



ISBR

*International Society
for Biosafety Research*

9th ISBGMO

Session VII

**Risk Management and
Monitoring**

Joachim Schiemann

- Suzy Renckens:** **Post Market Environmental Monitoring**
- Blair Siegfried:** **Monitoring for Bt Resistance in ECB**
- Dong-Hern Kim:** **Risk Assessment and Management in Korea**
- Nick Kalaitzandonakes:** **Costs of Biosafety Regulation: Impacts on Biotechnology R&D**
- Alex Owusu-Biney:** **Regulatory Biosafety Framework in a Developing Country**



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Suzy Renckens:

**Post Market Environmental
Monitoring**

Relevance to Risk Assessment

**Case-specific monitoring of potential risk identified in
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**

Use by Regulators

**Results of monitoring could lead to revision of RA
and RM decisions**

Next Steps in Research

Importance of analysis of monitoring data: central reporting office?

Amend existing networks to be more fit for GMO monitoring

Regional and national scale beyond control of the applicant (involving public sector?)

Synergistic / antagonistic effects between several different events?

General Conclusions

**Recommendations to risk managers to make the
system working**

Central reporting office

Blair Siegfried:

**Monitoring for Bt
Resistance in ECB**

Relevance to Risk Assessment

Effective monitoring and surveillance of resistance among target pests is an important component of environmental risk assessment for Bt crops

Use by Regulators

**Annual assessment of susceptibility in target pests:
a regulatory requirement for all registrants of Bt
crops**

Next Steps in Research

Utilize existing resistance strains to improve detection sensitivity and to refine resistance risk assessments

Improve standardization of toxins for bioassays

General Conclusions

Based on available techniques, European corn borer remains susceptible to Bt toxins 10 years post-commercialization of Bt maize

Reliable, accurate, and efficient bioassay methods: critical to future monitoring efforts

Nick Kalaitzandonakes: Costs of Biosafety Regulation: Impacts on Biotechnology R&D

Relevance to Risk Assessment

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 biotech pipeline

Use by Regulators

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.

Next Steps in Research

Evidence presented here is first attempt to organize and characterize compliance costs associated with biotech regulation. More research is necessary to confirm and extend such estimates for other crops, traits, and over time.

General Conclusions

Regulatory compliance costs for global corn pre-market 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 biotech 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.

Alex Owusu-Biney:

**Regulatory Biosafety Framework
in a Developing Country**



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Relevance to Risk Assessment

Provide feedback data on risk assessment

**Enhance knowledge & familiarity in managing GM
products**

Use by Regulators

Build global biosafety research capacity / expertise

**Harmonize existing databases: biosafety research,
ERA (BBI, OECD, BCH)**

Update unique identifier

Develop protocols / guidance on risk management

Next Steps in Research

Update product biology databases

Sampling methodologies

**Develop / harmonize detection / validation
procedures**

GM product profiling

General Conclusions

Scientific leadership / stronger voice needed in current global debate

National / regional / global commitment to biosafety research

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