



## Global Alliance for Ag Biotech Trade (GAABT)

*Our world population has grown to seven billion, and is predicted to reach nine billion by 2050. The United Nations Food and Agriculture Organization (FAO) estimates that in order to feed everyone, farmers must produce 70% more food by then. Annual demand for cereals alone will reach three billion tonnes – that's 30% more than in 2011-2012. Annual demand for meat is also expected to rise by an estimated 180 million tonnes, to reach 465 million tonnes by 2050.*

*Tools of **agricultural biotechnology** are being used in countries around the world to help meet this need. Crops that are improved through biotechnology have brought many economic and environmental benefits to farmers, consumers and others involved in producing and processing food. Because many **commodity** food and crops – especially cereals – are produced in one part of the world, and then shipped to consumers in another part of the world, steady and affordable supplies of food rely on efficient and effective trade between countries. A significant share of some of these commodities are now the product of biotech crops, especially those originating from major exporting countries where their safety has been established and their benefits have led to wide adoption by farmers.*

*The plant science industry estimates there will be a three- to four-fold increase in the number of commercialized **biotech crops** available to farmers in the coming years, incorporating innovative benefits for insect protection, weed control, fuel, and fiber, as well as nutritional benefits to consumers. It is crucially important that trade in agricultural commodities – and the seeds used to produce them – flows easily and reliably if we are to continue to meet the world's growing food needs and take advantage of new advances in agricultural innovation.*

### About Us

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, grain and processing ingredients, and reduce the potential for trade disruptions.

The Alliance includes stakeholders from grower and producer groups, grain and feed handlers, food and seed industries, and technology providers.

Current participants include representatives from producer groups, the seed industry, the grain trade and technology providers:

- American Seed Trade Association (ASTA)
- BASF
- Bayer Crop Science
- Canada Grains Council
- Canadian Seed Trade Association
- Canola Council of Canada
- CropLife International and its Global Network of Regional and National Associations
- Dow AgroSciences
- DuPont Pioneer
- The Grain and Feed Trade Association (GAFTA)
- Grocery Manufacturers' Association (GMA)
- Monsanto
- North American Export Grain Association (NAEGA)

National Corn Growers Association (NCGA)  
Syngenta  
U.S. Grains Council  
U.S. Wheat Associates

## Objectives

The Alliance seeks practical solutions to agriculture biotechnology trade-related issues, especially that of asynchronous approvals and **low-level presence (LLP)**.

These solutions should:

- Prevent trade disruption by supporting a proactive approach.
- Be predictable, efficient and achievable for all stakeholders, including governments and industry.
- Be enforceable by government authorities.
- Be amenable to specific thresholds that are realistic, practical and based on the realities of grain handling practices and international trade.
- Be comprehensive in scope, covering products developed and marketed in any country, including products intended for FFP, and both private and public sector traits.
- Be transparent, providing safety assurance to the public.

Additionally, practical LLP solutions for FFP should be based on the following principles:

- Zero presence of commercialized agricultural biotech-derived products in global trade is not practical or achievable due to underlying biological realities, production constraints and commodity handling systems.
- The very definition of LLP includes only products that have already passed a safety assessment by at least one regulatory authority according to the Codex Plant Guideline, thereby reinforcing the fact that products detected as LLP are safe for food and feed purposes.
- Food and feed safety assessments should be science-based.
- Application of LLP solutions is temporary and hence does not replace the goal of obtaining full approval for imports of FFP.
- Risk management approaches should be proportionate to risk.
- Existing national legal frameworks and sovereign authority of individual governments should be respected.
- Solutions should be compatible with international standards and agreements.
- Importing and exporting governments should work together to harmonize agricultural biotechnology policies and synchronize trait approvals for FFP.
- Information related to the commercial and regulatory status of agricultural biotechnology traits should be publicly available, comprehensive and up-to-date.

