EFSA Scientific Colloquium 8

Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches

20-21 June 2007 Tabiano (PR), Italy

BRIEFING NOTES FOR DISCUSSION GROUPS

The objectives of the Colloquium are to

- consider the approaches to environmental risk assessment in the light of current scientific thinking,
- address issues, such as environmental fitness, effects on non-target organisms, long-term effects, effects of large scale production, effects on life cycles of production systems, broader environmental considerations and risks versus benefits,
- review the current environmental risk assessment methodology if necessary.

These briefing notes have been prepared to stimulate an open interactive exchange of views and expertise on scientific aspects and issues to be considered when risk assessing GM plants.

Focus should be on the risk assessment methodology of GM plants and, in particular, as regards the potential effects on non-target organisms, the long-term effects as well as how to predict potential effects through modeling tools. Finally, broadening the scope of the environmental risk assessment, your input to the discussion on the risk-benefit analysis of GM plants for the environment is expected.

DISCUSSION GROUP 1 - Testing non-target organisms

INTRODUCTION

The EFSA Guidance Document for Risk Assessment of GM plants and derived food and feed says…" *an assessment is required of the possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GM plant with non-target organisms, including impact on population levels of competitors, herbivores, symbionts (where applicable), predators, parasites and pathogens*". Tests on non-target organisms along bi- and tritrophic interactions including direct and indirect effects are widely accepted in risk assessment. However, there are broad discussions on the power and flexibility of risk assessment conclusions based on above tests.

DISCUSSION POINTS

In this discussion, consideration should be given to the following points:

1. How to define the different risk assessment approaches for the potential effects of GM crops on non-target organisms? In the case of import for processing and for cultivation purposes?
   What are the rationales?
   Are they considered complementary approaches for testing non-target organisms?
   What would be the advantages and/or disadvantages of both approaches?
   Linking the measurement of endpoints with an overall goal.
   Is it possible to have trigger values?
2. How to formulate the problem? How to select the most representative (functional) non-target organisms groups of the receiving environment (e.g. large-scale production)?
3. How to predict and assess an ecological effect (e.g. environmental fitness)?
4. Representativeness of selected non-target organisms for various receiving environments in Europe ?

BACKGROUND DOCUMENTS

1. Andow, D.A & Zwahlen, C. (2006). Assessing environmental risks of transgenic plants. Ecology Letters, 9**:** pp. 196-214.
2. Andow, D.A. *et al.* (2006). Non-target and biodiversity risk assessment for genetically modified (GM) crops. 9th ISBGMO Proceeding, pp. 68-73.
3. Garcia-Alonso, M. *et al*. (2006). A tiered system for assessing the risk of genetically modified plants to non-target organisms. Environ. Biosafety Res. 5: pp. 57-65.
4. Johnson, K.L. *et al.* (2007). How does scientific risk assessment of GM crops fit within the wider risk analysis? Trends in Plant Science, 12 (1).
5. Kelly, C.K, Bowler, M.G., Breden, F., Fenner, M. & Poppy, G.M. (2005). An Analytical model assessing the potential threat to natural habitats from insect resistance transgenes. Proc Roy Soc B – Biol Sciences 27, 1759-1767.

6. Poppy, G.M.. (2003). The use of ecological endpoints and other tools from ecological risk assessment to create a more conceptual framework for assessing the environmental risk of GM plants. Proceedings of the BCPC International Congress Crop Science and Technology, Vol 2 pp1159-1166. Glasgow UK
7. Poppy, G.M & Wilkinson, M.J. (2005). Prospects for managing risk – A Road Ahead? In: Geneflow from GM plants – A manual for assessing, measuring and managing the risks. (eds G.M. Poppy & M.J. Wilkinson) Blackwell Publishing pp 225-238.
8. Romeis, J. (2006). Non-target risk assessment of GM crops and regulation. IOBC/wprs Bulletin 29(5) pp. 197-200.
9. Romeis, J. *et al*. (2006). Moving through the tiered and methodological framework for non-target arthropod risk assessment of transgenic insecticidal crops. 9th ISBGMO Proceeding, pp. 62-67.
10. Rose, R.I. (2006). Tier-based testing for effects of proteinaceous insecticidal plant incorporated protectants on non-target arthropods in the context of regulatory risk assessment. IOBC/wprs Bulletin 29(5) pp. 143-149.
11. Sutherland, J.P. **&** Poppy, G.M (2005). Quantifying exposure. In: Geneflow from GM plants – A manual for assessing, measuring and managing the risks. (eds G.M. Poppy & M.J. Wilkinson) Blackwell Publishing pp186-212.
12. Sweet, J.B. (2006). A commentary on the Bright programme on herbicide tolerant crops and the implications of the BRIGHJT and farm scale evaluation programmes for the development of herbicide tolerant crops in Europe. Outlooks on Pest Management December 2006, pp. 249-254.

