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Book Review

Environmental Risk Assessment of Genetically Modified Organisms: Volume 1. A Case Study of *Bt* Maize in Kenya Edited by Angelika Hilbeck and David A. Andow

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The adoption of crops with novel traits produced by genetic engineering poses vexing problems for public policy. Regulatory decision-makers worldwide are expected to balance two goals: the minimization of risk and the maximization of food security or economic opportunity. The former goal is made difficult for genetically engineered organisms (GMOs) whenever uncertainty reduces the predictability of environmental risk, and the latter by the complexity of local and global markets. The best possible case-by-case understanding of the crop, the trait and the environment into which it will be introduced supports policy decisions on both counts. In the absence of case studies, scientific uncertainty forces policy makers to sift through available, sometimes contradictory data, analyses and claims, and often to extrapolate from crop to crop, trait to trait and from one geographic region to another. In this context, a new series of volumes on environmental risk assessment, which will present detailed cases of genetically modified organisms in different parts of the world, is a critically important and timely contribution.

The first volume on *Bt* maize in Kenya sets the stage for making these case studies valuable in several ways. First, it is an excellent reference for understanding the contexts and levels of inquiry involved in scientifically rigorous environmental risk assessment. It embodies a fresh approach to risk assessment that addresses many of the criticisms leveled at common practices for regulatory decision-making. Second, the volume arises from an international collaborative process to help strengthen scientific and technical capacity in biosafety assessment for GMOs worldwide. Third, a treatment of *Bt* maize in Kenya is timely, since its framework for risk assessment precedes the introduction of these GMOs for field-testing. The book is meant to help governments, scientists, potential users of GMOs and civil society organizations to strengthen their understanding of current scientific knowledge and methods in risk assessments of GMOs. In this regard, the book is extremely useful for Kenya, other African countries, and generally as a guide for conducting case-by-case risk assessments under different environmental and social conditions.

Chapter 1 by editors Hilbeck and Andow provides an elegant summary of the science of *Bt* maize, including transgenesis and breeding procedures, and discusses the relevance of this background information in conducting risk assessment to support regulatory policy. Its contextual discussion of the role of rigorous, science-based methods and transparency in meeting the requirements of the Cartagena Protocol on Biosafety includes a critical overview of risk assessment approaches, standards of comparison, and appropriate experimental design. Hilbeck and Andow present the case study of *Bt* maize in Kenya as the effort of public-sector scientists to bring the collective wisdom of the scientific community to bear on the aspirations of the Protocol. One of their aims is to aid Kenya to act as a regional center of expertise in the adaptive and dynamic process of risk assessment for GMOs in Africa. While the chapter clearly concerns *Bt* maize and Kenya, its content is broadly useful for its treatment of how GMOs are developed, used, and evaluated scientifically.

Chapter 2 is an excellent review of maize production in Kenya, including regional differences in socio-economic conditions, climate, soil conditions, weed, disease, and lepidopteran pest pressures, cultivar/landrace preferences, and alternative pest control systems. This contextual information is used in Chapter 3 to discuss the potential utility of *Bt* maize in Kenya and frame the questions and problems associated with the design and adoption of this technology in the Kenyan context. The format includes a trial run of a Problem

Formulation and Options Assessment (PFOA) process, in which participants brainstorm about what societal needs will be met by the GMO, at what potential level of risk for different sectors. The process requires a comparative assessment of alternative futures, which responds to criticisms of common approaches that limit comparisons of new technologies to a single, conventional practice. The PFOA Model is shown here as a useful way of taking complex issues wrought with controversy, and airing them in a way that lends social legitimacy to the decision-making process.

Chapters 4, 5, 6 and 7 collectively authored by over 40 scientists from Kenya and around the world, treat different avenues of potential risk for maize – development of unexpected gene products or unintended interactions with other plant genes, non-target species effects and biodiversity impacts, gene flow to cultivated relatives, and development of resistance in maize pests, respectively. Each of these chapters clearly identifies hazards that could arise from maize in Kenya, and lays the foundation for testing for, assessing, or avoiding these hazards. These chapters use a refreshingly transparent approach in which the guts of scientific inquiry are visible and limits to discovery are openly described. The resultant almost stream of consciousness lists of questions and painstaking discussions of procedural rationales in some sections show how the process of scientific inquiry works, and what criteria or lines of reasoning are used for incremental decisions and assumptions along the way. These approaches arise as an improvement to common shortcuts appearing in "first generation" risk assessments evaluated recently (NRC 2002, Royal Society of Canada 2001). The model risk assessment process illustrated in this volume presents a thorough investigative framework with concrete methods for evaluating risk. Optimum data for decision-making is the goal. Data shortfalls are addressed explicitly, whether a question has not been investigated, cannot be investigated, or the results are not publicly available.

For example, characterization of the transgene locus structure and transgene expression in a particular environment is critical for risk assessment, yet has not been routine. A scientific strategy for gaining this knowledge and reducing uncertainty is outlined for maize transformation events and varieties adapted to growing conditions in Kenya. Risk assessment steps for each event, cultivar, and location require expanded efforts (Bergelson and Purrington 2002), but design improvements suggested in this chapter, such as removal of marker genes, are geared to reducing other risk assessment efforts. Determining potential impacts of GMOs on local biodiversity is difficult in any context. However, protocols for selecting relevant species for non-target impact and biodiversity assessments are outlined, as well as specific testing procedures for above- and below-ground biotic communities. The logical sequence of hypothesis formulation, testing procedures, and transparent communication of rationales detailed in this volume is widely applicable, with Kenya as an illustrative example. These chapters provide in-depth engagement, with recommendations for field experiments, laboratory studies, and how to grapple with questions that cannot be answered adequately in the pre-deployment stage. Chapter 8 discusses and synthesizes key findings in each chapter, prioritizes scientific information needs, and gives substance and process recommendations for completing a risk assessment for maize in Kenya. In essence, this volume lays out what science is needed for the best possible environmental risk assessment of a GMO. A common challenge to a precautionary approach in risk assessment is to distinguish what we need to know from what would be nice to know to assess risk. The counter-challenge in this volume, I think, is to require an open discussion of when and why a risk assessment falls short of rigorous scientific standards.

The first volume of this series on environmental risk assessment for GMOs (edited by A. R. Kapuscinski and P. J. Schei) is broadly useful as a case study that presents a lucid framework for how participatory risk assessment can be done. In a few cases, the organization of information in the chapter sections and chapters could be improved. For example, the fact that this volume precedes the introduction of any maize in Kenya is not stated explicitly until later chapters. Obviously, a risk assessment process should precede introduction of the GMO, but the subtitle "A Case Study of Maize in Kenya" on a cover picture of maize in the field can be misleading without more contextual information up front. Also, in some cases the most useful definition of a term or example of a potential hazard is expressed pages after the term is used or a route to a potential hazard is described. Overall, the volume is very well written, packed with accessible information, and aptly models a transparent mode of the risk assessment process. The book is multifaceted, and includes a variety of insights not found in other treatments of GMO risk assessment. It sets the stage for a new standard of risk assessment, in which the methods, quality of evidence, and barriers to discovery are discussed openly. Such a conscious treatment of scientific process puts another nail in the coffin for using the term 'scientifically based' for risk assessments that clearly do not meet the kinds of standards described in this volume.

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