EFSA and GMOs

1. The role of EFSA within the EU regulatory framework

Providing scientific advice

EFSA's role within the European regulatory framework for GMOs is to carry out scientific risk assessments or give scientific advice on GMOs. It exercises this responsibility upon two distinct legal bases: **Regulation (EC) No 1829/2003** on genetically modified food and feed, and **Directive 2001/18/EC** on the deliberate release into the environment of genetically modified organisms.

In providing scientific advice with respect to GMO applications, the way EFSA is involved depends on the regulatory framework applicable. On pages 2 and 3 you will find graphical charts illustrating EFSA's role within these two frameworks.

In both cases, EFSA provides the scientific advice that underpins EU decisions on GMOs, but it is the European Union Member States and the European Commission who take the decision whether or not to approve a given GMO. EFSA does not decide on market approval for GMOs.

Under Regulation 1829/2003, EFSA assesses both the human/animal safety as well as the environmental impact of a GMO. In the case of Directive 2001/18, this corresponding risk assessment is carried out by a Member State and EFSA only becomes involved if Member States have diverging views on the risk assessment of the initial Member State.

However, the essential role of EFSA, namely providing scientific risk assessment, and the risk assessment criteria used, remain the same under both procedures.

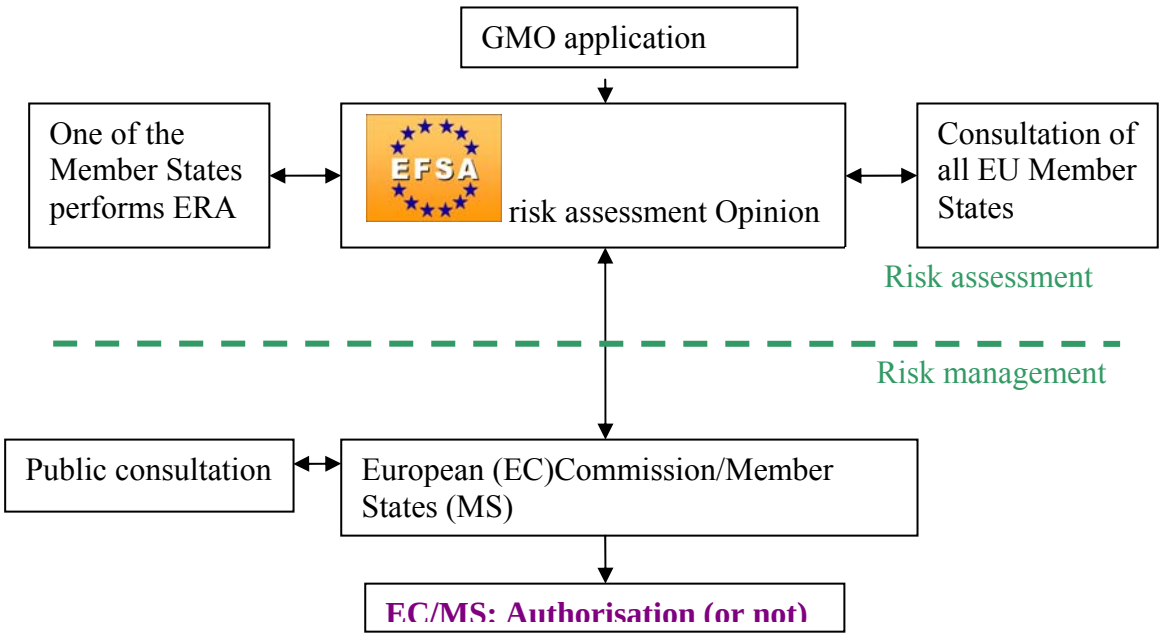
For further information on the regulatory framework for GMOs, please consult the Q&A prepared by the European Commission: (http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en).

The authorisation procedure under Regulation (EC) No 1829/2003

According to this procedure, often referred to as the 'centralised procedure':

- The GMO application is sent to a Member State who immediately forwards it to EFSA who must endeavour to deliver an Opinion within 6 months.
- All Member States have full access to the application and to full studies and data presented by the applicant.
- Member States have the possibility of raising concerns and commenting on the application, including on the full data and studies presented by the applicant.
- If the application includes the cultivation of a GMO, a Member State is asked to perform the environmental risk assessment (ERA).
- EFSA finalises the full scientific risk assessment of the GMO (within 6 months unless additional data is requested from the applicant) in its Scientific Opinion.
- EFSA forwards the Scientific Opinion to the European Commission along with all other information required under Regulation 1829/2003.
- The overall Opinion is published on the websites of both EFSA and the European Commission.
- The public has the opportunity to comment on the overall Opinion via the European Commission's website.

