



Implementation of National Policies for Seed Low Level Presence

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Executive Summary

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 low level presence (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. The International Seed Federation (ISF) presents its view on the implementation of national policies for seed LLP.

The implementation of national policies for seed Low Level Presence (LLP) is discussed by utilizing criteria ISF has identified as being critical to maintaining the global movement of seed. These criteria are used as benchmarks for the discussion of a range of possible policy options for seed LLP. In general, any national seed LLP policy should be proactive, predictable, transparent and science-based. A proactive, science-based, policy that is initiated before trade begins provides the legal certainty necessary to facilitate the movement of seed.

A combination of policy options presented in this paper would make up the components of a comprehensive policy that best meets the described criteria. These components include:

- Thresholds that are based on existing seed quality and varietal purity standards
- Proactive mutual recognition of safety assessments
- Use of “familiarity” to proactively exempt from a safety assessment in seed LLP situations classes of traits with established history of safe use
- Standard sampling and testing protocols if testing is required

Purpose and Scope

This paper presents an analysis of options for the development and implementation of national policies for seed Low Level Presence (LLP). The policy options presented in this paper are discussed in the context of criteria the global seed industry considers to be important to the movement of seed between countries and to maintaining a predictable and sustainable supply chain. The paper only considers policies for LLP in seed and does not address LLP in commodities, food or feed.

- Definition of seed LLP: *The unintended low level presence of GE seed that have been approved for unrestricted cultivation in at least one country but not in the country of import.* This definition is based on the definition used by the OECD.²

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

² Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information. Series on Harmonisation of Regulatory Oversight in Biotechnology No. 55. ENV/JM/MONO(2013)19

The paper, ISF's View on Low Level Presence in Seed³, describes the principles that the global seed industry considers to be important to the development of national or regional seed LLP policies. This paper builds upon those principles and converts them into a set of criteria by which LLP policies can be measured. The paper also describes a range of policy options available to national authorities. These policy options are discussed in relation to the policy criteria important to global movement of seed.

1 Description of the Criteria

The criteria described in this paper focus on the conditions that are needed to facilitate the movement of seed. In general, any national seed LLP policy should be proactive, predictable, transparent and science-based. The criteria described below are not prioritized and are best considered in their totality, rather than as “stand-alone” criteria. As an example, an important criterion is having legal certainty at the border. This legal certainty to a large extent will depend upon a predictable and transparent implementation of policy. Likewise, the criteria of facilitation of trade will be dependent on the other criteria being met. Most importantly, for any policy to create legal certainty and to facilitate trade, that policy should be proactive.

- A proactive policy is a policy that is initiated before trade begins and is not triggered reactively when a seed LLP situation is identified. A proactive seed LLP policy will ensure a predictable and sustainable supply chain.

A science-based, proactive policy will inherently be protective of the environment and public health and will also meet the other criteria listed in the table.

1.1 The Criteria

1.1.1 Environmental and public health are ensured

Given the definition of seed LLP (at least one authorization for unrestricted cultivation), a national seed LLP policy that meets the criteria described in this paper will ensure that the environment and public health is maintained.

1.1.2 Absolute zero is not possible

The most fundamental criteria for the implementation of national seed LLP policies is the recognition that it is not practical nor technically and biologically achievable to require zero presence of GE seed that have been approved for cultivation in one country but not approved in the country of import. It has long been recognized within the seed industry and across the agricultural value chain that, despite rigorous quality management systems that minimize LLP, achieving an absolute zero in managed biological systems, such as seed production, is not possible.

³ ISF View on Low Level Presence in Seed, Adopted in Athens, Greece, 29 May 2013.

1.1.3 Seed quality management practices are recognized

Although achieving an absolute zero is not possible, achieving a high level of seed product integrity and varietal purity is essential to the seed industry in order to meet customer needs and the demands of the marketplace. Therefore, there are best practices that are used in commercial seed production to maintain a high level of seed product quality. National and international standards exist to set upper limits for varietal “off-types” and other species in commercial seed batches. These upper limits recognize that the presence of low levels of off-types is inevitable in seed production. The best practices imbedded in these quality standards are widely accepted by the industry and national seed regulations.

