushels	Number of soybeans	0.01% GM
Bushel		1	181,333	18 beans
Truck (25 tons)	1	918	166.4 M	16,640
Vessel (50,000 tons)	2500	1.84 M	330 Trillion	33 M

Source: Giroux (2008).

d. Key decision parameters

The problem described above is very much like a standard utility maximization problem. A rational and benevolent decision maker chooses the best regulatory options to maximize total welfare. But what are the choice variables? The tolerance level is the most obvious, but three other parameters can be seen as b crucial; the two timing variables $\Delta t_1$and Δt_2, which correspond to the maximum time lapse before a decision of processing a LLP application and authorizing (or rejecting) the application, and the shift parameter K representing the lack of confidence in a given exporter's regulations.

While marginal effect parameters would need to be estimated to provide a possible solution, one can always conduct a comparative statics exercise to determine what effect each of these parameters would have on total welfare. Table 2 shows the basic price and welfare effects of an increase in each parameter by component and in total. The price effect is separated both to explain changes in consumer surplus and as an indicator of whether a specific regulatory choice would have an inflationary price effect.

Table 2. Effect of an increase in each key parameter on the total welfare of a LLP policy

Increase in	**Price**	**Consumer surplus**	**Risk avoidance**	**Cost of implementation**	**Total welfare**
$\boldsymbol{\tau}$	$\downarrow$	$\uparrow$	$\downarrow$ or $\rightarrow$	$\downarrow$	$\downarrow$ or $\uparrow$
$\boldsymbol{\Delta t_1}$	$\uparrow$ or $\rightarrow$	$\downarrow$ or$\rightarrow$	$\rightarrow$	$\uparrow$ or $\rightarrow$	$\downarrow$ or $\rightarrow$

Δt_2	↑	↓	→	↑	↓
K	→	→	↓	→	↓

Source: Author.

Simple derivations show that:

- A higher tolerance level, by reducing rejection rates, does decrease the expected price of the imported good, which therefore increases consumer surplus (ceteris paribus). At the same time, the tolerance level either maintains or decreases the risk avoidance factor of the regulation (depending on K), and it decreases the cost of implementation. As a result, the effect on total welfare is ambiguous, and could be negative or positive, balancing perceived risk avoidance and consumer surplus.
- A rise in the LLP processing delay increases price except if the tolerance level is zero, and therefore either maintains or decreases consumer surplus. The risk avoidance effect is similar, and the cost of implementation may increase or remain unchanged. As a result the total welfare effect is either negative or zero.
- Similarly, but regardless of the tolerance level, a longer delay in LLP approval will decrease consumer surplus and increase implementation cost with a resulting decrease in welfare.
- Lastly, increasing K, the lack of trust in the exporters' regulation, will only reduce the risk avoidance effect of any LLP policy and therefore reduce total welfare.

These results suggest that decision makers will always benefit from reducing approval delays and increasing confidence in exporters' regulation. Still, reducing delays may or may not affect the marginal benefit of a LLP policy versus no LLP policy. If the maximum delay of LLP approval is too long, the policy will not provide any benefit and will just replicate a regular authorization.

The results also show that setting up the tolerance level is not a simple decision, it involves both risk perceptions and economic considerations. Setting up a higher tolerance level can be summarized as trading lower transaction costs and prices for higher potential risks. A decision on such key parameter needs to take into consideration benefits and costs.

Lastly Table 2 shows that price may increase with long delays especially in LLP approval, and with lower tolerance levels. In both cases, importers will have to purchase more expensive products, either GM from another source or pure non-GM for a premium. Note that a lower threshold (associated with higher rejection uncertainties) will also result in higher insurance for shipments, which will likely translate into the price of imported commodities.

The next section uses this framework to provide an empirical application of the model in the case of countries of APEC, that have been discussing the use of LLP policies.

3. Application to APEC

The goal of the application is to illustrate the conceptual framework, and to provide benchmark estimates of the effects of different regulatory options. The application focuses on APEC, a regional group that has been keen on discussing this issue. Interestingly, APEC includes a varied group of member countries that largely trade agricultural commodities and differ in their use of GM crops. Some produce and export GM crops, others do not, and import regulations largely vary in their scope and enforcement (Gruere and Rosegrant 2008).

The application focuses on maize and soybeans, the two main GM commodity crops. We use the general assumptions of the analytical framework, with perfect enforcement and non-GM used as an alternative to GM. Using bilateral 2000-2004 trade data from the UN Comtrade (as in Gruere and Rosegrant 2008), we compute the potential volume that could be subject to trade interruption due to asynchronous approval in each APEC economy. We use this volume as a maximum estimate of trade interference. The application therefore does not aim at providing precise cost estimates but rather a qualitative assessment of what is at stake.

We then use the model described in section 2 to compute an estimate of the cost of implementation and consumer surplus associated with different LLP options. Because of large uncertainties and the lack of reliable data on risk perceptions, we do not compute the risk avoidance term of the welfare function. Instead we compare the costs and consumer surplus effects of each regulatory option to provide a first estimate of what risk perception differences would a particular option imply for welfare maximization.

a. Data and calibration

One of the major assumption relate to the price of the non-GM alternative. A rapid review of the literature shows that two types of estimates can be used: the relative cost of non-GM segregation (a lower range proxy for non-GM) and non-GM price premia. Table 3 shows the values of selected estimates by source and type. Obviously price premia are closer to the actual price of non-GM, so we prefer to use sources closer to the market. Most of the reported price premia are qualitative citation from sources and therefore largely vary.

For maize, we use $85/ton based on the average of industry estimates of Euro 50/ton and 70/ton, as it accurately reports an actual recent case. In the case of soybean, we derive price premia from actual market quotes at the Tokyo Grain Exchange (TGE) in 2008. The TGE is the only stock market to separate a quote for non-GM soybeans. We use 10 month future of GM and non-GM quotes and compute the differences overtime. Figure 3 shows the evolution of the price premium from February 2008 to February 2009. The price premium varies from 0 to 50% overtime, but we use the average value of 26% for our simulations.

