

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

DRAFT EFSA GUIDELINES FOR THE RISK ASSESSMENT OF
GENETICALLY MODIFIED MICROORGANISMS

Issue

EFSA has issued an open consultation on its guidance document for the risk assessment of genetically modified microorganisms (GMMs). The Committee is asked to consider the draft guidelines for the risk assessment of GMMs and is invited to provide comments that will form the basis of the UK's response to this consultation.

Introduction

1. EFSA's Scientific Panel on GMOs published draft guidance for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use on 15th July (**Annex 1**). Written comments were initially invited before 15th September, but this deadline has now been extended to the end of September.
2. In accordance with Articles 5(8) and 17(8) of the Regulation (EC) 1829/2003 on genetically modified food and feed the European Commission has requested that EFSA publish detailed guidance to assist applicants in the preparation and presentation of applications for the authorisation of GM food and/or feed.
3. EFSA has previously published guidance on the assessment of GM plants used as sources of food and feed, covering all the aspects of the risk assessment in relation to food safety, feed safety and environmental effects. The Committee commented on this guidance in May 2004 (ACNFP/66/2). This new guidance document is intended as an aid to applicants requesting authorisations for genetically modified microorganisms (GMMs) and their derived products intended for food and feed use.

Assessment of Microorganisms used in food and feed

4. In a recent opinion the EFSA Scientific Committee, which oversees the work of the individual Panels and considers cross cutting issues, took steps towards establishing a generic approach to the safety assessment, by EFSA, of microorganisms used in food/feed and the production of food/feed additives. This proposes the introduction of the concept of the "Qualified Presumption of Safety" (QPS), which could be applied to selected groups of microorganisms according to 4 criteria:
 - (1) The taxonomic group of microorganisms
 - (2) Whether enough is known about the group to reach a conclusion on safety
 - (3) Whether the group contains known pathogens
 - (4) The intended use.
5. This approach is described in more detail in accompanying information paper ACNFP/73/9.

Guidance on GM microorganisms

6. The current document covers GMMs and derived products ranging from pure compounds used in food and feed (e.g. additives and flavourings) to viable GMMs (e.g. probiotics and starter cultures for dairy products or beverages). Typical GMMs covered by the guidance document are various forms of non-harmful prokaryotes and eukaryotes (bacteria, yeasts, fungi and microalgae) used in food or feed.
7. The document identifies 3 groups of products obtained from GMMs:
 - Group 1: Pure compounds or simple mixtures derived from GMMs
 - Group 2: Complex products derived from GMMs, but not containing viable GMMs
 - Group 3: Viable GMMs and products containing viable GMMs
8. Different levels of scrutiny are proposed for these 3 different groups of products, with the highest level of scrutiny reserved for products containing viable GMMs. A flow diagram on page 50 of the draft guidelines outlines a

decision tree for the approach to the environmental risk assessment of GMMs and their products.

Scope of the guidance

9. The document provides guidance to enable an applicant to cover the following: (1) the drawing up of Annex IIIA of the Directive 2001/18/EC on the deliberate release into the environment of GMOs. (2) The preparation of the conclusion of the environmental risk assessment as stated in Annex II paragraph D.1, and (3) the establishment of an environmental monitoring plan according to Annex VII of that Directive. This guidance is in addition to the supplementary guidance notes 2002/623/EC and 2002/811/EC established within the framework of Directive 2001/18/EC.
10. This document does not cover the use of tissue cultures of plant or animal cells, nor does it cover issues related to risk management. Socioeconomic and ethical issues are also outside the scope of this guidance. This guidance does not cover the contained use of GMMs or the deliberate release into the environment of GMMs for any other purpose than for the placing on the market (Directive 2001/18/EC) as these are covered by other community legislation.
11. As regards the use of GMMs as plant protection products, bioremediation agents¹, biofertilisers or phytostimulators, these applications also fall into the wider scope of Directive 2001/18/EC, and further guidance in this area will be developed. The principles of risk assessment of GMMs intended for these other applications which are likely to enter the food or feed chains, is unlikely to differ significantly with respect to their presence in food or feed.

