

## EFSA Scientific Network on Risk Assessment of Genetically Modified Organisms

### Background

The European Food Safety Authority (EFSA) is the keystone of European Union risk assessment regarding food and feed safety, animal health and welfare, nutrition, plant protection and plant health. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent and transparent scientific advice and clear communication on existing and emerging risks associated with the food chain. On request from the European Commission, European Parliament or Member States or on its own initiative, EFSA provides scientific opinions on issues falling under its remit.

EFSA and the Scientific Panel on Genetically Modified Organisms (GMO Panel) provide independent scientific advice on the safety of:

- Genetically modified organisms (GMOs) such as plants, animals and micro-organisms, on the basis of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- Genetically modified food and feed, on the basis of Regulation (EC) No 1829/2003 on genetically modified food and feed.

EFSA and the GMO Panel carry out risk assessments in order to produce scientific opinions and advice for risk managers. Its risk assessment work is based on reviewing scientific information and data in order to evaluate the safety of a given GMO. This helps to provide a sound foundation for European policies and legislation and supports risk managers in taking effective and timely decisions. Most of EFSA's work on GMOs is carried out in the context of authorisation applications, since all GM food and feed products must be evaluated by EFSA before they can be authorised in the EU.

According to Regulation (EC) No 1829/2003, EFSA shall, within the context of assessing each GMO application, consult with Member State Competent Authorities during a three-month consultation period. In order to fulfil this requirement EFSA has formed the GMO ExtraNet for applications. Members are found in federal and national agencies, authorities and ministries of all EU Member States. They submit to EFSA comments and questions regarding content of specific applications. The members of the ExtraNet do not convene in person. Instead, the electronic submission of comments and questions by members and the weekly newsletter from EFSA to members constitute the mode of operation. Questions and comments raised by ExtraNet members have assisted the EFSA GMO Panel to pinpoint weaknesses and strengths in applications and have been useful in the context of the risk assessment. Each comment or question is addressed by EFSA in an annex to the EFSA overall opinion, once adopted.

In order to enhance discussion and scientific exchange between EFSA, the GMO Panel, and Member State experts, EFSA established in 2010 the Scientific Network for Risk Assessment of GMOs (also known as “the GMO Network”). Since then, the GMO Network has met once a year; at these meetings, risk assessment principles and approaches, and several guidance documents were discussed, providing EFSA with valuable input.

The GMO Network appointed experts *liaise* as appropriate at national level before and after each meeting in order to make sure all the necessary information is shared without prejudice to Article 10 of the Decision of the Management Board concerning the establishment and operation of European Networks of scientific organisations operating in the field within EFSA’s mission.<sup>1</sup>

## Objectives of the GMO Network

The specific objectives of the GMO Network are:

- To facilitate harmonisation of risk assessment practices and methodologies by:
  - Sharing best practices in GMO risk assessment;
  - Discussing ongoing issues of GMO risk assessment such as new guidance developed or new opinions adopted;
  - Discussing new scientific developments in GMO risk assessment and discussing their implications on risk assessment practice.
- To enhance exchange of information between EFSA and Member States by:
  - Discussing issues of availability and quality of data required for GMO risk assessment;
  - Sharing information on new scientific developments in the field of GMO risk assessment.

The overall objective of the GMO Network is to build mutual understanding of the principles underlying the risk assessment of GMOs and to provide increased transparency in the current process between Member States and EFSA.

EFSA may entrust to the GMO Network certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, and collection of data.

## Terms of Reference

### Members of the GMO Network

The Members of the GMO Network are organisations appointed for three-year terms through the EFSA Advisory Forum Members, in accordance with Articles 2 and 3 of the Decision of the Management Board of EFSA on the establishment and operations of networks. These organisations cover two areas of competence: molecular characterisation / food-feed safety (MC/FF) and environmental risk assessment (ERA).

The Members of the Network appoint experts and alternates to represent them at GMO Network meetings; the appointment (or confirmation, in case the

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<sup>1</sup>[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/networksoperation.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/networksoperation.pdf)

appointment is renewed) is done on a yearly basis, through the Advisory Forum and Scientific Cooperation (AFSCO) Unit of EFSA.

The profile of experts appointed to attend the GMO Network meetings should include the following:

- Experience in GMO food and feed or environmental risk assessment and research at the national level;
- Knowledge of the national status and of the European and/or international context of GMO food and feed and environmental risk assessment.

The Chair of the GMO Network is the Head of the EFSA GMO Unit.

#### Working methods

The GMO Network shall meet at least once a year. Nominated MS scientists shall liaise as appropriate at national level before and after each meeting.

In addition to the meetings, the Network will communicate by e-mail on specific questions or issues.

English will be the working language of the GMO Network.

#### Access to meetings

Experts from GMO Network Member organisations shall be invited to GMO Network meetings: per country, one expert should represent the MC/FF Member organisation and one expert should represent the ERA Member organisation. Representatives of the European Commission are entitled to attend meetings of the GMO Network as observers.

EFSA may invite representatives of other agencies, bodies or institutions of the European Union, third countries or international organisations to attend meetings of the GMO Network as observers.

EFSA may invite scientific experts from regulatory or academic bodies of the European Union or third countries, or from international organisations, as speakers, to update the GMO Network on developments in the field of GMO risk assessment.

#### Outputs of the GMO Network

The proceedings of GMO Network meetings shall be recorded in meeting minutes; after adoption, these minutes will be published on the EFSA website.<sup>2</sup>

The activities of the GMO Network shall be recorded in annual technical reports issued by EFSA. These reports will be published on the EFSA website and presented to the EFSA Advisory Forum.

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<sup>2</sup> <https://www.efsa.europa.eu/en/gmo/networks>