## History

In the mid-2000s, when it became clear that LLP was becoming a significant trade issue, members of the value chain recognized the need for international coordination around LLP, particularly at the international level. CropLife International formed the Global Adventitious Presence Coalition (GAPC) to bring together several organizations with the common goal of proactively increasing awareness of the trade issue within the international community, and to drive international policy developments on LLP.

In recognition of developments at the global level, the GAPC has evolved into the Global Alliance for Ag Biotech Trade (GAABT). Today this work continues through the Alliance,

whose name reflects the shift in focus. The Alliance has largely the same representation as GAPC, with the addition of several producer and commodity groups across multiple countries.

The GAABT is internationally focused and has a close links to national teams worldwide, including members of the International Grain Trade Coalition (IGTC). It also has engagement from producer groups, and maintains a focus on parallel trade policy development efforts in both grain and seed.

### **Activities and management**

Participants in the Alliance work together on a variety of activities to support our policy goal of safe and efficient trade in agriculture biotechnology commodities. These include:

- Participation in policy dialogues and international meetings to develop consensus on trade issues, including the FAO's [Technical Consultation on Low Levels of Genetically Modified Crops in International Food and Feed Trade](#) (March 2014) and the [Global LLP Initiative](#), a government-led initiative to develop a harmonized approach or set of approaches to address LLP at the global level (2013-2014).
- Development of [briefing papers and other resource materials](#) to review and analyze issues related to biotechnology trade.
- Sharing our views with stakeholders through in-person, written and online communications.
- Supporting capacity development to facilitate development of science-based regulatory policies and training to facilitate the use of existing safety assessments and resources

The Alliance is managed by [CropLife International](#), the global federation representing the plant biotechnology developers. Sarah Lukie serves as the Executive Secretary.

## **I. Our Issues**

### **A. Regulatory review and approval**

Crops that are improved through biotechnology help farmers increase the production of much-needed grains, oilseeds and fiber while better coping with the effects of climate change and using natural resources more efficiently. In order to help secure food supplies and pricing, trade in all agriculture goods must flow safely and efficiently from markets where crops are produced to places where they're needed.

However, the introduction of each new biotechnology crop product raises the potential for disruptions to agriculture trade. To understand why, it's important to understand the dynamics of **regulatory review and approval**<sup>1</sup> for biotechnology crops, within and across countries.

#### ***Approval processes***

New crops improved through biotechnology must undergo rigorous approval processes by competent **national authorities** before entering the marketplace.

The **regulatory systems** in many countries follow principles and guidelines for **food safety assessment** that have been developed by the **Codex Alimentarius Commission**. The safety of biotech food products is systematically assessed relative to their conventional counterparts, identifying and analysing any hazard (such as allergenicity or toxicity), nutritional or other potential difference in safety between the two.

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<sup>1</sup> Red text indicates a defined term. Please see Annex I.

These review processes usually take at least one year in countries where these crops are grown. When the crop is approved (in some countries, **approval** is referred to as “**authorization**”), it may be grown by farmers in that country and go into commodity grain shipments meant for domestic processing and food manufacturing systems.

Importing countries sometimes review and complete their approval decisions for new biotech products in step with review and approval timelines in exporting countries. Ideally this is achieved within 24 months from the date of submission. **Synchronized approvals** in exporting and importing countries thus avoid trade disruptions.

Because grain from the new crop is not allowed into shipments destined for countries where it has not yet been approved, the timing of approvals across agricultural trading partners is critically important for avoiding trade disruptions.

#### *Asynchronous and asymmetric approvals*

**Asynchronous approvals** occur when there is a gap of time between the approval of a biotech trait in the country of origin (or exporting country) and an importing country. Although developers of biotechnology crops strive to apply for regulatory review in all key countries at the earliest opportunity, importing countries generally take longer to complete their process than countries of origin. Also, some importing countries will not accept applications for regulatory review until full approval (authorization) has been granted by one or more countries. This gap in time, which can range from several months to multiple years, results primarily from dissimilar regulatory regimes with differing statutes and review processes across countries.

