# SCIENTIFIC OPINION

## Scientific Opinion on Guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes[1]

**EFSA Panel on Genetically Modified Organisms (GMO)**

European Food Safety Authority (EFSA), Parma, Italy

**SUMMARY**

In view of new types of GM plants under development, the European Food Safety Authority (EFSA) asked its Panel on Genetically Modified Organisms (GMO Panel) to establish guidance for the risk assessment of GM plants used for non-food or non-feed purposes. A working group of selected GMO Panel Members and external *ad hoc* experts was formed to prepare the Opinion. A draft opinion was prepared and submitted to the European Commission for legal consultation and the European Medicines Agency for comments prior to online consultation with the public and stakeholders. The submitted comments were considered and the draft amended where appropriate. The amended Opinion was submitted to the EFSA GMO Panel for final adoption on 22 April 2009.

The scope of this Opinion covers GM plants and plant parts deliberately released into the environment via cultivation, import or processing for a wide range of potential non-food or non-feed uses, such as the production of industrial or medicinal products, energy production, phytoremediation, landscape improvement and ornamental use.

In view of the many possible combinations of type of genetic modification, type of plant and location of the genetic modification in the plant, the guidance given is generic and does not pre-empt the case-specific risk assessment of future applications.

The EFSA Guidance Document for the risk assessment of GM plants and derived food and feed contains information on the requirements for the preparation and presentation of the GM plant application. The present Opinion supplements this Guidance Document by discussing issues for the assessment of GM plants used for non-food or non-feed purposes that would need special attention or may have more/less stringent requirements compared with the risk assessment requirements for GM plants for food and feed purposes.

[1] On a request from EFSA, Question No EFSA-Q-2007-176, adopted on 22 April 2009.

The Guidance Document with the templates for submission of dossiers, together with this Opinion on the additional elements for the risk assessment of plants for non-food or non-feed purposes, is to be taken into account by future applicants. EFSA herewith advises applicants/regulators to read this Opinion in parallel with the Guidance Document. A regulatory flowchart is provided showing the interplay between the intended uses of a GM plant and the respective EU legislation applicable. The flowchart also gives an overview of the regulatory bodies that are involved in scientific risk assessment and the ones that are responsible for risk management and decisions on authorisations.

When a notification under Directive 2001/18/EC is to be evaluated by EFSA, it is expected that the necessary data for the environmental risk assessment (including aspects of human and animal health) are all provided in a comprehensive technical dossier submitted to EFSA. In case the GM plant is used to produce a medicinal product, it is expected that this technical dossier includes relevant data as expected in a marketing authorisation application as submitted to EMEA. Possible deviations from this requirement have to be scientifically substantiated by the applicant. EFSA and EMEA support the idea that an innovator wishing to bring a plant-derived medicinal product to the market should consult closely with regulatory authorities to ensure that all appropriate regulatory steps are undertaken.

The EFSA GMO Panel considers that for GM plants used for non-food or non-feed purposes the comparative approach is valid, but will need to be applied carefully. For these plants, the assessment of the potential impact of the differences identified in the comparative analysis is particularly important with regard to accidental intake by humans, livestock and wildlife animals, the exposure of farmers and workers handling the GM plants, and the exposure of passers and of people living in the vicinity.

The focus of the evaluation for human and animal safety is on the risks resulting from oral exposure through accidental intake (through inadvertent entry in the food and feed chain via admixture or gene flow or through accidental consumption in the field) of the GM plants/plant parts used for non-food or non-feed purposes by humans and animals.

The risk assessment for plants used for non-food or non-feed purposes has to take into account the confinement measures when applied. To allow for a quantitative risk assessment, this is to be integrated in a two-step risk assessment. In a first step, risks for human and animal health and the environment of the GMO need to be assessed based on an exposure assessment without the consideration of the confinement measures and in a second step, confinement measures as proposed and applied by the applicant should be taken into account.

The use of GM plants for non-food or non-feed purposes, for example the production of novel compounds, expands the role of crop plants. The target products could have adverse effects when in contact with humans, animals or the environment, or when consumed by humans or animals. Where new potential GM plant risks are identified, the plants are likely to require more specific risk management conditions, such as methods of production stewardship, defined confinement measures, safety thresholds and inspections.

To assess the reliability of confinement (and how the effectiveness of confinement will be monitored) the following should be taken into account. The effectiveness of confinement

measures may be influenced by external factors such as abiotic and biotic conditions. The applicant therefore should provide data that allow the assessment of confinement measures under all environmental conditions envisaged taking worst-case scenarios into account. In this regard it may be necessary and useful for the applicant to narrow the geographical area in which he seeks permission for the product.

Applicants should describe for each GM product the details and rationale for the proposed physical and biological confinement strategy, where applicable. The proposal should specify the methodology used and its effectiveness in reducing accidental intake or preventing gene flow into the environment. Methods of enforcing monitoring and emergency measures for restricting gene flow should also be described. Regarding non-food or non-feed GM plants that produce bio-active substances that are stable, or that persist for a long term in the environment, it should be considered whether the confinement should also prevent or reduce herbivory and leakage through drainage or sewage.

**KEY WORDS:**

Molecular farming, plant production platforms, GMO, GM plants, risk assessment, non-food, non-feed, phytoremediation, ornamental use, plant-made industrial compound (PMI), plant-made medicinal product (PMP), Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 726/2004, Regulation (EEC) No 2309/93.