

Global Low-Level Presence Initiative (GLI) Statement:

Principles, Criteria and Practical Approaches for Addressing Low-Level Presence (LLP) in International Food and Feed Trade of Plant Material

Recalling earlier statements to encourage development of practical approaches to address LLP globally and to work collaboratively to address the overarching problem of asynchronous authorizations, including the *International Statement on Low-Level Presence*, the *Communiqué on Approaches to Reduce Asynchronous Authorizations in Food and Feed Derived from Recombinant DNA (rDNA) Plants*, and the *Memorandum on Improving Access to Data and Information for Food and Feed Safety Assessment in Situations of Low-Level Presence (LLP) of Recombinant-DNA (rDNA) Plant Material*,

Acknowledging in accordance to the *International Statement on Low Level Presence*, for the purposes of this statement the definition of LLP for food as 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 determined; and recognizing that practical approaches need to cover both food and feed,

Noting that LLP is an issue of mounting importance, and that alongside the significant growth in global trade in agricultural products, a growing number of countries, including GLI members, are developing, commercializing, exporting, and importing rDNA plant products, and that predictable and reliable trade of food and feed helps contribute to innovation, development of new plant varieties, reduction in the environmental footprint of agriculture, and ultimately to an increase in global food security,

Recognizing that food and feed handling requires careful management to achieve specified quality; that it is unavoidable that bulk commodities may contain low levels of other materials and that occasional commingling in handling, along with biological factors, such as cross-pollination, can result in low levels of foreign materials, including rDNA plant products, in food and/or feed shipments,

Noting that disruptions to trade due to LLP, including those relating to risks of rejection of imports and regulatory non-compliance, can impact both exporting and importing countries in different ways, including reduced access to food and/or feed from imported sources, an inability to meet contractual requirements, and significant commercial losses to importing and exporting parties

Acknowledging that this proposal presents principles and approaches developed to give guidance on practical measures on LLP situations, while maintaining public trust and ensuring transparency;

Recognizing that because individual countries devise measures consistent with their domestic legal and regulatory requirements, each approach may not necessarily be applicable to every country,

In this context, underlining that this document is not binding and its aim is to suggest tools for addressing trade disruptions due to LLP,

We, the undersigned countries, support and encourage the acknowledgement of the following principles for the development of practical approaches to addressing LLP by governments and for bolstering continued industry stewardship efforts:

Guiding Principles for the Development of Practical Approaches to LLP

- Approaches to addressing LLP should recognize that, while food and feed are produced and handled to meet rigorous quality standards through reliance on management systems that help limit the potential for LLP, the scale of bulk food/feed handling and transport makes it virtually impossible to completely prevent LLP.
 - Approaches to addressing LLP should recognize that a zero tolerance policy for LLP may not be practicable under current food and/or feed handling systems and will become increasingly trade-disruptive as new rDNA plant products are approved and commercialized.
- Approaches to addressing LLP should strive to prevent LLP occurrences before they occur and reduce the likelihood and/or number of LLP occurrences.
 - Approaches to addressing LLP taken by governments would ideally work in concert with industry initiatives, including as those designed to prevent the occurrence of LLP.
 - Approaches to addressing LLP by industry should consider the potential for LLP occurrences as soon as a product is authorized in the country of origin but not yet in the country of import.
- Approaches to addressing LLP should recognize that the rDNA plant product of a potential or actual LLP occurrence has, by definition, received regulatory authorization for food and/or feed use in at least one country.
 - Approaches to addressing LLP should foster confidence and trust in safety decisions among countries.
 - Approaches to addressing LLP should take into account information supporting authorization of the rDNA plant product in other countries. Such information may be available at the Food and Agriculture Organization (FAO) of the United Nations Genetically Modified (GM) Foods Platform database or through product sponsors.

- Approaches to resolve actual LLP occurrences should encourage commercial entities to make available to importing countries relevant information about the safety of plant products that have received regulatory authorization in other countries.
- Approaches to addressing LLP should be science-based and practicable, facilitate predictable trade, minimize disruption to trade, and be consistent with relevant domestic law and regulations and international trade obligations.
- Approaches to addressing LLP should recognize that routine detection testing and monitoring of imports for LLP in food and/or feed is a complex and expensive process that may be prone to inaccuracies. Such detection testing and monitoring will become more challenging, both technically and practically, as well as costly, as more rDNA plant products are approved globally.

In addition to the above principles, we support and encourage the following essential elements of a given approach or approaches for addressing LLP, which include efforts by both governments and industry.

