



IGTC

International Grain Trade Coalition

Low-Level Presence (LLP) Risk Management Policies for Transboundary Movements of Grains and Grain Products for Food, Feed or Processing

September 2013

The International Grain Trade Coalition (IGTC) urges importing governments to adopt policies immediately to minimize trade disruptions resulting from Low Level Presence (LLP) of GM in imported agricultural products currently threatening importing and exporting countries alike and global food security in general.

What is Low-Level Presence (LLP)? LLP is “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) in one or more countries, but may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined¹”

Why is LLP a trade issue? Once an event is commercialized in one or more countries it is only a matter of time before trace levels of the event will appear in international grain shipments. Most countries employ zero thresholds for events not authorized by their competent authorities. Today’s detection technology has made zero a very small number. The international grain industry cannot manage to zero thresholds. Detection of low levels in an importing country of an event authorized in one or more countries at 100% consumption is not a food safety issue. But it is a legal compliance issue – trade stops thereby adversely impacting importing and exporting countries and threatening global food security.

Why is the threat of trade disruptions caused by LLP increasing? The global area seeded to biotech crops continues to increase at about eight per cent per year as producers employ the technology to increase food production per unit of land area in a sustainable manner. In 2012 the area seeded to GMOs in developing countries for the first time exceeded the area seeded to biotech crops in developed countries. The threat of trade disruptions caused by LLP detection continues to increase yearly as the number of countries commercializing the new technology

¹ International Statement on Low Level Presence Policy signed by Australia, Argentina, Brazil, Canada, Chile, Costa Rica, Mexico, Paraguay, Philippines, Russia, United States, Uruguay and Vietnam in 2012

increases and the percentage of GMO products in global trade continues to soar. New policies are urgently required to minimize trade disruptions.

What causes LLP?

- **Asynchronous approval:** may occur when the country of export has already approved a GM event for cultivation, while the country of import is in the process of authorizing it.
- **Isolated foreign approval (often described as asymmetric approval):** may occur when the country of export approves a GM event for commercial production and in the country of import no submission for the approval is sought by the developer of the event or in which an approval is not to be granted for reasons falling outside food safety.
- **Discontinued event:** may occur when in the country of import the approval of the GM event expires and the technology developer does not submit an application for the continuation of the approval.

What does LLP not include?

- **Adventitious Presence (AP) of research events (often described as “field escape”):** AP refers to the unintentional presence of GMOs that have never been authorized in any country on the basis of the Codex international guidelines for food plant safety assessment. There is a significant difference in risk to human and animal health between an event that has never undergone a risk assessment and an event that has passed a Codex based scientific risk assessment and has been determined to be of minimal risk to human health at 100% exposure.

LLP policy objectives:

- provide for human, animal and environmental safety in all circumstances as well as be practical and facilitate trade;
- be scientifically based and internationally consistent by being in line with international food standards from organisations like the Codex Alimentarius;
- encourage importing and exporting governments to work together to improve harmonization of GM policies and synchronization of GM event approvals;
- minimize disruptions of the market by being in line with the reality of the international grain bulk handling and transportation systems as well as food and feed manufacturing processes;
- ensure the viability of the supply of raw materials at sustainable and affordable prices in the country of import and provide legal certainty for the food and feed business operators;
- require biotech developers, producers and subsequent holders to be fully responsible for the commercial activities under their respective remit. However, under no circumstances should the responsibility of the biotech developer in managing the GM event presence and related risk of market disruption be shifted to the producers and subsequent holders.

LLP policy options:

- **Policies for the elimination of LLP:** the full synchronization of event approvals and the full recognition of other government(s) risk assessment systems eliminate the possibility of LLP by having all events approved in both exporting and importing countries simultaneously. These options are the most effective ways of reducing trade disruptions due to LLP. However, while there is an immediate need to address the risk to trade arising from LLP, full synchronization and recognition are difficult to achieve and implement by importing countries;
- **Policies for the management of LLP:** If the risk cannot be eliminated in the short term by synchronization of event approvals and full recognition of risk assessments by other governments, governments have to adopt other options to immediately reduce and manage the risk created by LLP trade disruptions. Proactive domestic risk assessment/risk management policies and proactive international risk assessment processes for LLP are options that are easier and faster to implement by importing governments.

LLP policy scope:

- **LLP policies must apply to both food and feed.** Nearly all crops are produced for food, feed and for processing. While separate risk assessments may be performed for food and feed, final LLP risk management policies adopted by governments must apply to both food and feed;
- **LLP policies must not cover AP of GM events that have never been approved in any country** on the basis of the Codex based food plant safety assessment.

Most LLP policies are temporary:

- LLP policies designed to address asynchronous approvals are in place while the importing government's competent authority performs 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). When approval is granted by the competent authority the LLP policy will no longer apply as the event is fully authorized to enter the country;
- LLP policies designed to address asymmetric approvals and discontinued events remain in place until traces of the event no longer appear in international shipments.