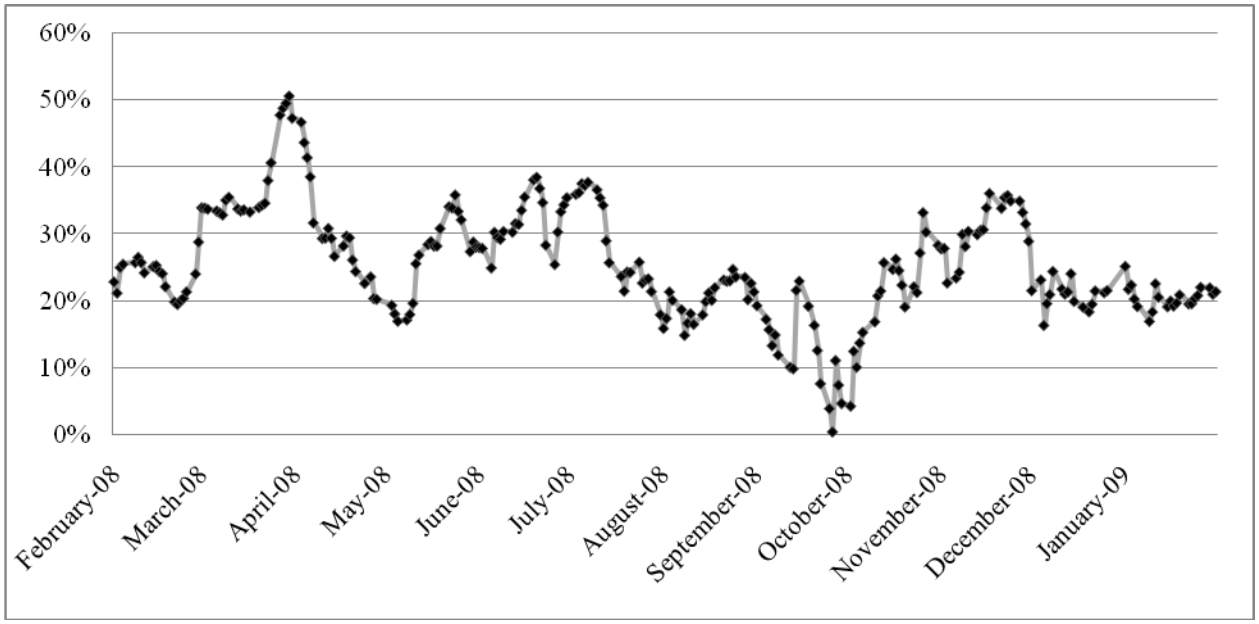
Table 3.Costs of segregation and non-GM premium from selected sources

Country	**Year**	**Crop**	**Segregation cost**	**Non-GM premium**	**Source**
Australia	2005	Canola	4-6% farm price		Foster (2006)
Canada	2003	Wheat	C$6.82-8.57/mt [1]		Huygen et al. (2003)
Canada	2004	Wheat	C$ 11.36/mt [2]		Carter et al. (2005)
Canada	2003	Wheat	C$4-15.35/mt [3]		Canada Grains Council (2003)
Europe	2008	Maize		€50 to 80/mt	Schumacher (2008)
Europe	2004	Soymeal		$5/mt	Schumacher (2008)
Europe	2005-07	Soymeal		$10/mt	Schumacher (2008)
Europe	2007	Soymeal		$60-80/mt	Schumacher (2008)
Europe	2008	Soymeal		€30-40 /mt	Schumacher (2008)
Global	2005	Wheat	5% market price		Berwald et al. (2006)
Global	1999	All	5*15% farm price		Buckwell et al. (1999)
Global	2002	All	5-15% farm price		Burton et al. (2002)[4]
South Africa	2007	Maize		4 to 6%	Gruere and Sengupta (2008)
USA/Canada	2008	Wheat	$2.65-5.81/mt [5]		Wilson et al. (2008)
USA	2000	Maize	12% farm price		USDA ERS (2000)[6]
USA	2004	Maize	$2 - $10/mt		Foster and French (2007)
USA	2002	Maize	12% farm price		Lin (2002)

USA	2000-02	Maize	22% farm price[7]	Lin and
USA	2000	Soybeans	11% farm price	USDA ERS (2000)[6]
USA	2002	Soybeans	4% farm price	Lin (2002)
USA	2000	Soybeans	14% farm price [7]	Lin and Johnson (2003)
USA	2002	Soybeans	8% farm price [7]	Lin and Johnson (2003)

Notes: 1. the low cost reflects a tolerance level of 5%, the high cost a tolerance level of 1%. 2. 0.5% tolerance level, 3. the low cost reflects a tolerance level of 5%, the high cost a tolerance level of 0.5%. 4. As cited by Anderson and Jackson (2005). 5. the low cost reflects a tolerance level of 5%, the high cost a tolerance level of 0.5%.6. As cited by Noussair et al. (2004). 7. Total IP cost including grower premium.
Sources: Bansal and Gruere (2009).

Figure 3. Daily non-GM price premium for soybeans in Japan in 2008



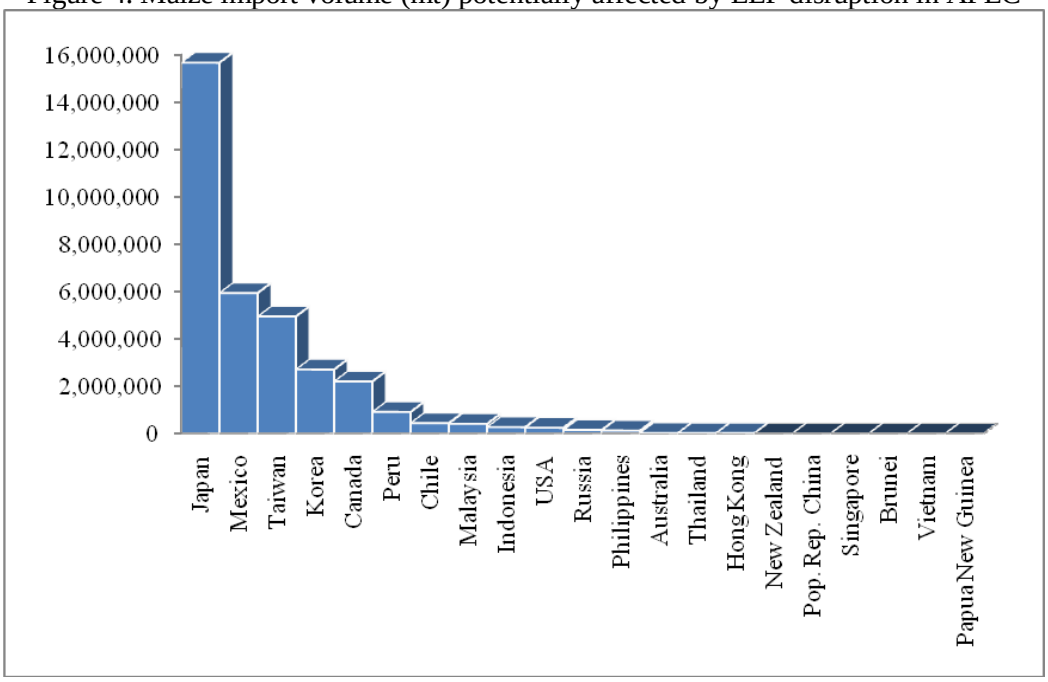
Source: Authors, based on Tokyo Grain Exchange.