Based on the overall Opinion, the European Commission and the Member States are then responsible for taking a decision on the applicant's request.

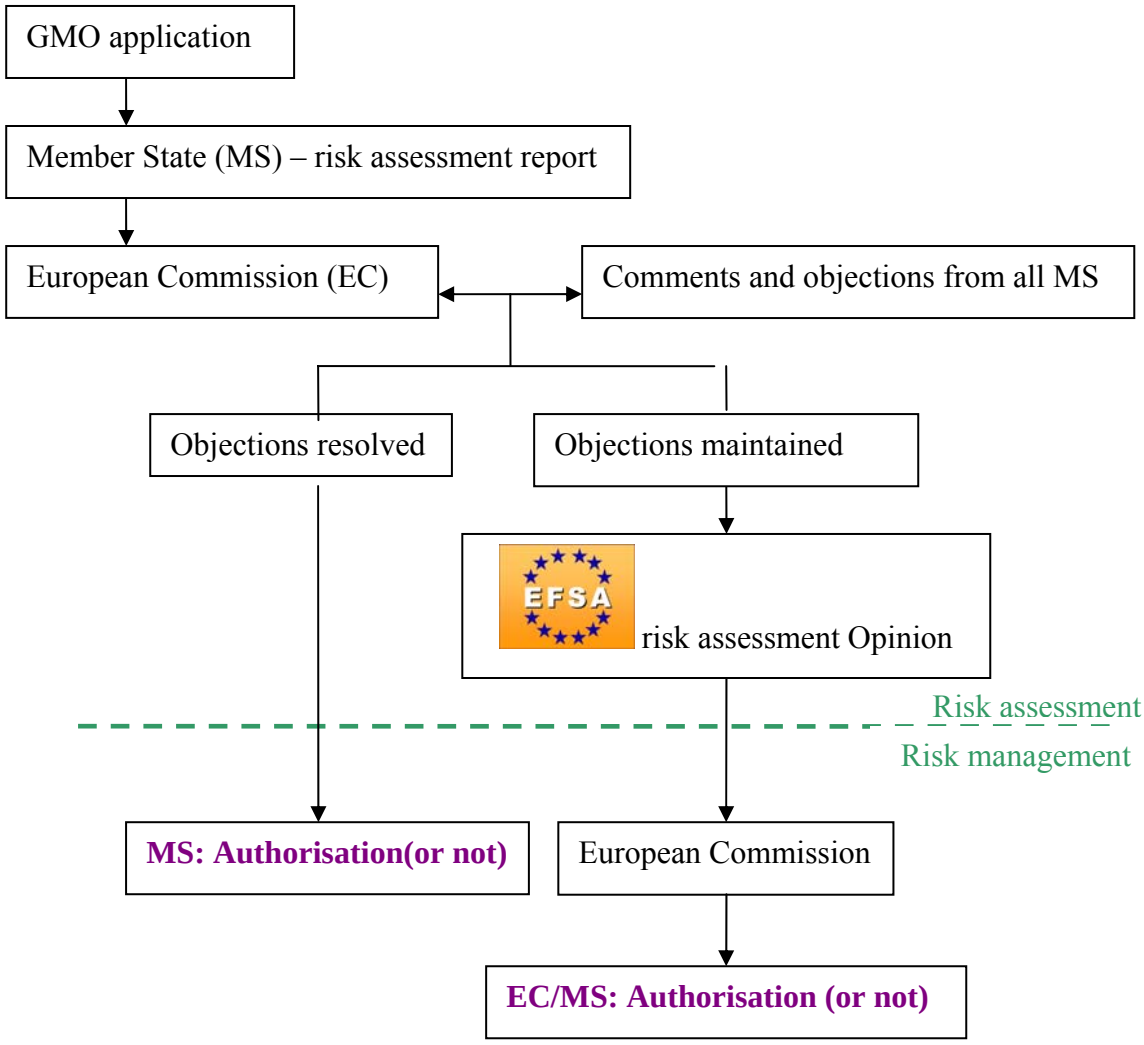


The authorisation procedure under Directive 2001/18/EC

According to this procedure:

- The risk assessment of a GMO is carried out by the Member State where the GMO application is first notified.
- The Member State's risk assessment is sent to the European Commission which then forwards it to all Member States for their comments and input on the risk assessment (so-called "Community period").
- If objections are raised by Member States and cannot be resolved amongst the Member States, EFSA is asked to provide a Scientific Opinion (within 90 days) especially focusing on the points of scientific divergence between the Member States.

