Environ. Biosafety Res. 5 (2006) 201–203
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DOI: 10.1051/ebr:2007023

Available online at:
www.ebr-journal.org

Session VII: Risk Management and Monitoring

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PRESENTERS

The EFSA Opinion on Post Market Environmental Monitoring of GM Plants
Suzy Renckens
European Food Safety Authority
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Ten Years of Monitoring for *Bt* Resistance in the European Corn Borer: What We Know, What We Don't Know, and What We Can Do Better
Blair Siegfried
University of Nebraska
Lincoln, USA

Risk Assessment and Management of LMO-FFPs in Korea: Current Status of Research and Regulatory Framework
Dong-Hern Kim
NIAB
Kwonson-Ku, Korea

Measuring the Costs of Biosafety Regulation and the Potential Impacts on Biotechnology Research and Development
Nick Kalaitzandonakes
University of Missouri-Columbia
Columbia, USA

Developing a Regulatory Biosafety Framework: Trends, Challenges and Issues on Risk Assessment and Management in a Developing Country Context
Alex Owusu-Biney
Biotechnology and Nuclear Agriculture Research Institute
Accra, Ghana

Biosafety regulatory frameworks are intended to serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. In several regulatory systems GMO risk assessment has been separated from GMO risk management. As a consequence, risk assessment can be performed on a purely scientific basis, whereas risk management can take additional aspects (*e.g.* socio-economic or ethical) into consideration. For instance, the European Food Safety Authority (EFSA), the keystone of European Union risk assessment regarding food and feed safety, provides independent scientific advice and clear communication on existing and emerging risks in close collaboration with national authorities and in open consultation with its stakeholders. Risk management measures are not within the remit of EFSA, and remain the responsibility of the European Commission and Member States.

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Understanding the potential for adverse environmental effects from GMOs and the characterization of associated risks depends not only on the quality of biosafety research, but also on ongoing interaction between risk assessors, regulators and researchers. The purpose of Session VII "Risk Management and Monitoring" was to present methodologies that manage and mitigate risk and allow feedback for validation of the initial assessment. The relationship between assessment and the identification of risk mitigation measures was discussed. The session also emphasized the iterative nature of the overall risk assessment process. Risk management and monitoring are thought of very differently in different legal settings. Risk management is considered as part of the risk analysis process, while monitoring may or may not be part of the risk analysis process for any particular case.

Session VII "Risk Management and Monitoring" consisted of five presentations reflecting the views of different stakeholders:

- Suzy Renckens – The EFSA Opinion on Post Market Environmental Monitoring of GM Plants
- Blair Siegfried – Ten Years of *Bt* Resistance Monitoring in the European Corn Borer: What We Know, What We Don't Know, and What We Can Do Better
- Donghern Kim – Risk Assessment and Management of LMO-FFP in Korea: Current Status and Regulatory Framework
- Nicholas Kalaitzandonakes – Measuring the Costs of Biosafety Regulation and the Potential Impacts on Biotechnology Research and Development
- Alex Owusu-Biney – Developing a Regulatory Biosafety Framework: Trends, Challenges and Issues on Risk Assessment in a Developing Country Context.

In the frame of the European GMO regulations, post-market environmental monitoring (PMEM) is considered as an integral part of placing GM plants on the EU market. PMEM aims at identifying unanticipated adverse effects on human health or the environment that could arise directly or indirectly from GM plants. PMEM is composed of case-specific monitoring and general surveillance. EFSA is asked to assess the scientific quality of PMEM plans submitted with each application. The EFSA GMO Panel also makes a number of recommendations for the management and conduct of PMEM by both applicants and risk managers. A mechanism should be established for considering the interactions of several different GM plants subject to different applications. It is proposed that national Competent Authorities should establish liaisons with different applicants in order to coordinate data collection and analysis from different monitoring programs. Mechanisms should be developed by risk managers for reporting and collating monitoring data, at both the Member State and EU level. This will facilitate scientific analysis of these data, and provide scientific conclusions for informing decisions on the future cultivation of GM crops as well as future risk assessments. The interplay between applicants, risk assessors and risk managers should be close, in order to acquire the best possible experience and effectiveness for PMEM.

The ability to effectively monitor the development of insecticide resistance prior to a control failure is an essential component of resistance management strategies for transgenic plants that express *Bt* toxins and a regulatory requirement for registration of *Bt* events in the U.S. Until now, there was no evidence of increasing frequency of resistance among field populations based on subsequent sampling of the same area. Analyzing the results of ten years of *Bt* resistance monitoring in the European Corn Borer illustrates the sensitivity of the current monitoring efforts to identify resistance among field populations and the necessary steps that are taken to confirm and characterize the resistance and assess risk for product failure.

The current status and regulatory framework for GMO risk assessment and management in Korea has been discussed. Korea is now developing a national framework for risk assessment and management, to ensure GMO biosafety for contained use and for environmental release to confined and open fields, and to comply with domestic and international regulations. It is believed that sound and transparent regulations would be one key factor for the success of modern biotechnology.