Following Gruere and Rosegrant (2008), the average trade volume potentially affected by LLP related trade disruption is a proxy for the exposure to any commercial risk. Figure 4 provides a histogram of total volume potentially affected for APEC countries. Over 34 million metric tons of maize are concerned. Five major importers are singled out: Japan, Mexico, Taiwan, South Korea and Canada as the most potentially affected. Figure 5 provides percentages of total imports potentially affected in each member country.

Mexico, Canada, Taiwan and Japan are also in the leading countries in terms of relative imports potentially affected by maize trade interruption. South Korea is only importing about 30% of its maize from GM sources, so it may be able to divert sources in case of LLP of unapproved GM event. In contrast, Japan, Mexico, Taiwan and Canada are both large importers and import almost solely maize from the United States. Canada may not face the same issue as others, as new GM crops tend to be commercialized simultaneously in Canada and the United States, therefore avoiding the issue of asynchronous approval. Japan does already have a low level threshold for unapproved GM maize used for

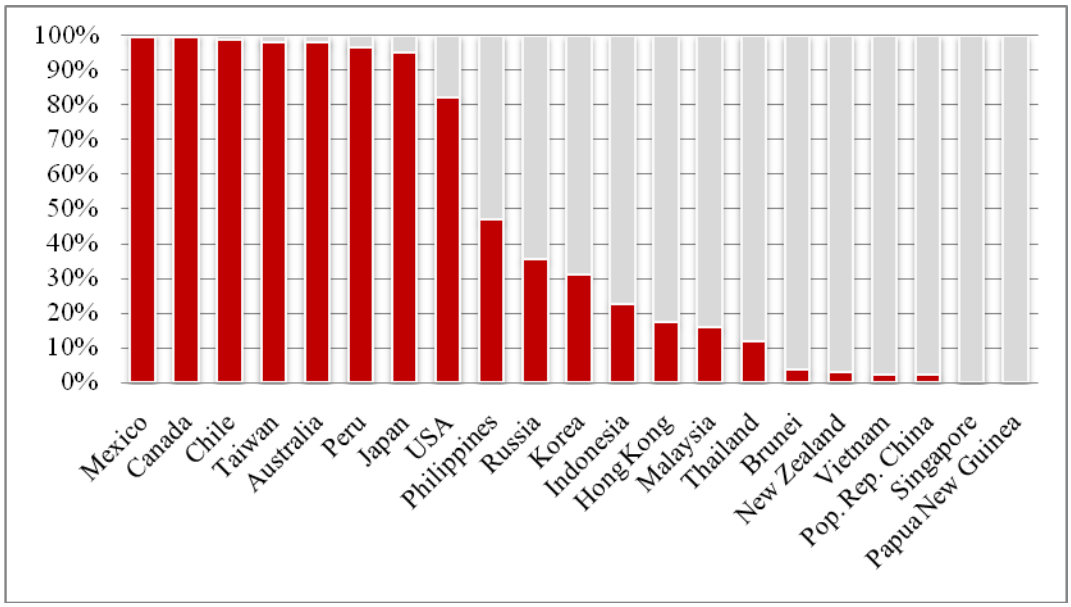
animal feed, but it also imports non-GM maize from the United States for food and is starting to import GM maize for food without LLP policies. Lastly, Mexico and Taiwan do not have any LLP policy.

Figure 4. Maize import volume (mt) potentially affected by LLP disruption in APEC



Source: author.

Figure 5. Percentage of imported maize with potential LLP issue.

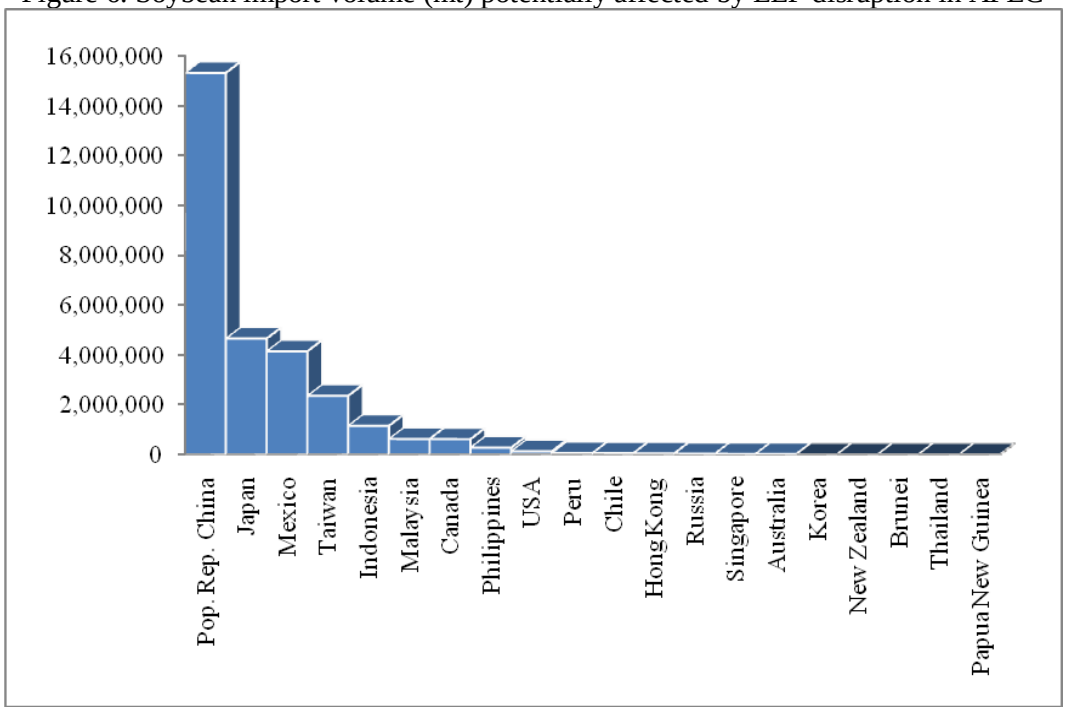


Source: author.