Based on EFSA's Opinion, the European Commission and the Member States are then responsible for taking a decision on the applicant's request.



Member State participation in GMO risk assessment

It should firstly be noted that EFSA's Scientific Panel on GMOs is composed of leading experts selected from the EU and, if needed, from beyond, bringing expertise from their different scientific backgrounds and acting independently on behalf of EFSA. Every three years the Panels' membership is renewed.

In the regulatory procedure for GMO risk assessment, Member States either carry out the initial risk assessment themselves (under Directive 2001/18) or, under Regulation 1829/2003, have the opportunity to examine all GMO applications in detail and provide input to EFSA while it is carrying out the risk assessment. In the latter procedure, and when cultivation of the GMO is involved, Member States are asked to volunteer to carry out and provide EFSA with the Environmental risk assessment.

Under Directive 2001/18, the Member States are involved early in the process and EFSA only becomes involved when scientific divergences with respect to the risk assessment cannot be resolved amongst the Member States.

Under Regulation 1829/2003, Member States have the opportunity to examine all GMO applications in detail and provide input where appropriate through a dedicated extranet called "EFSAnet" that EFSA has developed to provide Member States with a privileged channel of communication on the Risk assessment process. While carrying out its risk assessments, EFSA is thus regularly in contact with the competent authorities in the Member States, who are offered a weekly update from EFSA on the progress of open dossiers.

EFSA's GMO Opinions have in the past taken into consideration all scientific comments received from Member States on an applications dossier and will continue to do so. Moreover, in the interests of transparency EFSA has undertaken to indicate how specific comments have been addressed in its Opinions on GMOs by including a list of comments and responses in an annex. This procedure takes effect from June 2006.

Further ways for Member States to be involved in risk assessment

Member States can also use a tool to discuss fundamental divergences of scientific opinion with regard to risk assessments delivered by EFSA. The possibility exists in EFSA's Founding Regulation for Member States to invoke Article 30, which initiates a procedure for EFSA and the Member State(s) in question to address fundamental divergences of opinion in a formal, transparent framework.

Last but not least, EFSA has an Advisory Forum made up of representatives from all Member States which meets at least 4 times per year. This Advisory Forum allows Member States to transmit any concern or question to EFSA and be involved in the activities of EFSA.

2. How does EFSA carry out a GMO risk assessment ?

Working procedures

Each GMO risk assessment is carried out by EFSA's GMO Panel (http://www.efsa.eu.int/science/gmo/catindex_en.html) which is made up of 21 independent scientific experts. The Panel assesses the safety of each GM product on a case by case basis following the criteria laid down in EFSA's "Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed" (for more details, see below).

For all applications, each of the following elements is considered in the risk assessment process:
- the molecular characterisation of the GM product, taking into account the characteristics of the donor and recipient organism
- the compositional, nutritional, and agronomic characteristics of the GM product;
- the potential toxicity and allergenicity of the GM product;
- the potential environmental impact following a deliberate release of the GM product.

Type of data evaluated

As required by Regulation 1829/2003, EFSA has published detailed guidance on the type of data that applicants are required to include in any GMO application dossier, as well as the way it should be prepared and presented. EFSA developed this guidance in open consultation with the public and stakeholders.

The "Guidance Document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed" is available at: http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html. GMO applicants need to follow this guidance to enable EFSA to assess the safety and the environmental impact of a GMO.

The guidance sets out what the GMO Panel requires in terms of data and quality of data, including guidance on the tests to be carried out on aspects such as molecular characterisation, toxicity, allergenicity and the environmental impact of the GMO. Fixed protocols are mentioned especially for scientific issues where harmonization in tests is possible and valid test methods are agreed upon by international risk assessment bodies – for instance on the testing of chemical substances. The applicant has to justify any decision to propose a new type of protocol which is not mentioned in the guidance but serves for the same purpose and delivers the necessary data.

