

Global Alliance for Ag Biotech Trade (GAABT)¹
Practical Approach to Address Low Level Presence (LLP) of Agricultural
Biotechnology-derived Plant Products in Food, Feed, and Grain for Processing (FFP)

Proactive Threshold Based on Exporting Country Authorization

This approach proposes a proactive solution that could be implemented by a national government of an importing country. It does not require development of bilateral or multilateral agreements between trading partners. The approach includes a combination of: (i) a provision creating a proactive LLP threshold for the LLP of biotech-derived plant products in FFP imports that have been authorized by at least one country (e.g. the exporting country), on the basis of a food safety assessment undertaken in accordance with the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline), but where that product has not yet been fully authorized as FFP in the importing country; and (ii) a mechanism to motivate the submission to the importing country's regulators a safety assessment dossier for the product in question within a certain period of time.

Definition

- LLP is defined as low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline in one or more countries, but may on occasion be present in food in importing countries in which the regulatory approval process is not yet complete.

Detection Limits

- The analytical limit of detection (a "practical zero") is defined as a value of 0.2%, which provides predictability by avoiding false positive detections caused by either sampling inhomogeneity or detection method variability. It is considered the reliable quantitative threshold for routinely used method after accounting for measurement uncertainties from sampling and analytic procedures.

Thresholds

- An LLP threshold of 5% for FFP products is defined for events authorized for use as food in at least one other country whose regulatory system operates in accordance with the Codex Plant Guideline.²
- An LLP threshold is based on single events only; LLP thresholds are not cumulative.

¹ The Global Alliance for Ag Biotech Trade is a "farm to fork" industry coalition that brings together different parts of the agricultural value chain. Working together, we encourage the development of trade policies which facilitate the movement of seed and grain and reduce the potential for trade disruptions. The Alliance represents stakeholders from grower and producer groups, grain and feed handlers, food and seed industries, and technology providers. For more information, please visit www.gaabt.org.

² The GAABT LLP approach is similar to that proposed by the Colombian Ministry of Health and Social Protection in a draft resolution of May 2014. That resolution includes a provision creating a 5% LLP threshold for LLP in food imports that have been approved by at least one country on the basis of an assessment of food safety in accordance with Codex Plant Guideline where that product has not yet been approved for food use in Colombia.

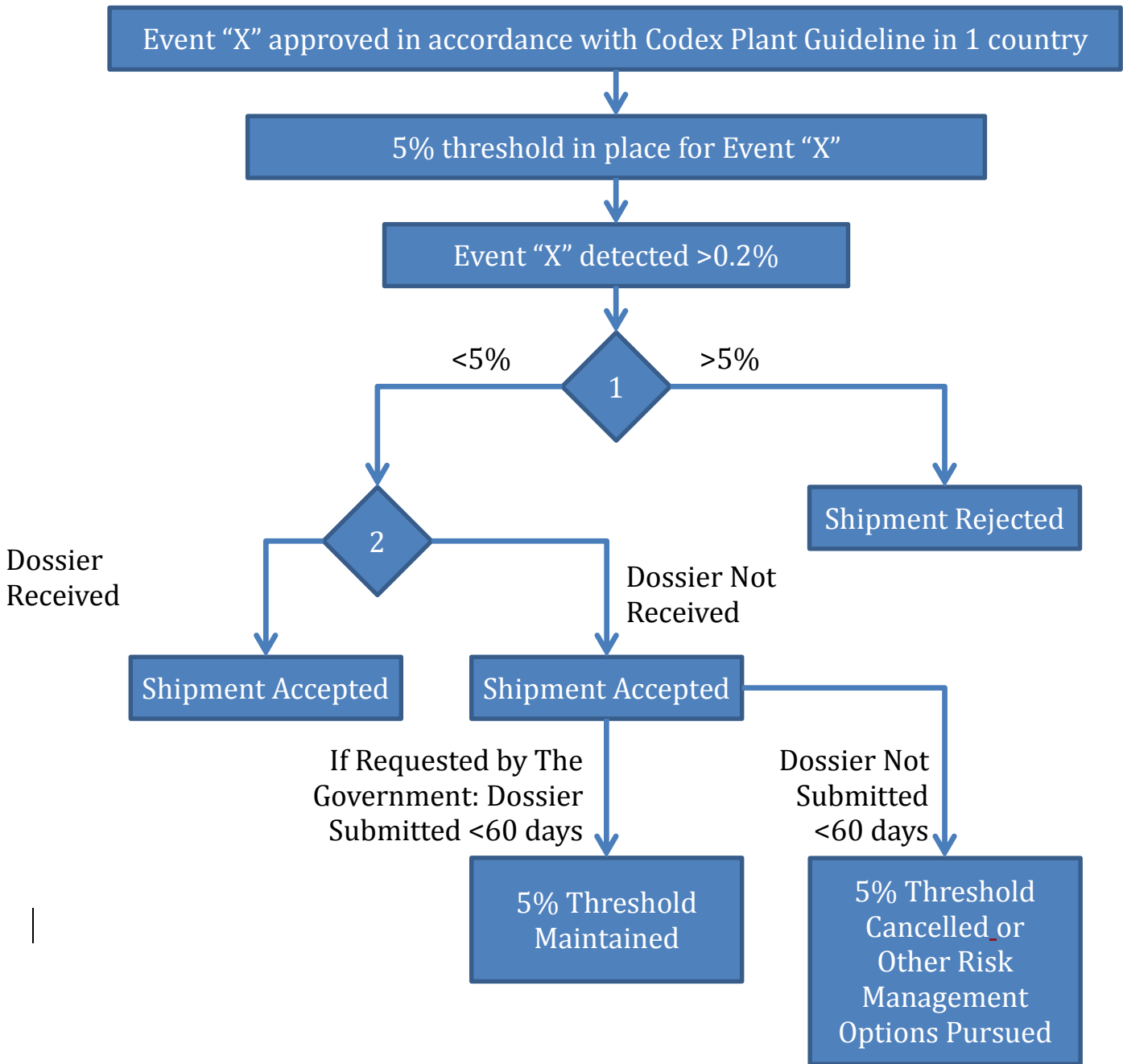
Process (See Appendix 1 for a visual representation of the process)

