IPC Alert

International Food & Agricultural Trade Policy Council

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Avoiding a Biotech Trade Wreck

Addressing Regulatory Asynchronicity and Low Level Presence of New Biotech Crops

Farmers around the world, increasingly also in developing countries, are adopting biotech crops given their farm-level yield and efficiency gains. 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, and a significant number of events lie in both research and regulatory pipelines. As the biotech pipeline has expanded, however, regulatory approvals of new biotech crops across different countries have become less synchronized. A large and increasing number of new biotech crops has received regulatory approval for use and cultivation in one or more countries but is still unauthorized in others. Since asynchronicity in regulatory approvals between producing and importing countries implies that some agricultural commodity trade flows may contain events not yet authorized in the importing country, it could lead to costly trade disruptions.

Even when attempts are made to segregate commodity supply chains, low level presence (LLP) of biotech events which are authorized in the exporting but not in the importing country is likely. Trade disruptions arising from zero thresholds for events that have not been authorized in an importing country have already occurred. With the increasing numbers of biotech crops reaching the marketplace, such disruptions are likely to increase and can have significant economic implications across the supply chain unless countries and companies undertake efforts to address asynchronous approvals and adopt a practical approach when faced with LLP situations. One such approach is advocated by the Codex *Annex on Food Safety Assessment in Situations of Low-level Presence (LLP) of Recombinant-DNA Plant Material in Food*, which 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 and if appropriate, declare the unauthorized event "safe for food and feed at low levels" while they wait for the full regulatory review to be completed.

IPC's latest Position Paper, "The Economic Impacts of Asynchronous Authorizations and Low Level Presence: An Overview" emphasizes that a predictable and effective regulatory environment that minimizes asynchronicity of regulatory approvals and implements a transparent, trade-facilitating LLP policy is desirable in order to keep trade options open and agricultural commodity prices in check, in particular amidst renewed interest in food security in the face of escalating commodity prices and tight global supplies of agricultural commodities.

Considerable analysis and attention have been devoted in particular to the likely economic implications of trade disruptions arising from a zero threshold for LLP to European livestock producers, who depend in

particular on imported soy-based feed. **A new IPC series of case studies accompanying the overview examines the likely implications for other countries and regions, demonstrating that LLP related concerns are certainly not isolated to Europe.** These papers examine the extent of regulatory asynchronicity impacting **China, Vietnam and Latin America** and the likely economic implications stemming from LLP trade-related disruptions.

China

China has a biosafety regulatory framework in place for both domestic GM crop commercialization and imports. China imported about four times as many soybeans as it produced domestically in 2010 and is also expected to become a major importer of maize in the near future. Both China's soybean and maize imports are dominated by GM varieties, with most soybean imported from the US, Brazil and Argentina and maize imported mainly from the US.

China's import approval process takes on average 2-3 years, and can only *commence* when a submitter for import approval has already received full regulatory approval in their country of origin, resulting in significant asynchronicity (for maize, for example, only 11 out of some 29 GM events authorized in the US had been approved in China by late 2010). This Discussion Paper indicates that trade disruptions due to China's zero threshold approach to LLP could result in a slight increase in domestic maize price and large rise in soybean price, with knock-on effects on the livestock sector and overall social welfare, and also have repercussions in the export markets.

The paper also points out that although China has commercialized several GM crops and has a significant number in the research and regulatory pipeline, it has so far not opted to seek approval of its GM crop events in any foreign country. This could lead to trade disruptions affecting Chinese rice exports, although these exports are declining, but also growing exports of processed rice products.

Key China recommendations include:

- Soy and maize exporters are well advised to pay close attention to Chinese import approval regulations.
- China should consider embarking on its import approval process before a GM event has been authorized in the country of origin, so as to shorten the regulatory delay.
- China should also take a pragmatic and cost-effective approach to LLP that ensures the safety of imported commodity shipments and minimized disruptions to international trade and domestic market price stability.
- Although China's biotech program is focused on improving its domestic agricultural productivity and food security, it should nonetheless request approvals in trade partners, in order to avoid import bans affecting its rice and processed rice products.

