

Risk Assessment of GM Crops; Challenges in Regulations and Science

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Recent years have witnessed rapid advancements in the application of genetic engineering in the field of agriculture. The acreage of land planted with Genetically Modified Organisms (GMOs) across the world has increased dramatically in the last few years. Totally, 160 million hectares of GM crops were planted in 2011, which makes biotech crops the fastest adopted crop technology in the history of modern agriculture [1]. In spite of the advantages, opponents and critics always focused on some potential risks of GMOs on human health and environment which caused anxiety and caution of governments and policy makers. As result of these comments and toward safe use of GM technology advantages, during the last decade different international biosafety regulations, guidelines and frameworks, including Cartagena Biosafety Protocol, Codex Alimentarius were prepared, approved and implemented.

The main objectives of the biosafety regulations and guidelines are risk assessment, risk management and finally safe trade of GMOs. Based on the biosafety regulations and guidelines, the deliberate release of GMOs into the environment or market should be governed by a framework of science-based risk assessment and risk management measures. This is usually implemented through the integration of hazard identification and characterization of all the elements of risk associated with a new GM crop or derived product [2]. Typical categories of hazards arising from the introduction of transgenic crops include: possible unintended negative human health effects, the possible evolution of resistance in the targeted pest/pathogen populations when the transgene confers resistance to a pest or pathogen; non-target effects associated with the transgenic organism or its products outside the plant; and those associated with the transgene escape and expression in a different organism or species following gene flow [2]. Environmental risk assessments can provide high confidence of minimal risk by testing theories, "risk hypotheses", that predict the likelihood of unacceptable harmful events. The creation of risk hypotheses and a plan to test them is called problem formulation. Effective problem formulation seeks to maximize the possibility of detecting effects that indicate potential risk; if such effects are not detected, minimal risk is indicated with high confidence. Poor problem formulation can increase environmental risk because it leads to the collection of superfluous data that may delay or prevent the introduction of environmentally beneficial products [3].

Risk assessment of GMOs should be performed case by case in a scientific manner. As at the present time, a wide range of GM organisms with different new recombinant genes and traits have been produced. So, risk assessment now is very complicated and ambiguous, and it is necessary to prepare general and also specific guidelines for different organisms and traits. These guidelines should focus on particular types of living modified organisms, particular intended uses of living modified organisms, particular types of risks, particular receiving environments, long-term monitoring of living modified organisms released into the environment, or on the relationship between and the involvement of Competent National Authorities responsible for risk assessment in conservation and sustainable use of biological diversity. Furthermore, at this time there is not available any internationally agreed guidance on some GMOs, including GM microorganisms used as biological control agents of plant pests and diseases, live vaccines for use in animals, GM biofertilizers, bioremediation agents, GM trees, etc., which should

be developed in future. Also, despite the existence of a great deal of scientific information relevant to risk assessment, including experience gained with GMOs in specific environments over the past several years through research, contained use, field trials, commercial releases, and associated risk assessments, there are often limitations in access to information, as well as understanding of how existing information can be used to support risk assessment [4,5]. Limitations in access to the biosafety related journals and other resources where new data or studies are reported, as well as material that is not yet available in the literature, can make it difficult for risk assessors to stay up-to-date on information related to risk assessment, so availability of open access journals and publications are of important. One key factor contributing to poor accessibility of guidance materials is language, particularly in countries where the local languages are not commonly used at a global level. Many existing guidance documents are not translated, or are translated into few languages. So, it is necessary to develop more comprehensive relevant open access journals, databases and information sources, and should be made available through the Biosafety Clearing-House.

The Journal of Biosafety can play an important role in preparing new information on biosafety, especially on risk assessment strategies and methodologies which because of its open access nature will be available for all people through the world.

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