1.1.4 Science- based processes and decisions are in place

Having a science-based underpinning to a national seed LLP policy upholds the integrity of the process and mitigates arbitrary processes and outcomes. A science- based approach is also consistent with a proactive approach in which the policy clearly articulates if and how safety assessments will be addressed in situations of seed LLP.

1.1.5 Policy implementation relies on predictable processes and outcomes

Any national seed LLP policies should be implemented using processes that are well-defined, with explicit and realistic timeframes. The outcomes of these processes should be predictable such that following the process leads to a predictable result or outcome in a timely manner.

1.1.6 Policy implementation includes transparent processes and outcomes

A national LLP policy is unlikely to be predictable unless it is clear to those entities affected by the policy what is expected of them. National decisions and the rationales for those decisions need to be transparent to both the entities directly affected by the policy and the general public so as to promote trust in the policy.

1.1.7 There is legal certainty at the border

Without legal certainty, at both the points of export and import, seed movement is subjected to unnecessary impediments and economic risks. Predictable and transparent processes and outcomes help to provide that legal certainty. Policies that are proactive, rather than reactive, are crucial to providing importers and exporters the confidence and assurance that following the policy will result in a successful movement of seed across a national border.

1.1.8 The policy facilitates international trade

The facilitation of international trade is embedded in the criteria of predictability, transparency and legal certainty. Trade will not be facilitated without these other criteria being met.

1.1.9 Unnecessary regulation is avoided

Any national policy should avoid unnecessary regulation. To the extent that national seed LLP policies can be implemented under existing regulatory frameworks, and meet the other

described criteria, it will not create an undue resource constraint to national regulatory authorities or to regulated entities.

2 Description of the Policy Options

This paper attempts to anticipate and describe a broad range of possible policies that a government could put in place. The possible policy options are not limited to those that could meet the criteria described in this paper as being important to the global seed industry. In fact, some of the options presented below would not adequately meet these criteria. A national LLP policy could, and probably would, encompass more than one option. The options described fall into two general areas: options that center on quality management processes and options that focus on safety assessments.

2.1 The Options

2.1.1 Incorporation of thresholds based upon national or international quality standards

A national seed LLP policy that incorporates seed varietal purity standards recognizes that a variety-specific standard has been met by industry (either international or national). This standard is utilized as the threshold for any unintended presence of seed containing GE traits meeting the LLP definition.

2.1.2 Standardized and accredited sampling and testing protocol

This option recognizes that an absolute zero is not possible and emphasizes the need to have reliable and recognized testing methods in order to minimize the risk of results that are not valid. This approach, sometimes referred to as “defining zero,” would aim to establish the presence/absence of LLP. It would not be utilized as a LLP threshold. Depending on implementation, the protocol could be required at point of export or at import.

2.1.3 Defined criteria for determining the necessity of a safety assessment in situations of seed LLP

Under this policy option, a national authority would define the criteria that would be utilized to determine whether a safety assessment was needed in a situation of seed LLP. The underlying assumption in this option is that a safety assessment would not always be necessary. Some examples of criteria that could be utilized under such a policy are:

- The fact that there is low exposure to the trait
- The fact that a safety assessment for full authorization has been completed by at least one other national authority
- Familiarity with the trait/crop combination and the existence of available safety data
- Identifying a class of traits that would not need a safety assessment

2.1.4 Mutual acceptance of safety assessments

Under this option a national authority would formally agree to accept the safety assessment of another national authority. This mutual acceptance would then be applied in a seed LLP situation such that a *de novo* safety assessment would not be required in that seed LLP situation. The mutual recognition could be very broad, encompassing all traits/crops, or could be more narrowly focused on specific traits/crops. The mutual recognition could be on a bilateral or regional basis. Mutual acceptance of safety assessments would not necessarily extend to mutual acceptance of decisions or to taking no action in a seed LLP situation.

2.1.5 Safety assessment with utilization of existing data

Under this option, a national authority would not require the development of new safety data when addressing a seed LLP situation. This policy option could result in a range of actions by the importing country, including conducting a safety assessment based on the data from the existing cultivation safety assessment.