Biosafety regulatory frameworks should serve as mechanisms for ensuring the safe use of biotechnology products without imposing unintended constraints to technology transfer. To be able to judge the sensitive balance between these aspects of GMO risk management, measuring the costs of biosafety regulation and the potential impacts on biotechnology research and development is crucial. A necessary first step to answering questions about the causes and consequences of the process of regulatory approval for new biotech crops is to understand the operation of the regulatory system and the size and structure of the costs of compliance. It seems that the compliance costs incurred by biotechnology developers are quite high, and the regulatory burden of novel biotech crops might be out of balance.

Reflections on trends, challenges and issues on risk assessment and management in a developing country context were presented. Biosafety regulatory frameworks were reviewed in relation to the development process, challenges and trends in its formulation, especially in the context of risk assessment and management. The choice of a biosafety regime in the context of developing countries is influenced not only by the science-based approach in risk analysis but also by the social, political and environmental governance mechanisms and experience gained in relation to practice and conventions within a particular country.

https://doi.org/10.1051/ebr:2007023 Published online by Cambridge University Press

The chair has asked the speakers to formulate/phrase the main take-home messages from their talks to be presented at the end of Session VII. These take-home messages/key statements are summarized below in the order of the topics (i) Relevance to Risk Assessment, (ii) Use by Regulators, (iii) Next Steps in Research, and (iv) General Conclusions.

THE EFSA OPINION ON POST MARKET ENVIRONMENTAL MONITORING OF GM PLANTS

(1) Case-specific monitoring of potential risks identified in Risk Assessment (RA): confirm RA or provide feedback to complete RA; general surveillance: more related to risk management – if unanticipated adverse effects are identified, define cause relationship and feed back into RA.
(2) Results of monitoring could lead to revision of RA and Risk Management decisions.
(3) Importance of analysis of monitoring data – a central reporting office might be established; amend existing networks to be more suitable for GMO monitoring; regional and national scale might be beyond the control of the applicant – public sector might be involved; synergistic/antagonistic effects between several different events should be considered.
(4) Recommendations to risk managers to make the system work; establishment of a central reporting office.

TEN YEARS OF *Bt* RESISTANCE MONITORING IN THE EUROPEAN CORN BORER: WHAT WE KNOW, WHAT WE DON'T KNOW, AND WHAT WE CAN DO BETTER

(1) Effective monitoring and surveillance of resistance among target pests is an important component of environmental risk assessment for *Bt* crops.
(2) Annual assessment of susceptibility in target pests: a regulatory requirement for all registrants of *Bt* crops.
(3) Utilize existing resistant strains to improve detection sensitivity and to refine resistance risk assessments; improve standardization of toxins for bioassays.
(4) Based on available techniques, European corn borer remains susceptible to *Bt* toxins ten years post-commercialization of *Bt* maize; reliable, accurate, and efficient bioassay methods: critical to future monitoring efforts.

MEASURING THE COSTS OF BIOSAFETY REGULATION AND THE POTENTIAL IMPACTS ON BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

(1) Risk assessment methods, data requirements, review timetables, *etc.*, directly translate into compliance costs. Such costs are directly related to incentives/disincentives for innovation – and influence the biotechnology pipeline.
(2) While the benefits of GM regulation are explicitly considered (ensuring safe use of GMOs without unacceptable health and environmental risks), regulatory costs are rarely accounted for. Regulatory effectiveness requires that an appropriate cost-benefit balance is ultimately established. Both risk managers and risk assessors should be aware of and sensitive to such cost-benefit balance, and account for it in their deliberations.
(3) Evidence presented here is a first attempt to organize and characterize compliance costs associated with biotechnology regulation. More research is necessary to confirm and extend such estimates for other crops, traits, and over time.
(4) Regulatory compliance costs for global corn premarket approval are found to be high. Such compliance costs are important indicators as they are closely connected to innovation incentives and output. There is some initial evidence that biotechnology innovation is slowing down, and regulatory costs have been viewed as a primary cause. Regulators must tend to a delicate balance of managing risk, while preserving the opportunity for innovation so that social welfare is maximized.

DEVELOPING A REGULATORY BIOSAFETY FRAMEWORK: TRENDS, CHALLENGES AND ISSUES ON RISK ASSESSMENT IN A DEVELOPING COUNTRY CONTEXT

(1) Provide feedback data on risk assessment; enhance knowledge and familiarity in managing GM products.

(2) Build global biosafety research capacity/expertise; harmonize existing databases: biosafety research, ERA (BBI, OECD, BCH); update unique identifier; develop protocols/guidance on risk management.

(3) Update product biology databases; improve sampling methodologies; develop and harmonize detection/validation procedures; improve GM product profiling.

(4) Scientific leadership and a stronger voice are needed in current global debate; national/regional/global commitment to biosafety research is needed; continuous cooperative research initiatives between North and South to enhance global capacity; continuous research-regulator engagement to build knowledge in biosafety research and biotechnology product development.

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