Through its guidance, EFSA's GMO Panel applies a case-by-case approach treating each application as unique. Owing to the individual nature and traits of each GMO, the type of tests needed to assess safety often vary according to the particular type of GMO being tested and the comparative assessment between the GMO and its non-GM

counterpart. Therefore the guidance is not prescriptive as to specific study protocols and does not stipulate a mandatory list of exactly which tests should be done and under which precise parameters.

Studies must comply with the OECD principles of Good Laboratory Practice (GLP)[1], where applicable and be accompanied by a formal statement of Quality Assurance. The data supplied are often prepared by independent private laboratories on behalf of the applicant, operating according to international laboratory standards, such as GLP, GMP, ISO, etc. and under governmental compliance surveillance of the country where they are based.

Whenever EFSA's GMO Panel is not fully satisfied with the data received, the applicant is required to provide the appropriate data for EFSA's Panel properly to assess the safety/risks for human health and environment of the GMO. This has occurred in the vast majority of past and on-going evaluations.

The 21 members of the GMO Panel – who have a wide degree and breadth of experience in assessing GMOs and extensive knowledge of the latest scientific developments and information in the GMO area – also collectively share their knowledge of relevant studies or data. As detailed above, Member States are also provided with the opportunity to give scientific input to each individual application through EFSAnet.

Why doesn't EFSA carry out its own studies?

Under present EU legislation, the GMO applicant is obliged to present a dossier for approval which contains all of the necessary human/animal safety and environmental impact data sufficient for the European authorities to carry out a risk assessment for the GMO concerned. According to EU rules, the cost of these studies must be borne by the applicant which has a commercial interest in obtaining an approval from the EU, i.e. European Commission and Member States. It is not foreseen that EFSA carry out such studies as the onus is on the applicant to demonstrate the safety of the GM product in question. For the GMOs that EFSA has evaluated thus far, when there have been any doubts about the data presented by the applicant, EFSA has obliged the applicant to provide further data or studies before delivering its final risk assessment.

Assessing long-term effects for human health and the environment

The assessment of potential long term effects is one of the fundamental pillars of EFSA's risk assessment work. GMO applicants are obliged to provide adequate data to allow the assessment of the potential long-term adverse effects on both the human/animal health and environmental aspects of a GMO as part of their

[1] EFSA's GMO Panel may accept non GLP studies provided full assurance is provided that the quality of the study is of an equivalent standard.

application, as described in EFSA's guidance document (http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html).

In order to carry out a comparative analysis between the GM plant and its non-GM counterpart to detect potential adverse effects on human or animal health and the environment, the applicant has to present data covering several seasons of field growing trials. Applicants may be requested to submit data on animal feeding trials to assess the safety of long-term consumption in humans.

The applicant also submits, as a mandatory part of its application, a post-market environmental monitoring plan demonstrating how it will monitor the GMO product in the environment with annual and longer term reporting on any possible adverse environmental impact or unanticipated adverse effects of GMOs. This allows for a close monitoring of the GM product so that unanticipated effects can be detected during the 10 year authorization period. In addition, every GMO product must be re-evaluated after 10 years in order for its authorisation to be renewed.

Public access to application dossiers

All EFSA opinions and the summary of the GMO application dossier are published and made available on the EFSA website. In addition, according to EU rules, all members of the public may request access to the full documentation submitted by applicants and third parties to EFSA. Normally access is allowed to such documentation except where information is identified as confidential. If the applicant claims confidentiality of data in a dossier it is up to the European Commission or a Member State (depending on the applicable legislation) to decide whether the claim for confidentiality is justified or not.

3. Keeping EFSA's risk assessments at the forefront of science

In addition to carrying out product-specific risk assessments based on GMO applications received, EFSA also initiates its own work ("self-tasking activities") in order to stay at the forefront of new scientific developments and further to develop GMO risk assessment approaches. For example, EFSA is carrying out work on statistics; allergenicity assessment; the use of animal feeding trials; post-market environmental monitoring of GMOs; and plants used as a production platform for non-food/feed products (e.g. medicinal products).

Example: toxicity study based on animal feeding trials
An ongoing self-tasking study called "The use of animal feeding trials for the safety evaluation of whole GM food/feed" looks at the animal studies used to test the potential short and long term toxicity of the gene product and to evaluate the safety and nutritional aspects of whole GM food/feed.