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Environmental Risk Assessment for Low Level Environmental Exposure to Genetically Modified Plants: Grain Import Scenarios

Key Findings

- Environmental risk assessment for GM plants under grain import scenarios follows established processes for risk assessment under cultivation scenarios, modified to account for the much lower exposure.
- The data generated for risk assessment under commercial cultivation scenarios (high exposure) are generally sufficient to conduct the risk assessment under grain import scenarios (low exposure).
- Local studies are not warranted in the country of import unless the import environment differs from the cultivation environments in a meaningful way that would increase the weediness or invasiveness potential of the crop or a sexually compatible wild relative.
- There is no evidence that increased weediness or invasiveness of any crops or their wild relatives has occurred as a result of either commercial cultivation or import of a GM crop.

Introduction

Genetically modified (GM) varieties of major commodity crops (maize, soybean, canola) are grown on 80 to 100% of the crops' cultivated areas in major export countries including the USA, Canada, Brazil and Argentina. While food and feed safety assessments of GM grain are conducted in all importing countries with functional regulatory systems, a limited number of countries additionally require an Environmental Risk Assessment (ERA) to account for potential exposure arising from spillage of viable grain near transportation or processing facilities. This document provides considerations for conducting such a risk assessment that accounts for low environmental exposure relative to exposure under commercial cultivation conditions.

Environmental Risk Assessment

Environmental risk assessment is a structured approach used to gather and analyze data to support risk management decision-making against the backdrop of agreed societal protection goals such as protection of biodiversity, cultural preservation, or wilderness preservation. The approach consists of problem formulation (based on understanding relevant properties of the GM trait and crop as well as the receiving environment), characterization of hazard (e.g. toxicity) and exposure (intensity or frequency), and then combining the information on hazard and exposure to analyze potential risks to valued elements of the environment identified in the protection goals. This approach has been used successfully to assess risks of many different potential environmental stressors, including GM crop cultivation and low level environmental exposure of GM crops arising from grain import.

Environmental Risk Assessment for Grain Import

a) Problem Formulation

During problem formulation, applicable protection goals are identified and information is gathered about the biology of the GM crop, any changes introduced via the genetic modification, and the expected receiving environment. For any crop, potential environmental exposure is linked to biological, operational, temporal, and spatial factors. Potential routes of exposure and potential environmental hazards that could lead to unacceptable environmental effects are identified during this phase of the risk assessment process. Risk hypotheses arising from the identified exposure and hazards are then developed. Plausible risk hypotheses are evaluated based on the available information, and if necessary, additional data are developed to address specific hypotheses.

b) Risk Scenarios

Two environmental risk scenarios are considered for imported GM grain. The first is that the GM crop could become established in the receiving environment as a result of grain spillage and germination, with subsequent establishment of feral populations that are difficult to control. The second risk scenario considered is cross-pollination of a GM crop with a local sexually compatible wild relative ("gene flow") leading to introgression of the GM trait into the population of a sexually compatible wild relative, in turn altering the weediness or invasiveness of that population.

Neither of these scenarios is unique to GM crops – genes have been transferred back and forth between domesticated crops and wild relatives for millennia. The relevant question is whether the gene that confers the GM trait will persist in feral populations of the crop species or wild relative, create a biologically significant selection advantage, and increase weediness or reduce biodiversity. Plant populations are controlled by a large number of environmental stressors – temperature, water, seed behavior, competition from other plants, and many pests including diseases, arthropods, etc. If the problem formulation indicates that the GM crop could confer a trait to the feral populations of the crop or wild relative(s) in a way that could increase weediness or invasiveness, the risk assessment for grain import would consider the probability that importation of the GM grain will lead to greater harm relative to importation of their conventional counterparts.

