Brussels, 15 May 2006

Frequently Asked Questions on EFSA GMO Risk Assessment

What is the approval process for GMOs in the European Union ?
There are two principal sets of legislation for approving GMOs in the European Union: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMO's) and Regulation (EC) No 1829/2003 on genetically modified food and feed. Regulation (EC) No 1829/2003 has among others introduced a single risk assessment process for GMOs in the EU by centralising it with EFSA. Since its introduction, more and more applications for the authorisation of new GMOs have been introduced through this more recent legal route.

The procedures for these two legal routes differ and the role of EFSA changes according to the legislative framework applicable. The European Commission has produced a Questions and Answer document on the legal background of GMOs in the EU which can be found at: (http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en).

What is EFSA's role and involvement ?
EFSA's role is to carry out scientific risk assessments or give scientific advice on GMOs under the two regulatory frameworks outlined above.

In providing scientific advice with respect to GM applications, EFSA's involvement varies according to the regulatory framework concerned, but the role of EFSA, namely providing scientifically based risk assessment and the risk assessment criteria used, remain the same. Under Regulation 1829/2003 EFSA assesses both the human safety and environmental impact of GMOs. In the case of Directive 2001/18, this 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.

In both cases, when EFSA prepares an Opinion on a GMO, it is forwarded to the European Commission and Member States and published on EFSA's website. It is the European Union Member States and the European Commission who then take the decision to approve GMOs. EFSA provides the scientific basis for EU decisions on GMOs but is not at all involved in this decision-making process which is under the responsibility of the European Commission and Member States. (please see Commission Q&A for further information)

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EFSA's involvement depends on the procedure chosen by the applicant. Below you will find 2 tables which explain EFSA's role in the risk assessment process:

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

According to this procedure:

● The GMO application is sent to a Member State who immediately forwards it to EFSA who must 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 via EFSA's dedicated extranet.

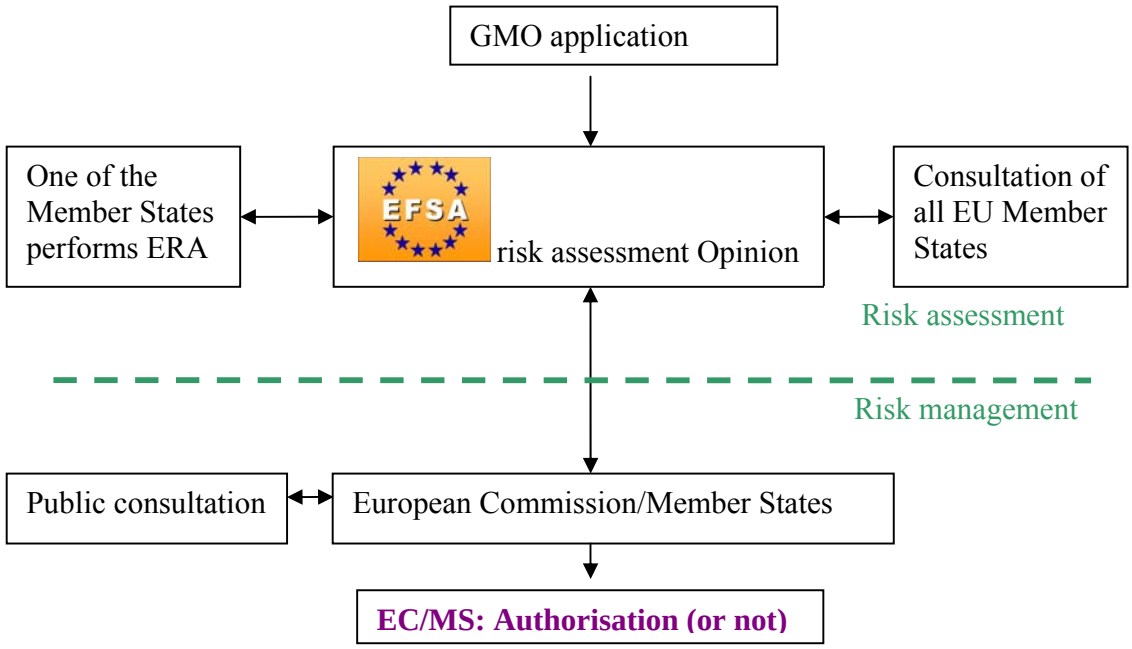
● Member States have the possibility of raising objections and commenting on the application, including on the full data and studies presented by the applicant.

● If the application includes the cultivation of a GMO, one of the Member States must perform the environmental risk assessment.

● EFSA finalises the full scientific risk assessment of the GMO (within 6 months unless additional data is requested from the applicant), forwards it to the European Commission and publishes its opinion on the EFSA website.

After delivery of all other required information under 1829/2003, an overall opinion is published on the websites of both EFSA and the European Commission. As prescribed in the Regulations, the overall opinion can be commented on via the 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 (see European Commission Q&A for further information on this process).



