

Editorial

Information tools for environmental risk assessment of low level presence

An introduction to the reviews of the environmental safety of proteins used in genetically engineered plants

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Since the first regulatory approval of a genetically engineered (GE) plant was issued in 1992, hundreds of additional GE plants, thousands of regulatory decisions and millions of tons of GE grain and seed have been produced. In an increasingly global economy, the grain and seeds move relatively freely across national jurisdictions, but the regulatory decisions and associated data and analyses do not. Combined with the realities of agricultural production, this has led to a legal and regulatory challenge due to the low level presence (LLP) of GE grain or seeds that do not have regulatory approvals in the country of destination. In order to assist regulators in conducting environmental risk assessments related to LLP, reviews of environmental safety data, including associated regulatory analyses and decisions, for proteins commonly introduced in GE plants have been produced.

INTRODUCTION

The first regulatory decision allowing unrestricted environmental release of a GE plant was issued in 1992, for a tomato with delayed ripening characteristics (USDA APHIS, 1992). Although much has been written about the tomato in the popular press, it is primarily remarkable for being the first of many GE plants introduced under a new regulatory paradigm for agriculture. This paradigm involves a pre-market environmental risk assessment as a prerequisite for the unrestricted environmental release of a GE plant and was the result of nearly a decade of deliberation following the first introductions of novel genes into plants beginning in the early 1980s. Previously, introductions of new plant varieties, if subject to any regulation at all, were typically only subject to agronomic performance and varietal purity standards. Through incorporation into national laws and regulations, as well as through international agreements such as the Cartagena Protocol on Biosafety, this new regulatory paradigm has become nearly universal, and most countries do not permit the release of a GE plant into the environment prior to a regulatory decision informed by an environmental risk assessment.

Although this regulatory paradigm has allowed for the introduction of GE crops on millions of acres in more than 25 countries (James, 2011), it has also created a new regulatory challenge in dealing with the low-level presence (LLP) of GE varieties that may be approved in the country of origin but not in the country of arrival.

LOW LEVEL PRESENCE (LLP) OF UNAPPROVED VARIETIES

There is no single, agreed upon definition for low-level presence as it relates to GE plant material, but the common understanding is that it occurs when a small amount of unapproved GE plant material is found mixed in with otherwise authorized material (CFIA, 2010; Kershen et al., 2005; Stein and Rodríguez-Cerezo, 2010a; USDA APHIS, 2007). The authorized material may consist of non-GE material, approved GE material or a combination of the two. LLP occurs internationally when exported material is approved in the country of origin but not in the country of destination, a situation that arises from asynchronicity in the issuance of approvals by regulatory authorities.

It is worth noting that there is nothing about GE plants or their transgenes that is uniquely susceptible to the types of movement that lead to LLP. It has long been known to farmers and seed producers that 100% varietal purity is not practically achievable. The presence of so-called “off-types” stemming from cross-pollination, seed mixture, comingling during handling and transport, or human error can be reduced with proper management, but not reduced to zero (Kershen et al., 2005; OECD, 2011). However, the unique regulatory status of GE plants combined with modern technologies that make the detection of transgenes in bulk grains or seeds possible, even at very low levels, has created a regulatory problem that has not previously been experienced (Stein and Rodríguez-Cerezo, 2010b).

TOOLS FOR ENVIRONMENTAL RISK ASSESSMENTS OF GE PLANTS UNDER LLP CONDITIONS

Depending upon the jurisdiction and the specifics of a particular LLP scenario, a risk assessor may be asked to undertake an environmental risk assessment (ERA) to evaluate potential adverse environmental impacts. This may be especially true for LLP in seed, which is intended for release into the environment compared to shipments of grain which may only be incidentally released into the environment. The ERA paradigm for GE plants takes into account the plant, the introduced trait, the receiving environment and interactions between them. In situations of LLP, the risk assessor may have access to information from the exporting country or the product developer (or both) that can be used to inform their assessment. However, this may not always be the case and an assessor may be asked to develop an ERA with limited information about the GE plant that is the subject of the assessment. Fortunately, after nearly 20 years of international experience with the risk assessment of GE plants, information is readily available in the public domain to assist risk assessors in gathering information for their assessment.

There are a number of useful resources available that have been specifically developed to provide information about the untransformed plant species in order to inform ERA. Prominently, the OECD’s Working Group on Harmonization of Regulatory Oversight of Biotechnology has 12 consensus documents on the biology of crop plants detailing the aspects of the plant’s biology that are relevant for ERA. These documents are internationally recognized as valuable resources and are often included in regulatory submissions related to GE plants. Additionally, national governments, including Australia, Canada and India have assembled similar biology documents that provide

additional detail relevant to the biology of a particular plant species in the respective countries.

Information regarding the environmental safety of specific proteins that are expressed in commercially cultivated transgenic plants that may enter trade is less readily available.

THE PROTEIN SAFETY MONOGRAPHS

The purpose of the protein safety monographs developed by the Center for Environmental Risk Assessment is to provide specific information related to the safety of a protein that has been introduced into GE plants in the environment. All of the data used in generating the monographs come from publicly available sources, including peer reviewed literature, regulatory submissions and regulatory decision documents. The monographs are not environmental risk assessments of any particular GE event. Instead, they summarize and review available information that may be relevant to those tasked with undertaking risk assessment of GE plants, and may be particularly useful for risk assessments of GE plants associated with LLP situations.

The format for the monographs includes a brief introduction, followed by a review of the origin and function of the subject protein. This includes a description of what is known about how the protein functions along with a short history of its discovery and use in order to facilitate any additional investigation by readers. The monograph also includes regulatory data specific to the protein, including any data on interactions with non-target organisms as well as observed expression levels in GE plants. In addition, a review of information related to the interaction of the protein with the plants into which it has been transformed is provided. This includes a summary of the phenotypic data describing the GE plant in comparison to the untransformed plant and addresses characteristics related to survival and persistence in the environment. It also includes a review of data related to compositional analyses of GE plants that express the protein, when compared to their untransformed counterparts. The monographs provide a brief review of regulatory analyses of the likelihood and consequences of movement of the protein (through gene flow) to sexually compatible wild or weedy relatives. Each monograph also contains one or more annexes with supporting data.

SUMMARY

It is important to keep in mind that the protein safety monographs are not, by themselves, an environmental risk

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assessment of any particular GE plant in the environment, or under any particular instance of LLP. The monographs are limited to information and data specific to the subject protein that are available in the public domain, much of which is independent of the individual transformation event. However, in conjunction with other available information relevant to the plant species and the receiving environment, the protein safety monographs provide a valuable resource for risk assessors, particularly those considering LLP situations that involve the subject proteins. By collecting regulatory data from multiple transgenic events expressing the same protein, it is possible to make conclusions about the behavior of the protein in GE plants. For example, none of the subject proteins shows any discernible pattern of impact on growth habit or composition of the GE plant indicating that the protein itself is unlikely to have an impact on these characteristics in future transformation events. Coupled with data presented on levels of expression and potential adverse impacts on other organisms in the environment, these monographs provide a valuable resource for risk assessors and others interested in the environmental safety of these proteins.

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