We derive similar figures for soybeans. Figure 6 shows the volume potentially affected by LLP trade disruption. Overall over 29 million tons of soybeans could be affected by LLP disruption in APEC. Half of this amount is imported by China. Japan, Mexico, Taiwan, and Indonesia are distant followers, but each with over a million ton potentially affected. In relative terms, Figure 7 shows that most APEC economies import soybean mostly from GM sources. The five countries are all importing over 90% of GM soybeans with China close to 100% GM soybeans from the United States and Latin America. Interestingly China has set up temporary import permit for GM soybeans over the years, but bans the use of GM soybeans domestically. Imports are segregated and used for feed and oil, while domestic supply is used for food.

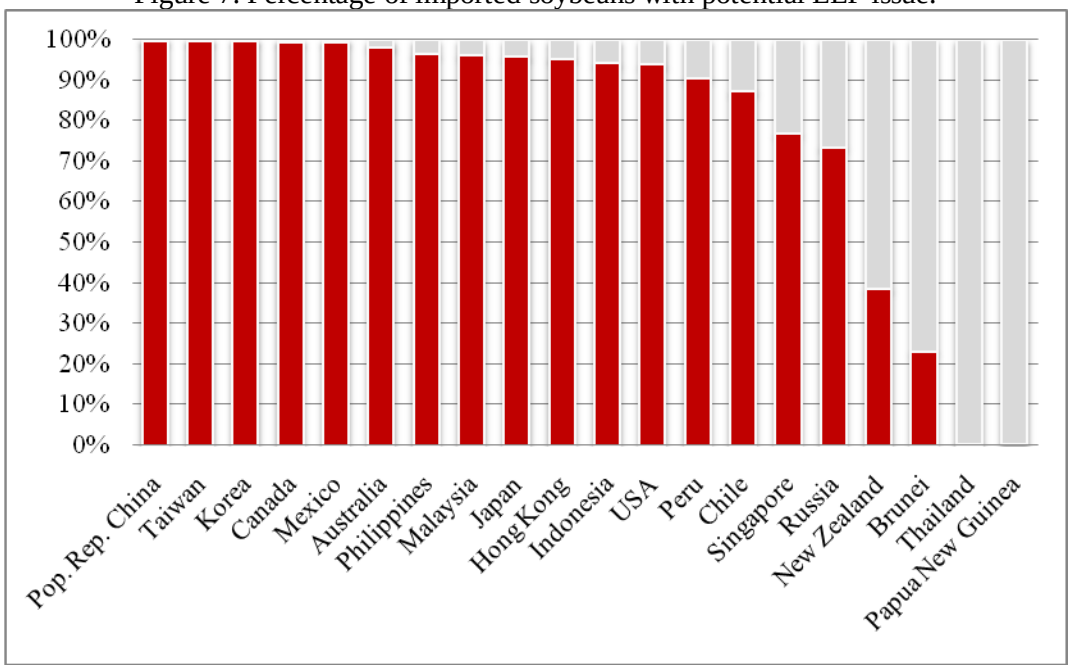
These results suggest that China and the four leading importers of GM soybeans are the most concerned. That does not mean that other countries are not, but it does mean that differences in regulatory options will be more visible for these leading countries than for countries importing much less soybeans.

Figure 6. Soybean import volume (mt) potentially affected by LLP disruption in APEC



Source: author.

Figure 7. Percentage of imported soybeans with potential LLP issue.



Source: Author.

In the same fashion, using data from Gruere and Rosegrant (2008), we also derive the totals for all GM food and feed crops, (adding cottonseed and canola to maize and soybeans) and find that over 67million tons could be affected, which represents in average over 84% of all APEC imports of these products.

Other assumptions and derivations are summarized in Table 4. The calibration of π and CI(Q) are shown in Table 5. For CI(Q) we assign cost values between \$0.5 and \$5/ton depending on the scenario, based on

Gruere and Rosegrant (2008). Note that these are not precise estimates and would need to be more specifically measured with actual testing costs. For the probability of rejection we use expected probabiliies based on the schedule shown in Figure 1 from t_0 to t_2+1. These schedules are also exogenously taken, and could alter the result. For comparison purposes, these approximations may not matter that much, but we do plan to conduct sensitivity analysis in the future.

Table 4. Main assumptions and equations used in the application

	Maize	**Soybean**
p_0	\$200	\$400
p_{n0}	\$285	\$504
η_0	$-1.1+\theta$	
a	$p_0/(Q_0\eta_0)$	
b	p_0-aQ_0	
p	$\pi p_0+(1-\pi)p_{n0}$	
Q	(p-b)/a	
CS	(b-p)Q/2	
w	1000	

Note: θ is the proportion of import likely affected (see figures 5 and 7), Q_0 is the total import volume affected (see figures 4 and 6).
Source: author's assumptions.

Table 5. Calibration of π and CI(Q) under the different scenarios.