Essential Elements of Practical Approaches

- **Safety:** Before structuring an approach to mitigate the trade impact of LLP incidents, countries should consider how safety can be addressed. The food and feed safety of the rDNA plant product should be established, for example, by consideration of already completed safety assessments done either domestically or by other countries consistent with the Codex Alimentarius “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants” or by conducting a science-based assessment taking into account, as applicable from the same guideline, “Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food”. These safety assessments can inform risk management decisions by regulatory authorities and determination of appropriate measures for bringing an LLP occurrence into compliance.
- **Compliance:** Before an LLP occurrence, countries should put mechanisms in place to ensure that legal or compliance requirements to protect public health can be satisfied without unnecessarily disrupting trade.
- **Industry Stewardship:** Industry has an active and ongoing stewardship responsibility to ensure that only lawful products are traded in commerce. Practical approaches to addressing LLP developed by countries should fully take into account industry stewardship efforts and, where appropriate, build upon these efforts.

Based upon these principles and essential elements, we support consideration of the following possible approaches by governments and industry as practical means to address LLP. We recognize that these approaches require the establishment of various supporting mechanisms, and

that they could present challenges (e.g., technical, economic, or political) to governments and industry stakeholders.

Practical Approaches

Governments:

- Establish processes to take into account current information, including existing authorizations for full food and/or feed use of rDNA plant products.
 - Consider recognition of authorizations for food and/or feed use made by another country or countries, especially for plant products with a long track record of safety; such recognition could be applied as means of reducing asynchronous authorizations, addressing LLP, and improving credibility of and confidence in oversight decisions.
 - Consider using a list of rDNA plant products that have been reviewed for food and/or feed use by many regions and countries around the world and that are not likely to have adverse impacts on human or animal health as a resource to facilitate a recognition policy and/or inform decisions.
 - Cooperate with other governments, including regionally, to recognize authorizations.
 - Consider information from authorizations for food and/or feed use made by another country or countries.
 - Consider whether information from domestic authorizations for food and/or feed use of similar rDNA plant products is relevant for evaluating the risks posed by an LLP incident and, if so, apply such information, as applicable, to safety assessment of the unauthorized LLP material.
 - Increase communication among and between trading partners regarding new authorizations of rDNA plant products, so as to improve global information exchange.
 - Seek to develop and expand the use of technical dialogues with regulatory agencies from different countries to explore practical options for decision-making related to rDNA plant products.
 - Encourage year-round submission and review of applications for authorization of rDNA plants and plant products.
 - Promptly inform the importer or the importer's agent of an LLP occurrence and of any additional information required to allow the importing country to make a decision regarding an LLP occurrence;

- When available, provide to the exporting country a summary of any risk or safety assessment that the importing country has conducted in connection with the LLP occurrence;
- Work to synchronize authorizations of rDNA plant products over the long term and enhance confidence in authorizations made by other countries.
 - Where possible and appropriate, coordinate regulatory authorizations and develop mechanisms for alignment of regulatory processes.
- Pro-actively identify the potential for LLP situations to occur and provide mechanisms to proactively address food and/or feed safety in such situations.
- Pro-actively develop compliance measures for practical prevention and/or resolution of LLP occurrences. These could include establishment of trade-facilitative compliance thresholds under defined LLP circumstances that address the potential presence of trace amounts of foreign materials.

Governments and Industry:

- Establish mechanisms for early communication and active engagement with product developers, commercial interests, and other governments so that safety considerations can be established before an LLP occurrence or be confirmed expeditiously at the time of an occurrence.
- Ensure availability and accessibility to information on completed domestic food and/or feed safety assessments and authorizations, as national regulations and policies allow.

Industry:

- Conduct a trade assessment to identify key countries of production and import, prior to the commercialization of any new biotechnology product (crop by event).
- Work to synchronize the submission of applications of rDNA plant products over the long-term to reduce asynchronous authorizations.
- Meet applicable regulatory requirements in identified key countries for imports for each country of production prior to the commercialization of a new biotechnology product, unless determined otherwise in consultation with the value chain.
- Conduct early stage consultations (~ 3 years prior to projected commercialization) among the value chain to determine the production management method (e.g., identity preservation) to be used to minimize LLP occurrences after product commercialization.

This includes prompt and transparent communication on the product stewardship and supply chain management practices, and their implementation.

- Follow generally accepted best seed quality practices to prevent the presence of unauthorized products and minimize unintended incidental presence of products authorized in the country of production but not in the destination country.
- Make available prior to commercialization a reliable detection method or test for use by growers, processors and buyers that enables crop identity verification for intended use.

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