

Low Level Presence in Seed: A Science Based Approach to Expedited Environmental Risk Assessment

WORKSHOP PROCEEDINGS

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INTRODUCTION

Increasingly, trade in seed is crossing national borders: according to the International Seed Federation, the growth in the international seed trade increased in value from approximately \$3.5 billion in 2000 to \$10 billion in 2012. The widespread adoption of genetically engineered (GE) plants means that there is increasing likelihood of incidences of seed trade disruption due to the low level presence (LLP) of GE events that have been approved in the country of origin, and that are present in seed shipments to importing countries that have yet to approve these events. LLP situations are the consequence of two realities: (1) at the country level, there are disparate approaches to the regulation of GE crops and, particularly, the time it takes from submission of a regulatory dossier to a risk management decision by the appropriate competent authority; and (2) a zero tolerance of unapproved GE events in imported seed is currently the regulatory norm in many countries throughout the world.

There are opportunities to mitigate the seed trade disruptions that can arise from asynchronous decision-making about GE events. One of these is to address the potential adverse environmental impacts that might arise from an LLP in seed situation using a consistent and scientifically defensible approach to environmental risk assessment. The OECD's Working Group on Harmonization of Regulatory Oversight in Biotechnology (WGHROB) initiated a program of work to address this topic in 2007. A project proposal was developed as the outcome of a

2008 workshop with project approval by the Working Group in 2009. This was followed by the distribution of a questionnaire to OECD member and non-member countries, and observer groups with the responses compiled for the purpose of information sharing. The WGHROB subsequently prepared the guidance document *Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information* which was declassified by the OECD in 2013 (OECD 2013). This publication emphasizes the scientific basis and approach for undertaking an environmental risk/safety assessment in an LLP situation, and provides additional information including useful resources and a compilation of country's responses to the questionnaire.

A number of other regional and international organizations have also prepared resource documents or policy statements about LLP in seed, but with only cursory attention to environmental risk assessment *per se*. The following list is provided for information purposes only and is not exhaustive:

- ISF View on Low Level Presence in Seed¹ (International Seed Federation, 2013)
- Low Level Presence² (CropLife International, undated)
- Adventitious Presence, Bringing Clarity to Confusion³ (European Seed Association; undated)
- Seed Movement in the Americas and SAA

Statement on Seed Low Level Presence⁴ (Seed Association of the Americas, 2009 and 2011 respectively)

¹http://www.worldseed.org/cms/medias/file/PositionPapers/OnTrade/ISF_View_on_LLP_in_Seed_2013.pdf

²http://www.croplife.org/low_level_presence

³<http://www.euroseeds.org/publications/brochures-1/adventious-presence>

⁴<http://www.saaseed.org/site/>

DESCRIPTION OF THE WORKSHOP

Environmental risk assessment of LLP in seed was the topic of the workshop *Low-Level Presence in Seed: A Science Based Approach to Expedited Environmental Risk Assessment* held in Buenos Aires, Argentina from 18-19 December 2013 (see Annex I). The workshop included 25 participants from nine countries in the Americas: Argentina, Brazil, Canada, Chile, Colombia, Mexico, Paraguay, the United States and Uruguay (see Annex II). Workshop participants were requested to read OECD (2013) and Roberts et al. (2013) in advance of the workshop.

The purpose of the workshop was to:

- Identify points of consensus or divergence for each of three options presented in a discussion document prepared by the Center for Environmental Risk Assessment, Agriculture & Food Systems Institute and circulated to participants in advance of the workshop (see Annex I); and
- Elaborate a plan for moving forward on the points of consensus that could permit regulatory authorities to address ERA of LLP in seed in a scientifically robust and expeditious manner.

For the specific context of the workshop, the definition of LLP in seed was taken from OECD 2013:

Seed that contain low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release)

in one or more exporting countries but not in a country of import.

The workshop focussed on LLP in seed intended for planting. It did **not** address sampling and detection, situations arising from confined field trials, situations where an event has yet to receive authorization in any country, or LLP issues related to food/feed safety.

