SEED LLP: ACTIVITIES OF THE CENTER FOR ENVIRONMENTAL RISK ASSESSMENT (CERA)

Who we are…

- Part of the non-profit ILSI Research Foundation
- CERA's purpose: To enable the development and application of sound science to the environmental risk assessment of agricultural biotechnologies so their contributions to sustainable production of food, fuel and fiber may be safely realized

How we work…

- Focus is on science support for ERA
- As a non-profit, CERA's activities are carried out for public benefit
- Tripartite participation – academia, government, private sector (and NGOs)
- Expert panels, networks and cooperative programs on issues related to ERA with international representation from the scientific and regulatory communities

Program platforms

- Platform 1: Improving systematic approaches to ERA of GM plants.
- Platform 2: Understanding the receiving environment
- Platform 3: Science support for rationalizing ERA in the context of limited releases to the environment
- Platform 4: Capacity building to support and strengthen regulatory and scientific communities involved in ERA of agricultural biotechnologies

CERA's work related to LLP in seed

- Environmental Risk Assessment (ERA) of LLP in Seed
- Other work:
  - Protein monographs
  - Data transportability
  - ERA in low exposure scenarios

ERA of LLP in Seed

- Workshop in Buenos Aires, Argentina in December 2013 to discuss opportunities to address LLP in seed situations through expedited environmental risk assessment

Participants









- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Mexico
- Paraguay
- United States
- Uruguay

Scope of the workshop

- What was considered:
  - LLP in seed for planting
  - ERA (science, not policy)
- What was not considered:
  - Sampling and detection
  - CFTs
  - Events that have yet to receive authorization in any country
  - LLP issues related to food/feed safety

Charge to the workshop

- Identify points of consensus or divergence for each of three options presented in a discussion document prepared by CERA and circulated to participants in advance of the workshop; 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.

Outcome: consensus points

- 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.

Outcome: consensus points

- 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 provide clarity to seed producers.
  - For example, proactive ERAs could be used to develop a "white list" of events or categories of events *i.e.*, crop/trait combinations that are considered low risk to the environment based on accumulated expert knowledge and experience.

Next step

- 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.

EWG on ERA of LLP in Seed

- Met in July 2014 in Santiago, Chile
- Scope: elaboration of criteria that could inform the population of a white (exclusion) list of GE plants that could be considered safe for the environment under conditions of LLP

General criteria

- Experience and knowledge with the plant species indicates that the plant will not survive, persist and multiply in the receiving environment
- A previously conducted ERA concludes that the plant does not have altered characteristics with respect to growth or reproduction that would affect survival and persistence in the receiving environment
- Experience and knowledge with the trait (either the phenotype or the gene/protein) indicates that it does not pose a risk to the environment under conditions of LLP in seed

Experience and knowledge with the plant species indicates that the plant will not survive, persist and multiply in the receiving environment

- The crop has been grown in the country for a significant period of time and does not survive or persist in the environment
- The species is cultivated in other countries with comparable environments and has not been shown to survive or persist in the environment
- Specific management conditions are relevant to the agricultural use of the crop which limit the ability of the species to survive and persist in the environment
- Whether or not the crop species has any wild relatives to which gene flow may occur, leading to increased exposure or persistence of the GE trait in the environment

A previously conducted ERA concludes that the plant does not have altered characteristics with respect to growth or reproduction that would affect survival and persistence in the receiving environment

- The assessment is transparent and accessible
- The use of the GE plant considered in the ERA is comparable to the use in the country of import
- The ERA considers whether the GE plant has altered growth, survival or reproductive characteristics when compared to the untransformed plant
- The potential for the GE plant to survive, persist or reproduce in the environment where the ERA was conducted is comparable to its potential to survive, persist or reproduce in the country of import

Experience and knowledge with the trait (either the phenotype or the gene/protein) indicates that it does not pose a risk to the environment under conditions of LLP in seed

- Prior assessments of the plant species and transgene combination for cultivation have concluded that the trait is not likely to pose a risk to the environment
- Prior assessments of the transgene in one or more other plant species have concluded that the trait is not likely to pose a risk to the environment
- Approvals or experience with similar/comparable traits in the same crop generated by a different transgene or introduced through alternative production methods (e.g. through traditional breeding) indicate that the trait is unlikely to pose a risk to the environment

Outcome from EWG meeting

- Consensus on criteria that provide a scientifically sound mechanism for identifying GE events that are unlikely to pose a significant risk to the environment under the low environmental exposure conditions associated with LLP in seed
- Using these criteria, a national authority could proactively prepare a listing of GE events that do not require additional ERA under LLP conditions in order to facilitate regulatory decision making

Next steps

- Publication of EWG deliberations
- Undertake a pilot project to apply such an approach that would focus on familiar crop/trait combinations.

Protein monographs

- "A Review of the Environmental Safety of…"
  - CP4 EPSPS
  - Cry1Ab
  - Cry1Ac
  - Cry1F
  - Cry2Ab
  - Cry3Bb1
  - Cry34Ab1 and Cry35Ab1
  - PAT
  - Vip3A

Data transportability

Garcia-Alonso, M., Hendley, P., Bigler, F., Mayeregger, E., Parker, R., Rubinstein, C., Satorre, E., Solari, F. and M.A. McLean. (2014). Transportability of confined field trial data for environmental risk assessment of genetically engineered plants: a conceptual framework. *Transgenic Research* 23(6): 1015-1041.

ERA in low exposure scenarios

Roberts, A., Devos, Y., Raybould, A., Bigelow, P., Gray, A. (2014). Environmental risk assessment of GE plants under low-exposure conditions. *Transgenic Research* 23(6):971-983.

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