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for Ag Biotech Trade
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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 LLP Thresholds Based on Exporting Country Authorization

INTRODUCTION:

This document outlines a specific preferred policy position endorsed by the Global Alliance for Ag Biotech Trade (GAABT) to address trade disruptive situations occurring because of the asynchronous approval of products of plant biotechnology. In addition to the position, this document also outlines some potential implementation options that a country could consider. Together, this type of approach can meet the needs of a proactive solution that is temporary in nature to minimize potential trade disruptions while also ensuring predictability, safety and enforceability and facilitating the adoption of new innovations.

Definitions:

Grain: The seeds or fruits of various food plants including the cereal grasses and in commercial and statutory usage other plants (such as the soybean). For the purposes of this policy, "grain" includes primary processed products such as protein meals and may include all such seed or fruits from a given country of origin.

LLP: Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline[2] 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.

Process Controls: The wide array of measures that exist or can be put in place along the value chain to manage a range of quality standards and regulatory or commercial requirements. In the context of this document, process controls are measures implemented by stakeholders (e.g., technology providers, growers, grain operators and processors) at their respective points in the value chain which manage the presence of an event in commodity shipments (see examples in Annex 4, Question 3).

Compliance Verification Approach: The approach used by a regulatory agency to assess compliance with a policy, requirement or rule.

[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] http://www.fao.org/input/download/standards/10021/CXG_045e.pdf

Enforcement Response: Appropriate actions taken by a regulatory agency in response to non-compliance with a policy, requirement or rule.

Setting an LLP Threshold:

GAABT recommends an LLP threshold of 5 percent for imports of grain for food, feed and processing (FFP). This threshold level is not linked to safety, because it is applied only to events authorized for use as food in at least one other country whose regulatory system operates in accordance with the "Codex Plant Guideline" (the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)).

A 5 percent threshold is pragmatic and often achievable in the bulk grain handling system without significant cost increases. An LLP threshold is based on single events only. LLP thresholds are not cumulative. A cumulative event threshold would be impractical to implement and increase compliance uncertainty for government officials, grain exporters and importers. This is further discussed in Annex 4, Question 8.

This approach proposes a proactive solution to manage LLP that can be implemented by an importing country government. This approach does not rely on having bilateral or multilateral agreements in place between governments, although such agreements may also offer value in some situations. It does require government communication with, and actions by, the value chain. The approach includes a combination of:

i) An importing country deciding to apply an LLP threshold for an event in imports of grain for FFP. This could occur automatically, as a matter of standard practice following any approval of a new event for cultivation by a trading partner, or on a case-by-case basis, upon request from the relevant technology provider or another party. Thresholds could be applied in one of two conditions:

   a. When an event has not yet been authorized for FFP use by the importing country, but that event has undergone a food safety assessment and been authorized by at least one other country (e.g., the exporting country) or,

   b. When an event that at one time was fully authorized by the country for FFP use has been retired from commercial production and the event's approval has not been renewed by the country.

   Such a threshold is hereafter identified as an "LLP Threshold".

ii) Technology developers providing an LLP focused protein safety summary, based on or consistent with the Codex LLP Annex, on a publicly available website immediately following the first Codex-consistent food approval of the event in any country.

iii) Prior submission of a safety assessment dossier to the importing country by the technology developer, or a commitment to promptly do so.

iv) Provision of a detection method and reference materials by the technology developer, for use by the importing country for appropriate compliance verification (note: testing is not always required, depending on the importing country's approach, discussed below).

v) A timely notice from the importing country on the adoption of an LLP threshold that provides information to industry stakeholders about acceptable options for meeting importing country requirements.

Implementing an LLP Threshold:
(See Annex 1 for a visual representation of the process)

After an importing country decides to manage LLP using a threshold approach, import authorities must determine how LLP thresholds will be implemented. This includes communicating with stakeholders and discussing any practical considerations that may arise.

Regulators will also need to consider the need for compliance verification activities (if any). A compliance verification approach should recognize that the safety of the product has already been established as it is approved for consumption by at least one country in accordance with the Codex Plant Guideline.

Regulatory agencies might take a variety of factors into account when selecting a risk-proportionate compliance verification approach for an LLP threshold while providing for the least trade-disruptive measures. These are factors such as:

- The status of the domestic approval for the event (e.g., has a dossier already been received and is its safety review underway or complete?)
- Regulatory cooperation with countries in which the event is approved for FFP
- Practical considerations learned from past official and commercial successes and experiences implementing LLP and other thresholds and process controls throughout the logistic chain. For example, quality standards, process controls that include marketing thresholds, and SPS measures that include tolerances and mitigation measures.
- Chain of product custody and end use
- Information about the export supply chain and the various non-regulatory measures in place that serve to manage LLP (e.g., process controls)
- Principles of risk-based resourcing and the potential need to assign compliance resources to issues which, unlike LLP, could pose health or environmental risks at the border.

