Draft
EFSA Guidance for Traditional Foods from Third Countries

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BACKGROUND & TERMS OF REFERENCE

Regulation (EU) 2015/2283, EFSA shall consider:

- whether the **history of safe food use** in a third country is substantiated
- whether the composition of the food and the conditions of its use do **not pose a safety risk** to human health in the Union;
- where the Traditional Food from the third country 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.

Commission asked EFSA to provide scientific and technical guidance for the preparation and presentation of applications for authorisation of **Novel Foods**, and for notifications and applications for authorisation of **Traditional Foods (TF) from third countries**.

GUIDANCE FOR TRADITIONAL FOODS

OBJECTIVES

- Guidance to assist applicants with a common format in the preparation of a well-structured notification dossier on the **history of safe food use** in a third country and **conditions of use** of a TF.
- To support applicants in providing the **type and quality of information** needed for such notifications.

SCOPE

- For Art. 14 notifications and for Art. 16 applications for the authorisation of TF under the new Regulation (EU) 2015/2283.

For responding to duly reasoned safety objections (Art. 16) concerning data other than on the history of safe food use & the proposed conditions of use > **Guidance on the preparation and presentation of applications for authorisation of a novel food.**

GENERAL PRINCIPLES (1)

- This document should be read in conjunction with **Regulation (EU) 2015/2283 on Novel Foods**, other EU guidelines and Regulations, with other **relevant EFSA Guidance** documents from EFSA.
- **Stand-alone dossier: all of the available data** (**data in favour** and **not in favour**) that are pertinent to the safety of the TF should be provided. If available, **full study reports** should be provided.
- Information on the **description, production process, compositional data, specifications, data from experience of use** and **proposed conditions** of use in the EU market.
- The **methods used to identify relevant data**, including databases used and criteria of literature searches, should be reported. The published literature should be reviewed following systematic review principles.

GENERAL PRINCIPLES (2)

- The **applicant should provide its considerations** at the end of individual sections on how the information supports the safety of the TF under the proposed conditions of use. **Uncertainties should be addressed**, and a **critical appraisal** on the provided data should be provided.
- **Deviations** should be justified.
- Analyses/tests should be performed in a **competent facility that can certify the data**. Information on the **accreditation** of involved facilities and certificates of analyses should be provided. Indication whether quality system is in place and whether national and/or international guidelines.

DATA REQUIREMENTS - OVERVIEW

1. **Description of the Traditional Food**
2. **Production process**
3. **Compositional data**
4. **Specifications**

„History of safe food use“

5. **Data from experience of continued use for a least 25 years**

6. **Proposed conditions of use for the EU market**
   - 6.1. Target population
   - 6.2. Proposed uses and use levels
   - 6.3. Intended role in the diet
   - 6.4. Precautions and restrictions of use

Concluding remarks

SCIENTIFIC DATA - COMPOSITIONAL DATA (1)

1. Description of the Traditional Food

Foods consisting of, isolated from or produced from

1.1 microorganisms, fungi or algae

1.2 plants or their parts

1.3 animals or their parts

1.4 cell or tissue culture derived from animals, plants, fungi or algae

2. Production process

Detailed description: growth-, breeding-, farming-, harvesting-, storage- and transport conditions; focus on potential by-products, impurities or chemical and microbiological contaminants that could raise safety concerns.

SCIENTIFIC DATA - COMPOSITIONAL DATA (2)

3. Compositional data

- Qualitative and quantitative data on the composition, validated analytical methods, certificates of analyses
- At least five representative, independently produced batches.
- Proximates analyses (i.e. ash, moisture, protein, fat, carbohydrate).
- Information on components which characterise the nature of the TF.
- Qualitative and quantitative data on nutritionally or safety relevant inherent constituents; impurities, by-products, contaminants.

4. Specifications

Key parameters with limits; info on employed analytical methods

SCIENTIFIC DATA - EXPERIENCE OF CONTINUED USE

5. Data from experience of use

5.1. Experience of food use in a third country

- Extent of use
- Characteristics of the population group(s) of consumers
- Role of the Traditional Food in the diet
- Precautions for the preparation and restrictions of use
- Human data (if available)

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Type of data: include scientific publications, scientific expert opinions, monographs, information from international or national organisations, governmental documentation, figures on cultivation, harvesting, sales, trade, cookbooks, recipes, anecdotal data.

5.2. Other information (from non-food uses)

SCIENTIFIC DATA - PROPOSED CONDITIONS

6. Proposed conditions of use for the EU market

- Target population
- Proposed uses and use levels
- Intended role in the diet
- Precautions and restrictions of use

Concluding remarks

ARTICLE 16 - APPLICATIONS

Documented data in response to

"duly reasoned safety objections"

raised on Art 14 notifications

- Guidance for notifications fully applicable also for Art 16 applications regarding compositional data, data on the experience of use and proposed conditions of use.
- Regarding *other* type of data (e.g. ADME, data, toxicological data) guidance for novel food applications provides support.

EFSA's ACTIVITY ON NOVEL/TRADITIONAL FOODS

- DRAFT Guidance documents for Novel Foods and Traditional Foods (by September 2016)
- Public consultation: 18 February - 21 April 2016
- Stakeholder meeting, 11 April Brussels
- EFSA-webinar: web-based live question-and-answer session (Q4/2016)
- Info session (H1/2017)

Thank you for your attention !