DISCUSSION GROUP 2 – Using upscaling for modelling and assessing spatial and temporal effects

INTRODUCTION

Modern risk assessment requires a sophisticated approach to problems of scale. Firstly, whilst studies and predictions are often made at the field scale for a single season, we need to assess effects over a landscape or region and to do so at the temporal scale of rotations or decades. Scaling results up often requires a modelling approach, since resources are too scarce and time unavailable for large-scale experimentation. Models are now available that demonstrate how we may upscale in space and in time, and simulate large-scale agronomic processes within which models may operate.

DISCUSSION POINTS

The focus is made on risk assessment and NOT on co-existence issues. Whilst gene transfer has long been a concern in coexistence, it may not be crucial for environmental risk assessment, where the focus is on the *consequences* and not the *amount* of gene flow.

In this discussion, consideration might be given to the following points:

1. How to use modelling (e.g. of Bt resistance) as a tool to upscale environmental risk assessment?
2. How to quantify the effect(s) of upscaling (both in space and time) on an environmental risk assessment?
3. How to measure potential effects on insects population dynamics (e.g. shifts in pathogen populations, insurgence of secondary pests, etc.) from large-scale cultivation of GM crops?
4. How to integrate effects due to landscape and farming systems, into models that may aid environmental risk assessment?

5. Could the approaches used in the EU Water framework and the Habitats Directive (e.g. concept of basin, preservation of the receiving environment) be useful in GMO-related Environmental Risk Assessment?,
6. Can any recommendation be developed for the systematic integration of current modelling tools into the procedures and guidance for environmental risk assessment?

BACKGROUND DOCUMENTS

General paper:

1. Wiens, J.A. (1989). Spatial Scaling in Ecology. Functional Ecology, 3(4), 385-397.

Papers specific to risk assessment or to GMOs:

2. Butler *et al*. (2006). Farmland biodiversity and the footprint of agriculture. Science 315 (5810), 381-384 ; and the subsequent discussion by the UK ACRE Competent Authority: http://www.defra.gov.uk/environment/acre/meetings/07/min070222.htm
3. Final Report of the UK DEFRA-funded project: Assessing the environmental impact of crop production practice: beyond the GM farm-scale evaluation (joint with CGMP) (AR0317). http://www2.defra.gov.uk/research/Project_Data/More.asp?I=AR0317.
4. Proceedings of ISBR Conference in Jeju (24-29 September 2006) and in particular at Mike Wilkinson paper entitled *Gene Flow from GM Crops; Quantitative Approaches for the Assessment of Exposure on a Landscape Scale.*

For spatial upscaling see papers by the group headed by Broder Breckling, such as:

5. Breckling, B., Müller, F., Reuter, H., Hölker F. & Fränzle, O. (2005). Emergent Properties in INdividual-Based Ecological Models - Introducing Case Studies in an Ecosystem Research Context. In: Ecological Modelling 186, 376-388.
6. Mander, Ü., Müller, F. & Wrbka, T. (2005). Functional and Structural Landscape Indicators: Upscaling and Downscaling Problems. Ecological Indicators Vol. 5, Issue 4, 267-272.
7. See also the GenEERA project described on the webpage: http://www.gmo-safety.eu/en/safety_science/74.docu.html.

For an example of how population dynamic modelling may be used for temporal upscaling see:

8. Heard, M.S., Rothery, P., Perry, J.N. & Firbank, L.G. (2005). Predicting longer-term changes in weed populations under GMHT management. Weed Research, 45, 331-338.

For an example of how modelling can be applied to the descriptions of rotations in agronomy, see:

9. Castellazzi, M.S. *et al* (2007). New measures and tests of temporal and spatial pattern of crops in agricultural landscapes. Agriculture, Ecosystems & Environment, 118, 339-349.