2.1.6 Independent safety assessment for each seed LLP situation without utilizing other country's data

Under this option, a national authority would not utilize any other existing safety data, nor would it set out any criteria for when a safety assessment would be necessary. They would require a safety assessment with new safety data in each circumstance of seed LLP.

2.1.7 Guidance from national authority on specific crop/trait combinations

Under this policy option, a national authority would make advanced, specific guidance on a trait/crop combination basis. This guidance would be based on the familiarity with that trait/crop combination. The guidance would not provide definitive exemptions. However, the guidance, for example, could provide, on a more general basis, the likely response of the national authority to an LLP situation for that specific trait/crop combination.

3 Discussion of policy options in relation to criteria

3.1 Regulation and practices for seed quality minimize seed LLP

As an identity preserved product, seed must meet a set of quality standards driven by the market and based on science and accepted production practices to achieve the varietal purity desired by that market. The concept is very simple – consumer desires are driven back through the agricultural value chain to the seed industry, a crucial starting point in delivering what the customer is demanding. 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 varietal purity.

As an example, OECD Seed Schemes is a certification process that ensures the varietal identity and purity of seed through requirements and controls that cover cropping, seed processing and labeling operations. Certification under the OECD Seed Schemes sets

maximum thresholds for varietal off-types and provides for official recognition of "quality-guaranteed" seed, thus facilitating international trade and contributing to predictability and the removal of technical trade barriers.

Quality standards and the seed industry's best practices minimize the incidence of LLP in seed. These practices are embedded throughout the steps of new seed variety development, including trait development, breeding, field trials and seed production. Quality standards also recognize the inevitability of the presence of off-types in seed lots and set maximum acceptable thresholds for those off-types. The policy options that are based on these quality standards and seed industry practices will provide the predictability and transparency important to policy implementation by utilizing international systems already in place.

3.2 Regulatory processes for the assessment of safety of GE plants for environmental release

Countries that allow the unrestricted cultivation of crops containing genetically engineered traits have regulatory processes in place for the assessment of the safety of genetically engineered plants for environmental release. Additionally, authorization for unrestricted cultivation will include the assessment and authorization for food and feed. The general principles used for assessments for unconfined release (unrestricted cultivation) are the same as for situations of seed LLP. The safety assessments are based on the characteristics of the plant, the introduced trait, the environment in which the plant will be released, the interaction between the plant/trait and the environment and the intended application. In addition, the OECD has acknowledged that there is existing data on environmental effects that countries can use in their safety assessments⁴.

Safety assessments are derived from the principle that risk equals hazard X exposure. Most safety assessments for unconfined cultivation assume 100% exposure over an extended period of time. In contrast, an LLP situation should be seen in a different context, one of extremely limited exposure over a relatively limited period of time. In a seed LLP situation, there has been at least one safety assessment completed for unconfined release. The information from previous safety determinations is directly applicable in LLP situations. For those genetically engineered plants with broadly used traits, there is an extensive set of information and data that can be utilized.

3.3 Importance of short and long term options

Depending on legal and regulatory frameworks, developing, institutionalizing and implementing a comprehensive national seed LLP policy may take national authorities a period of time before the policy is actually finalized and implemented. While the ultimate goal should be the implementation of a comprehensive policy, there are some shorter term

⁴ Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information. Series on Harmonization of Regulatory Oversight in Biotechnology No. 55. ENV/JM/MONO(2013)19

measures national authorities can take to help minimize disruptions in seed movement and address seed LLP.

3.3.1 Role of standard sampling and testing protocols in short term options

The absence of, or non-standardized, sampling and testing protocols relative to seed LLP have detrimental impacts on the movement of seed and result in legal uncertainty for importers and exporters. Requests of “100% purity” or “absolute zero tolerances” are terms that are not compatible with the realities of plant breeding, seed production, or agriculture in open-field environments.

Establishing standard protocols that are recognized among trading partners will provide relief from the existing uncertainty and patchwork of protocols. Additionally, standardized protocols should include a process that accredits third party and private company laboratories. If sampling and testing is required, as part of a seed LLP policy, it should only be required at the point of export. Testing at the point of import creates unnecessary legal uncertainty and economic risk to both the exporter and importer.

