Development of a Decision Supporting System to improve risk analysis related to GMO's releases into the environment.

Life+ project: Validation of risk management tools for genetically modified plants in protected and sensitive areas in Italy (MAN-GMP-ITA). Action C3.

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In Europe, the environmental release of Genetically Modified Organisms (GMOs) is ruled by Directive 2001/18/EC and Regulation 1829/2003/EC. The Directive refers to the deliberate release into the environment of GMOs and sets out two regulatory regimes: Part C for the placing on the market and Part B for deliberate release for any other purpose than for placing on the market (i.e. field trials). The Regulation provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to GM food and feed, it lays down Community procedures for the authorisation and supervision of GM food and feed, furthermore it lays down provisions for the labelling of GM food and feed. Even if, the Regulation's objectives are food and feed, it shall be applied to GMOs intended for food or feed use, thus it includes the GM cultivations. In both legislations the release into the environment of GMOs asks to the notifier[1] to perform an Environmental Risk Assessment (ERA) indeed, on this issue, the Regulation clearly refers to the Directive procedures. The objectives and principles, together with the methodology for the ERA, are outlined in Council Decision 2002/623/EC. The same Decision refers to Annex II to the Directive and establishes guidance notes to perform ERA itself.

The ERA is defined as "the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose", it should be carry out on a case by case basis meaning that its conclusion may depends on the GM plants and trait(s) concerned, their intended use(s), and the potential receiving environment(s). Moreover, ERA should be carried out in a scientifically sound and transparent manner based on available scientific and technical data and on common methodology for the identification, gathering and interpretation of the relevant data.

The ERA process should leads to the identification and evaluation of potential adverse effects of the GMO, and at the same time it should be conducted with a view to identifying if there is a need for risk management and it should provides the basis for the monitoring plans.

Starting from the step by step ERA approaches, developed worldwide for chemical or other environmental stressors (Andow & Zwahlen 2006; Hill 2005; Hill & Sendashonga 2003;), the EU framework foreseen 6 steps (see figure 1).

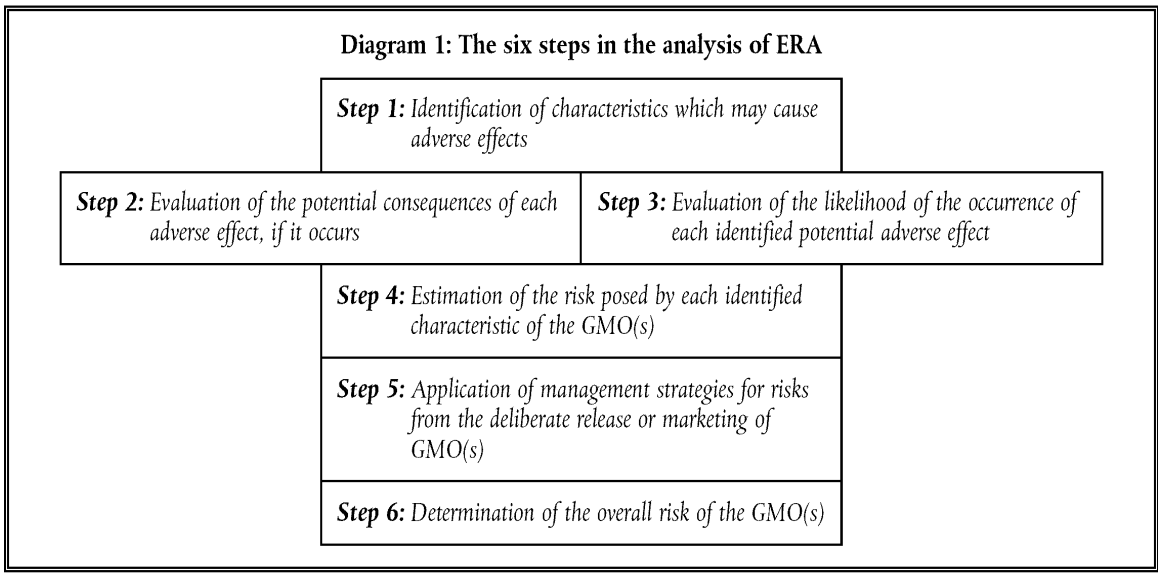

Fig.1: The six steps of the ERA as indicated in Council Decision 2002/623/EC

The European Food Safety Authority[3] (EFSA) on 12 November 2010, have published the "Guidance on the environmental risk assessment of genetically modified plants " document (EFSA GMO Panel 2010). The document represents a big effort to summarise and organize the operational needs to conduct a comprehensive ERA of GM plants. It describes and discusses the six steps for the ERA of GM plants, as indicated in the Council Decision 2002/623/EC, giving a better comprehensive interpretation of each step, taking into account the results of different *ad hoc* Technical Groups. Furthermore, EFSA Guidance gives the rationales for the data requirements for a comprehensive ERA and, in addition, it is supplemented with several general cross-cutting considerations (e.g. choice of comparator, receiving environment(s), general statistical principles, long-term effects) that need to be considered in the ERA.

The above summarized complicated legislative plot and the fast development of agro-biotechnologies asks for an harmonized and operative approach in risk analysis of GMO's applications, where risk analysis includes risk assessment, risk management and risk communication.

For this reasons, in 2003, based on the information requested by the European legislative framework on GMOs, a multidisciplinary group developed a methodological proposal to perform ERA on GM Plants (GMPs) field trials (Sorlini et al. 2003).