DISCUSSION GROUP 3 – Predicting and assessing long-term effects

INTRODUCTION

It is recognised that an environmental risk assessment is only as good as our state of scientific knowledge at the time it was conducted. Thus, under current EU legislation, environmental risk assessments are required to identify areas of uncertainty or risk which relate to areas outside current knowledge and the limited scope of the environmental risk assessment. These include such factors as the impact of the large scale exposure of different environments when GM plants are commercialised, the impact of exposure over long periods of time and cumulative long-term effects. The scientific knowledge and experiences gained from monitoring GM crops will in turn inform the risk assessment process. Thus the results of monitoring are opportunities to continually update environmental risk assessments in the light of any new knowledge.

For the purpose of discussion group 3, a pragmatic definition on long-term effects (of GMO) is given by Crawley (1994): a process (or effect) is long-term if its characteristic time scale is of the order of 10 to 100 generations. Thus for most organisms long-term effects should emerge after a minimum of 10 to 20 years.

The assessment of potential long-term effects is one of the fundamental pillars of EFSA's risk assessment work. GMO applicants are obliged to provide adequate data to allow the assessment of the potential long-term adverse effects on both the human/animal health and environmental aspects of a GMO as part of their application, as described in the EFSA Guidance Document.

DISCUSSION POINTS

In this discussion, consideration should be given to the following points:

1. How can appropriate data be collected for risk assessment?
2. What are the relevant sources of information?
3. How can information databases (e.g. Molecular Register) help?
4. Your views on modelling for assessing potential long-term effects?
5. How to consider potential large-scale production of several GM crops?
6. What guidance for the overall assessment of long-term effects?
7. What potential long-term effects should be monitored?
8. How should the post-market monitoring of long-term effects be carried out?

BACKGROUND DOCUMENTS

1. Butler, S.J., Vickery, J.A. & Norris, K. (2007). Farmland biodiversity and the footprint of agriculture. Science, 315, 381-384.
2. Crawley, M.J. (1994). Long term ecological impacts of the release of genetically modified organisms. In: CDPE (ed.) Pan-European conference on the potential long-term ecological impacts of the release of genetically modified organisms. pp 29-50.
3. DEFRA study as regards the risk assessment following the Farm Scale Evaluation http://www.defra.gov.uk/environment/gm/fse/
4. Den Nijs, H.C.M., & Bartsch, D. (2004). Introgression of GM plants and the EU guidance note for monitoring. In den Nijs H.C.M., Bartsch D., Sweet J. (eds) Introgression from genetically modified plants into wild relatives. CABI Publishing: pp 362-389.

5. EFSA (2006). Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. EFSA Journal 99, 1-100.
6. Henri, C. (2006). Cumulative long-term effects of genetically modified (GM) crops on human/animal health and the environment: risk assessment methodologies. Reference: No 07-0402/2005/414455/MAR/B4 http://ec.europa.eu/environment/biotechnology/pdf/report310306.pdf

DISCUSSION GROUP 4 - Broadening the scope of environmental risk assessment (Risk-benefit analysis)

INTRODUCTION

In addition to the case-by-case environmental risk assessment of GM plants, one considers paramount to broaden the environmental considerations to a comprehensive risks versus benefits analysis. Citizens/consumers are willing to better know about the potential advantages/benefits and/or disadvantages/risks that GMOs might have on the receiving environment in a broad sense, namely on ecology, biodiversity, agro-ecosystem, etc

DISCUSSION POINTS

In this discussion, consideration should be given to the following points:

1. Life cycle: what’s this? How to define it? And implications thereof on the risk-benefit analysis from an environmental perspective?
2. What does the cost-benefit analysis cover (from an ecological viewpoint)?
3. What are the methods to assess biodiversity effects of agricultural practices in general (e.g. insecticide use – case study)?
   What are the implications on the environmental risk assessment?
4. How to use the modeling approach to analyze the environmental risk-benefit balance?

BACKGROUND DOCUMENTS

1. Brookes, G. (2007). The benefits of adopting genetically modified, insect resistant (Bt) maize in the European Union (EU): first results from 1998-2006 plantings. PG Economics Ltd. http://www.pgeconomics.co.uk/pdf/Benefitsmaize.pdf
2. Brookes, G. & Barfoot, P. (2006). Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use. AgBioForum, Vol. 9, No. 3. http://www.agbioforum.org/v9n3/v9n3a02-brookes.htm