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Non-target and Biodiversity Risk Assessment for Genetically Modified (GM) Crops

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Abstract

We outline a methodology to assess directly the potential harms posed by genetically modified (GM) crops to non-target organisms and biological diversity. The essential components include: 1) a risk endpoint selection process, 2) a process relying on risk hypotheses to guide the characterization of exposure, adverse effects and risk, and 3) a dynamic and adaptive tiered process. Significant properties of the methodology include: 1) it relies on all available scientific information, 2) it relies first on qualitative information and methods and proceeds to quantitative approaches only as necessary, 3) it is structured in a way to overcome the lack of information common in developing countries, and 4) it attends to the special needs of highly biodiverse countries

Keywords

Risk endpoint, risk hypothesis, tiered assessment, non-target risk, biodiversity risk

Introduction

The 1997 US Presidential/ Congressional Commission on Risk Assessment and Risk Management addressed the "clear need to modify the traditional approaches used to assess and reduce [environmental] risks", and in the final documents (1997a, 1997b) the Commission stated "Conclusions about risk are based almost exclusively on observations of toxicity from high doses of the chemical in laboratory animals or in the workplace. While these approaches have contributed to tremendous progress in reducing health, safety, and environmental risks in recent decades, they are not adequate for addressing the more complex risk problems we now face (1997a, p. 2)."

For genetically modified (GM) plants, in particular, there has been a significant shift in the approaches used by several national authorities to assess risks of GM plants to non-target organisms and biological diversity. These shifts have been foreshadowed by shifts in the methods used for assessing pesticidal chemicals and several other toxic chemicals in the environment. The historical details of how these shifts occurred are complex and not unidirectional, but as scientific knowledge has accumulated, attention has shifted from assessing a specific set of "indicators" that might be indicative of possible adverse environmental effects to assessing directly the potential harms (risk endpoints) that could be caused (Snow et al. 2005; Andow & Zwahlen 2005).

In this paper, we outline a methodology that aims to assess directly the potential harms to non-target organisms and biological diversity that could be caused by a specific GM plant in a particular receiving environment. The methodology has several important features, of which

three will be emphasized here: 1) a process to select a restricted number of species and ecosystem processes for risk assessment, identifying appropriate risk endpoints and selecting those considered most at risk, 2) a process relying on risk hypotheses (USEPA 1998) to guide qualitative and quantitative exposure characterization, adverse effects characterization and risk characterization, and 3) a dynamic and adaptive tiered process. Important properties of the methodology include: 1) reliance on all available scientific information and information from local experts, 2) use of generally available scientific information and qualitative methods, proceeding to quantitative methods and experimental data only as necessary, 3) a structure that overcomes the lack of information common in developing countries, and 4) attention to the special needs of highly biodiverse countries. Many of these properties make the adoption of proposed methodology attractive for developing countries.

Risk endpoint selection

The selection of risk endpoints starts by specifying the receiving ecosystem (crop environment) and listing relevant ecological functional groups so that the biological diversity of the ecosystem is simplified into a smaller number of functional categories (Andow & Hilbeck 2004). This reduces the complexity of the system as the number of species and ecosystem processes far exceeds the number of distinct ecological functions in any ecosystem ("functional redundancy") (e.g., Hubbell 2006). For each of these functional groups, a characteristic risk endpoint is identified. For example, "herbivores of the GM crop" is a functional group that is associated with the risk endpoint of yield losses caused by secondary pests. Depending on the crop, the kind of GM trait and the receiving environment (including the crop management environment), some of the functional groups may be selected and some may be ignored. We illustrate this process by comparing a Bt crop, an HT crop, and a VR crop.

The next step is to list relevant species and ecosystem processes within each selected functional group (Birch et al. 2004; Hilbeck et al. 2006). A single species or process may be classified into more than one functional group. For example, some adult coccinellids may be predators and pollen feeders and some syrphids have predatory larvae and flower-feeding adults. Within each functional group, a series of qualitative ecological characteristics can be used to rank the species in relation to the likelihood of the risk endpoint associated with the functional group (Sujii et al. 2006; Arpaia et al. 2006; Faria et al. 2006; Pallini et al. 2006; Mendonça et al. 2006). The aim at this point in the process is to bracket the risk using min-max methods rather than to estimate the expected risk.

Overall, the selection of risk endpoints is a process that relies on informed expert judgment about the crop, the kind of GM trait, and the receiving environment, but does not rely on specific information about the transgene or transgene product or products. This process typically has resulted in a 90-95% reduction in the number of species and ecosystem processes to be considered for risk assessment, can be done in about one day with experts who have little experience in risk analysis or the methodology, and relies on very general and qualitative information that is often readily available.

Risk hypotheses

Subsequent to the selection of risk endpoints, the methodology develops risk hypotheses to facilitate risk characterization. A risk hypothesis is a causal chain starting from the GM crop and ending with a risk endpoint (USEPA 1998). Typically, risk hypotheses are complex interconnected nets of multiple chains because there are multiple pathways by which a given GM crop could generate a given adverse effect to the environment. Constructing a risk hypothesis for

a GM crop requires information about the transgene, the transgene product(s) and the expression of the transgene in the GM plant. A risk hypothesis is comprised of an exposure pathway or a series of exposure pathways (Andow et al. 2006) coupled to pathways that lead to specific adverse effects Coupled with knowledge about the receiving environment and the selected species or ecosystem process from the previous section, it is possible to represent diagrammatically all of the known and hypothetical significant causal pathways by which a GM crop may result in an adverse effect for a given risk endpoint and species or ecosystem process. This can be done efficiently using event-tree and fault-tree analysis, making sure that all possible risk hypotheses are represented in the diagram, regardless of their likelihood.