Workshop participants were divided in to three discussion groups, each of which was asked to consider two of the three options outlined in Box 1, and to specifically address the following questions:

1. Is the option a scientifically defensible approach to addressing LLP in seed situations in its current form or with minor modifications? Please capture points of convergence and divergence arising from this discussion.
2. Could this option be implemented?
 - a. If “yes”, what information resources or tools are available or are needed to do so?
 - b. If “no”, what are the constraints to implementation?

The options were provided to help initiate dialogue during the breakout sessions, and each of the three groups advanced discussion beyond this initial charge. Each group reported on their deliberations, followed by a plenum discussion that resulted in a series of agreed points and suggestions for next steps.

DISCUSSION OF OPTIONS

Common to all of the discussion group deliberations about options to address LLP in seed situations was the understanding that:

1. Developing an approach to address LLP in seed situations in an expeditious, scientifically defensible manner is in no way an attempt to try to legalize LLP;

BOX 1

Option 1: ERA based on a subset of data, relevant only to plausible risk hypotheses

A case-specific ERA is undertaken for situations when there is uncertainty about the potential for increased spatial and temporal exposure, either through persistence of the unauthorized plant or through stable introgression of the trait into populations of sexually compatible relatives. The risk assessment can likely be completed using existing information and data (e.g., risk assessment undertaken by the country of export).

Option 2: Conditional recognition of the scientific opinion by the regulatory authority in the country where the GE plant has been approved for cultivation under LLP scenarios

In order for a plant to present a significant environmental risk under a situation of LLP in seed, it would either have to be extremely hazardous, or have characteristics that increased the likelihood of survival and persistence in the receiving environment, such that the low level introduction leads to a high level of exposure over time. The generalized ERA paradigm considers these possibilities, and risk assessments for GE plants routinely assess the ability of a GE plant to survive, persist and multiply compared to its conventional counterpart, as well as describing any hazard posed by the plant. Under this option, the importing country recognizes the applicability of the exporting country's ERA for the purposes of decision-making (risk management) in LLP in seed situations. The importing country would not have to evaluate specific data; instead it would have to be satisfied that the exporting country considered the same assessment end-points and that the respective receiving environments were comparable.

Option 3: No requirement for any ERA for LLP in seed scenarios

This option recognizes that, to date, no GE crop plants have had adverse environmental impacts at levels of 100% exposure and so, in the low exposure scenario of LLP in seed, it is extremely unlikely that an adverse environmental impact could arise. In essence, the regulatory authority would undertake a risk assessment of taking no action in the case of LLP in seed situations, to ensure that such an approach is scientifically defensible. A regulatory authority could do this on a categorical basis (i.e., it would apply to all LLP in seed situations) or could pre-emptively undertake crop and/or trait specific risk assessments to determine if LLP in seed situations would or would not trigger a regulatory action.

- Existing seed systems will continue to implement quality assurance practices designed to maintain plant product integrity, i.e., avoid LLP in seed.

Option 1 was considered as a scientifically defensible approach to addressing LLP in seed situations but that it needed to be clarified (as

below) to avoid any inference that an ERA would be required in every case of LLP in seed. An ERA would not be necessary in those cases where persistence of the unapproved event is not possible in the receiving environment. (e.g., affected seed lots are destroyed before any environmental release occurs).

Revised text for Option1: ERA based on a subset of data relevant to concrete (operational or specific) risk hypotheses.

A case-specific ERA is undertaken to evaluate the potential for increased spatial and temporal exposure, either through persistence of the unauthorized plant or through stable introgression of the trait into populations of sexually compatible relatives.

In those cases where an ERA is warranted, the regulatory authority in the importing country would need to determine if the unapproved event(s) could potentially establish and persist in the receiving environment. In most cases this assessment could be completed using existing knowledge about the biology of the non-transformed plant species in the receiving environment, together with information from studies that compared the phenotypic characteristics of transformed and non-transformed plants that are relevant to establishment and persistence in similar agro-ecozones i.e., transportability of field data needs to be taken into account. This information should be available in the risk assessments undertaken in those countries where the event has been approved for cultivation. Rarely, the risk assessment from the exporting country may need to be supplemented to address specific protection concerns that are unique to the country of import.