The risk assessment strategy (Section II)

12. The risk assessment strategy is outlined in section II of the document (Annex 1, p12-17) and includes hazard identification, hazard characterisation, exposure assessment and risk characterisation. The sequential steps in risk assessment of GMOs identify characteristics that may cause adverse effects, evaluate their potential consequence, assess the likelihood of occurrence and estimate the risk posed by each identified characteristic of the GMO.

¹ i.e. the use of microorganisms to mitigate the effects of pollution.

Information required (Section III)

13. Information relating to the GMM: This information should include the most recent taxonomic classification and should identify the specific characteristics of the organism. This will allow for species-specific analyses, e.g. the known occurrence in the genus/species of specific toxins that are typically expressed at low levels in the unmodified recipient strains, but that may be unintentionally increased following the genetic modification process. Information should be provided on all issues of potential concern, such as the presence of natural toxins, allergens or virulence factors. Data should be provided on the previous use of both the donor and recipient organisms. Specifically information should be provided on the following:

- Characteristics of the recipient or parental organism
- Characteristics of the donor organism(s)
- Description of the genetic modification process
- Identification of the conventional counterpart organism and its characteristics
- Information relating to the GMM and comparison of the GMM with its conventional counterpart

14. Information relating to the GM product. The information required can be summarised in the following categories:

- Information relating to the production process
- Information relating to the product purification process
- Description of the product
- Assessment of the potential risk of horizontal gene transfer
- Comparison of the GM product with its conventional counterpart
- Considerations for human health and animal health of the GM product (*toxicology/allergenicity/nutritional assessment*)

15. **Potential environmental impact of GMMs and derived products.** The document stresses that the analysis of the potential environmental impact of GMMs used for the production of food or feed, or food or feed consisting of or containing GMMs, is an essential part of the safety assessment. This analysis should be designed to identify and evaluate the potential adverse effects that the deliberate release or the placing of GMM food/feed on the market may pose to receiving environments. Comments on this aspect of the guidance have been sought from the Advisory Committee on Releases to the Environment (ACRE).

16. **Summary of the risk assessment requirements.** A summary of the information to be included in applications for the placing GMMs and derived food/feed on the market is provided in Table 1 (Annex 1, section III, E, p51-56). This table, based on the approach described in Chapter II, 2, p12 and in Figure 1, contains the main items required for the risk assessment of GMMs and derived food and feed with cross-references to the text. It provides a simple and immediate list of the requirements for an application. However, the applicant's are advised to refer to the main text of the guidance to address the requirements for the submission of an application in sufficient detail.

Risk characterisation of GMMs regarding food/feed safety and environmental impact (section IV)

17. The risk assessment process consists of a number of steps *i.e.* hazard identification, hazard characterisation and exposure assessment, which culminates in a final integrative risk characterisation. Applicant's are referred to various documents dealing with risk assessment procedures in general in this section. A detailed strategy for risk assessment and risk characterisation of foods derived from GMMs has recently been described by FAO/WHO (WHO/FAO, 2001b: Annex 1, p67, L20). Codex guidelines for the safety assessment of foods derived from GMMs were published in 2003 (*Codex Alimentarius*, 2003: Annex 1, p62, L13).

18. Risk assessment involves generating, collecting and assessing information on a GMM and its derived food/feed in order to determine its impact on human/animal health and the environment relative to current equivalents, and thus its relative safety. In order to carry out the risk assessment sufficient scientific data must be available in order to arrive at qualitative/quantitative risk estimates. The final risk characterisation is intended to result in informed

qualitative, and if possible quantitative, guidance to risk managers with clear explanations of any assumptions that have been made during the risk assessment and the nature and magnitude of the uncertainties associated with establishing these risks.

19. Further information is provided on:

- How to carry out the risk characterisation
- Issues to be considered for risk characterisation
- The result of the risk characterisation

Committee action required

20. Members are invited to consider the draft guidance document and to discuss any points that ought to be brought to the attention of EFSA's GMO Panel. Members' views will be incorporated into a formal Food Standards Agency response to the consultation, which will be forwarded to the EFSA in the next few days.

**Secretariat
September 2005**

Annex attached

Annex 1: Draft guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use. EFSA, 5 July 2005.

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Draft guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use. EFSA, 5 July 2005.

This document has been published on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_consultations/1035/gmo_consultation_guide_gmm2_en1.pdf

**Secretariat
September 2005**