Guidance on Novel Foods

General Principles and their relevance for the safety assessment

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efsa
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INTRODUCTION AND OUTLINE

- Short background information
- Mandate, objective and scope of EFSA Guidance documents
- GENERAL PRINCIPLES and their relevance

COMMON STRUCTURE OF THE PRESENTATIONS

- Presenting the two EFSA Guidance documents
- Aspects raised in the public consultation
- Examples from past applications on presented data and considerations of the EFSA NDA Panel
- Recurrent issues from past evaluations.

BACKGROUND - REGULATION (EU) 2015/2283

Regulation (EU) 2015/2283, definitions:

‘Novel food’ means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, (10 categories listed in the Regulation)

‘Traditional food from a third country’ is a novel food derived from primary production (plants/animals/ micro-organisms etc., processed/unprocessed) with a history of safe use in a third country.

‘History of safe food use in a third country’ means that the safety of the food in question has been confirmed with **compositional data** and from **experience of continued use** for at least 25 years in the customary diet of a significant number of people in at least one third country.”

BACKGROUND - REGULATION (EU) 2015/2283

EFSA shall consider the following:

- whether the **Novel Food** in question is safe;
- 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;
- whether the normal consumption of the NF/TF 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 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".

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

- To facilitate the work of the EFSA experts in **assessing the data**.

SCOPE OF THE TWO GUIDANCE DOCUMENTS

- General Guidance for **Novel Foods** for *Art. 10 Applications*
- Guidance for **Traditional Foods** for *Art. 14 notifications* and for *Art. 16 applications* under 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 (for Art. 10 applications) and other EFSA Guidance may assist depending on the type of data provided.

GENERAL PRINCIPLE (1) – NOVEL FOODS

1) To 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.

2) **Stand-alone dossier**

3) **Comprehensive and complete**: All available (proprietary, confidential and published) scientific data, **data in favour** and **not in favour,** that are pertinent to the safety of the NF. Whenever available, **full study reports** should be provided.

GENERAL PRINCIPLE (2) – NOVEL FOODS

4) **Identification of pertinent data:** information on search strategy, incl. the sources, the terms and limits used; where applicable, the published literature should be reviewed by taking into account systematic review principles (EFSA, 2010). **Full study reports** should be provided if available.

5) Common format to assist applicants in the preparation of **well-structured applications**, and to assist EFSA in assessing the data.

6) Information on the **identity, production process, compositional data, specifications, proposed uses and use levels and anticipated intake** constitute the minimum requirements. **History of use of the NF and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity:** to be justified if not covered in the application.

GENERAL PRINCIPLE (3) – NOVEL FOODS

7) 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.

8) Analyses/tests should be performed in a **competent facility** certifying 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. Whenever **official guidelines** (e.g. OECD, EMA and ICH) and quality systems (e.g. GLP, GMP, GCP and applicable ISO systems) were followed, the applicant should indicate compliance.

9) Deviations should be justified.

GENERAL PRINCIPLE (4) – NOVEL FOODS

10) The decision on **confidential treatment** of information falls under the responsibility of the **European Commission**. **EFSA** shall take necessary measures to ensure appropriate confidentiality of the information, except for information which is required to be made public in order to protect human health.

11) The decision on granting the **protection of proprietary** data falls under the responsibility of the **European Commission**. Where evidence for the safety of a novel food includes a request for the protection of proprietary data, the **EFSA NDA Panel** considers in its opinion whether the safety of the novel food could have been assessed without the data claimed as proprietary.

12) In accordance with Directive 2010/63/EU and reiterated in Regulation (EU) 2015/2283, **tests on animals** should be replaced, reduced or refined, duplications avoided, where possible.

PUBLIC CONSULTATION

- *Make clear the **minimal information that must be submitted**. Flexibility is needed.*
- *It was recommended to involve the experts working on the EFSA compendium in the evaluation of **botanicals**.*
- *Toxicity studies are too expensive for **small and medium enterprises.***

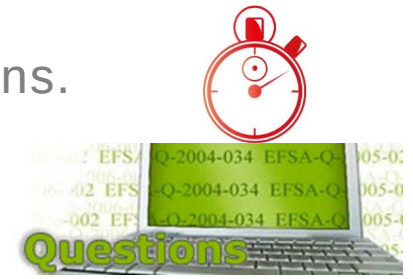
The Panel agreed with this comment and referred to General Principle 6 *(minimum requirements)* and 9 *(deviations).*

EFSA Botanical experts were consulted during the public consultation. Their comments are reflected in changes in several sections of the guidance.

The same scientific principles for the safety assessment of novel foods apply, irrespective of the size of applying companies.

RECURRENT ISSUES IN PAST APPLICATIONS

- **Other EFSA Guidance** not considered (e.g. Guidance on genotoxicity, default values, use of EFSA Food consumption database....).
- No information on **identification of data, search strategy**.
- **Incomplete dossier**, missing study reports, pertinent data available in the literature not indentified (and not provided), particularly data not in favour or uncertainties not considered, discussed and addressed.
- **Lacking information** or studies **without scientific justification**.
- Specific requests - see following presentations.



Thank you for your attention !