



Draft **EFSA Guidance for** **Traditional Foods from Third** **Countries**

Prof. Karl-Heinz Engel
Technische Universität München
Member of the CEF Panel and
EFSA's WG on Novel Foods

REGULATION (EU) 2015/2283

Article 3, paragraph 2

- **‘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, prior to a notification referred to in Article 14.
- **‘TRADITIONAL FOOD FROM A THIRD COUNTRY’** means novel food as defined in point (a) of this paragraph, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from **primary production** as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country.

(Recital 16: ‘... processed or unprocessed foods.’)

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.

GENERAL PRINCIPLES

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- 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

- 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 have been followed.



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

COMPOSITIONAL DATA

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.



COMPOSITIONAL DATA

3. Compositional data

- Qualitative and quantitative data on the composition, validated analytical methods, certificates of analyses
- Preferably 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



EXPERIENCE OF 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)

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)

EXPERIENCE OF USE

5. Data from experience of use

5.1. Experience of food use in a third country

5.1.1 Extent of use

Length and continuity of its use, quantity of consumption, information on the serving size(s) and average, high and maximum daily intake levels per person, available intake estimates, geographical areas.

5.1.2 Characteristics of the population group(s) of consumers

General population or limited consumption by a specific sub-populations (age, sex, ethnic background, physiological and/or disease conditions...). Information on the size of the population (groups).

5.1.3 Role of the Traditional Food in the diet

Consumption pattern and frequency, context of the consumption (e.g. for specific purposes, ceremonies, combined consumption with other foods), type of dish or meal for which the food is used.



EXPERIENCE OF USE

5.1.4 Precautions for the preparation and restrictions of use

Handling, storage, preparation of the food prior to its consumption, e.g. breakup or milling, peeling, removing or making use of only specific parts of the food, any kind of heat treatment, or any other type of treatment.

Information on precautions to be taken during the preparation to reduce levels of toxic, allergenic or anti-nutritional substances or to improve digestibility, information on reported limitations and restrictions for sensitive/specific population groups

5.1.5 Human data

Comprehensive literature search for human data (e.g. toxicological, nutritional and microbiological data, or data on allergenicity).

5.2. Other information (from non-food uses)

If available, other data (e.g. cosmetic, medical, feed, toxicological.)

PROPOSED CONDITIONS OF USE

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 or other EFSA Guidance documents may provide assistance depending on the nature of the raised safety objections.

NOVEL FOOD APPLICATIONS FROM THE PAST

Assessed under Regulation (EU) 258/1997. Dossiers were limited to the “history of use” (which includes compositional data).

- **Baobab dried fruit:** favourable UK Opinion, Member States agreed
- **Chia Seeds:** insufficient data in 2005, favourable EFSA Opinion in 2009
- ***Arracacia xanthorrhiza*:** insufficient data on description, composition and production process; no response from applicant.



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for your
attention !