c) Potential Environmental Exposure

Potential environmental exposure associated with the small number of plants that might arise in association with imported viable grain is many orders of magnitude lower than exposure when GM seeds are intentionally planted for commercial cultivation. If viable grain is imported, exposure to GM plants (or plant products such as pollen) could occur if there is spillage of grain at ports, around transportation lines (rail, road, water) or at processing facilities. For exposure of the GM crop to occur in the receiving environment, spilled grain would have to reach soil and be exposed to specific favorable environmental conditions, such as light, moisture, temperature, etc., so that germination and plant establishment can occur. In such conditions, established plants could subsequently flower and produce seeds that could enable a population to persist. In the risk scenario involving gene flow, pollination of a sexually compatible wild relative in the vicinity of the feral crop population, followed by introgression of the GM trait into the wild relative population, would also be necessary. For persistent environmental exposure, any established plants would be left unmanaged to compete with native vegetation However, since any spillage is expected to be incidental to the transportation of the grain, it would generally occur in industrial or semi-industrial areas that are highly disturbed habitats unsuitable for significant plant establishment. In such settings, a plant would be much less likely to flower, release pollen and set seed than the same plant in a managed agricultural setting.

d) Potential hazard

If spilled grain from a GM crop were to germinate and result in established plants, environmental consequences may include the establishment of feral populations of the GM crop in the environment at higher levels than establishment of non-GM counterpart as a result of the GM trait. The risk assessment considers whether a feral population of GM plants or a population sexually compatible wild relatives that contains the GM trait could be more weedy and difficult to manage than their conventional counterparts, or more invasive and likely to displace native vegetation than their conventional counterparts, and subsequently reduce biodiversity. Only in cases where an introduced gene conferred some type of biologically significant selection advantage compared with conventional counterparts would feral populations of GM plants be more likely to become established and spread beyond the original point where the grain was spilled. It is highly unlikely that a crop plant with this characteristic would be commercialized since it would cause difficulties with crop rotation and other agronomic practices.

e) Risk evaluation

A crop's ability to persist and spread in the environment is greatest under commercial cultivation where large fields are planted and managed to optimum growth and productivity. Any unintended changes in agronomic and phenotypic properties of a GM crop that may affect the weedy characteristics would be observed in these favorable agricultural settings. Any varieties with these properties are unlikely to be commercialized. In contrast, the number of plants and the area where they grow are much smaller for grain spillage associated with grain import and transportation than under cultivation and thus potential exposure is also much lower. Furthermore, under grain import scenarios, the industrial and disturbed habitats where incidental grain spillage may occur are less conducive to plant establishment and growth than under cultivation settings.

During product development, breeders observe the agronomic and phenotypic properties of crop varieties under development and reject or breed out any unexpected or adverse characteristics that would make the crop less suitable for cultivation. This process is applied to new hybrid/variety development whether or not the breeding process includes genetic engineering, and screens out lines that would cause agronomic problems, especially unwanted persistence or spread in the environment.

The potential for increased weediness and invasiveness of GM crops relative to their conventional counterparts is part of the risk assessment for environmental introduction under commercial cultivation. Data on intended or unintended effects of the genetic modification on the agronomic and phenotypic equivalence between the GM crop and its conventional counterparts are generated in confined field trials at multiple locations and under diverse environmental conditions across the intended cultivation geography. Data gathered typically include parameters such as plant morphology, growth habit, height and vigor, biotic and abiotic stress responses, and reproductive characteristics (time of flowering, pollen production, seed drop or shattering, grain yield, and grain size). In addition, GM (and non-GM) seed lots are evaluated for dormancy and germination under a variety of environmental conditions for agronomic acceptability. These studies are suitable to detect any unintended changes to the plant phenotype that would affect weedy or invasive characteristics.

In addition, the environmental risk assessment for cultivation considers the effects of the intended novel trait on the agronomic properties of the crop. Traits added through genetic modification are unlikely to provide GM plants, including sexually compatible wild relatives, with significant competitive advantages that are absent from the conventional counterparts, except under very specific and easily identifiable circumstances (such as a tolerated herbicide being the only available tool for managing the crop where it is not intended, or herbivory by a targeted insect pest being a key limiting factor in the plant's ecology).

