

Global Adventitious Presence Coalition
Risk Management Guidance for Setting Low Level Presence (LLP) Thresholds for rDNA
Plant Material in Bulk Grain and Grain Products Shipments

Summary

Adventitious presence (AP) of biotechnology-derived materials in commodity shipments of grains, oilseeds, and their processed products (in this document referred to ***grain and grain products***) remains a significant trading issue and resolution of this issue between trading partners is critical to enable global bulk commodity supply chains to function effectively and efficiently.

In this guidance document, a specific instance of AP will be discussed and referred to as low level presence (LLP). LLP is the adventitious presence of biotechnology-derived plant material in imported commodities that has undergone a full safety assessment and been authorized for use in food, feed, grain and derived products by the competent government authority in one or more countries, including the country of cultivation.

With the approval of the *Codex Alimentarius* Annex on Food Safety Assessment in Situations of Low-level Presence (LLP) of Recombinant-DNA Plant Material in Food, national governments have the opportunity to implement this guidance document and declare that low level presence of a transgenic event not yet approved in the importing country is “safe for food and feed use at low levels”. With the implementation of this guidance document, governments also have the opportunity to establish *de minimus* or marketing thresholds for the LLP of biotechnology-derived materials in grain and grain products.

In general, *de minimus* or marketing thresholds are created to allow bulk commodity supply chains to *maximize the value* of the grain product and *minimize cost inefficiencies* and handling costs associated with grain channeling and quality management. In all cases, *de minimus* or marketing thresholds have been developed based on PRACTICAL application of generally accepted agricultural and manufacturing practices with the goal of assigning technically feasible, cost effective, and practical thresholds for shipment of grain and grain products associated with channeling and quality management.

While defining the threshold for LLP will be the responsibility of individual governments as part of their risk management policy development, the Global Adventitious Presence Coalition (GAPC)¹ believes that guidance on what are technically feasible, cost effective, and practical *de minimus* or marketing thresholds for LLP is warranted. As such, the GAPC encourages governments to consult this guidance document and consider the adoption of a 5% level as the definition of LLP in grain and grain products.

Background

Adventitious presence (AP) of biotechnology-derived materials in grain and grain products remains a significant trading issue and resolution of this issue between grain trading partners is critical to enable global bulk commodity supply chains to function effectively and efficiently. In this guidance

¹ The GAPC is a global industry stakeholder coalition representing the full “food chain”, including the biotechnology industry, grain trade industry, seed industry and food products industry, working together to develop proactive tools for governments to consider in order to avoid trade disruptions due to low-level presence of ag biotech products.

document, a specific instance of AP will be discussed and referred to as low level presence (LLP). LLP is the adventitious presence of biotechnology-derived plant material in imported commodities that has undergone a full safety assessment according to the Codex Plant Guideline and been authorized for use in food, feed, grain and derived products by the competent government authority in one or more countries, including the country of cultivation. Asynchronous approvals of biotechnology-derived products are a major contributor to LLP situations.

As discussed in a companion paper titled “IGTC Strategy for the Development of a Global AP Strategy for Commercialized Transgenic Events”, the GAPC believes that governments can address and resolve the LLP issue through a multi-step process requiring trade and governments to:

- 1) *Focus the international discussion of LLP on the specific case of transgenic events in an LMO or non-LMO FFP shipment that has completed a positive science-based regulatory assessment in the exporting but not the importing country.*
- 2) *Establish an international agreement on the safety assessment standards and mechanisms that would allow for recognition of a positive safety assessment conducted within a rigorous regulatory framework.*
- 3) *With safety of the event established at low levels, initiate the discussion of practical and achievable standards for international de minimus thresholds for LLP of transgenic events that have successfully completed the acceptable regulatory framework.*

With the approval in July 2008 of the *Codex Alimentarius* Annex on Food Safety Assessment in Situations of Low-level Presence (LLP) of Recombinant-DNA Plant Material in Food, the implementation of this Codex guidance by national governments and its application to commercialized products of modern biotechnology would allow governments to declare the low level presence of an event not approved in the importing country as “safe for food and feed use at low levels”.

GAPC envisions that, with safety of the LLP of transgenic events established between trading partners, the development of *de minimus* or marketing thresholds for LLP can be established based on what thresholds are technically feasible, cost effective, and practical for shipment of FFP grain.

The GAPC acknowledges that LLP is not unique to the bulk grain and grain product shipments and believes that LLP is an issue for global supply chains including the seed, food, and feed sectors. The GAPC has already endorsed a companion paper for “Risk Management Guidance for Authorized Events Under Low-Level Presence Conditions in Processed Food Products”. A similar paper addressing LLP in seed is planned for development to complement the work proposed under the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology.

In all cases, setting these LLP levels will be the responsibility of individual governments as part of their risk management policy development. GAPC believes that guidance on what are technically feasible, cost effective, and practical *de minimus* or marketing thresholds for LLP in bulk grain and grain product shipments is warranted. As such the GAPC encourages governments to consult this guidance document and consider for adoption of a 5% level as the definition of LLP in grain and grain products.

What is Low Level?

The potential for the unintended mixing between different crops or other impurities within grain and grain products is well recognized and widely understood in international trade. Numerous standards currently exist to account for the incidental low-level presence of these materials, such as broken kernels, foreign material, diseased kernels. As well, long before the advent of biotechnology, it was well established that seed itself is not 100% pure and has been regulated accordingly.