1. If an event that is not yet authorized in the importing country is detected above the LLP threshold, then the shipment should be managed in accordance with relevant national laws and regulations.
2. If an event that is not yet authorized in the importing country is detected at or below the LLP threshold AND the government has previously received a regulatory submission for FFP for that event, then:
 - The shipment shall be accepted.
 - No action is required by the importer, shipper, or developer.
3. If an event that is not yet authorized in the importing country is detected below the LLP threshold AND the government has not received a regulatory submission for FFP for that event, then:
 - Option 1: The government can decide if any further action is warranted.
 - Option 2: The shipment shall be accepted and the government will notify the developer of the event that they have 60 days to submit a dossier for approval of the event as FFP.
 - If the developer submits a dossier within the 60-day period, the 5% threshold will remain in force until the FFP evaluation process is completed.
 - If the developer does not submit a dossier by the end of the 60-day period, the 5% threshold may expire for subsequent imports or the government may take further risk management actions at its discretion.
 - If the FFP evaluation process results in a negative opinion or unauthorized status, the 5% threshold will expire and the government may take further risk management actions at its discretion.

Regulatory Action by the Importing Country

- Given that a full safety assessment has already been undertaken by at least one country, this approach does not require or rely upon a separate LLP risk assessment by the importing country detecting the LLP.

Appendix I
Proactive Threshold Based on Exporting Country Authorization
Process Flow Chart



Appendix II
Additional Questions About GAABT Positions on LLP Policies

1. Why does GAABT support a 5% threshold in this practical approach?

- Recognizing that LLP situations involve agricultural biotechnology products that have been determined by a risk assessment consistent with the Codex Plant Guideline to be safe to human and animal health and the ag biotech product is subject to further regulatory clearance by the importing government - the respective importing government should assign a technically feasible, cost effective and practical threshold to accommodate the importation of commodities that may contain the crop biotechnology event that is yet to be provided full import approval for use in food, feed and processing.
- Economic modeling indicates that a threshold at excessively low percentage will lead to a significant increase of the price of food. GAABT supports a 5% threshold as all food safety concerns have been addressed, and governments are encouraged to adopt LLP policies that do not create unnecessary and costly disruptions to supply chains globally. International trade experience confirms that 5% levels can be achieved with minimal cost impact within the global handling and transportation system.

2. What are some key best practices for developing an LLP policy?

- Harmonization of policies for both food and feed imports: LLP policies must apply to both food and feed. Nearly all crops are produced for food, feed and for processing. History confirms that split approvals (separate approvals for food or feed only) often lead to costly trade disruptions. While separate safety assessments may be performed for food and feed, LLP management policies adopted by governments should apply to both food and feed.
- Proactive protocols applied in all cases: Recognizing that the purpose of LLP policies is to avoid trade disruptions, protocols to manage LLP must be proactive, transparent and predictable. Agreements between buyers and sellers of bulk commodities are typically finalized three-six months ahead of delivery. Understanding the legal status well in advance of harvest of an ag biotech product currently in production is critical to ensure that products move predictably from areas of surplus to areas of deficit and in the most efficient manner possible. Failure to develop and implement a proactive, transparent LLP policy could lead to increased trading risks, such as demurrage charges, risk premiums and supply shortages for the country of import.