An **asymmetric approval** (also known as an isolated foreign approval) occurs when a cultivating country has approved a biotech crop, but its developer does not seek approval in key importing countries. This is more common in Asia where biotech crops are developed for domestic consumption rather than export, so they are less likely to be submitted for approval in the EU or United States.<sup>2</sup>

#### *Impacts*

Asynchronous approvals and asymmetric approvals can have the same disruptive impact on trade if a new biotech product is found in a country where it is not approved, and the risk increases as the time gap lengthens. The disruption occurs when **low level presence (LLP)** of the unapproved trait is detected in grain or seed shipments, or in an ingredient or finished food product. Such a situation can result in costly fines, lost revenue on the total grain shipment, expensive testing and clean-up, unsold or destroyed grain or seed, product recalls in importing countries, and the loss of export market share as the importing country sources grain from another country.

Because of this risk, sometimes the lack of approval in an importing country leads to a delay of the commercial launch in the country of origin itself. Even though the country may have approved the biotech seed, seed developers may choose not to make it commercially available until it is approved in key importing countries. For farmers, this means a lack of access to the latest technologies, and a delay in access for new agronomic, environmental and economic benefits.

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<sup>2</sup> Low-Level Presence of New GM Crops: An Issue on the Rise for Countries Where They Lack Approval, A.J. Stein and E. Rodriguez-Cerezo, European Commission, Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS) <http://www.agbioforum.org/v13n2/v13n2a08-cerezo.htm>

Therefore, asynchronous and asymmetric approvals increase the commercial risk and uncertainty for the technology provider and the entire food value chain.

### ***B. Understanding low level presence (LLP)***

Since **comingling** of grain cannot be completely avoided in agricultural production and transport, new plant biotechnology products approved in the country of cultivation may be unintentionally present in small amounts in shipments to countries that have not yet approved them. This is known as “**low level presence**” (LLP): the unintentional, low level presence of an agricultural biotech product approved in one or more countries, but not yet approved in the importing country.

Because the product has already undergone a full and rigorous safety assessment, found to be safe and has been authorised for unrestricted use in food, feed, and derived products by the **competent government authority** in at least one country, low level presence 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.

While there is a complex infrastructure dedicated to the bulk handling and movement of grain and seed from farms to consumers around the world, even the most sophisticated infrastructure cannot prevent different crops or crop varieties — biotech and conventional — from potentially coming into contact with one another. Therefore, despite the robustness of our production and grain trading systems and careful stewardship of all shipments from field to shelf, LLP may occur.

#### *LLP in seed*

Global trade in seed, including for purposes of seed and grain production, testing and breeding, is significant and continues to increase. The seed industry has many practices, processes and systems to manage seed product integrity, with the specific goal of facilitating international seed trade. With growing adoption and use of biotech varieties; however, seed lots may sometimes contain LLP of seed products approved for cultivation in the country of export but not approved in the country of import. Therefore, seed movement is vulnerable to costly impediments and restrictions related to LLP policies. In some instances, these policies have resulted in destruction of crops in the field and seed shortages at critical planting times.

#### *LLP of stacks*

Several biotech products now available have more than one technology, or event, incorporated, or stacked, into the same crop plant. These are sometimes known as ‘**stacks**,’ and the same LLP principles apply as long risk assessments are established for each event in the stack. The increasing number of stacked events makes the need for a global LLP policy even more critical. Today there are approximately 30 approved stacked events in the marketplace.

### ***C. National policies to support biotech trade***

If commodity grain shipments are stopped when LLP is detected, economic consequences can be very significant. These include steep financial costs associated with detaining the shipment (demurrage), financing of goods, costs related to delays while waiting for results of grain analysis, and deterioration in grain quality as the shipment is diverted to other markets, repurposed or destroyed. Trade in a particular commodity can eventually cease if the risks associated with importing that commodity are too high and markets are lost as importers and exporters engage in discussions with inspectors, trade officials, and buyers. Grain supplies and ingredient

pipelines can be disrupted, and commodity or food shortages can occur in the importing country, which can impact food prices.

