Draft Guidance Novel Foods

ToR and General Principles

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BACKGROUND - REGULATION (EU) 2015/2283

EFSA shall consider the following:

- whether the **Novel Food** concerned is as safe as food from a comparable food category already existing on the market within the Union;

whether the history of safe food use of a **Traditional Food** in a third country is substantiated by reliable data by the applicant;

- whether the composition of the food and the conditions of its use do **not pose a safety risk** to human health in the Union;

- when the NF/TF which is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be **nutritionally disadvantageous** for the consumer.

MANDATE

Commission asked EFSA to provide scientific and technical guidance for the preparation and presentation

- of applications for authorisation of **Novel Foods**, and

- of notifications and applications for authorisation of **Traditional Foods (TF) from third countries**.

OBJECTIVES OF THE GUIDANCE DOCUMENTS

to assist

- applicants with a **common format** for the organisation of the information to be presented in order to assist the applicant in the preparation of a **well-structured dossier** to demonstrate the safety of the Novel Food, or for Traditional Foods - to demonstrate its “history of safe food use in a third country”.

- applicants in providing the **type and quality of information** needed for such applications and notifications.

SCOPE OF THE TWO GUIDANCE DOCUMENTS

- General Guidance **Novel Foods** for *Art. 10 Applications*
- Guidance for **Traditional Foods** for *Art. 14 notifications* and for *Art. 16 applications* for the authorisation of TF under the new Regulation (EU) 2015/2283 concerning the history of safe use and the proposed conditions of use

  - For responding to duly reasoned safety objections (Art. 16 applications) concerning data other than on the history of safe use & the proposed conditions of use > the general Novel Food Guidance and other EFSA Guidance may assist depending on the type of data provided.

GENERAL PRINCIPLE (1) – NOVEL FOODS

- This document should be read in conjunction with **Regulation (EU) 2015/2283 on Novel Foods**, other EU guidelines and Regulations, and with other **EFSA Guidance** documents e.g. from the EFSA Scientific Committee, the Food Additive Panel, where applicable.
- It is the duty of the applicant to provide a **stand-alone and complete dossier including all** available (proprietary, confidential and published) scientific data (**data in favour** and **not in favour**) that are pertinent to the safety of the Novel Food. Whenever available, **full study reports** should be provided.
- The **methods used to identify relevant data**, including databases used and criteria for literature searches, should be reported. The published literature should be reviewed following systematic review principles.

GENERAL PRINCIPLE (2) – NOVEL FOODS

- The applicant should provide its **considerations** on how the information supports the safety of the NF under the proposed conditions of use at the end of individual sections in the application. **Uncertainties** should be addressed, and a **critical appraisal** on the provided data should be provided.
- Description, information on production process, compositional data, specifications, proposed uses and use levels and anticipated intake constitute the minimum requirements. Further sections on the history of use of the Novel Food and/or its source, absorption, distribution, metabolism, and excretion, nutritional information, toxicological information and allergenicity should be considered by the applicant by default. If not covered in the application, this should be justified.
- **Deviations** should be justified.

GENERAL PRINCIPLE (3) – NOVEL FOODS

- Analyses/tests should be performed in a **competent facility** that can certify the data. **Quality systems** in place for control/documentation should be indicated. Information on the **accreditation** of involved facilities and **certificates of analyses** should be provided. The applicant should indicate compliance with **official guidelines** (e.g. OECD, EMA and ICH) and quality systems (e.g. GLP, GMP, GCP and applicable ISO systems) were applicable.
- Unnecessary animal tests should be avoided.

GENERAL PRINCIPLE (4) – NOVEL FOODS

- The decision on granting the protection of **proprietary data** under Article 26 of Regulation (EU) 2015/2283 falls under the responsibility of the European Commission. With respect to the handling, use and protection of proprietary data by EFSA, it should be noted that where an application includes a request for the protection of proprietary data, the NDA Panel considers in its opinion whether the safety of the Novel Food could have been assessed without the data claimed as proprietary by the applicant.

- The decision on **confidential treatment** of information submitted under Article 23 of Regulation (EU) 2015/2283 falls under the responsibility of the European Commission. As per Article 23(5) of the Regulation, EFSA shall take necessary measures to ensure appropriate confidentiality of the information received under this Regulation, except for information which is required to be made public in order to protect human health.

Thank you for your attention !