

**AN OPERATING MODEL FOR THE ENVIRONMENTAL RISK ASSESSMENT
APPLIED TO ITALIAN SITES OF COMMUNITY IMPORTANCE:
IDENTIFICATION OF POTENTIAL EFFECTS ON SOIL**

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The fast development of agrobiotechnologies asks for an harmonised approach in risk assessment of GMO's releases. Risk assessment consists in the evaluation of the likelihood that an hazard occurs, associated to the presence of the receptor(s) in the receiving environment, and the determination of their potential degree of exposure to the hazard. The whole process has to be both science based and case by case applied, and it involves a very complicated procedure that needs to be transformed in an operational and standardized tool.

In 2003, moving from this purpose an expert group on behalf of the Italian Ministry of the Environment has elaborate an Operating Model for the Environmental Risk Assessment (OMERA). OMERa is based on a logic scheme, moving 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: a) source b) diffusion factors c) migration routes d) receptors e) potential effects. It comprises two main components: a conceptual model represented as a flowchart and an electronic Questionnaire (eQ) driven by a relational database (Microsoft Office Access). The eQ includes sets of questions specifically formulated for each box of the flowchart that create a "decision tree" that can be followed from the source to all the components of the conceptual model.

Within the framework of a LIFE+ project (MAN-GMP-ITA) a multidisciplinary group was formed to validate and improve this methodology. The questionnaire has been filled simulating, as Source, crops cultivated with herbicide tolerant GT73 oilseed rape and insect resistant MON810 maize in diverse experimental areas. Completing the eQ leads to the identification of the potentially affected receptors and related potential effects. Examples of affected Receptors are: man, consumers, rural environments, natural habitats, soil, rizosphere, symbiontes, parasites and pathogen. As far as for the soil receptor the identified potential effects are: potential changes to soil microbe and fungus biodiversity, changes in edaphic fauna biodiversity, and potential changes to agricultural practices. The listed potential effects could lead to changes to soil fertility as consequence. The identified potential effects related to the soil receptor are the same in all the case studies. Potential effects do not depend on soil characteristics, but are essentially due to lack of information on changes in bromatological composition of plant residues. The occurrence of effects can be assessed with targeted monitoring activities.

The results attested that OMERa allows the collection and comparison of experimental data in a consistent way and at the same time leads to the identification of receptors, potential effects and related monitoring activities specifically for the case study. The application of the OMERa method can be considered a tool for collecting and elaborating data in a standardized way, and would help the harmonization of the Environmental Risk Assessments performed by different actors. For these reasons, the whole methodology can be considered a Decision Support System not only for the elaboration of risk hypotheses and the establishment of monitoring programs, but also for the selection of the most effective management strategies and in planning land use.