#### *National policies*

To prevent trade disruptions and their potential to impact food supplies, countries must immediately work towards solutions and trade policies that minimize the risk to trade that stems from unresolved LLP situations.

Recognizing this reality, some countries have implemented policies to promptly review regulatory applications for new biotech products in advance of their entering global trade. Other countries may rely on regulatory safety assessments from another country as reason to allow shipments with certain low level presence, temporarily or permanently.

**Threshold levels** are commonly used to allow a certain level of ‘off-type’ or non-standard grain to be present within commodity supplies without decreasing the value of the product or requiring additional handling costs associated with grain channeling and quality management. Developed based on practical global experience with unintentional comingling of conventional grain products, threshold levels could be applied to LLP of biotech products as well. Furthermore, a **marketing or ‘de minimis’ threshold** may be set by a business in order to market a product with even less or no non-standard (i.e., biotech) content.

However, many other countries are only just beginning to identify mechanisms to address LLP, and many still have *de facto* **zero tolerance** policies for unapproved biotech products. This means that within those markets, it is illegal to sell or distribute a product known to contain a biotech product not approved for food, feed or processing use in that country.

Ideally, countries with fully functioning regulatory systems can manage LLP situations by striving for synchronized approvals with exporting countries, or for completion of biotech product reviews within 24 months from the date of submission. In this context, countries could recognize (or at least consider) valid risk assessments that have been conducted by an exporting country in accordance with the **Codex Plant Guideline** as a basis for granting full approval to the event. The use of Codex Guidelines should encourage countries to move away from current **zero thresholds** and establish practical low-level marketing thresholds.

#### **D. International Support for LLP policies**

##### **Codex LLP Annex**

The **Codex LLP Annex** was adopted by the **Codex Alimentarius Commission**, the international food-standard setting body, in 2008. This guidance document outlines the international consensus that there is a fundamental difference with respect to food safety requirements for instances of LLP when a product has been approved for human consumption in at least one country, as opposed to **adventitious presence** of a product that has not yet been approved by a regulatory authority anywhere in the world.

The LLP Annex was developed to enable importing countries to consider an abbreviated, yet internationally recognized, regulatory review process or risk assessment in instances of LLP. The LLP Annex recognizes that those products are considered “safe” and are fully authorised in one or more countries. Codex members believed the guidance would begin to address and mitigate the problematic impacts of LLP experienced to date.

The Codex LLP Annex calls for the establishment of a publicly accessible online platform hosted by FAO to share information on safety assessment of foods derived from recombinant-DNA plants approved in accordance with the “Codex Guideline for the conduct of food safety

assessment of foods derived from recombinant-DNA plants.” This database, called the [FAO GM Foods Platform](#), summarizes the information on which authorising countries base their decisions on for full food safety assessments, consistent with the Codex Plant Guideline. Participating governments agree to supply the information to the database as soon as they authorise a biotech event for commercial production for food, feed, or processing. Importing countries can then consider this information in order to take a proactive decision on LLP.

While various reactive precedents have been established in specific instances, robust proactive policies have yet to be enacted. When these policies are not possible, the Alliance recommends the proactive use of the Codex LLP Annex by importing countries to conduct an LLP risk assessments and assign LLP thresholds for new biotech products. Upon monitoring the FAO database and learning of a new biotech product, importing countries can proactively review the available safety assessment and perform an LLP risk assessment to create a product-specific policy. This could be done before there is any real possibility of the biotech product appearing in import shipments, thereby avoiding potential trade disruption.

