

EFSA updates guidance on GM plants

The European Food Safety Authority (EFSA) has published updated guidance for the environmental risk assessment (ERA) of Genetically Modified (GM) plants, reflecting the scientific state-of-the-art in this field.



Maize field

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Scientific experts on EFSA's GMO Panel have updated and further developed its guidance for the environmental assessment of GM applications submitted for authorisation in the EU, in particular with respect to data generation, collection and analysis. The ERA guidance document also addresses the evaluation of possible long-term effects of GM plants and potential effects on non-target organisms (NTOs) [1]. This guidance implements the stringent requirements for the environmental

risk assessment of GMOs as provided by Directive 2001/18/EC on the deliberate release of GMOs in the environment.

The European Commission requested EFSA in 2008 [2] to further develop and update its guidance on environmental risk assessment, enabling EFSA to build on the work it had initiated in this area in 2007.

In accordance with the conclusions of the Environment Council of December 2008, Member States and stakeholders were closely associated with the review of this guidance. EFSA organised a series of technical discussions on the guidance document with representatives of EU Member States [3], with non-governmental organisations (NGOs) and with GM applicants [4] to exchange views on the scientific issues. A draft version of the ERA guidance was also launched earlier this year for public consultation [5] which received 494 comments.

In order to assess the safety of a GM plant submitted for authorisation in the European Union, EFSA requires all applicants to follow its guidance documents which specify the type of data and information that should be submitted. In the ERA guidance, EFSA reviewed and updated seven specific areas that need to be addressed when assessing the environmental impact of a GM plant. These include in particular the persistence and invasiveness of the GM plant, taking into account possible plant-to-plant gene transfer; the likelihood and consequences of gene transfer from the plant to microorganisms; the potential evolution of resistance in target organisms; the potential effects on non-target organisms; the biogeochemical processes, such as changes in soil composition, and the potential impact of the cultivation, management and harvesting techniques of the GM plant.

The guidance document includes detailed requirements for: the choice of appropriate non-GM comparators [6] and types of receiving environments to be considered; long-term effects and the experimental design of laboratory and field studies; and their statistical analysis.

- [Guidance on the environmental risk assessment of genetically modified plants](#)

[1] A section of the document is specifically dedicated to the assessment of the effects that GM plants may have on non-target organisms (NTOs), that is, those insects which are not meant to be the target of the toxin produced by some GM plants.

[2] [Mandate](#)

[3] [EFSA meets Member State experts on environmental risk assessment of GM plants](#)

[4] [EFSA's technical meetings with stakeholders](#)

[5] [Outcome of the public consultation on the draft Scientific Opinion of the Scientific Panel on Genetically Modified Organisms \(GMO\) on the guidance document on the environmental risk assessment of genetically modified plants](#)

[6] GM comparators are the non-GM plants with which the GM plant is compared during the safety evaluation.

Press release

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