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

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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 US, Canada, Brazil and Argentina. While food and feed safety assessment of GM grain is conducted in all importing countries with functional regulatory systems, a limited number of countries additionally require an environmental risk assessment 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 (ERA) 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 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 risk to valued elements of the environment identified in the protection goals. This approach has been used successfully to assess risks of many different environmental exposures, 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, protection goals are identified and information is gathered about the biology of the crop that has been genetically modified (GM), 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) Potential Exposure

Potential exposure associated with a 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 of a GM crop 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, 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. 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. For persistent environmental exposure, any established plants would have to be left unmanaged to compete with native vegetation; however 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.

c) 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 as weeds 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 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, reducing biodiversity. However, only in cases where a new gene conferred some type of major 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.

Cross-pollination of a GM crop with a local sexually compatible wild relative ("gene flow") could lead to introgression of the GM trait into the population of a sexually compatible wild relative, which in turn could alter the weediness or invasiveness of that population. This is not a new phenomenon with GM crops – genes have been transferred back and forth between domesticated crops and wild relatives for millennia. The key is whether the gene that confers the trait will persist in populations of the wild relative, create a biologically significant selection advantage, and thus increase the weediness potential of the wild relative. 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 there are sexually compatible wild relatives present in the environment near to grain transportation routes, and the that GM crop is materially different from the non-GM counterparts in a way that could increase its weediness or invasiveness, the risk assessment for grain import would consider the probability of gene flow from the GM plants leading to greater harm to natural biodiversity than gene flow from their conventional counterparts.

d) 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 grain production. 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. In contrast, the number of plants and the area where they grow are much smaller for grain spillage during import and transportation than under cultivation. Furthermore, under grain import scenarios, the industrial and disturbed habitats where incidental grain spillage may occur is 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 will reject or breed out any unexpected or adverse characteristics that would make the crop less suitable for cultivation. This process is applied to breeding whether or not the process includes genetic engineering, and strongly impedes the development of crops 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. Because crop plants have been bred to not be weedy or invasive, but instead to provide yield for harvest, these studies would reveal any unintended changes to the plant phenotype that would affect weedy or invasive characteristics.

In addition, the risk assessment considers the effects of the intended novel trait on the agronomic properties of the crop. Traits added through genetic engineering are unlikely to provide GM plants with significant competitive advantage that is 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 group insect being the 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, additional data for import scenarios, where the exposure is much lower, are not warranted.

Chinese Ministry of Agriculture Data Requirements

The Chinese Ministry of Agriculture (MOA) is one of very few agencies globally that currently requires 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 in China as a result of the import of grain as well as potential impacts on biodiversity. Recently, the Ministry of Agriculture has been requesting additional in-country data when considering applications for import approval, in-country data that are not requested for import approvals in other countries. However, as discussed here, 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 from the cultivation environments in a meaningful way that would alter the effect of the genetic modification.

For example, MoA has requested in-country data on characteristics such as seed shedding (shattering), seed dormancy, and volunteers depending on crop (maize, soybean, canola etc).

a) Shedding (or shattering)

Shedding, or shattering, is the property of plants whereby seeds fall from the plant after maturity. MOA is now requiring determination of the number of seeds that have dropped from mature plants on weekly intervals for five weeks following crop maturity. , Shedding will be a rare occurrence in an import scenario. As a prerequisite, spilled viable grain must land on soil and germinate under environmental conditions that are favorable for plant growth. Plants must become established in industrial or semi-industrial settings and not be subjected to management. Established plants would have to flower and set seed prior to a shedding event. Even if shedding were to occur at a higher rate with a GM plant than with its conventional counterparts, cultivated commodity crops varieties do not exhibit weedy characteristics and any seed dropped would be unlikely to become established in industrial or semi-industrial settings.

During product development and breeding, seed producers would reject any breeding lines, including GM or non-GM breeding lines, that showed increased propensity to shatter as this would not be agronomically suitable. Furthermore, seed shedding (shattering) is typically included in the parameters measured for weed risk assessments under cultivation conditions. These data are generated in extensive studies across multiple environments. There is no plausible hypothesis whereby shedding would be equivalent between GM and conventional counterparts in cultivation geographies and not equivalent in China. There is no indication that seed shedding is greater in China than in other geographies and no suggestion that a GM trait could cause increased shedding in China and not in cultivation countries. Furthermore, seed shedding is not a likely target for genetic engineering, and any plants that showed unintended increased tendency to shed seeds would not be selected during the product development process because this would not be a desirable agronomic characteristic. Therefore, conducting an extended field trial to assess shedding after maturity will not provide information that enhances the risk assessment conclusions in China.

b) Seed dormancy

Seed dormancy is a survival mechanism for plants and is an important characteristic that is often associated with plants that are weeds. Standardized germination assays in cultivation countries are routinely conducted during breeding as well as in specific studies of GM crops to measure the germination potential of seed under warm and cold conditions. If agronomic trials indicate there are no differences in seed size or moisture and no other agronomic differences compared with conventional counterparts which could affect seed persistence, while germination studies demonstrate expected germination under warm and cold conditions, there is no plausible hypothesis whereby imported GM grain could show altered dormancy characteristics that would lead to increased weediness or invasiveness in China. There is no indication that seed dormancy is greater in China than in other geographies and no suggestion that a GM trait could cause increased dormancy in China and not in cultivation countries.

Furthermore, seed dormancy is not a likely target for genetic engineering, and any seeds that showed unintended extended dormancy would not be selected during the product development process because this would not be a desirable agronomic characteristic. Therefore, conducting an extended field trial to assess seed dormancy will not provide information that enhances the risk assessment conclusions in China.

c) Volunteer monitoring

A volunteer is a plant that grows in the following field season, which is the result of a seed being dropped by a plant that grew during the previous field season. MOA is now requiring that the number of GM plant volunteers in test plots be determined up to 13 months after the original planting date. Volunteer monitoring is not commonly a component of an agronomic equivalence study, other parameters that are measured provide sufficient evidence that increased volunteers will not occur. Agronomic and phenotypic parameters under cultivation conditions, such as seedling emergence, seedling vigor, lodging, number of seeds, shattering, seed moisture, seed weight, and yield, are sufficient to determine whether or not increased volunteers would be anticipated for a GE plant than for its conventional counterparts. If there are no indications of differences in agronomic or phenotypic characteristics compared for a GM crop with conventional counterparts that could lead to increased volunteer production in cultivation countries under conditions favorable for plant growth, there is no plausible hypothesis whereby spillage of imported GM grain could lead to increased population persistence in China. There is no indication that volunteer establishment occurs more extensively in China than in other geographies and no suggestion that a GM trait could cause volunteer establishment in China and not in cultivation countries. Therefore, conducting extended volunteer monitoring will not provide information that enhances the risk assessment conclusions in China.

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 seeds are able to germinate and plants become established. Crops are not well suited to becoming established in such settings, and GM traits rarely allow crops to overcome the barriers to establishment and spread. 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 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.

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- 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.