- Implementation costs and the impact of the measures on trade predictability. Burden on the value chain should be minimized to the extend practical and appropriate

Depending on these and any other relevant factors, the importing country should assess a range of potential compliance activities that could be undertaken, e.g.,

- employing no specific import control measures related to LLP
- Requesting information around process controls or other non-regulatory measures taken by industry and exporters along the entire supply chain to prevent or reduce LLP.
- Reporting, audit or testing of the grain supply at an appropriate frequency (e.g., at a low frequency (up to 5 percent of relevant supply) or at a higher frequency (greater than 5 percent of relevant supply)

GAABT supports the use of science-based and risk-commensurate compliance verification criteria. Sample compliance considerations and approaches are presented in Annex 2.

Possible Outcomes of Applying an LLP Threshold:

A. If all compliance measures set by the importing country are met:
   - Grain is accepted for food, feed and processing; and
   - No further action is required by the developer, importer, or shipper.

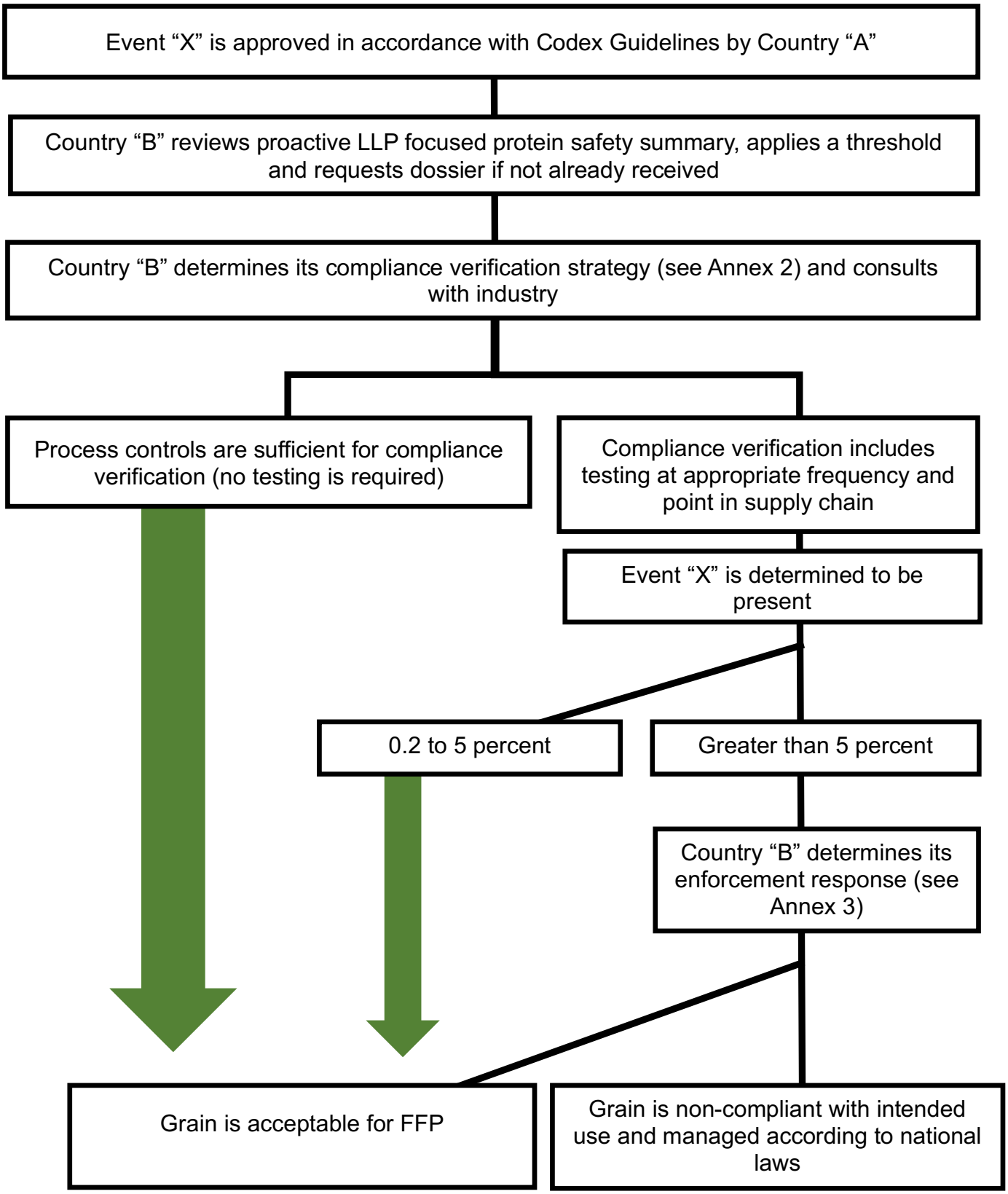
B. If the event is present above the threshold, or if other requirements (e.g. submission of a dossier within 60 days, LLP focused protein safety summary, etc.) are not met:
   - The importing country will select an appropriate response (e.g., ranging from warnings to more significant measures, depending on the nature of the non-compliance) in accordance with their enforcement approach and all relevant laws, regulations and policies (see Annex 1 and Annex 3).

