



ISF View on Low Level Presence in Seed

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Low Level Presence (LLP) in seed is an issue that affects the seed industry at large. The seed industry is global in nature and the movement of seed across national borders is increasing. With the growing adoption and use of genetically engineered (GE) varieties¹, and the current status of global regulatory frameworks and processes, countries are increasingly facing the situation that seed lots can now include LLP of GE varieties approved for cultivation in the country of export but not approved in the country of import. As global seed trade continues to increase, including for purposes of seed production, testing and breeding, seed movement is vulnerable to restrictions related to LLP. Therefore, governments are increasingly devoting more resources to this issue and the seed industry is facing possible costly impediments to seed movement. The International Seed Federation presents this view of LLP in seed with the intent of putting forward information that will be useful to national authorities as they develop their policies for addressing this important issue.² The commitment of the seed industry is to provide farmers with a safe and reliable supply of high quality seed varieties for cultivation.

Definition of Low Level Presence (LLP) in Seed

- LLP in seed is defined as the unintended low level presence of GE seed that has been approved for cultivation in at least one country but not in the country of import.³

General Considerations for LLP Policies

- LLP policies should be science-based, practical, and transparent.
- LLP policies should provide for mechanisms that are proactive and predictable for the global movement of seed.
- LLP policies should provide flexibility with respect to risk assessment approaches.
- LLP policies should acknowledge that it is not practical or achievable to require zero presence of GE seed approved in one country but not approved in the country of import.

¹ Note that in some countries, such as the European Union GE varieties are referred to as Genetically Modified (GM) varieties

² Note that some markets will only tolerate extremely low levels of GE or Genetically Modified (GM) material approved for cultivation in that market in a conventional seed lot. This situation is often referred to as Adventitious Presence (AP). This paper does not address this situation.

³ Note that this seed LLP definition is based on the LLP definitions found in Codex Alimentarius Guideline For The Conduct Of Food Safety Assessment Of Foods Derived From Recombinant-DNA Plants, Annex 3: Food Safety Assessment In Situations Of Low-Level Presence Of Recombinant-DNA Plant Material In Food (CAC/GL 45-2003) and the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology, Environment Risk/ Safety Assessment and Use of Information in Situations of Low Level Presence of Transgenic Material in Seed and Grain Commodities that Can Act as Seed (ENV/JM/BIO/2011/6)

LLP in the Context of Producing High Quality Seed

- Seed production requires management of biological systems. The presence, in low amounts, of other genotypes in a commercial seed lot has historically been recognized as unavoidable and acceptable to the market.
- The importance of seed quality and product integrity has been recognized by the industry since its inception. Tracking, recordkeeping, testing and other measures with appropriate management systems are essential parts of product development and the commercial life cycle for purposes of quality assurance and seed product integrity.
- Existing seed quality standards provide the framework within which seed is moved internationally. Some level of variability is inherent in any biological reproductive system and is reflected in these quality standards.
- The most widely recognized quality standards for variety identity and purity are those established under OECD Seed Schemes and other internationally recognized seed standards. The objective of the OECD Seed Schemes is to encourage participating countries in the use of consistently high quality seed.
- The seed industry manages seed product integrity through production processes based on best management practices, quality assurance processes and quality control systems with the goal of facilitating international seed trade.
- Maintaining a seed variety's trueness to type is critical for market acceptance and quality standards recognize the limits of biological systems.

Principles for Seed LLP Policy Development and Implementation

- In their policy development and implementation, national authorities should recognize and take into account existing seed quality standards and seed industry practices in producing seed products with a high level of genetic integrity.
- If a LLP risk assessment is determined to be necessary, national authorities should take into consideration:
 - Environmental safety as the focus of the risk assessment
 - The low environmental exposure levels associated with seed LLP
 - The existing safety information on the trait-crop combination
 - The publically available data on and familiarity with the trait
 - Recognition of the difference between a LLP risk assessment and a risk assessment for commercial cultivation
- Intentional introduction of GE seed for cultivation in the importing country would need to meet the importing country's normal authorization process.
- National authorities should work toward mutually recognizing risk assessments performed by other competent authorities to facilitate addressing seed LLP situations and to avoid unnecessary disruption of seed movement.
- Risk mitigation should be performed in a manner proportional to an identified risk.
- Zero presence of GE seed approved in one country but not approved in the country of import is not a practical or achievable expectation by national authorities.
 - Testing of individual seed lots at the point of import does not guarantee zero presence.

- Testing for zero presence can create false positives creating unnecessary restrictions to seed movement and trade.
- Implementation of a “zero presence” policy places an unnecessary economic burden on the seed industry not justified from a safety perspective.
- Implementation of a “zero presence” policy limits the availability of advanced seed variety choices for farmers in the importing country.

The members of the International Seed Federation welcome the opportunity to cooperate with national authorities to better understand the importance of LLP to the seed industry and to better understand seed LLP in the context of industry practices and international quality standards. The international seed industry remains committed to providing farmers with seed that is of the highest quality and product integrity.