As is true for other AP standards for grain and grain product shipments, it is well recognized that products from biotechnology-derived plants may be incidentally present at low levels in shipments between producing and importing countries, despite the application of good agricultural and manufacturing practices by the commodity supply chain.

Adventitious presence or low level presence of plant material derived from rDNA plants is the UNAVOIDABLE trace levels of plant materials in commodity grain and grain products that can reasonably be expected to be present consistent with current production practices and industry standards. To this end, the technology developers are committed to stewarding their products in such a manner that the likelihood of LLP of an event not approved in the importing country will remain low. As such, for global bulk commodity supply chains, the primary approach for managing LLP must remain the implementation of rigorous good agricultural practices for the cultivation of biotechnology-derived plants.

In the context of a grain and grain product shipment intended for direct use as food, feed, or further processing, unintentional low-level presence of transgenic events in that shipment could reasonably be expected consistent with generally accepted agricultural and manufacturing practices. The GAPC believes it is useful to look at existing grain and grain product standards to understand and provide guidance on what existing trade and commerce have identified as generally accepted agricultural and manufacturing practices.

Guidance for setting a low-level threshold:

In the evolution of global grain and grain product supply chains, *de minimus* and marketing thresholds have been set for attributes that are not related to safety (like broken kernels) and these thresholds are generally set as a compromise between a reduced quality attribute and the cost of attaining higher thresholds of purity. In general, these thresholds are created to allow grain and grain product supply chains to *maximize the value* of the grain or grain product and *minimize cost inefficiencies* and handling costs associated with channeling and quality management.

As a general rule, the lower the threshold the higher the costs to achieve this specification. Existing standards that strive to maintain low cost and maximize handling efficiencies for grain and grain products, thresholds tend to be in the 3-5% range.

International Standards

De minimus thresholds for grain and grain product shipment attributes have been, and continue to be, established at the international level, including such forums as ISO and Codex. For example, the international ISO wheat standard (Wheat - Specification ISO 7970: 1989) includes maximum

tolerances for other cereals (3%), shriveled grain (8%), harmful or toxic seeds (0.5%), etc. Similarly, the Codex Maize standard (Codex Stan 153-1985) defines thresholds for factors such as broken kernels (6%), foreign matter (2%), diseased kernels (0.5%), etc.

Grain Marketing Standards

In addition to international standards, several marketing standards provide guidance as to what marketing standards for AP are reasonable for grain and grain products that are subject to generally accepted agricultural and manufacturing practices to minimize commingling.

Several US grade standards have been set at 5% for AP including:

- No.2 wheat tolerance for wheats of other classes (FGIS standards May 2006)
<http://archive.gipsa.usda.gov/reference-library/standards/810wheat.pdf>
- US standard for yellow corn. No more than 5.0% of corn of other colors is allowed. (FGIS Feb 2005)
http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/7cfr810.305.pdf
- FGIS Special grades and special grade requirements Flint corn. Corn that consists of 95% or more of Flint corn. (5% AP tolerance) <http://www.oznet.ksu.edu/library/grsci2/ep96.pdf>
- Waxy corn. Corn that consists of 95 percent or more waxy corn according to procedures prescribed in FGIS instructions.(5% AP tolerance)
<http://www.oznet.ksu.edu/library/grsci2/ep96.pdf>

For agricultural biotechnology specifically, there are several examples of AP tolerances that are set to trigger documentation or labeling at the 5% level, including:

- NAFTA trilateral arrangement for labeling a cargo to comply with BSP BCH listing:
<http://bch.biodiv.org/database/record.shtml?id=7375>
- Trade Canada text http://www.agr.gc.ca/itpd-dpci/english/topics/bsp_trilateral.htm
- GM Food labeling tolerance for products derived from modern biotechnology for Japan
- Voluntary GM food labeling tolerance for Canada and Hong Kong

For organic agriculture certification, there are several examples of 5% tolerances that are set to trigger documentation or labeling, including:

- The Canadian Organic Products Regulations. Only multi-ingredient products, the contents of which are at least 95% organic products and single ingredient organic products may bear the logo "Canada Organic;" <http://canadagazette.gc.ca/partII/2006/20061221-x6/pdf/g2-140x6.pdf>

- USDA National Organic Program. The USDA Organic Seal may appear on organic agricultural products that are certified 100% organic or products that are certified as containing at least 95% organic ingredients. <http://www.ams.usda.gov/NOP/indexIE.htm>
- 'Organic Farming - EC Control System' [[Regulation \(EEC\) No 2092/91](#)] to be used by producers whose systems and products have been found on inspection to satisfy EU regulations. Consumers buying products bearing this logo can be confident that at least 95% of the product's ingredients have been organically produced; http://ec.europa.eu/agriculture/qual/organic/logo/index_en.htm

In all cases, these *de minimus* or marketing standards have been developed based on PRACTICAL application of generally accepted agricultural and manufacturing practices. Generally these standards (or thresholds) have been established in consultation between government and industry with the goal of assigning technically feasible, cost effective, and practical standards for shipment of grain and grain products that maximize the value of the product and minimize cost inefficiencies and handling costs associated with channeling and quality management.

GAPC acknowledges that the establishment of LLP thresholds for products made from biotechnology-derived plants is a national government decision and encourages governments to consider this guidance document. Additionally, GAPC encourages governments to consult with their local grain and grain products industry in setting the LLP threshold during the implementation of the Codex guidelines for LLP of Recombinant-DNA Plant Material in Food.