It was not considered practical for expert bodies (e.g., biosafety committees or commissions) to have to address LLP in seed situations as these need to be resolved very quickly. Convening an ad hoc or unscheduled meeting of an expert body may preclude timely decision-making and so alternative mechanisms or approaches are needed. This is less of an issue for those regulatory authorities that have full-time, professional risk assessment staff.

Option 2 was considered to be an acceptable approach in general terms, recognizing that an ERA may be only part of the decision-making process for managing LLP in seed. For example, in some countries case-specific decisions may be impacted by protection goals that are unique to the importing country and hence not addressed in the ERA undertaken by the country of export. These protection goals may affect the management practices applied to bring the situation back in to compliance.

Implementing Option 2 would require immediate access to the risk assessment criteria, protection goals and endpoints considered in the country of cultivation (i.e., the country where the ERA was completed). Familiarity with the crop and trait was also repeatedly mentioned as an important factor, as well as the history of safe cultivation in one or more countries. Local experience with similar traits in other species (whether transgenic or conventional) was also considered to be important in informing management decisions. Option 2 might be considered first on a regional basis. Additional actions for implementing Option 2 were also identified:

- Regulatory agencies should publish their ERA criteria, protection goals and endpoints, or a comparative analysis of these for multiple countries should be undertaken and made accessible;
- The format of decision documents or scientific opinions should be harmonized and the content substantially improved to enhance their utility as a tool for ERA of LLP in seed;
- A network of contacts should be created to better enable inter-agency collaboration and joint work between countries;
- Develop protocols for dealing with LLP situations e.g., how to proceed, points of contact in regulatory agencies, information resources, risk communication tools etc.

Option 3 was considered feasible in situations where there is significant familiarity with the crop/trait combination and advantageous as it does not require the direct solicitation of information from other regulatory authorities. Inherent in this option is the concept that LLP in seed situations could be dealt with proactively versus reactively; a regulatory authority could undertake an analysis of the situation regarding the history of safe use of GE crops generally or of specific product families. Examples discussed included glyphosate tolerant soybean in countries like Argentina, Brazil, Canada, Mexico or the United States where cultivation has taken place for many years over large areas, or a stacked product where the parental lines are approved in the country of import but the stack is not. In such cases, special management provisions may not be needed to bring a situation back into compliance, but traceability of the seed production process might be implemented. As is the case with Options 1 and 2, there are informational resources available in most countries that have functional regulatory systems, or from credible third parties that curate databases with information about product approvals, dates, acreage, adoption in different countries, etc.

In the case of some new events where the crop/trait combination is unfamiliar or of limited familiarity (i.e., recent and limited cultivation in only one or a few countries), Option 3 was considered to be less viable. However, it should be possible to apply Option 3 even to unfamiliar events if there is no possibility of establishment, persistence or spread, which will be largely determined by the biology of the crop in the country of import.

POINTS OF AGREEMENT

After the reports from each of the discussion groups, the participants engaged in an extended and vigorous plenary discussion that resulted in the following points of agreement, and suggestions for next steps. The text in italics provides additional context for some of the points.

1. Conceptually, all three options could be implemented to address ERA of LLP in seed. They represent points on a continuum, and common to all three is the underlying need for confidence in the risk assessments undertaken in the country (countries) of export.
2. ERAs conducted in the country (countries) of export should be used by the importing country (countries); data transportability is scientifically defensible.
3. Improvements in the quality of information that may be used to inform a proactive ERA are required. This could be achieved through standardization of the ERA components described in scientific opinions e.g., protection goals, endpoints etc.
4. Information needs to be easily accessible.

Efforts should be made to increase confidence in the risk assessment Governments can take a pro-active approach by ensuring that risk assessments are made publically accessible in a timely manner.

5. LLP in seed will be best addressed by developing a proactive and predictable approach to ERA. This recognizes LLP in seed situations are a reality of international seed trade, but proactive ERAs for LLP in seed situations are **not** an attempt to normalize LLP in seed; LLP in seed remains a situation that is to be avoided. Pro-active approaches would take into account the familiarity of transgenic proteins/traits.