Scenario	**Assumed π**	**Assumed CI(Q)**
Ban	1	5Q
τ=0%	0.8	4Q
τ=1%	0.62	3Q
τ=2.5%	0.39	2Q
τ=5%	0.22	Q
τ=10%	0.16	0.5Q

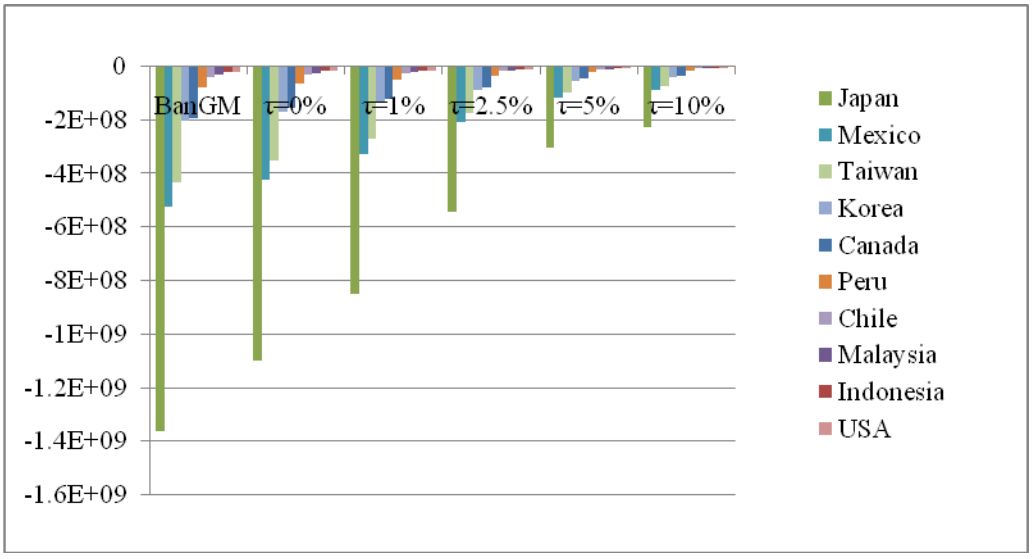
Source: author's assumptions.

b. First results

The results are expressed in welfare differences (consumer surplus changes plus cost of implementation effects) from no regulation. As noteds above the results do not claim to be precise estimates of the economic effects of these regulatory options, but rather benchmark value providing a sense of what could happen with generalized asynchronous approvals in the region for maize and soybeans. We are more interested in comparisons across countries and especially scenarios.

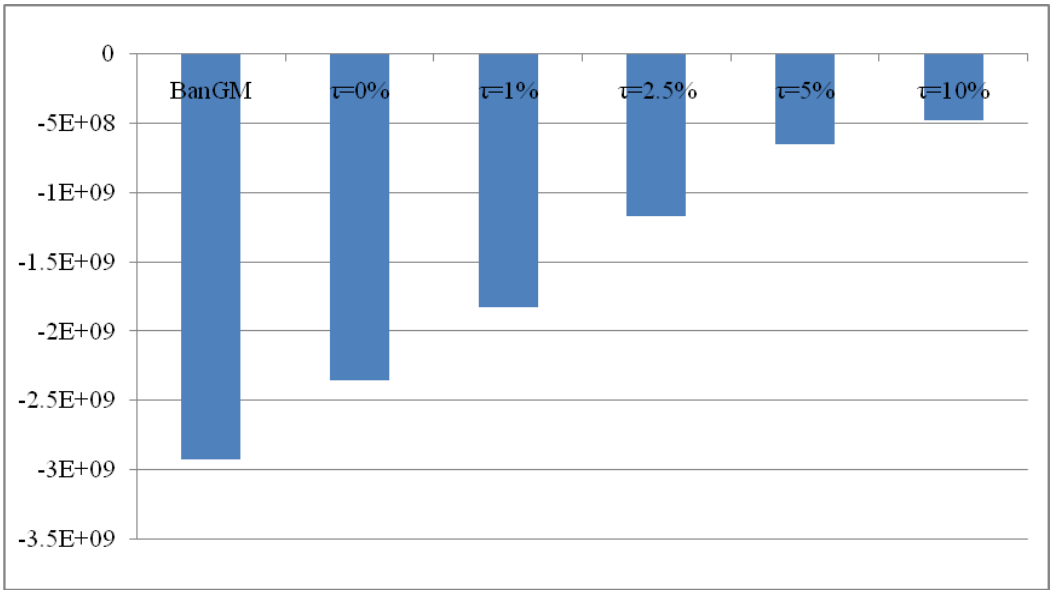
Figure 8 shows the results for maize in the case of the most affected importers. It shows relatively proportional changes across scenarios for all countries involved, mostly because of the same method and calibration across countries. Nonetheless, the results show that Japan would be the most affected by a LLP trade disruption, while Taiwan and Mexico would follow at less than half the effect, reflecting the affected volumes. The maximum total effects for Japan range from -\$200 million to -\$1.3billion per year.

Figure 8. Change in consumer surplus + implementation cost for large maize importers (USD/yr)



Source: Author's derivations.

Figure 9. Change in consumer surplus + implementation cost for maize for APEC (USD/yr)



Source: Author's derivations.

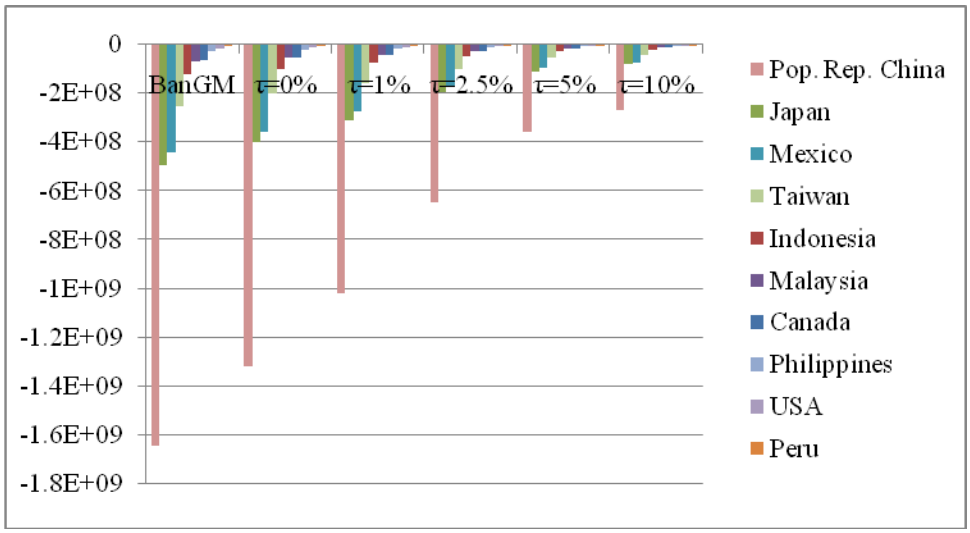
Although these are likely large overestimate of the total possible damage for Japan, given its infrastructure, regulatory knowledge and capacity of adaptation, the totals for other less advanced countries may be relatively accurate. In particular, Taiwan, Mexico or Peru are likely to have significant cost if they enforce a 0% LLP policy. Figure 9 shows the total effects for APEC which ranges between -$500m to -$3billion annually. If we divide these totals by the volumes, we find that on average a GM ban could cost up to $80/ton, a 0% tolerance level $65/ton while a 5% would only cost a maximum $19/ton and a 10% an average $14/ton.