A causal chain in a risk hypothesis is structured as the intersection of multiple causal links. Hence, for a risk hypothesis to be true (or likely), all of its component links must also be true (or likely). Consequently, a risk hypothesis can be falsified by disproving any one of its component links. In our methodology this property of falsifiability can be used to allocate effort so that the most significant risks receive the most effort during the risk assessment.

Risk hypotheses can be analyzed to identify weak links, testable links, and master links. A weak link is one that can occur but not likely to occur. A testable link is one that can be readily and inexpensively quantified whether it is likely or not. A master link is one through which multiple causal chains pass, and so may be targeted as a high priority for risk assessment research. These categories are not mutually exclusive.

A causal chain containing multiple weak links is *a priori* an unlikely risk hypothesis. It may not be necessary to quantify such pathways, but this determination should be carefully considered. Ignorance about link strength, inappropriate inference about link strength based on faulty analogical reasoning or inappropriate extrapolation from previous data, and scientific bias against a risk because, for example, it may seem preposterous, can influence an assessor to perceive a link as weak. An assessor should consider how much it would cost to confirm that at least one of the links is weak (and thus convincingly refute this link) versus making a faulty conclusion. In many cases weak links are testable links, and the cost of assessment would be low.

After eliminating unlikely hypotheses with multiple weak links, the assessment strategy is to focus effort on testable master links and the remaining weak links, keeping in mind that the goal is to falsify the risk hypotheses. If at any point, the risk hypothesis is falsified (or determined to be unlikely), the assessment process can be terminated. By using this strategy, ultimately the most effort will be spent on the risk hypotheses that are the most likely, and these hypotheses will have the most accurately estimated risk.

Dynamic and Adaptive Tiered Process

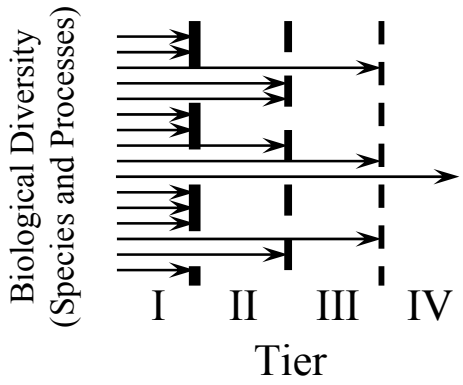
A tier is a process within a risk assessment that is initiated by a decision to collect information and data and ends with a decision. This decision is either that the risk can be and is assessed based on the available information and data, or that the risk cannot be assessed and additional information or data are needed (Andow & Zwahlen 2006). There seems to be consensus that GMO environmental risk assessment(ERA) should be tiered. The reasons vary among the advocates, but important factors include reducing the cost of environmental risk assessment, concentrating effort on the most serious risks, and providing a rapid assessment procedure for some GM plants where there is already a large amount of compatible ERA data available. In general a tiered risk assessment is expected to allocate more effort and time to more serious risks and less to less serious risks.

Our methodology is also structured as a tiered risk assessment process, but the tiers are substantially different from those used in the typical environmental toxicology system and

different from those proposed by other authors for GM plants. For GM plants, other authors propose tiers that correspond to confined experiments with GM plants and field experiments with the purpose of removing particular ecological receptor entities from assessment. This proposal has a clear logistical rationale, but it is not yet clear that it meets the risk-based rationale for tiers. Hence we propose a different tiered system that meets the logistical and risk-based criteria for tiers. Our system focuses on removing risks and adverse effects via tiers rather than the ecological receptor entities.

Within the scope of this discussion, the risk assessment problem is to evaluate the potential adverse effects of a given GM plant in a given receiving environment to all elements of biological diversity in that receiving environment. Because there are thousands of species and hundreds of ecosystem processes that could be evaluated, it is not feasible to evaluate each one. Our methodology, however, provides four "tiers" to assess risks to biological diversity in particular receiving environments (Fig. 1).

Fig 1. Tiering in risk assessment process. All species and processes start on the left and are progressively evaluated through the four tiers.



Tier I is the determination of relevant functional groups (first part of the identification of risk endpoints). Implicit with this determination is that the functional groups that are excluded are deemed irrelevant because there are no substantial risks associated with them. Tier II is the selection of species and processes considered most associated with a risk endpoint. This tier further reduces the potential candidates for further risk assessment, because the unselected species and processes are judged to be at lower risk (and thus negligible) than the selected ones. Although our tiers I and II are classically considered a part of the problem formulation process in ecological risk assessment (e.g., USEPA 1998), we recognize that these determinations include important elements of risk characterization and therefore have removed them from the problem formulation process. Tier III is a qualitative assessment of the risk hypotheses (including simple tests of weak links), considering both direct and indirect effects. At which time it may be possible to determine that the risk to several of the selected species and processes is unlikely and small. This tier removes specific risk hypotheses, but the ecological entity may still be affected via other risk hypotheses.

Tier IV is the quantitative assessment, and could include acute toxicity tests and other laboratory tests, greenhouse trials, and field trials on the non-GM crop and/or the GM crop. By focusing on falsifying the risk hypothesis, several alternative evaluation processes may also be possible that could efficiently and effectively evaluate the risk hypotheses. The most appropriate sequence of tests may be designed for the settings available to researchers in each country. For example, one may consider the feasibility of the study to attain a certain level of statistical power. Available methods to detect 20% differences in population density generally require such a high number of replications to have a proper statistical power that it is logistically impossible to conduct such an experiment. In such cases, alternative assessment strategies must be considered.

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