

**Guidance document of the Scientific Panel
on Genetically Modified Organisms
for renewal of authorisations of existing GMO products
lawfully placed on the market, notified according to
Articles 8 and 20 of Regulation (EC) No 1829/2003¹**

(Question No EFSA-Q-2003-005C)

Adopted on 6 December 2006

Terms of reference

In accordance with Articles 11(6) and 23(6) of Regulation (EC) 1829/2003 on genetically modified food and feed, the European Commission has requested the European Food Safety Authority (EFSA) to publish detailed guidance to assist applicants in the preparation and presentation of the application for renewal of authorisation of GM food and/or feed.

1. SCOPE

This guidance aims to assist applicants in the preparation and presentation of applications for renewal of authorisation of existing products according to Articles 11 and 23 of Regulation (EC) No 1829/2003 on genetically modified food and feed. It is applicable for authorisation-holders who have products referred to as existing products, notified according to Articles 8 and 20, which have been published in the Community Register established according to Article 28 in the same regulation. The Community Register can be found at the following website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

An application for renewal of authorisation for an existing (notified) product can only be submitted for the 26 products listed in the Community Register of existing products.

It should be noted that this document is not aimed at providing guidance for renewal of products authorised according to Articles 7 and 19 of the said regulation. It is foreseen that applications for renewal of such authorisations will need to be submitted, at the earliest, one year before the expiry of the authorisation, which will first take place in year 2015. The European Food Safety Authority (EFSA) may consider the need for guidance for such products in the light of future revisions of the Guidance documents of the GMO Panel (EFSA, 2006a, b).

2. LEGAL BACKGROUND

According to Articles 11(6) and 23(6) of Regulation (EC) 1829/2003 on genetically modified food and feed, the EFSA shall publish detailed guidance to assist applicants in the preparation and presentation of their application for renewal of authorisation of GM food and/or feed.

In Articles 8(4) and 20(4) operators responsible for placing products on the market according to Articles 8 and 20, referred to as notified (existing) products, shall submit an application in accordance with Articles 11 or 23, which shall apply *mutatis mutandis*.

¹ For citation purposes: Guidance document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003
The EFSA Journal (2006) 435, 1-4

3. RENEWAL OF AUTHORISATIONS FOR EXISTING PRODUCTS

3.1 INFORMATION ON THE ASSESSMENT

The EFSA assessment of an application for renewal of the authorisation for an existing product is an adaptation of the procedure used to assess a new GMO application and takes into account any new information, experience and data that have been collected during the authorisation period. EFSA will issue an opinion on the application for renewal of authorisation and include a report describing its assessment of the GMO according to Articles 6 and 18 of the regulation.

Applications for renewal of microbial products

For renewal of the two microbial products in the Community Register, not all provisions in this guidance are applicable and the applicants are also directed to the Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (EFSA, 2006b).

3.2 PRESENTATION OF THE APPLICATION

To enable the case by case risk assessment according to the Guidance document (EFSA, 2006a), an application for renewal of an authorisation for an existing product should be accompanied by a dossier containing all of the information required for a risk assessment of the product in question. It is recommended that this dossier is presented and structured according to Annexes I to IV of the Guidance document, amended with the information specified in this section (see below).

The scope of the application shall in principle correspond to the scope of the existing product in the Community Register and shall cover one or more of the categories provided for in Articles 3(1) and 15(1) in the regulation (see also Annex II of the Guidance document (EFSA 2006a)).

The information in Articles 5(3), 5(5), 17(3) and 17(5), that accompanied the original notification to the European Commission according to Articles 8(2) and 20(2) should, where applicable, be updated according to this guidance document and accompany the application. Where relevant the application should also include the information specified in Articles 5(6) and 17(6), respectively.

If an application for renewal concerns a GMO for which EFSA has issued an opinion, the applicant need not resubmit all the information in Articles 5(3), 5(5), 17(3) and 17(5), but can refer to the appropriate sections in the original application dossier submitted under Regulation (EC) No 1829/2003.

If the applicant is of the opinion that the information required according to the Guidance document is not relevant for the risk assessment, the applicant must provide justification. In this regard, it must be pointed out that EFSA can ask for additional information according to Articles 6 and 18 if the GMO Panel considers the information necessary to issue an opinion.

3.2.1 Specific information to accompany the application

In addition to the particulars mentioned above, the application shall be accompanied by the particulars and documents indicated in Articles 11(2) and 23(2) respectively, as specified below.