The comparison across scenarios shows that going to 0% to 5% tolerance reduces the cost by 71%. This means that choosing 0% over 5% is only justified if the regulators considers that the value of the risk of

importing maize shipments with a 5% LLP approved materials increases by over 71% compared to a 0% LLP tolerance level.

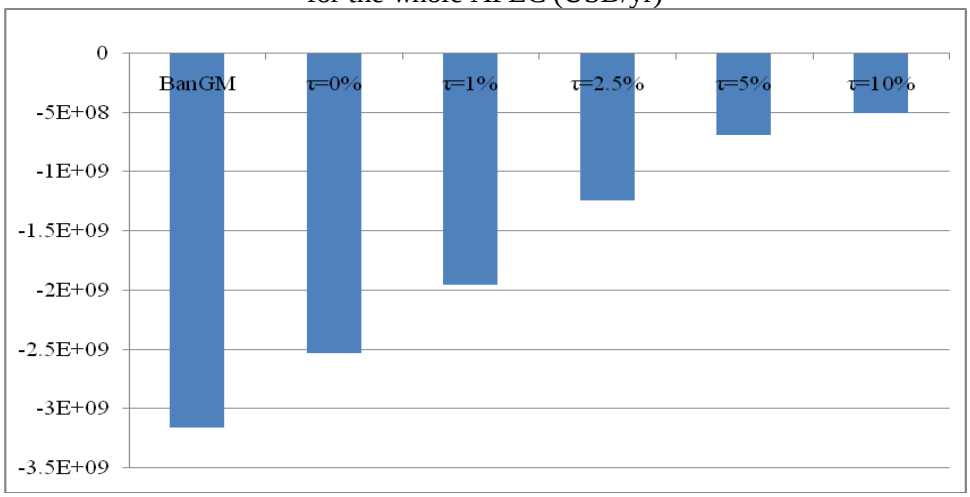
Similar results are shown in the case of soybeans in Figure 10 and Figure 11. The same proportionality is observed ; China ix the first and foremost country likely to be affected by any trade disruption. The total APEC values range from -$500m to -$3.2b, theyexceed the one for maize, because of higher price differences.

Figure 10. Change in consumer surplus + implementation cost for large soybean importers (USD/yr)



Source: Author's derivations.

Figure 11. Change in consumer surplus + implementation cost for soybeans for the whole APEC (USD/yr)



Source: Author's derivations.

The per unit results are shown on Table 6, for both maize and soybeans. The cost associated with more stringent regulations are higher in absolute value for soybeans, but they are proportionally higher for maize. Overall going from 0% to 5% reduces cost by 73% in the case of soybeans, which means that a 0%

LLP policy can only be justified if the additional risk of 5% tolerance level is considered at least 73% higher than the one with 0% LLP.

Table 6. Total changes in implementation costs and consumer surplus per metric ton

Scenario	Maize	Soybeans
Ban	$80	$107
τ=0%	$65	$85
τ=1%	$51	$66
τ=2.5%	$34	$42
τ=5%	$19	$23
τ=10%	$14	$17

Source: Author's derivations.

The use of the same model can help obtain interruption in one source rather than all GM sources. For instance, we focus on the United States, which is the largest provider of maize and one of the largest provider of soybeans in APEC. Looking at the major importers, we find that the costs are reduced proportionally to the volume of exports. Tables 7 and 8 show some of the results for the main importers with trade disruption due to an unapproved event of maize or soybean in the United States. These tables show that the countries that should prepare in priority to such possibility are Japan, China and Mexico.

Table 7. Changes in implementation costs and consumer surplus with a LLP of a new GM soybean event in the USA ($ million/yr)

Importer	GM ban	τ=0%	τ=1%	τ=2.5%	τ=5%	τ=10%
China	-680	-555	-435	-281	-158	-118
Mexico	-413	-332	-257	-164	-91	-67
Japan	-378	-305	-237	-152	-84	-63
Taiwan	-191	-154	-120	-77	-43	-32
Indonesia	-108	-87	-67	-43	-24	-18
Canada	-65	-52	-40	-26	-14	-11
Malaysia	-22	-18	-14	-9	-5	-4

Source: Author's derivations.

Table 8. Changes in implementation costs and consumer surplus with the LLP of a new GM maize event in the USA ($ million/yr)

Importer	GM ban	τ=0%	τ=1%	τ=2.5%	τ=5%	τ=10%
Japan	-1312	-1063	-823	-526	-292	-217
Mexico	-522	-419	-324	-207	-115	-85
Taiwan	-425	-342	-264	-169	-94	-69
Canada	-193	-155	-120	-76	-42	-31
South Korea	-165	-139	-111	-74	-42	-32
Indonesia	-13	-11	-9	-6	-3	-3
Malaysia	-6	-5	-4	-3	-2	-1
Chile	-5	-4	-3	-2	-1	-1

Source: Author's derivations.

c. Discussion

These results first show that a short run shock due to the presence of an unapproved GM product could have significant economic costs regardless of the regulatory option. But they also show that the choice of option makes a significant difference in cost and welfare implications. As noted above, the question for

decision makers is therefore whether the risk avoidance associated with a very low tolerance level (0% or 1%) is worth the potential additional cost in case of shock.

The figures also show that there are disparities in shocks across countries depending mainly on trade volumes with current GM producers and on whether the unapproved GM event would come from the main provider or not. Volumes matter notably because of the model we use, but even without the assumption on implementation costs, it is expected that large importers of GM commodities will be the first and foremost affected by an asynchronous approvals and the low level presence of unapproved GM products.