### **Global Low Level Presence Initiative**

The Global LLP Initiative grew out of a meeting hosted by the Government of Canada for like-minded, interested countries to work collaboratively on the issue of LLP, with the understanding that finding global solutions to facilitate the management of LLP will reduce the likelihood of trade disruptions and increase transparency and predictability of trade.

Meetings in March and September 2012 and in September 2013 brought together representatives from the following countries: Argentina, Australia, Brazil, Canada, Chile, Costa Rica, Indonesia, Mexico, Paraguay, Philippines, Russia, South Africa, United States of America, Uruguay and Vietnam. Governments participating as observers have included: China, Colombia, the European Union, Japan and South Korea. The Initiative issued an [international statement](#) on LLP in 2012.

The Alliance supports the government-led efforts in the Global LLP Initiative to establish a harmonised approach to handling of LLP and minimizing asynchronous approvals among participating governments.

### **For more information about GAABT**

#### **CropLife International Contacts**

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# Global Alliance for Ag Biotech Trade

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## Annex I Glossary

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**Adventitious Presence (AP):** refers to detection of the unintentional presence of biotech crops that have not been approved in any countries on the basis of a food safety assessment according to the relevant Codex guidelines. (From working definition in FAO survey)

**Agricultural value chain:** According to [Wikipedia](#), the whole range of goods and services necessary for an agricultural product to move from the farm to the final customer or consumer.

**Agricultural biotechnology:** see biotechnology.

**Approval:** see Regulatory Review and Approval.

**Asymmetric approval** (also known as an isolated foreign approval) occurs when a cultivating country has approved a biotech crop, but its developer does not seek approval in key importing countries.

**Asynchronous approvals** occur when there is a gap of time between the approval of a biotech trait in the country of origin (or exporting country) and an importing country, resulting primarily from dissimilar regulatory regimes with differing statutes and review processes across countries.

**Authorization:** see Regulatory Review and Approval.

**Biosafety system:** See Regulatory system

**Biotechnology:** According to [GMOanswers.com](#), biotechnology is “a set of tools that uses living organisms (or parts of organisms) to make or modify a product, improve plants, trees or animals, or develop microorganisms for specific uses. Examples of biotechnology include traditional applications, such as the making of bread, cheese, wine and beer, and more modern applications to grow or culture cells for research...” **Agricultural biotechnology** uses techniques of genetic engineering to make **biotechnology-derived crops** (or genetically modified crops) for food, feed, fuel and fiber.

**Biotechnology-derived products, biotech products:** Refers to a range of agricultural commodities and products that have been created or produced with the use of genetic engineering, or with an ingredient or component that has been created or produced with such tools. Food-related products may include ingredients, additives and processed foods, while non-food products include industrial products, fuel, and fibers.

**Codex Alimentarius Commission:** An international body established by the UN to develop “harmonised food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. The Commission also provides the coordination of all food standards work undertaken by international governmental and non-governmental organizations... Codex standards are based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO. While being recommendations for voluntary application by members, Codex standards serve in many cases as a basis for national legislation.” The Codex Alimentarius Commission has developed principles and guidelines for food safety assessment of foods derived from modern biotechnology, namely the *Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) (**Codex Plant Guideline**). Annex 3 of the Codex Plant Guideline, *Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food* (**Codex LLP Annex**), describes the recommended approach to food safety assessment in the case of LLP.

**Co-mingling:** Co-mingling occurs when commodity grain produced in one place mixes with grain produced elsewhere, as in a common storage container or shipment.



**Competent government authority:** see National authority.

**Event:** the insertion of a combination of genes (or ‘construct’) into a plant genome to give it a new trait or characteristic, such as insect resistance. A **Stacked Event** is the insertion of two or more combinations of genes into the same plant species to give it more than one new characteristic.

**Food safety assessment:** A food safety assessment for products of ag biotechnology is a special kind of **risk assessment** which is designed to identify whether a hazard, nutritional or other safety concern is present in foods derived from the new products, and if so, to gather information on its nature and severity. The internationally-recognized Codex “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants” follows the ‘principle that the safety of foods derived from new plant varieties, including recombinant-DNA plants, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.’