The authorisation procedure - under Directive 2001/18/EC

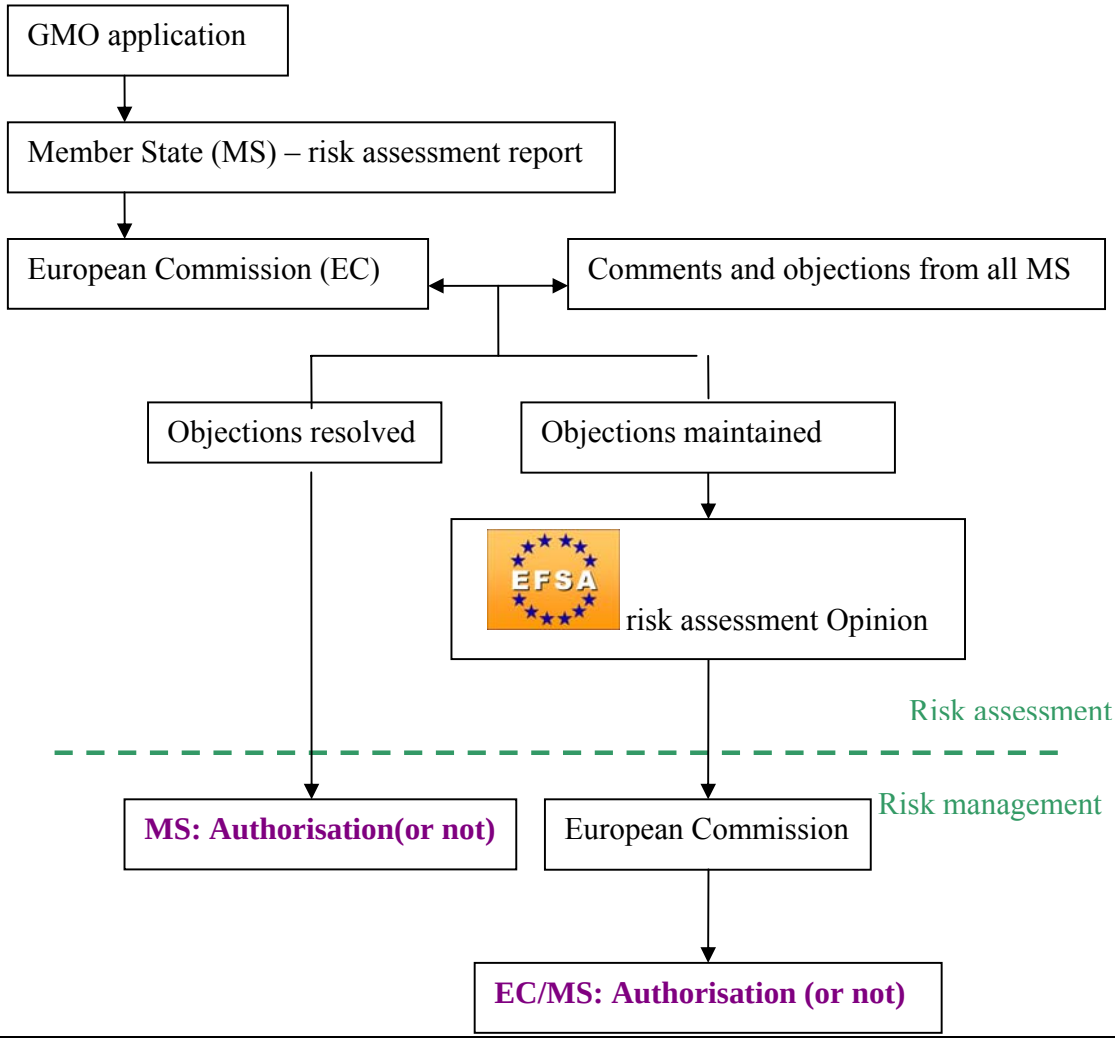
According to this procedure:

● 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 an 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.



How is a GMO risk assessment carried out by EFSA ?

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" (http://www.efsa.eu.int/science/gmo/gmo_guidance/660/guidance_docfinal1.pdf) and in a recent section "General Surveillance of unanticipated adverse effects of the GM Plant"(http://www.efsa.eu.int/science/gmo/gmo_guidance/1275/gensurveill_gm_plants_guidance201220051.pdf)

For each application, each of the following elements are 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.

What does EFSA do in addition to assessing GMO applications ?

In addition to carrying out product-specific risk assessments based on applications received, EFSA also initiates its own work ("self-tasking activities") in order to stay at the forefront of new scientific developments and to further develop GM risk assessment approaches. For example, EFSA has carried out work on: statistics; allergenicity assessment; 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).

What type of data is used in each case-specific GMO evaluation ?

According to EU legislation and owing to the product-specific nature of GMO applications, the GMO applicant has to provide sufficient data in its application to enable EFSA to assess the safety and the environmental impact of the GMO. As required in the Regulation 1829/2003, EFSA has published detailed guidelines on the type of data that companies should include in their dossier (http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html), as well as the way it should be prepared and presented.