Two elements of LLP Policies:

1. LLP risk assessment: Must be science based to ensure that the event is safe to human and animal health;

- **LLP risk assessment options:**
 - **Recognition of another country's Codex based risk assessment up to a marketing LLP threshold.** Such a policy enables the

country's competent authority to focus on completing full risk assessments to achieve synchronous approvals and avoid LLP situations;

- **Conduct an LLP risk assessment on the GM event based on the Codex LLP Safety Assessment Annex guidelines**, i.e. Codex guideline for the conduct of food safety assessment in situations of low-level presence of recombinant-dna plant material in food²;
- **International risk assessment process to provide countries without risk assessment capacity assurance that events authorized by countries employing Codex risk assessment guidelines are safe at low levels.** Process must be proactive with an objective of having LLP decisions taken within 6 months of the event's first approval.

2. LLP risk management: Once safety is established, LLP risk management policies must provide for different approaches depending on the different LLP sources outlined above.

- **LLP risk management considerations:**

- **Commercially acceptable LLP threshold levels** must be established commensurate with risk
- **LLP risk management policies must not create unintentional increases in food and feed prices.** LLP threshold levels established by the importing government will have significant impact on food and feed prices. Costs increase exponentially as thresholds decrease. International grain trade experience confirms that 5% threshold levels can be achieved with minimal cost impact within the global bulk handling and transportation system. Guillaume Gruere of the International Agricultural Trade Research Consortium in a paper presented in June 2009 on what LLP Policies would mean for APEC countries reported that "going from 0% to 5% would reduce total cost by over 70% in both the case of maize and soybeans."³
- **Environmental concerns should be of minimal consideration in establishing LLP threshold levels for products destined for food, feed or for processing.** These products are not intended for introduction into the environment. Spills can be addressed through notification and clean-up to the satisfaction of competent authorities rather than reducing thresholds and increasing food and feed prices to minimize environmental impact in case of a spill
- **Provide for automatic Di Minimus level** for all events commercialized by a country that employs Codex based risk assessment processes to apply to both food and feed:
 - **Di Minimus Levels** to be in place while Codex based LLP risk assessment is conducted

² http://www.codexalimentarius.net/input/download/.../CXG_045e.pdf

³ "Asynchronous Approvals of GM Products, Price Inflation, and the Codex Annex: What Low Level Presence Policy for APEC Countries?" by Guillaume P. Gruere of the International Agricultural Trade Research Consortium, June 2009

- **Di Minimus levels** are not necessary if the importing government decides to recognize the risk assessments of other countries up to the LLP threshold level established.
- **IGTC recommends a 5% LLP marketing threshold level** for all GM events that have passed the Codex based LLP risk assessment. internationally consistent, commercially practical and achievable at minimal cost

Industry Responsibility: To be linked to the commitment of public and private biotech developers to be fully responsible for the GM event commercialization.

As such biotech developers shall:

- accept full responsibility for the event during the event’s life cycle, following the successful completion of the Codex based plant risk assessment in the country of export. This includes responsibility from the time the decision is taken to commercialize the event for seed to produce grain for food, feed or for processing in countries of origin to the time following discontinuation when final traces of the event fall below regulatory requirements in major markets;
- seek LLP and full approvals for new events simultaneously in the importing countries, before there is a risk of the event appearing in international shipments. When events are discontinued, they have to ensure that the discontinued events continue to meet the regulatory requirements in place in major markets, while being placed in a specific LLP category;
- adopt Biotechnology Industry Organization’s (BIO) 20012 Product Launch Stewardship Program of no commercialization of new modern biotechnology crop events until major market approvals are in place unless the product is in an LLP Stewardship Program employing channeling systems to be in compliance with the established LLP threshold in an importing country
- Producers and subsequent members of the supply chain must be in compliance with regulatory requirements to ensure shipments are in compliance with LLP thresholds.

Conclusions: The most effective LLP policies are policies designed to eliminate LLP

- **Fully Synchronized Approvals of Events:**
 - If the approval process in importing countries is fully synchronized with the approval process employed in exporting countries, then no LLP trade disruptions will occur
 - **Exporting and importing governments** must work together to improve synchronization
 - work together to develop common approval data packages
 - work together and exchange information during the risk assessment process

- recognize a portion of the risk assessment that they determine to be equivalent with their own analysis, such as animal health
 - **Importing governments** must examine their approval systems to ensure there are no unnecessary impediments that could create delays
 - **Technology developers** must submit necessary approval data packages to major importers at the same time as data packages are submitted to exporters.
- **Full Recognition of Risk Assessment Processes:** Another effective policy option available to countries to avoid LLP trade disruptions is for governments to enter into bilateral or regional agreements with other governments to recognize equivalency in each country's Codex based risk assessment system. This option would stop LLP from occurring as the events would be approved as soon as the first country approved the product.