Vietnam

Vietnam has plans for its own biotechnology program system with import authorization and its imports of maize and especially soy and soymeal shipments likely containing GM events have increased considerably since 2005: reaching 80% of total imports in these commodities in 2010. Vietnam is still in the process of implementing its biosafety regulatory framework. Since Vietnam has already been importing large amounts

of GM crops, upon entry into force of its regulations, it will be confronted with having to undertake a large number of regulatory approvals, which can be granted after a product successfully undergoes a ca. 6 months long food safety application process in Vietnam *or* a ca. 2 months long accelerated procedure, if a product has been permitted by at least five developed countries for use as food and no risk has been seen in these countries. The Discussion Paper indicates that whereas twenty-four GM events approved for planting in North America have been approved in at least five developed countries and would therefore be eligible for the expedited approval system, at least thirteen GM events would be subject to the longer approval process.

The paper finds that implementing Vietnam's proposed zero tolerance LLP policy could lead to additional costs ranging from a few million to over $50million a year. A zero tolerance is found to be significantly more expensive than a 1% and 5% tolerance. Furthermore, the paper finds that a zero tolerance would result in a consumer welfare decline of 15%.

Key Vietnam Recommendations include:

- Vietnam's expedited regulatory process for GM events authorized in five developed countries will help address regulatory delays and as such could be used by other countries that will be faced with the need to approve a large number of GM events upon implementation of their biosafety decrees, but it should consider having it apply to GM events authorized in three or less (and not necessarily only developed) countries.

- Vietnam should adopt a non-zero tolerance level for LLP to avoid the significant costs associated with zero tolerance approaches and balance safety objectives with the practical realities of commodity trade.

- To reduce regulatory delays, LLP dossiers should be better aligned with exporter's approval, with a rapid information flow via a reliable database. In cases of limited capacity, small countries like Vietnam should aim to rely on regional expertise or use an integrated regional clearance system.

Latin America

This regional case study examines Latin America, which is home to a large number of importers of agricultural commodities which trade with exporters in both North and Latin America. All major exporters in North and Latin America have extensively adopted biotech crops, while most of the Latin American importers generally have not. With major exporters and significant importers in close proximity, much of the trade of maize, soy and soybeans and processed products occurs through a dense network of exchanges crisscrossing the continent. While there have only been a few cases of trade disruption resulting from regulatory asynchronicity to date, the Discussion Paper argues that the potential for such disruption is likely to increase, with significant economic implications. As new events are brought to market at an increasing rate, the divergent regulatory capacities of individual countries imply the chance for ongoing asynchronicities in the regulatory approvals of new biotech crops across the Americas.

The paper shows that smaller importing countries, whose trade can be more easily shifted across alternative suppliers, would likely experience 2-8% price increases as a result of trade disruptions, whereas larger importers would experience price increases of 9-20%.

Key Latin America Recommendations include:

- Since many Latin American countries with limited technical and scientific regulatory capacity and financial resources will confront a difficult reality upon more fully implementing their biosafety laws,

they should first opt for ways to effectively evaluate the safety of new biotech events at a fast pace or risk costly trade disruptions.

- A pooling of regulatory resources, i.e through regional partnerships and common leveraging reviews and assessments undertaken by countries with well-developed regulatory capacity should be explored.
- Countries in the region are also advised to adopt a non-zero tolerance level for LLP in order to balance safety objectives with the practical realities of commodity trade.

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These studies will be presented at Coexistence 2.0: Achieving Coexistence of Biotech, Conventional & Organic Foods in the Marketplace, being held on October 26-28, 2011 in Vancouver, Canada.

IPC Series on Low Level Presence of Biotech Crops

Position Paper:

- "The Economic Impacts of Asynchronous Authorizations and Low Level Presence: An Overview"
  By Nicholas Kalaitzandonakes

Discussion Papers:

- "China's Agricultural Biotechnology Regulations - Export and Import Considerations"
  By Jikun Huang and Jun Yang
- "Asynchronous Approvals of GM Products and the Codex Annex: What Low Level Presence Policy for Vietnam?"
  By Guillaume P. Gruere

All papers are available at http://www.agritrade.org/Publications/LowLevelPresenceBiotech.html.

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For more information, please contact Katharine Shaw, Program and Communications Manager, at shaw@agritrade.org.

About IPC

The International Food & Agricultural Trade Policy Council promotes the role of trade in creating a more open, equitable, productive and sustainable global food & agricultural system. IPC makes pragmatic trade policy recommendations to help solve the major challenges facing the global food & agricultural system in the 21st century—the need to promote global food security, to sustainably increase productivity, and to contribute to economic growth and development.

IPC convenes influential policymakers, agribusiness executives, farm and civil society leaders, and academics from around the world in order to clarify complex issues, foster broad stakeholder participation in policy deliberations, and build consensus around pragmatic policy recommendations. More information about the organization and its membership can be found on our website: www.agritrade.org.