**Food safety assessment in cases of LLP** are informed by Codex Annex guidelines which recognize that “dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in [the] Annex” describing the recommended approach to the food safety assessment in such situations or in advance preparation for such potential circumstances.  
See also **Risk Assessment**.

**Genetic Engineering:** According to [GMOAnswers.com](http://GMOAnswers.com), genetic engineering is ‘the name for certain methods used to introduce new traits or characteristics to an organism typically involving the use of recombinant DNA methods. While these techniques are sometimes referred to as “genetic modification” or “GM”, “genetic engineering” is considered to be a more precise term.’

**Genetically Modified Organism (GMO):** According to [GMOAnswers.com](http://GMOAnswers.com), the term GMO is “often used to describe organisms developed using the tools of genetic engineering. In plants, GMOs commercially available include corn (field and sweet), soybeans, sugar beets, cotton, alfalfa, papaya, squash and canola. Farmers choose to use GM seeds to reduce crop damage from weeds, diseases and insects, as well as from extreme weather conditions, such as drought.”

**Living modified organism (LMO):** According to the [Cartagena Protocol on Biosafety](http://Cartagena Protocol on Biosafety), “a Living Modified Organism (LMO) is ...any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. ... In everyday usage LMOs are usually considered to be the same as GMOs (Genetically Modified Organisms), but definitions and interpretations of the term GMO vary widely.”

**Low level presence (LLP):** LLP is referred to by Codex 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) (Codex Plant Guideline) in one or more countries that 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.”

**National authorities:** Government regulators with expertise in environmental, food and feed safety who perform and/or review risk assessments of biotechnology crops. Also known as ‘**competent government authorities**’.

**Regulatory review and approval:** The process a country may use to evaluate the safety of biotechnology crops before they can enter the marketplace. Most countries require risk assessments in line with the Codex guideline, which are conducted and/or reviewed by government regulators with expertise in environmental, food and feed safety.

**Regulatory system:** collectively, the regulatory and risk assessment frameworks, processes, structures and authorities that evaluate and make approval decisions to enable research, development and commercialization of agriculture biotechnology crops and their use in food feed, fuel and fiber. Also known as ‘biosafety system’.

**Risk assessment:** According to the [World Health Organisation \(WHO\)](http://World Health Organisation (WHO)), “Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards.” In general, the process consists of the following steps:

- *Hazard identification* of known or potential health effects associated with a specific food

- *Hazard characterization*: evaluation of the adverse effects
- *Exposure assessment*: evaluation of the degree of intake likely to occur
- *Risk characterization*: Integration of the above evaluations into an estimation of the adverse effects likely to occur.

The Codex Alimentarius Commission has developed principles for risk assessment of ag biotechnology product. See also **food safety assessment**.

**Synchronized approvals**: when importing countries review and complete their approval decisions for new biotech products in step with review and approval timelines in exporting countries, ideally within 24 months from the date of submission.

**Threshold**: a maximum acceptable level of non-standard material that can be present in a product. In the context of agricultural trade, according to [GMO Compass](#), ‘the maximum level (in percent) of unintentional, technically unavoidable GMO content in seed, food, or feed that does not [legally] need to be labelled.’ A **Marketing Threshold** may be even lower and set by a business in order to market a product with even less or no GMO content.

**Trade disruptions**: when a commodity shipment or other product is returned, recalled or destroyed due to detection of GM products that have not been approved in the destination country, often incurring additional scrutiny, delays and costs for similar shipments or products.

**Zero tolerance (threshold) policy**: A policy making it illegal to sell or distribute a product known to contain any amount of a biotech product not approved for food, feed or processing use in that country, even if a very small percentage of the unapproved product is found in a shipment of biotech grain or seed products that have been approved.