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 literature and information in the GMO area – also collectively share their knowledge of relevant studies or data. Member States are also provided with the opportunity to give scientific input to an individual application through EFSA's GMO extranet called "EFSAnet".

How does EFSA deal with input from 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. Under Directive 2001/18, the Member States are involved early on in the risk assessment themselves and EFSA only becomes involved when scientific divergences cannot be resolved amongst the Member States. EFSA and the GMO Panel are presently looking at ways in which they can address the comments of Member States in a more visible way in its opinions.

What is the role of Member States in the risk assessment of GMOs?

Member States either carry out the initial risk assessment themselves or, under more recent GMO legislation, 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 GM is involved, one of the Member States must carry out and provide EFSA with the Environmental risk assessment.

How does EFSA deal with input from GMO stakeholders (Industry, NGOs, Consumers) ?

EFSA is open to scientific contributions from third parties. GMO stakeholders have participated significantly in the GMO-related public consultation processes already organised by EFSA (http://www.efsa.eu.int/science/gmo/gmo_consultations/catindex_en.html).

In addition, GMO stakeholders frequently communicate directly with EFSA on GMO issues and on specific risk assessments. EFSA has also created the possibility for this dialogue on GMO science in the framework of its meetings with GMO stakeholders, both through its Stakeholder Consultative Platform and through specific meetings. For example, such a meeting was organised early in 2006 in order to exchange views with some environmental NGOs on the scientific approaches to the EFSA risk assessment of GMOs.

In addition, for each GMO assessment prepared by EFSA, the European Commission organises an additional public consultation on its website thereby providing all third parties with the possibility to provide comment.

How is the independence and impartiality of the members of its GMO scientific Panel ensured?

Independence and scientific excellence are the cornerstone of EFSA's work and both are critical to building and maintaining public confidence in European risk assessment. EFSA seeks to select for its Scientific Panels and Scientific Committee the best scientific experts in their scientific field. The independence of the scientific experts and all those involved in the activities of EFSA is ensured by a mandatory declaration of commitment of independence and declarations of interests. These declarations are done annually and are public documents on the EFSA website. In addition to these annual declarations, members of the Scientific Committee, the Scientific Panels, external experts participating

in working groups and EFSA staff declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda. EFSA is constantly vigilant to potential conflicts whilst recognising that the top scientific experts in Europe can only gain their expertise where they are active in their fields and have experience and knowledge about the GM products to be investigated. EFSA is satisfied that members of its GMO Panel comply in full with the requirements of independence fundamental to their role and as required by the legal framework. In addition, as for all other scientific Panels, the opinion of the GMO Panel, made up of 21 members, is a collective position.

Does EFSA address the long-term effects of GMOs in its risk assessment ?
GMO applicants are obliged to provide data on the potential long-term adverse effects on both the human/animal health and environmental aspects of a GMO as part of their application as described in EFSA's guidance document (http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html). Based on all data available at present, EFSA's GMO Panel evaluates the possibility for long-term effects on both human/animal health and the environment in its assessment of the dossier. Like applications for all food authorisations, the applicant is obliged to submit data on animal feeding trials to demonstrate the safety of long-term consumption in humans. The applicant is also obliged to present data covering several seasons of field growing trials so that adverse effects on the environment and agronomic traits can be detected. The applicant also submits, as a mandatory part of its application, an environmental monitoring plan demonstrating how it will monitor the GMO product with annual and more 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.

For the GMOs which it has evaluated so far, EFSA's GMO Panel has not found sufficient scientific grounds to justify concern in terms of undesired long-term effects on human/animal health or the environment.

Has EFSA ever provided a negative opinion on a GMO ?
EFSA's role is to evaluate the human safety and environmental impact of GMO applications. It scrutinises each and every application according to established and extensive criteria (EFSA guidance: (http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html). To date, the GMO applications received by EFSA have been of a generally high scientific standard. Nevertheless, in each GMO dossier that EFSA has evaluated, EFSA has taken a cautious and conservative approach and requested further data or studies wherever it has had doubts concerning an application. On each occasion, the applicant has come back with the data lacking or further studies requested by EFSA. As to date all data requirements were eventually met by applicants, EFSA has not delivered any final negative opinion on

any of the GMOs presented to it so far (NB: EFSA has requested additional data in almost all of the finalized and currently pending dossiers). In one case, for a hybrid GMO, the EFSA panel requested an additional study from the applicant before finalizing its risk assessment.

Does EFSA provide access to all GMO studies and documents provided by the applicants ?
All EFSA opinions, documents and the GMO application dossier concerned are published and made available on the Authority's 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.

Why doesn't EFSA carry out its own studies for each GMO application ?
Under present EU legislation, the GMO applicant is obliged to present a dossier for approval which contains all of the necessary human 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 it to provide further data or studies before delivering its final risk assessment.

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