Enforcement responses are usually aimed at reducing the level of risk posed by the non-compliance, and in cases such as LLP where there are no risks posed, encouraging a return to compliance with applicable laws, regulations and policies.

Supplemental Information:

Additional detail about certain aspects of LLP thresholds, as well as GAABT positions on LLP policies is included in Annex 4.

Annex 1: LLP Compliance and Enforcement Flow-Chart[2]



2: In practice, the compliance and enforcement approach may be the same for most if not all events within a certain commodity or for products with similar end uses.

Annex 2: Sample Compliance Verification Approaches

Regulatory agencies may take a variety of factors into account when selecting a compliance verification approach for LLP. Some examples are outlined below for illustrative purposes. Country-specific considerations may vary. In practice, it is likely that the compliance verification approach will be the same for all events within a certain commodity, or for products with similar end uses.

	Compliance Verification Approaches		
Considerations	**Low:** e.g., measures may include reviewing available information (e.g., on process controls). Testing is not performed.	**Medium:** e.g., reporting or audit, may include low frequency clearance testing, (up to 5 percent of relevant grain supply)	**High:** e.g., reporting or audit, may include high frequency clearance testing, (greater than 5 percent of relevant grain supply)
Status of Domestic FFP Approval	Regulatory review is in progress	Dossier requested, but not received after 60 days	
Regulatory Cooperation	Familiarity/recognition of FFP approvals in other jurisdictions		
LLP Process Controls along supply chain	Effective	Effective	Unknown
Compliance resources	Risk-based resourcing in effect		
Cost to Importing Country	Low	Moderate	High to import prohibitive

Annex 3: Sample Considerations for Determining an Enforcement Response

Regulators may take a variety of factors into account when determining the most appropriate enforcement response when an LLP threshold is exceeded, while respecting national laws and guidelines. Some examples that may be relevant are outlined below for illustrative purposes (country-specific approaches may vary).

<table>
<tr><th></th><th colspan="3">Enforcement Approaches</th></tr>
<tr><th>Considerations</th><th>Low:
e.g., grain is accepted, and written or verbal warnings are issued</th><th>Medium:
e.g., grain is accepted, but warnings are issued and compliance approach is reviewed and strengthened if needed.</th><th>High:
e.g., grain is deemed non-compliant with intended use and managed according to national laws and regulations</th></tr>
<tr><td>Intention</td><td colspan="2">Process controls are in place, the non-compliance was unintentional</td><td>No willingness to put process controls in place</td></tr>
<tr><td>Frequency/Duration</td><td>Few or no prior instances of non-compliance</td><td>Increasing rate of non-compliance observed</td><td>Non-compliance is ongoing/systemic</td></tr>
</table>

Annex 4: Supplemental Information

1. Why does GAABT support a 5 percent 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 for human and animal consumption but are 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 in the price of food. GAABT supports a 5 percent 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 global supply chains. International trade experience confirms that 5 percent 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 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 of an event well in advance of harvest is critical to ensure that products move predictably from export to import markets in the most efficient manner possible. The proactive nature of an LLP policy is likewise essential to minimize risks prior to grain for food, feed and processing that may contain the event leaving the country of origin. Failure to develop and implement a proactive, transparent LLP policy could lead to increased trading risks, such as demurrage and concurrent operational cost and timeliness damages, risk premiums and supply shortages for the country of import.

3. What are LLP Process Controls?

The term “process controls” refers to the wide array of measures that exist or can be put in place along the value chain to achieve a range of quality standards and regulatory or commercial requirements. In the context of LLP, process controls are usually non-

regulatory measures implemented by stakeholders (e.g., technology providers, growers, grain operators and processors) at their respective points in the value chain to manage the presence of an event in commodity shipments.