3.2.2 Authorisation

The application shall contain a copy of the authorisation(s) for placing the food and/or feed on the market.

3.2.3 Monitoring report

All reports from general surveillance and the case specific monitoring specified in the authorisation shall be submitted. (More information on reporting the results of monitoring can be found in Chapter III, section 11.5 of the Guidance document (2006a)). Any relevant monitoring conducted for research purposes or conducted by third parties should also be reported.

3.2.4 Any other new information

New developments that have occurred since the first authorisation of the product in question and which could have an impact on the risk assessment must be taken into consideration when assessing the product to be renewed (see also Chapter II, section 6, Forthcoming developments in the Guidance Document (EFSA, 2006a)). The application for renewal shall therefore be accompanied by new information which has become available during the authorisation period with regard to the safety of the GM product for humans and animals (food and feed) and for the environment.

The applicant shall specifically consider whether new developments in molecular characterization, biochemistry, toxicology, allergenicity, impact on biodiversity, environmental risk assessment, changes to biotic and abiotic factors and long term effects or any methodological developments, such as strategies for data base searches could provide new information relevant for the risk assessment.

The applicant shall submit the following or otherwise give justifiable reasons for not providing the information requested:

1. a review of peer reviewed scientific data on the GMO and derived food and feed which may be relevant for the safety of the GM product for humans and animals and for the environment that have become available since the original authorisation,
2. a report on the areas and quantity of production, the importation and utilisation in Europe and information on known and estimated human and animal exposure,
3. updated molecular characterization, including sequence data for the flanking regions,
4. updated information on the levels of expression of the specific proteins and metabolites resulting from the genetic modification and on the composition of the GMO,
5. updated information on allergenicity and toxicology,
6. a report on the stability of the trait and the methods for detection over the authorisation period,
7. a report on any unintended and/or unanticipated effects,
8. if relevant, a post market monitoring plan, according to section III D.7.11 in the Guidance Document.

Where cultivation is part of the scope of the application:

9. a report on cultivation locations, areas, volume, stewardship and other relevant information related to agricultural practices,
10. a report on the range and type of specific agronomic practices associated with the event in the range of environments where cultivation occurs. The report should assess the impact on the agricultural and surrounding environments, including for example examination of possible cumulative effects of growing the event over several years,
11. a report on interactions that might take place with present cultivars, whether GM or not, and the possible agronomic and environmental consequences of these interactions which may require changes in cultivation, harvesting or processing,
12. an environmental monitoring plan according to section III D.11. of the Guidance Document.

Where applicable, reports submitted shall include methods, raw data, results, conclusions and recommendations.

The applicant should include a table with references to risk assessment reports on the event from risk assessment authorities in the EU Member States and third countries and reports of monitoring conducted in those countries, if performed. If not publicly available, copies of these reports should be provided.

3.2.5 Proposals for amendments

Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, including conditions concerning future monitoring, shall be provided. See also points 8 and 12 in section 3.2.4 above.

3.3 APPLICATION SUBMISSION

An application shall be submitted by the authorisation-holder to the European Commission. The European Commission sends the application to EFSA who in turn makes the full application available to Member States and the summary of the application available to the public.

An application for an existing product falling under Articles 8(1)(a) and/or 20(1)(a) shall be submitted within nine years from the date on which the products were first placed on the market, but in no case earlier than 18 April 2007. However, for products where the foreseen nine-year period ends earlier than 18 April 2007 the application for renewal has to be submitted on that date.

Application for products falling under Articles 8(1)(b) or 20(1)(b) shall be submitted before 18 April 2007.

4. PRACTICAL SPECIFICATIONS

With regard to the electronic version of the application, the maximum size for a single file in the dossier is 25 MB. If a file is larger it should be split into smaller files. Electronic files (both Word and PDF) shall be searchable though this is not a requirement for scanned documents files which should be kept to a minimum.

5. REFERENCES

EFSA, 2006a, Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal (2006) 99, 1-100.

EFSA, 2006b, Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use. The EFSA Journal (2006) 374, 1-115.

SCIENTIFIC PANEL MEMBERS

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Ralf Einspanier, Lieve Herman, Marc De Loose, Niels Hendriksen, Sirpa Kärenlampi, Jozsef Kiss, Ilona Kryspin-Sørensen, Harry Kuiper, Ingolf Nes, Nickolas Panopoulos, Joe Perry, Annette Pötting, Joachim Schiemann, Willem Seinen, Jeremy Sweet, and Jean-Michel Wal.
