

## Session V: Estimating Likelihood and Exposure

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### PRESENTERS

#### **Empirical Modeling of Genetically Modified Maize Grain Production Practices to Achieve European Union Labeling Thresholds**

David Gustafson  
Monsanto  
St. Louis, USA

#### **Physical Modeling for Assessing Out-crossing of Wind Pollinated Crops**

Franco DiGiovanni  
Airzone One Ltd.  
Mississauga, Canada

#### **Gene Flow From GM Crops; Quantitative Approaches for the Assessment of Exposure on a Landscape Scale**

Mike Wilkinson  
University of Reading  
Reading, UK

#### **Introgression and Gene Flow in Asian Rice**

Barbara Schaal  
Washington University  
St. Louis, USA

#### **Empirical Assessment of Gene Flow from Transgenic Poplar Plantation**

Meng-Zhu Lu  
Academy of Forestry  
Beijing, China

### INTRODUCTION

The objective of this session was to discuss information that is relevant in determining whether a potential hazard can occur and at what frequency. This session targeted setting the background for a more in-depth discussion on exposure assessment for GM crops by identifying key factors such as gene flow, frequencies and factors that affect them, as main components of exposure. Gene flow is a particularly complex subject, and estimating a frequency requires a great deal of information. Information on gene flow can be gathered using models (based on what is already known from the traditional crop), empirical data from fields, as well as molecular information, to understand gene flow from an historical perspec-

tive, complemented with biogeography or physical map distribution of compatible wild/weedy relatives with respect to crops. Towards that end, the speakers in this session focused in three areas of research related to exposure assessment: modeling, the use of GIS systems and landscape mapping, and empirical data on gene flow frequencies.

The session started with the presentation by Dave Gustafson, who discussed the use of empirical models to assess the degree of gene flow between crops, bearing in mind the coexistence of GM and non-GM crops, to achieve levels below the 0.9% threshold in the EU. Field data was provided using maize as a model, and gene flow was predicted within maize receptor fields at a series of distances from source fields having a marker. An empirical model was presented that fits the observed decrease of gene flow with distance. The model was parameterized to

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provide both worst case and expected case predictions of gene flow for various combinations of isolation distance and using border rows. The distance requirements vary according to the size of the source field. The model presented has been tested with published data gathered from peer-reviewed papers, and it fits the expected values. The model may be a resource tool for preliminary analysis of new targeted areas conditioned that environmental parameters such as wind direction and speed, temperature and relative humidity are available, as these are the main factors affecting the pollination rate of wind pollinated crops. Empirical data on gene flow frequencies was also illustrated in a perennial crop by Meng-Zhu Lu, describing issues on gene flow from transgenic poplars in China. In contrast to the work presented by Dave Gustafson and Meng-Zhu Lu, Franco DiGiovanni addressed the gap between empirical information on frequencies and uncertainty, by concentrating on mechanistic models. He emphasized how biological and environmental factors affect pollen dispersion (PD) and out-crossing (OC), therefore mechanistic models may be a more appropriate decision making tool, because they can be used to assess variability and define extreme or "worst-case" scenarios. He illustrated the use of physical modeling, when facing variability and uncertainties, using a recent model application to the problem of genetic isolation for forestry tree seed production. Lengthy discussions followed these two presentations. It was concluded that estimation of gene flow rate and distance either using empirical or mechanistic models have both advantages and constraints, and that their applicability is case-specific, depending on access to quality, reproducible data. In practice, regulators are more prone to using empirical models, due to the difficulty of having access to all the parameters needed to design accurate mechanistic models.

A very interesting illustration on modeling at a landscape level was presented by MJ Wilkinson, describing work on mapping populations of wild relatives using oilseed rape. The estimation of the frequency and distribution of hybrids allows targeting for post-release monitoring, the designation of field sites posing negligible risk of gene flow, and provides baseline data to calculate minimum efficacy thresholds for bio-containment. Landscape gene flow analysis is crucial, in particular for crops that have large numbers of cross-compatible local wild relatives in a legislative region, centers of origin and diversity of crop species, and to deal with the trans-boundary movement of genes, which currently is regulated internationally through the Cartagena Protocol. When viewed solely from a conservational perspective, one important category of concern centers on the capacity of a transgenic recipient to cause the decline or local extinction of rare or endangered species that are already afforded legislative protection. Whilst potential recipients are rare,

many may interact with endangered species of flora and fauna. The importance of assembling a list of endangered associates of crop wild relatives in targeted areas and crop species was highlighted as a first step to explore how changes to the ranking strategies adopted affects the relative importance assigned to the many relatives. At the end of the session, Barbara Shall described work on a major annual crop such as rice, designed to understand gene flow from an historical perspective using molecular tools. By understanding what had already happened in the past, risk assessors can more accurately paint scenarios for future gene flow (exposure).

Various questions were addressed to the panel during the discussion in this session. The main conclusions are summarized following each core question.

How is the research in the session relevant to risk assessment?

- Accurate models may facilitate identification of key factors requiring detail/further analysis.
- Knowledge of gene flow/introgression effects at the population/landscape level would clarify if transgenes are contained within an agro-ecosystem, and if/how they may affect sustainable agriculture.
- Knowledge of species associated with the gene receptor would facilitate identification of effects on other species in natural environments, if any (biodiversity/ecological functions).
- Physical/GIS mapping in combination with knowledge of gene flow/introgression effects would facilitate assessing risk for the release of a GMO in specific sites/regions.
- Baselines using non-GMOs would allow a better understanding of the persistence of domesticated traits in compatible wild/weedy relatives, reconstruct recurrent past introgression events, and foresee potential risks, if any, from the GMO.

How will risk assessors/regulators use the information?

- Modeling use depends on regulators.
- Models require generating another set of data (additional work).
- Need to complement empirical data with biological/meteorological data.
- There are standard methodologies to simulate worse case scenarios.
- Knowledge of worse case scenarios is not necessarily needed for a comprehensive assessment.
- Gene flow consequences: not enough data on interactions with associated species for all the crops.

## Estimating Likelihood and Exposure

- No clear factors needed/requested by regulators for the assessment. There is no consensus.
- Need clarity on factors needed for monitoring and for how long.

What are the next steps in this kind of research area?

- Empirical and mechanistic models need to be revised, look for complementary approaches, and adapted taking into account regulators needs.
- Need to know composition/frequency distribution of compatible wild/weedy relatives in areas prone to gene flow.
- Better understanding on interactions with associated species.
- Better understanding of factors controlling prevalence/distribution of populations of associated species in agro/natural environments.

Are there general conclusions that can be made? Is there available data to extrapolate to a relevant endpoint?

- Understanding needs/requirements from the regulator's perspective to identify priority gaps of knowledge.
- Clearly identify at the onset of the research the required key issues for risk assessment, to design well targeted studies (need to know vs. nice to know).
- If you cannot answer then so what? Then it is not a relevant study.

What assumptions are made and are the assumptions acceptable?

- Scientists involved in biosafety research may not have a clear understanding of what is needed from a regulator point of view.
- Broad diversity of biosafety regulatory requirements from country to country in addition to the case by case basis analysis.