LLP process controls include long-standing industry seed production and other best practices which pre-date LLP issues, as well as newer practices that have evolved to specifically address the trade challenges resulting from asynchronous approvals of new GM crops. Examples will vary regionally and by commodity, but may include:

- Seed production in accordance with standards to maintain varietal purity
- Limited and gradual seed availability during pre-commercial and early product introduction.
- Controlled sale and cultivation of new GM events in regions that do not flow to export channels
- Maintaining best practices for on-farm production and delivery of harvested grain throughout the handling and delivery system
- In some cases, closed-loop production may occur or the value chain may provide for delivery of a new GM event into markets where it is approved
- As appropriate, monitoring for LLP may be performed by industry representatives at various points in the value chain as part of a quality control maintenance

Process controls are complementary to other measures that also help to reduce the potential for LLP in commodity shipments such as:

- Minimization of asynchronous approvals through product developers applying for global authorizations in a concurrent and timely fashion to all significant markets
- Importing countries endeavoring to provide predictable time frames for completion of safety assessments

Process controls can assist regulators when considering the most appropriate and cost-effective way to verify compliance with an LLP threshold. They are common in other sectors of global agriculture to mitigate risk, achieve quality standards and to otherwise ensure that products meet regulatory and customer requirements.

In many ways, LLP process controls are like the systems-based approaches that have been adopted in other regulatory domains (e.g., OECD Seed Schemes for varietal certification, plant pest management systems approaches, organic certification, and even in food safety systems that rely on manufacturing controls rather than end-product testing).

4. Is Testing Necessary to Verify Compliance with an LLP Threshold?

Although testing may be a common compliance verification tool when thresholds are used to manage food safety risks, it should be remembered that LLP thresholds serve a different purpose. LLP thresholds are a legal compliance issue, not a food safety issue, because they are implemented only after an event has been approved for food use in at least one country in accordance with the Codex Plant Guideline. Several considerations should be carefully weighed before an importing country decides to test for compliance with an LLP threshold.

Countries will typically have finite resources that can be devoted to sampling and testing at the border. Allocation of resources to LLP testing may reduce an importing country's capacity to test for agents that do pose potential risk, such as microbial food-borne pathogens (E. coli) or quarantine plant pests.

In addition, a key objective of an LLP policy is trade predictability. Compliance verification strategies that rely on the regular testing of shipments may place the needs of importing country stakeholders at risk, given that imports of grains and the flow of commodities into an importing country may be disrupted. In addition, testing-focused approaches are expensive (capital investment in testing laboratories, personnel, etc.), time-consuming, and subject to sampling and detection errors. This translates to increased costs for all stakeholders, recognizing that bulk grain shipments move under commercial contracts which require a high level of predictability and performance along the supply chain.

Costs to consumers and regulatory agencies are important considerations, given the relative risk of LLP, its temporary duration (i.e., only until domestic approvals are in place) and capacity/resources available in some importing countries, particularly when there are alternative strategies.

The grain export supply chain provides assurance to its customers through recognized quality and monitoring processes. Application of such processes to LLP process controls would provide a more cost effective and efficient means to meet the same quality standard as testing (against a defined threshold) and are common in other sectors of global agriculture and food trade.

5. If testing is performed, where should detection limits be set?

The analytical limit of detection (a "practical zero") is defined as a value of 0.2 percent, 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.

6. What is GAABT's view of an LLP policy that includes an expedited LLP safety 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 GM crop products (events) 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. As a full safety assessment has already been conducted for the product, this approach does not explicitly necessitate the completion of a separate safety assessment for LLP purposes.

However, if a government still chooses, an expedited LLP safety assessment may be conducted by reviewing (1) information and conclusions in a country's prior assessment of a given protein, (2) published safety assessments from other competent regulatory authorities or (3) by evaluating the LLP protein safety summary made publicly available by technology developers.

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 is complete.

7. 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.

8. 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 that may be present in the grain for food, feed and processing 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.

9. What happens if an event for which a threshold has been set is not approved for FFP?

Developers will be strongly motivated to take actions that would support maintenance of an LLP threshold by ensuring that a safety assessment submission dossier is submitted within 60 days and other "LLP policy prerequisites" are met.
If the event is not authorized, the 5 percent threshold is cancelled for an event**.** The 5 percent threshold would be re-established when a dossier is received by the appropriate regulator.

10. 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 authorized 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.

11. What experiences have other countries had with LLP thresholds?

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 percent 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.

In addition, a number of countries have technical protocols in place to move away from zero tolerance approaches and facilitate predictable trade, including Japan, the EU, South Korea and Vietnam.