While establishing standardized protocols will, in the shorter term, help to introduce more certainty into seed movement, it should be noted that these protocols would be only one element of a more comprehensive seed LLP policy.

3.3.2 Role of national guidance in short term options

An additional, shorter term step national authorities can take is to provide advanced, specific guidance, on a trait/crop basis. One criterion that could be used in this type of guidance is familiarity with that specific trait/crop combination. Having such type of guidance would provide companies, exporters and importers a basis to make their own decision about a particular seed trade. The guidance could be a practical, interim option while a more comprehensive policy, with more legal certainty, is developed and implemented.

4 National seed LLP policy that relies on thresholds based on quality standards coupled with mutual recognition of safety assessments

A national seed LLP policy that incorporates both thresholds based on industry practices and existing varietal purity standards coupled with the recognition of safety assessments from other countries provides both industry and national authorities with a comprehensive policy that maintains safety standards and is proactive, predictable, transparent and science-based.

There are best practices followed in commercial seed production to maintain a high level of product integrity, including an upper limit on variety/genetic variability and the presence of other species. These best practices are imbedded in quality standards and are widely accepted by the seed industry and incorporated into national seed regulations. With respect to national biosafety regulations, the definition of seed LLP assumes there has been

at least on authorization for unrestricted cultivation. In most cases, there will be more than one such authorization. Therefore, by definition, there will be existing safety data and at least one existing safety assessment for full cultivation for the biotech trait. Additionally there will be low exposure to the trait, an important component to the evaluation of risk. Familiarity with the trait and existing safety assessments coupled with low and limited exposure means there will be negligible risk to the environment.

A national seed LLP policy that incorporates both quality standards and mutual recognition of safety assessments would:

- Recognize a specific standard had been met by industry, in the form of a threshold.
- Proactively recognize and accept the exiting safety assessment(s) for unconfined release (full cultivation) as part of an overall policy so as to provide predictability and legal certainty
- No further risk management steps should be required if the above two conditions are met.

4.1 Role of standard sampling and testing protocols in national seed LLP policies

As described in sections above, the absence of or non-standardized sampling and testing rules jeopardize the functioning of markets and trade and cause legal uncertainty for operators. Therefore, a national seed LLP policy should clearly specify the sampling and testing protocols required. A proactive seed LLP policy does not require sampling and testing on a shipment-by-shipment basis at the point of import.

A standardized lot-approval process that includes accreditation of third party labs and private company labs would provide predictability to the implementation of a threshold. If thresholds are not commercially viable and very low, there is the increasing possibility to consider as positive some results that are, in fact, false positives; thus, creating uncertainty and non-transparency in the process.

4.2 Role of familiarity in national seed LLP policies

The OECD has acknowledged that an environmental safety assessment may not be needed to address a particular seed LLP situation because of processes that have been put in place or because of the availability of information, data and experience with a particular crop/trait combination⁵. Coupled with risk management triggers, such as a threshold based on quality standards, the use of familiarity can be an effective tool in determining when and if a safety assessment would be necessary in an LLP situation involving seed. Familiarity with trait or class of traits involves history of safe use, availability of data and safety assessments.

⁵ Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information. Series on Harmonization of Regulatory Oversight in Biotechnology No. 55. ENV/JM/MONO(2013)19, page 40.

In order for this approach to be predictable and transparent, there should be clear criteria for determining whether a safety assessment will be done. A case-by-case approach to the determination of the necessity of a safety assessment for each seed LLP situation will not result in a predictable process and could create trade disruptions without increasing protection for the environment.

A proactive approach would create categories or classes of traits that would be exempt from safety assessment in LLP situations which would ideally be agreed upon among countries through a mutual recognition process. A proactive approach would result in an efficient use of human resources for national regulatory authorities.

5 Conclusions and recommendations: Elements of a national seed LLP policy that would best meet the policy criteria

As discussed in previous sections, a combination of policy options presented in this paper would make up the components of a comprehensive policy that best meets the described criteria. This section provides a discussion of which policy components would best be combined toward that end. It also explains why certain options would not fit as well into a proactive, comprehensive policy.