For GM crops that have been extensively studied and found to be agronomically equivalent to their conventional counterparts and to not possess GM traits that increase weediness or invasiveness under cultivation conditions, the data developed and used to assess potential environmental risks associated with cultivation are sufficient to support a conclusion of negligible risk for low exposure scenarios associated with imported grain. Additional data for import scenarios, where the exposure is much lower, are not needed to assess potential environmental risk.

Utility of In-Country Studies for ERA for Grain Import Scenarios

Occasionally regulatory agencies may require in-country field studies as part of the review process for import approval of biotech traits in import commodities. These studies are purported to help assess the risk of GM plants becoming weeds or invasive as a result of the import of grain as well as potential impacts on biodiversity. However, as discussed above, such data are not necessary to complete the risk assessment for grain import if the risk assessment data generated for cultivation countries does not indicate any increase in weedy or invasive characteristics and there is no indication that the import environment differs notably from the cultivation environments in a way that would alter the effect of the genetic modification.

Data from numerous field trials are compared to non-GM varieties as part of the weediness evaluation under cultivation conditions. If there are no indications of differences in agronomic or phenotypic characteristics for a GM crop compared with conventional counterparts that could lead to increased weedy characteristics in cultivation countries under conditions favorable for plant growth, there is no plausible hypothesis whereby spillage of imported GM grain could lead to increased persistence of the crop or a sexually compatible wild relative in the importing country.

Summary

Environmental risk assessment for GM plants under grain import scenarios follows established processes for risk assessment under cultivation scenarios, modified to account for the much lower exposure. Environmental exposure can arise in ports, along transportation routes and at processing facilities if grain spillage occurs and if grain is able to germinate and plants become established. Crops are not well suited to becoming established in such settings, and GM traits have not been shown to impact the crops' ability to establish and spread. The data generated for environmental risk assessments under commercial cultivation scenarios (high exposure) are sufficient to conduct the risk assessment under grain import scenarios (low exposure). Local studies are usually not warranted in the country of import unless the import environment differs from the cultivation environments in a meaningful way that would alter the effect of the genetic modification. Furthermore, if the GM trait does not impart weedy or invasive characteristics to the crop that are absent from its conventional counterparts, a conclusion of negligible risk of increased weedy or invasive characteristics of the GM crop or any sexually compatible wild relatives can be reached based on the existing data developed in the country of production. There is no evidence that increased weediness or invasiveness of any crops or their wild relatives has occurred as a result of commercial cultivation or import of a GM crop.

Recommended References

- **General Risk Assessment**
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- **Low Level Exposure**
  - CERA. (2014). Low-Level Presence in Seed: A Science Based Approach to Expedited Environmental Risk Assessment - Workshop Proceedings. Center for Environmental Risk Assessment (CERA), Washington, D.C. (http://www.cera-gmc.org/CERA_Publications)
  - Roberts, A. 2011. Information tools for environmental risk assessment of low level presence. Environmental Biosafety Research 10:1-3.
  - Roberts, A., Devos, Y., Raybould, A., Bigelow, P., Gray, A. (2014). Environmental risk assessment of GE plants under low-exposure conditions. Transgenic Research

23:971–983.

- **Examples of Published Risk Assessments Conducted for GM Crops**

    - Marvier, M., McCreedy, C., Regetz, J., Kareiva, P. 2007. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. Science 316(5830):1475-1477.
    - Romeis, J., Meissle, M., Bigler, F. 2006. Transgenic crops expressing *Bacillus thuringiensis* toxins and biological control. Nature Biotechnology 24:63-71.
    - Sanvido, O., Romeis, J., Bigler, F. 2007. Ecological impacts of genetically modified crops: Ten years of field research and commercial cultivation. Adv. Biochem. Engin/Biotechnol 107:235-278.

- **Other Sources of Information**
    - The International Life Sciences Institute – Center for Environmental Risk Assessment (ILSI-CERA) has produced a series of "Protein Monographs" that review the environmental safety for novel proteins expressed in GM plants: http://www.cera-gmc.org/Protein_Monographs. These include CP4 EPSPS, Cry1Ab, Cry1Ac, Cry1F, Cry2Ab, Cry3Bb1, Cry34Ab1 and Cry35Ab1, PAT, and Vip 3Aa.