Obviously, these are benchmark results; the reality is more complex than the model. First, even with maximum efforts, enforcement may not always be possible. It is generally considered that obtaining soybeans with 0% GM is now virtually impossible. Maize may also be difficult to source at 0%. Supposing enforcement is possible, the question is still to know whether countries that introduce a LLP policy will be able to implement it effectively at the border. The cost figures we propose only make sense if these countries use best practice sampling and testing. Yet there is a risk that many developing countries in APEC and elsewhere, for lack of capacity, budget or otherwise, will not in fact be able to fully implement their regulations. This means that if, officially, they do not take more than a certain tolerance level of unapproved elements, they will not necessarily check whether this is the case. Still, exporters will make the effort to comply with the regulation in most cases to avoid any rejection.

Regarding the cost of implementation, it should be noted that although we only talk about testing and verification, exporter costs also matter in the final result. Exporters are exposed to risks of losing markets and will have an incentive to over comply in order to avoid statistical test mistakes. For instance, a recent report on coexistence has shown that European suppliers of non-GM soybeans and maize tend to self-implement a tolerance level that is either 1/10 or ¼ of the actual regulatory tolerance level for labeling of GM food. This means that for a 0.9% tolerance level, they will try to achieve 0.09% or at most 0.275% of GM in their products. This enhanced purity level is costly and contributes to raising the costs of non-GM. Furthermore, the suppliers and/or traders will try to insure risks against rejection. Even if they do all efforts to be under a decided threshold, there will always be a chance that tests on the import side of a zero tolerance level country will find unapproved GM elements.

Other complexities may also appear as time goes by. Currently most new products are released in North America and then elsewhere, but the pipeline suggests that new GM products may be released elsewhere first. The outlook may be a world with multiple new GM events coming from various new sources. Regulators that want to apply a LLP policy with a particular tolerance level will have to maintain a database of testing samples for all shipments and increase the number of test per shipment, regardless of the origin.

The interest of the nonzero tolerance level is that if the LLP approvals can be obtained quickly, the sample will not be as large, the authorities will have more time to process all biosafety applications, and trade will not be interrupted at a large scale. New GM events may also come in a rapid succession, and a LLP policy would help in facilitate the thorough review of applications. So even if in theory a zero level policy appears more safe, in a world of multiple releases of complex GM traits, it may in practice be less secure than a LLP policy with a nonzero tolerance level, simply because no national agency can handle multiple applications in a rapid turnover without accelerating its reviews at the expense of thoroughness.

The Codex Annex is therefore a very useful basis for regulation, provided it is implemented pragmatically and in accordance with a country's preference and capacity. But at the regional level, what should be done? Harmonization may appear a first best, because different policies are always more tricky for traders to guarantee. Harmonized LLP application procedures could help applicants for new GM products to send

unified files to all importers for rapid review to the advantage of both importers and exporters. Heterogeneous requirements will encourage developing companies to only apply for LLP approval in major importers, to the detriment of small or less developed importers, who will have to decide whether to reject shipments of products approved in neighboring countries. The fact that borders are often porous in Asia, Latin America or Africa means that if a product is approved at a LLP in a port country, it may move in other countries relatively rapidly, regardless of testing at the major port of entry.

However, full harmonization may not be easy in regions that do not share the same preference and risk aversion for GM products. If it is not possible at the regional level, sub-region could try to have similar approaches. Any move towards synchronization would certainly help. If all countries have similar delays to approve LLPs, supposing they have a nonzero policies, could be quite positive for both importers and exporters. Regardless of regulatory choices, all steps that reduce transaction costs and/or increase confidence will help facilitate trade for the benefit of all concerned.

In the long term, and for countries with lower capacity, integration should be considered as a distinct possibility. Having a sub regional entity able to process LLP approval in a rigorous manner and keep track of movements of new GM events would both reduce costs (by pooling resources and capacities) for each country, and provide a guarantee of rapid reaction to any new occurrence of new GM event in trade shipments. This can also apply to the case of illegal and unwanted GM events that may escape from field trials (like Starlink corn or LL601 rice) but that have not been commercialized by exporters, and for which a zero tolerance level should naturally apply as long as they remain unapproved everywhere.

4. Conclusions

Genetically modified (GM) products are largely traded internationally in a commingled way. Despite the reluctance of their consumers, large western importers of maize, canola and soybeans, like Japan or the European Union have approved the imports of a number of key GM products. But with the acceleration in the release of new GM crop varieties in major commodity exporters (like the United States, Argentina, or Brazil), these and other importers are becoming concerned with delayed import authorizations and the increasing risk of temporary trade disruptions due to the adventitious presence of unapproved GM products conflicting with their zero percent tolerance for unapproved GM products.

To address this issue, members of the Codex Alimentarius have recently adopted a guideline ("the Codex Annex") which proposes the use of a simplified risk assessment procedure for GM products approved at exporters but not yet at importers and potentially present in low levels in commodity shipments. However, this guideline does not specify what level of tolerance countries should apply and which products it should cover.

In this paper, we model the economic effects of different implementation options of low level presence (LLP) policies as proposed the Codex Annex. We first develop a simple analytical model to identify factors for consideration in the design of regulations. We find that three factors will matter: the market effects, the risk avoidance effect and the implementation costs. Each of these factors will depend on the regulatory approach. Table 9 provides a summary of the general effects and conclusions under four different approaches: GM ban, a zero percent LLP policy, a nonzero percent LLP policy and no regulation (all passes).

Table 9. Summary of the main effects of each regulatory option

Option	Probability of rejection	Price effect	Risk effect	Cost effect	Conclusions
GM Ban	1	High	0	Very high	Valid only if any perceived risk exceeds total costs
0% LLP	~1	High until approval	Larger variance	Very high	Valid if high perceived risk and no trust in export
τ% LLP	Moderate	Moderate	Larger variance and mean	Moderate to high	Best solution from trade's perspective
All pass	0	0	Much larger variance and mean	None	Valid if prices matter more than anything else

Source: Author.

As expected, a GM ban is the most costly option, and can only be justified if the country does not import crops that could be GM and/or if it perceived consumption risk of GM products to exceed any possible cost. A LLP policy with a 0% tolerance level is almost identical, but it does not reject imports de facto, and may generate issues of asynchronous approvals. It is only justified if the perceived risks exceed the temporary costs, and/or if there is no trust in the exporter's regulation. A laissez-faire approach is only justified if prices and costs largely exceed perceived risks. Lastly, the use of a nonzero tolerance level LLP policy, as proposed by the Codex Annex, is the best from trader's perspective in that it balances risks and cost considerations.