5.1 Thresholds

Thresholds that are based on existing seed quality and varietal purity standards and industry best practices are an integral component of a comprehensive seed LLP policy. These types of thresholds have long been accepted, both by the seed industry and by national authorities responsible for seed regulations. They provide a practical and predictable component to a policy with international trading systems that already recognize these standards.

It is possible to implement thresholds that are not necessarily based on quality standards. While there is a certain amount of predictability with having any threshold, unless that threshold is commensurate with industry practices and the realities of dealing with biological systems, it will not provide legal certainty nor will it help to facilitate trade.

5.2 Proactive mutual recognition of safety assessments

As discussed in previous sections, in a situation of seed LLP, by definition, there will be at least one authorization for unconfined cultivation and therefore at least one safety assessment that has been completed. A seed LLP policy that incorporates mutual recognition of safety assessments will be science-based and provide the type of transparency and predictability necessary for a comprehensive seed LLP policy. As described previously this mutual recognition should be proactive.

A seed LLP policy could also utilize existing safety data and information and not include mutual recognition. While this approach is more science-based and predictable than

requiring *de novo* safety data for each LLP situation, it is not as comprehensive or proactive as moving toward mutual recognition.

5.3 Use of “familiarity” to proactively exempt from a safety assessment classes of traits with established history of safe use

This component of a national LLP policy would recognize there are certain trait/crop combinations for which there is significant familiarity. Using the substantial amount of information available for these trait/crop combinations, a policy could exempt from a safety assessment under seed LLP situations specific trait/crop combinations, classes of traits/crop combinations or classes of traits in any crop. The exemption could potentially be part of a mutual recognition agreement between or among national authorities. Under such an approach, industry would continue with their long history of best practices to minimize the occurrence of LLP.

5.4 Any testing required should have standard protocols for sampling and testing

If testing is required under the LLP policy, there should be standard protocols for sampling and testing that are recognized by national authorities, as discussed previously. If testing is required at the point of import, it introduces a high degree of uncertainty to importers and exporters, even with standard sampling and testing protocols in place. Therefore, if a policy does have a sampling and testing component, testing should be allowed before seed is shipped.

6 Annex: Sources for Safety Information, Safety Data and Safety Assessments

The following databases can be used to access information on safety data and assessments of genetically engineered (GE) seed:

- 1) GM Foods Platform, hosted by the Food and Agriculture Organization of the United Nations (FAO): <http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/>

From FAO GM Foods Platform website: the FAO GM Foods Platform is a simple online platform to share information on safety assessment of foods derived from recombinant-DNA plants authorized in accordance with the Codex "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008)". This Platform also facilitates the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food.

- 2) BioTrack, hosted by the Organization for Economic Cooperation and Development (OECD): <http://www.oecd.org/biotrack>

From OECD BioTrack website: this OECD public database allows regulatory officials and other interested stakeholders to easily share basic information on products derived from the use of modern biotechnology, as well as some products with novel traits acquired by the use of conventional breeding or mutagenesis, that have been approved for commercial application in at least one country, in terms of food, feed or environmental safety.

- 3) Biosafety Clearing-House (BCH) set up by the Cartagena Protocol on Biosafety (CPB): <http://bch.cbd.int/>

From Biosafety Clearing-House website: the Biosafety Clearing-House (BCH) is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in the six official languages of the UN.

- 4) GM Crop Database, hosted by the Center for Environmental Risk Assessment (CERA), International Life Sciences Institute (ILSI) Research Foundation: http://cera-gmc.org/index.php?action=gm_crop_database

From CERA GM Crop Database website: CERA's database of safety information (formerly hosted by AGBIOS) includes not only plants produced using recombinant DNA technologies (e.g., genetically engineered or transgenic plants), but also plants with novel traits that may have been produced using more traditional methods, such as accelerated mutagenesis.

- 5) GM Approval Database, hosted by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA): <http://www.isaaa.org/gmapprovaldatabase/>

From ISAAA GM Approval Database website: database features the Biotech/GM crop events and traits that have been approved for commercialization and planting and/or for import for food and feed use with a short description of the crop and the trait. Entries in the database were sourced principally from Biotechnology Clearing House of approving countries and from country regulatory websites.