The working group starts from the assumption that the occurring of a risk, associated to the release of a GMO into the environment, is strictly related to the presence of four components and of their relationships: Source - Diffusion Factors - Migration Routes - Receptors.

Where: Source (i.e. field trials), is the site where the organism is released and/or enabled to express its harmful characteristics; Diffusion Factors are linked to the biological

characteristics of the GMP; Migration Routes are linked to chemical, physical, biological characteristics of the receiving environment; Receptors are man, animals and different ecosystem's components.

Based on this conceptual model, the WG developed a flow chart (figure 2) in order to represent the relationships between potential receptors and the harmful characteristics of a GMP in a field trial. The diagram has been intentionally developed broad and detailed, in order to identify as many potential relationships as possible.

The methodological proposal further consists of a questionnaire and a software. The user, answering to specific sets of questions (edited for each box present in the diagram), is able to follow a "decision tree" starting from the Source, trough all the components of the conceptual model, and reaching the identification of potentially affected Receptors and theirs related impacts. The completion of questionnaire will result in a report where the potential impacts are identified on a case-by-case basis.

The questions derive from the information required in the Directive (Annex III) and refer to the GMP characteristics (i.e. molecular, botanic and agronomic) as well as the surrounding environment.

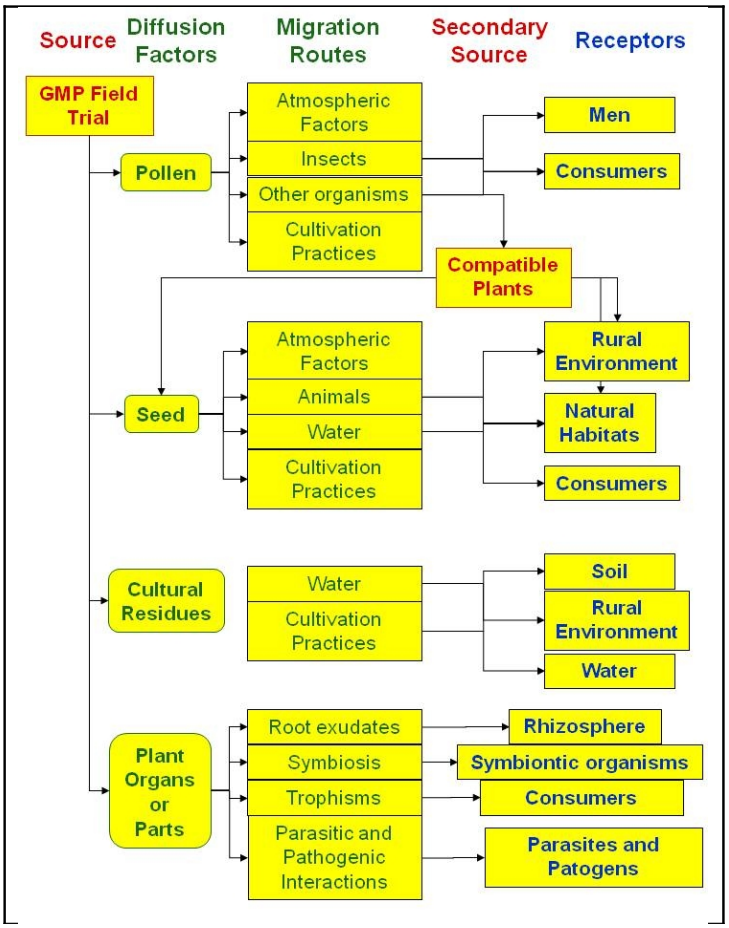

Fig.2 Flow chart representing potential relationships whitin GM plants and surrounding environment during a field trial.

The described methodology is going to be the applied and improved during the activities of the LIFE+ (MAN-GMP-ITA)[4] project (http://www.man-gmp-ita.eu) in order to obtain a computer-aided Decision Supporting System (DSS). Further goals of the Project are the validation of the methodology, the setting of specific protection goals for sensitive and protected areas near GM crops and the selection of relevant endpoints and monitoring schemes for managing environmental impacts of GMPs. It has to be underline that no GM crops will be used during the Life+ activities.

Finally the methodology, already available, will be made accessible in a newly produced software and tested in diverse crops /areas combinations.

After a first test-phase, where the questionnaire will be applied to the chosen studies areas, the edited questions will be reformulated to be more intelligible and the whole DSS will be developed to be easily modified and adapted to specific situations.

Even if different expertise have been requested in its development and a multidisciplinary approach in its application is welcome, the DSS could be applied without specific technical expertise or equipments.

In conclusion the resulting DSS would be an operative tool to elaborate risk hypotheses, to apply management strategies and to plane land utilization. Moreover, the system would allow the gathering of observations and proposals strictly referred to a specific step in the risk assessment procedure submitted by interested parties (including general public stakeholders, risk assessors and managers). Last but not least, such standardized procedure in performing ERA and in collecting data would improve information sharing and risk communication on GM plants and/or crops.

Notes

1. Corresponding Author: valeria.giovannelli@isprambiente.it
2. the notifier is who asks for the release of the GMO
3. EFSA is an independent European agency funded by the EU budget. EFSA's role is to assess and communicate on all risks associated with the food chain.
4. The Life+ group is composed by: ISPRA, ENEA, CRA_RPS and DISTA and started its activities on January 2010

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