Low level presence policies are therefore valid intermediates between GM bans and no regulations. That may explain why all countries at the Codex approved such guideline. But our model also shows that the specific characteristics of the policies critically matter. In particular we find three significant factors that will alter whether a LLP policy will be effective and efficient: the tolerance level, the delay for LLP approval, the delay for full approval and the degree of trust in exporter's regulations. If reducing regulatory delays and increasing confidence unambiguously increase total welfare, the choice of the tolerance level will balance perceived risks and costs, and needs to be selected based on local specificities.

We then apply our model to countries of the Asia Pacific Economic Cooperation (APEC), to assess the potential economic implications of different tolerance levels. We find that APEC economies would benefit from adopting LLP approaches, especially given that 63 million metric tons of imported maize and soybeans potentially subject to trade disruption (and with canola and cottonseed 67m tons or 84% of total imports of these products).

We derive the changes in cost of implementation and consumer surplus associated with the use of different tolerance levels compared to no regulation in the case of a new GM event interrupting trade in maize and soybeans. Among other results, we find that the costs associated with different approaches largely vary across countries and commodities. The total welfare costs are very large (up to around $3 billion/year for both soybean and maize if all countries have a GM ban), but they represent maximum values if all countries were affected in the short run and should be considered preliminary estimates. More interestingly, we find significant differences in costs between a zero percent tolerance level and nonzero tolerance level. For instance going from 0% to 5% would reduce total cost by over 70% in both the case of maize and soybeans. The question becomes whether policymakers consider that avoiding the risk of a 5% presence of a LLP approved event, that has been approved at exporters, in shipments, is worth the cost.

Apart from the direct cost implied, and the likelihood of price inflation on shipments going to regulating importers, it should be noted that the degree of flexibility of regulatory approaches will alter the global marketing system. Inflexible solutions will result in rejected shipments and could require rapidly responding transitions from GM countries to other GM countries and from GM products to non-GM products. This will have a cost for all with increased demand for non-GM goods in the short run and then potentially abandonment of higher productivity GM crops that will tighten the global supply of these crops. The choice of regulations is therefore likely to have an influence on global commodity prices, with potential repercussions on consumers, especially those already affected by the food price crisis.

Looking at the future, the question of harmonization will become more and more relevant as new GM products get commercialized. Pooling resources and lowering transaction costs will be essential for ensuring safety and affordability of major grains. The setting up of clear regulations could also help the development of publically or semi-publically developed GM crops with a non-pecuniary objective, which are facing obstacles of liability due to the possibility of unintended introduction into countries with 0% tolerance.

Given all these considerations, the way ahead will be for countries to design, introduce, and implement new LLP policies that are pragmatic, trustable and efficient. More specifically, the following three recommendations provide elements of guidance as to the choice of a tolerance level, limitations in regulatory delays and increased confidence in regulatory systems.

1. Countries should choose a nonzero tolerance level. Practically, these levels should be greater than detection level and compatible with other tolerance levels. They should try to adopt harmonized levels with major trade partners. If the use of a nonzero tolerance level is a sensitive issue, countries may choose different thresholds by type of product based on level of risk: a) fresh food, b) grains for processing or processed food, c) animal feed. Such three-tier approach will lead to new transaction costs but can lead to better results than 0% for all.
2. To reduce regulatory delays, it would be better if LLP dossiers are aligned with exporter's approval. There should be a rapid information flow via workable and reliable database. And if there is a low capacity, regions should rely on group of countries' expertise or use an integrated regional clearance system.
3. Lastly, to increase confidence in exporters' regulations, countries should try to use the same Codex guidelines. In some cases, integration and group decisions could be used to combine expertise. Ultimately, the development of some kind of international clearance system may be necessary to avoid over regulatory burden with 10s of new GM events.

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Appendix: The Codex Annex.

ANNEX 3: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

SECTION 1 – PREAMBLE

1. An increasing number of recombinant–DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (CodexPlant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances.[6]

3. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:

   a. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

   b. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not:

• address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate;

• preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline; countries can decide when and how to use the Annex within the context of their regulatory systems; or

• eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant- DNA plant material.

SECTION 2 – GENERAL AND OTHER CONSIDERATIONS

[6] This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration.

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

8. Paragraph 22 of the Codex Plant Guideline applies.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply.

DESCRIPTION OF THE DONOR ORGANISM(S)

10. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;
B. scientific name;
C. taxonomic classification;
D. information about the natural history as concerns food safety;
E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,
F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants)[7].

DESCRIPTION OF THE GENETIC MODIFICATION(S)

11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.

13. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include:

A) the gene product(s) (e.g. a protein or an untranslated RNA);
B) the gene product(s)' function;
C) the phenotypic description of the new trait(s);
D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and
E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.[8]

14. Paragraph 33 of the Codex Plant Guideline applies.

SAFETY ASSESSMENT

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

15. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.[9]

[7] The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline.
[8] The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline.
[9] The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline.

16. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.[10]
17. Paragraph 37 of the Codex Plant Guideline applies.
18. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. appropriate oral toxicity studies[11] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.[12]
19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.

Assessment of possible allergenicity (proteins)
20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.

Analyses of Key Toxicants and Allergens
21. Analyses of key toxicants[13] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.[14]
22. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.[15]

Evaluation of Metabolites
23. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the

[10] The text of this paragraph was adapted from paragraph 36 of the Codex Plant Guideline.
[11] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.
[12] The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.
[13] Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).
[14] The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.
[15] The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.

potential for the accumulation of metabolites in the food that would adversely affect human health. Food safety assessment in situations of low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).[16]

Food Processing

24. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.[17]

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

25. Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g. those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g. procedures for assessing the human safety of chemicals) should be applied.[18]

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

27. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

28. Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format:

a. name of product applicant;
b. summary of application;
c. country of authorization;
d. date of authorization;
e. scope of authorization;
f. unique identifier;
g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;
h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;
i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[19]; and

[16] The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.

[17] The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.

[18] The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline.

[19] This information may be provided by the product applicant or in some cases by Codex members.

j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

29. This process should facilitate rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

30. The authorizing Codex Members should make available complementary information to other Codex Members on its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

31. The product applicant should provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

32. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing Codex member should be made available.