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The European Association for Bioindustries

Structure and Content of Renewal Submissions

Applicable to GM products fully risk assessed and authorised under Regulation 1829/2003

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Outline

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- Proposed structure of a renewal application
- Concluding remarks

Background (1)

- **October 2014** – adoption of a draft for **public consultation** by the GMO Panel Plenary
- **March 2015** - a formal adoption of the guidance is foreseen
- As there are several products requiring renewal of their authorisations within the next few years, EuropaBio would like to understand the **format** for renewal applications, in order to prepare the applications.
  - The **first** renewal application (Maize 1507) will need to be submitted in **February 2015**.
- Multiple **stacked products** renewals accompanying single renewal applications might need to be prepared to maintain **synchronicity** of authorisations.

Background (2)

- All products for renewal have already been fully risk assessed under EU legislation and EFSA guidance as well as by other regulatory authorities as **safe**
- Products for renewal will have been placed on the EU market for a period of 9+ years (duration of consent) with no adverse effects as detailed in annual monitoring reports
- Lack of adverse effects during commercialisation of product confirms that original risk assessment was correct in terms of safety
- Renewal of approval should therefore be in line with the above and **not** trigger a new risk assessment under these conditions

Applicants' understanding

- The EFSA 2006 guidance applied to the renewal of authorisations of **existing** GMO products, **notified** according to Articles 8 and 20 of Regulation 1829/2003.
- This 2006 guidance does **not apply** to **authorised** products according to Articles 7 and 19 and **to be renewed** according to Articles 11 and 23 of Regulation 1829/2003.
- The requirements laid down in Implementing Regulation (EC) 503/2013 are **not** applicable to renewal applications, except for Article 8 (reference to detection methods).
- Hence, the 2013 EFSA submission guidance (updated to reflect Regulation (EC) 503/2013 requirements) is **not** applicable for products previously fully risk assessed and authorised according to Regulation (EC) 1829/2003 and now to be renewed according to Articles 11 and 23 of Regulation (EC) 1829/2003.

Renewal template proposal

Currently **no** format exists for developing an application for renewal of authorisations!

Therefore, EuropaBio has prepared an application template according to Articles 11 and 23 of Regulation (EC) 1829/2003.

Proposed structure of a renewal application

Structure	Content
Part I: General information	Part I: General information, as in EFSA 2011 Guidance (or Annex I, Implementing Regulation (EC) 503/2013)
Part II: Specific information	Articles 11 and 23 of Regulation (EC) 1829/2003 *(2)(a) Copy of authorisation* *(2)(b) Summary monitoring report and copies of all annual monitoring reports* *(2)(c) Any other new information which has become available with regard to the evaluation of the safety as applicable, notably after last annual monitoring report* *(2)(d) Monitoring plan proposal*
Summary information	Summary of Part I and Part II information to be published

Part II: Specific Information (1)

Note: The following sections address the requirements as specified in Regulation 1829/2003 Articles 11 and 23.

1. Copy of the authorisation for placing the food or feed on the market.

Note: Addresses Articles 11(2)(a) and 23(2)(a)

- A copy of the authorisation will be provided.
- Refer to EU register (Authorisation decision, monitoring plan, availability of reference material, previous EFSA opinion(s), detection method).

Part II: Specific Information (2)

2. Report on the results of the monitoring, if so specified in the authorisation.

Note: Addresses Articles 11(2)(b) and 23(2)(b)

- Executive Summary on the results of the monitoring since authorisation.
- Copies of all previous annual monitoring reports submitted to the European Commission will be provided.

Part II: Specific Information (3)

3. Any other new information which has become available with regard to the evaluation of the safety in use of the food or feed and the risks of the food or feed to humans, animals or the environment.

   Note: Addresses Articles 11(2)(c) and 23(2)(c)

   - Available new information relating to the genetically modified food or feed, as applicable

Note: This relates to information that (i) may have been provided by the authorisation holder according to Article 9(3), (ii) has become available since the last submitted annual monitoring report (i.e. review of published literature).

Part II Specific Information (4)

4. Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

   Note: Addresses Articles 11(2)(d) and 23(2)(d)

   - As applicable an updated monitoring plan will be proposed and the adaptations will be justified.
   - Article 8(2) provisions of Implementing Regulation 503/2013 will be addressed.

Concluding remarks

- The focus of the current template proposal is on import, food, feed renewal applications (and excludes cultivation).
- Products up for a renewal authorisation have been fully risk assessed prior to the first authorisation.
- In case no information has become available during 9 years of commercialisation that the product poses risk to human and animal health (Article 9(3) of Regulation (EC) 1829/2003), the product is considered having a history of safe use and does **not** require any repeat of previous risk assessment.
- Applicants will need to have some flexibility to accommodate:
  - —Submissions to be made prior to the publication of the final EFSA Renewal Guidance Document;
  - —To cover sub-combinations as part of a renewal for, *e.g.,* a triple stacked product;

Thank you!

Additional information

Part I General Information

Note: This part will provide updated general information, as applicable.

- Name and address of the applicant (company or institute).
- Name, qualification and experience of the responsible scientist(s) and contact details of the responsible person for all dealings with the European Food Safety Authority (EFSA).
- Designation and specification of the genetically modified plant and its products.
- Scope of the application:
  - Genetically modified food
    - Food containing or consisting of genetically modified plants
    - Food produced from genetically modified plants or containing ingredients produced from genetically modified plants
  - Genetically modified feed
    - Feed containing or consisting of genetically modified plants
    - Feed produced from genetically modified plants
  - Genetically modified plants for food or feed uses
    - Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
    - Seeds and other plant propagating material for cultivation in the Union.
- Unique identifier.
- Where applicable, a detailed description of the method of production and manufacturing.
- The conditions for the placing on the market of the genetically modified food(s) or feed(s), including specific conditions for use and handling.
- Note: This section will refer to the existing authorisation and corresponding EFSA opinion(s) on the safety of the product. It will summarize the conclusions of the EFSA opinion(s) and will outline the conditions to place the product on the EU market as determined in the authorisation, and thereby lead over to Part II Specific Information.

Part III Summary information

Note: This section provides a format for a summary to be published.

- Name and address of the applicant (company or institute).
- General description of the product
- Scope of the application
- Unique identifier
- The conditions for the placing on the market of the genetically modified food(s) or feed(s), including specific conditions for use and handling
- Conclusions on the results of monitoring
- Conclusions on any additional information that became available
- Proposals to adapt the monitoring plan
- General conclusions on the safety assessment of the GM product