



TERMS OF REFERENCE

of the Scientific Network on Risk Assessment of Genetically Modified Organisms

Introduction and purpose for establishing

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.

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, and genetically modified food and feed, on the basis of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1829/2003 on genetically modified food and feed, Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed, and EFSA related guidances¹.

Establishing a system of Networks of organisations operating in the fields within EFSA's mission is among the tasks of EFSA, according to its Founding Regulation (Article 22(7) and Article 23(g) of Regulation (EC) No 178/2002), in order to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices.

In accordance with Article 22(7) and Article 23(g) of Regulation (EC) No 178/2002, EFSA shall promote the networking of scientific organisations of EU Member States operating in the fields within the Authority's mission.

A new regulation on the transparency and sustainability of the EU risk assessment in the food chain (EU Regulation 1381/2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC), which came into force on **27 March 2021**, strengthens the Authority's ability to carry out its risk assessment functions in accordance with the highest transparency standards.

On 24 June 2021, the Management Board of the Authority has adopted the ***Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission*** which purpose is to optimise the operational procedures of EFSA scientific networks in accordance with the remit and strategic objectives of the Authority, specifically considering a greater involvement of Member State expertise in support of EFSA's mission.

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

¹ Available at <https://www.efsa.europa.eu/en/applications/gmo/regulationsandguidance>



Assessment of GMOs (hereafter, the GMO Network). Since then, risk assessment principles and approaches, and several guidance documents were discussed at the network meetings, providing EFSA with valuable input and facilitating harmonization of risk assessment and exchange of knowledge.

Objectives

Taking into account Art. 7.3 of the above-mentioned **Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission**, the main objective of the GMO network is to build mutual understanding of the principles underlying the risk assessment of GMOs between Member States and EFSA.

The specific objectives of the GMO Network are enhancing risk assessment practices and methodologies, and the exchange of information between EFSA and Member States by:

- sharing best practices in GMO/GM food & feed risk assessment expertise and experiences.
- discussing issues regarding GMO risk assessment such as EFSA guidance documents, adopted EFSA opinions and risk assessment of specific GMOs or GM food & feed.
- discussing new scientific developments in GMO risk assessment and discussing their implications on risk assessment practices, such as the development of GMOs with new genomic techniques.
- sharing information on the development of GMOs using transgenesis and other techniques, and the consequences regarding risk assessment.
- discussing issues of availability and quality of data required for GMO risk assessment.
- sharing regular information on forthcoming EFSA consultations and other scientific cooperation activities in the field of GMO risk assessment.

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

Subgroup(s) of the network

In April 2024, the Subgroup on New Genomic Techniques (NGTs) applied to plant, animals and microorganisms (*hereafter*, **Subgroup on NGTs**) is established.

The main objective of the Subgroup on NGTs is to foster knowledge sharing on the development of NGTs, their application to plants, animals and microorganisms and jointly address the risk assessment and monitoring challenges specifically linked to NGTs applied to plants, animals and microorganisms.

Members

According to Art. 6.1 of the **Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within**



the Authority's mission, following the receipt of all necessary information from EFSA, the Advisory Forum shall identify organisations in EU Member States which are capable of contributing to the tasks of the GMO Network.

In response to a request by the Nutrition & food innovation Unit, the Advisory Forum may formally designate the member organisation(s) of the GMO Network for each country.

The Advisory Forum, in cooperation with the member organisations formally designated in accordance with the previous paragraph, shall establish the names of network participants and alternate participants for the GMO Network within the designated member organisation(s). The network shall be composed of experts with the following profile:

- experience in GMO molecular characterization, 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.

For the Subgroup on NGTs, members can be appointed from any of the designated organisations nominated according to Art. 6.1 of the *Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission*. The members of the Subgroup on NGTs should have professional and scientific background in the field of NGTs (e.g., molecular biology and genetics, genomic techniques, bioinformatic) and experience in the area of molecular characterization (MC), food and feed (FF), and/or environmental risk assessment (ERA) of GMOs, including plants, animals and microorganisms.

Members should preferentially be selected from Member States which are actively engaged in the discussion on the risk assessment of organisms modified by NGTs, because of national projects, participation/representation in international discussion fora, etc. Member States interested in joining the Subgroup on NGTs may appoint one participant and one alternate. The Advisory Forum in collaboration with the national Focal Points members may liaise with the nominated members of the EFSA GMO Network to identify the candidates fulfilling the criteria described above. The content and the outcome of any discussions within the Subgroup on NGTs are reported back to the GMO Network for possible further elaboration.

The Chair of the GMO Network and the subgroup on NGTs is the Head of the EFSA Nutrition & Food innovation Unit.

Access to meetings

Other organisations may be invited, including those from outside the EU, with specific expertise to participate in a network meeting, where deemed appropriate or necessary. These organisations may be invited either to participate in full or as observers only.

In addition, representatives of the European Commission may participate in the work of the networks. Representatives of other EU agencies may also participate in the work of the networks as appropriate.

Working methods



The network shall meet physically or virtually at least once per year. The working language for the Network activities will be English.

The Subgroup on NGTs will meet according to the identified needs, ensuring ample advance notice to allow proper meeting arrangements.

In addition:

- email communication is used to inform on the main events (dates of the annual meetings and *ad-hoc* meetings, official invitation, finalized agenda, minutes for final endorsement).
- An IT platform is established to be used when sharing documents and other information not included in the previous point.

Deliverables and Outcomes

The proceedings of GMO Network and the subgroup on NGTs meetings shall be recorded in meeting minutes. After adoption, these minutes will be published on the EFSA website.

Timeline

The terms of reference for the Risk Assessment of Genetically Modified Organisms network and its subgroup can be updated whenever deemed necessary and are valid until a decision is of discontinuing the network/subgroup is taken.

The subgroup is created under the scope of a network, the duration of the subgroup can therefore be inferior or equal to the network timelines.

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