Proactive ERAs are an important approach to address LLP in seed that makes efficient use of government resources, ensures that protection goals are met, and provides clarity to seed producers. For example, proactive ERAs could be used to develop a "whitelist" of events or categories of events i.e., crop/trait combinations that are considered low risk based on accumulated expert knowledge and experience.

Whitelists would necessarily differ by country. Imbedded in this approach is the understanding that a prior risk assessment has already been conducted by a trusted authority. There was a divergence of opinion on whether an international expert body would be useful. Instead, there was consensus that a critical determinant for the success of a proactive approach is access to risk assessment information and confidence in the risk assessment processes of competent authorities in other countries.

6. Decisions on responses to specific LLP in seed situations would remain at the country level.

Irrespective of the low risks involved in LLP in seed situations, it is critical to identify the source of the LLP to be able to minimize occurrence. In addition, it was agreed that in the case of repeated incidents, developers should be asked to submit a dossier for full approval.

7. Harmonization remains an important goal e.g., two or more countries could work towards agreement on the criteria that should be considered for ERAs of crop/trait combinations.

Harmonization efforts were mentioned as desirable to achieve synchronization of approvals, although past experiences indicate that there is much to be done before this can be considered in most regions.

8. Communication will be key for successful implementation of any proactive process e.g., need to ensure confidence in the information and process used.

NEXT STEPS

The plenum recommended the following be undertaken as follow-on activities:

- A meeting to discuss development of a proactive approach for addressing ERA of LLP in seed, and specifically the criteria for the development and content of white lists.
- Undertake a pilot project to apply such an approach that would focus on familiar crop/trait combinations.

The Center for Environmental Risk Assessment was suggested as an appropriate convener to further this dialogue.

REFERENCES

- OECD. (2013). Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information/ ENV/JM/MONO(2013)19. Series on Harmonisation of Regulatory Oversight in Biotechnology No. 55. Organization for Economic Cooperation and Development (OECD), Paris. [http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2013\)19&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2013)19&doclanguage=en)
- Roberts, A., Devos, Y., Raybould, A., Bigelow, P., Gray, A. (2013). Environmental risk assessment of GE plants under low-exposure conditions. *Transgenic Research* 10.1007/s11248-013-9762-z. http://cera-gmc.org/uploads/ERA_of_GE_Plants_Under_Low-Exposure_Conditions.pdf

ANNEX I: WORKSHOP AGENDA

**Low-Level Presence in Seed:
A Science Based Approach to Expedited Environmental Risk Assessment
Hotel NH Crillón • Avenida Santa Fe 796 • Buenos Aires
18-19 December 18-19, 2013**

| | PRESENTATION/ ACTIVITY | PRESENTER/MODERATOR |
|------------------------------------|--|--|
| Wednesday, 18 December 2013 | | |
| 09:00 | Welcome | Morven McLean <i>Director, CERA</i> |
| 09:15 | Round table introductions and country/organization updates of LLP in seed initiatives (5 min each) | All |
| 10:15 | OECD Consensus Document: Low Level Presence of Transgenic Plants in Seed And Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information • Q&A | Marcus Vinícius Segurado Coelho <i>Coordenação de Biossegurança de OGM, Ministério da Agricultura, Pecuária e Abastecimento do Brasil</i> |
| 11:00 | Refreshment Break | |
| 11:30 | ERA in Low Exposure Scenarios | Morven McLean |
| 12:00 | Options for Addressing LLP in Seed • Charge to the Discussion Groups | Carmen Vicién <i>Consultor Senior, CERA</i> |
| 12:30 | Lunch | |
| 13:30 | Facilitated Breakout Groups to discuss options presented in the discussion paper and from the plenary session | All |
| 17:30 | Close of Day 1 | |
| Thursday, 19 December 2013 | | |
| 09:00 | Report from Breakout Groups | Rapporteurs |
| 10:00 | Facilitated plenary discussion to identify common approaches to address ERA of LLP in seed | All |
| 12:30 | Lunch | |
| 13:30 | Recommendations from plenum for taking action on common approaches to address ERA of LLP in seed | All |
| 17:30 | Close of Workshop | |

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