



WORKSHOP REPORT

The Center for Environmental Risk Assessment, ILSI Argentina and ArgenBio convened a workshop for regulators, risk assessors and scientists from public and private sector organizations from August 12-15 in Buenos Aires, Argentina. The purpose of the workshop was to introduce and discuss the application of problem formulation to the environmental risk assessment (ERA) of genetically modified (GM) plants.

The first day of the workshop included a series of presentations by invited speakers that introduced the science –based framework for problem formulation and explained how it may be applied to the ERA of GM plants generally and more specifically to the evaluation of potential for adverse impacts of GM plants on non-target organisms (NTOs) and due to out-crossing ([Full program](#)). The presentations were:

- [Setting the Context: Scientific criteria for ERA in Argentina](#) ([Dr. Moisés Burachik](#), Office of Biotechnology, Argentina)
- [Problem formulation](#) ([Dr. Alan Gray](#), Center for Ecology and Hydrology, UK)
- [Moving from problem formulation through to submission of a dossier](#): an industry approach to ERA ([Dr. Tom Nickson](#), Monsanto Company)
- [Generating relevant risk hypotheses](#): similarities and differences between basic ecological research and ecological risk assessment ([Dr. Alan Raybould](#), Syngenta)
- [Tiered approach to evaluating the impact of GM crops on non-target organisms](#) (Joerg Romeis, Agroscope ART)
- [Problem formulation applied to plant species with high outcrossing potential](#) ([Dr. Alan Raybould](#), Syngenta)

The second and third days of the workshop were devoted to applying problem formulation to two case studies of GM products currently in development in Argentina: a stress tolerant maize and a nitrogen use efficient sorghum. The participants in Days 2 and 3 were divided into two breakout groups and each member was provided with written case studies prior to the workshop that were prepared by the principal scientists developing these products, [Dra. Raquel Chan](#) and [Dr. German Serino](#). Drs. Chan and Serino also presented their research to the group members in plenary sessions. Each breakout group then applied problem formulation to the case studies using the framework below and reported back to plenary:

- Provide the definition of "the problem" that was formulated by the group for:
 - Potential adverse impact(s) of the subject plant on non target organisms OR
 - Potential adverse impact(s) of the subject plant due to out-crossing.
- What are the potential exposure pathways?
- What are the potential hazards or effects that may occur?
- What are examples of hypotheses that can be tested to solve the problem?
- What are the potential sources of information/data that may be available to help define or understand the problem?
- What are examples of methodologies that can be used to test the hypotheses?
- Consider possible timeline and resource implications.

The practical exercise of applying the problem formulation framework to the case studies led to an exchange of ideas during the plenary sessions. Some points of consensus were as follows:

Problem formulation is not a trivial undertaking. A risk assessor has to develop risk hypotheses that are relevant to the ERA of the subject GM event and guard against the practice of asking for data that may be scientifically interesting but irrelevant to the risk assessment. Most participants acknowledged that this is a challenge. It was recognized that **problem definition** is a model process to focus the ERA into a scientifically tractable problem.

For the ERA of GM crops, it is essential to refer to classical observations and consider the context of the problem being formulated and its basis in conventionally bred varieties, agronomic practices and productive systems.

Problem formulation should be applied as a risk assessment tool as early as possible in the product development process so that any potential adverse impacts that may be attributable to the subject GM event can be identified and taken into account as development continues. In order for this to happen, the management or **protection goals in the targeted markets need to be clearly identified**. While it is the responsibility of competent regulatory authorities to ensure that these goals are unambiguously articulated in legal instruments such as regulations, their definition should be achieved through stakeholder consultation as the consideration and prioritization of protection goals is typically a matter

of policy. It is only after management and protection goals are established by policy makers, that regulators (and sometimes other risk assessors) can work to operationally define ecological entities of value and how they may be evaluated (*i.e.*, problem context).

Problem definition can be improved if there is dialogue between regulators and product developers during the course of product development well in advance of the time when a dossier is prepared for regulatory submission. This is particularly true for new applications of genetic engineering to crop improvement so that problem definition can be addressed proactively instead of reactively, and regulations and/or associated guidance can be amended as required.

Product developers should be encouraged to make their research public as early as possible through peer-reviewed publication and/or other communication channels.

For additional information or inquiries ,

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