3. What is GAABT's view of an LLP policy that includes an expedited LLP risk assessment?

- GAABT understands that as each jurisdiction works with its industry stakeholders to find an approach that is achievable under existing legislative and regulatory frameworks, many approaches to managing LLP may be considered.
- GAABT's proposed solution supports creation of a proactive LLP threshold for ag biotech products that have been authorized by at least one country in accordance with the Codex Plant Guideline, but where that product has not yet been fully authorized for FFP in the importing country. It does not contemplate the

completion of a separate risk assessment for LLP purposes. Both the timeliness and outcome of such a process would be uncertain, and a policy that incorporates a separate risk assessment for LLP purposes may not provide adequate predictability nor facilitate trade.

- However, if a government desires to conduct an expedited risk assessment of the LLP situation, it should conduct that assessment in a proactive manner upon receipt of a request to do so by an applicant. GAABT supports a timeframe of no more than 60 days from receipt of an application to a finding by a regulator.
- Expedited risk assessments may be conducted by reviewing information and conclusions in published safety assessments from other competent regulatory authorities. Alternatively, regulators could define a limited data set of information to be provided by the applicant in relation to an LLP risk assessment, consistent with the requirements of Annex III of the Codex Plant Guideline.
- If the applicant has provided a complete data set and is currently seeking a full food/feed approval, the LLP threshold should be valid until the full food/feed approval process was complete.

4. How can an importing jurisdiction ensure compliance with the threshold?

- Once a low level presence policy has been established in a country of import, there may be requirements to assure that the presence of the event in imported commodity shipments intended for use as food, feed or for further processing is compliant with that policy, including that it does not exceed the threshold for that event.
- A key objective of LLP policy is trade predictability. Approaches that rely entirely on routine testing of imported commodity shipments to ensure any LLP is at or below the stated threshold do not meet the requirements of an LLP policy for assuring trade predictability and are not practical or efficient for the commodity supply chain. Testing is expensive (capital investment in testing laboratories, personnel, etc.), time-consuming, and is subject to sampling and detection errors. As such, it unnecessarily risks jeopardizing the predictable flow of commodities into an importing country. This increased risk translates to increased cost for all stakeholders.
- GAABT believes that one approach to compliance is through management practices employed in the country of production. Compliance with thresholds could be addressed using system evaluations or process control systems. These approaches can be designed to meet the same quality standard (i.e. a defined threshold), but in a more transparent, proactive, economical and efficient manner. Systems evaluations are common in other sectors of global agriculture and food trade (e.g. the OECD Seed Schemes for varietal certification), and these experiences could be adapted to production and handling systems that deliver food, feed, and grain for processing to customers around the world.

5. What is GAABT's view of potential work by governments in the Global LLP Initiative on a multilateral approach to LLP?

- GAABT supports ongoing bilateral and multilateral efforts by countries participating in the GLI to understand commonalities in their data requirements and safety assessment processes. GAABT encourages GLI governments to use the

knowledge of these similarities in their regulatory assessments to support efforts to develop workable national LLP policies that are consistent with the principles and criteria articulated in the GAABT documents.

6. Does the LLP approach described here apply to single events only?

- Biotech traits are typically introduced in crop plants as individual “events”. In turn, regulators evaluate the safety of, and authorize the use of individual single events.
- Increasingly, new varieties or hybrids contain combinations of individual events that are brought together by conventional breeding. These are referred to as “stacks” or “breeding stacks”. Events are often combined in a “stack” to deliver the characteristics that growers desire in a single seed. For example, insect protection traits may contain individual events that provide multiple modes of action or protect against more than one damaging pest.
- Where crops containing individual single events have each been determined to be as safe as their conventional counterparts in at least one country, it can generally be concluded, based on the knowledge and experience of conventional breeding, that the presence of a breeding stack containing multiple single events is also as safe as the conventional varieties (Steiner et al., 2013; Pilacinski, et al., 2011, Kok et al., 2014).
- Accordingly, GAABT believes that a reasonable LLP threshold should apply to individual events in a grain shipment and not cumulatively in the rare instance when multiple events that are not yet approved may be present. This stance is scientifically supported by the safety demonstrated for the numerous breeding stack products that have been on the market for many years and reflects the realities of the mixes of varieties present in commercial grain trade.
- A cumulative event threshold would be impractical to implement and increase compliance uncertainty for government officials, grain exporters and importers.

7. What happens if an event is not approved and a threshold is cancelled?

- Developers will be strongly motivated to maintain the 5% threshold (by ensuring that a safety assessment submission dossier is submitted within 60 days), as a failure to do so could cause disruption in the value chain.
- If the event is not approved, the 5% threshold is cancelled for an event (Event X). The 5% threshold would be re-established when a dossier is received by the appropriate regulator.

8. Why should LLP be considered differently than a product not yet approved by any regulatory authority (i.e., Adventitious Presence)?

- The very definition of LLP means that the product has already undergone a full and rigorous safety assessment, has been found to be safe and has been authorised for unrestricted use in FFP by the competent government authority in at least one country. For that reason, LLP of that product should not be thought of as a food or feed safety issue for other countries. Rather, it is an issue of noncompliance with the importing country’s regulations for a product with at least one existing completed full safety assessment and a history of safe use.