



Guidance on Novel Foods

# Experience of Use of a Traditional Food in a Third Country & Safe Conditions of Use in the EU

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# TRADITIONAL FOODS FROM THIRD COUNTRIES

## ‘HISTORY OF SAFE FOOD USE IN A THIRD COUNTRY’

means that the safety of the food 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. *Regulation (EU) 2015/2283 – Article 3*



Interpretation of  
Regulation  
Rationale behind  
Validation  
Labelling  
Authorisation  
Impose surveillance

### SAFETY:

Notification: history of use  
Application: additional info

### NUTRITION:

Should not be  
disadvantageous

# TRADITIONAL FOOD FROM A THIRD COUNTRY

## Traditional food can be

- ✓ Produced from plants/animals/microorganisms
- ✓ From primary production
- ✓ *Processed (!) or unprocessed*



## Traditional food cannot be

- x new molecules; from a new process, synthetic substances, from engineered nanomaterial; from mineral origin; already authorised vitamins; minerals for which a new process has been applied or contains engineered nanomaterials; food used only in food supplements

# 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 Traditional Food.
- 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 Traditional Foods under the new Regulation (EU) 2015/2283.

*\*documented data relating to the duly reasoned safety objections to “duly reasoned safety objections” raised by one or more EU Member States and/or EFSA.*

# EFSA GUIDANCE - TRADITIONAL FOODS

## Guidance for Traditional Foods from Third Countries

is applicable for both:

Article 14 - NOTIFICATIONS

Article 16 - APPLICATIONS

concerning identity, composition, production process, specification, experience of use, proposed conditions of use for the EU.

For Article 16 APPLICATIONS, if the duly reasoned safety objections (received on Art. 14 notifications) and/or the documented data in response to these objections concern other data >

**Guidance on the preparation and presentation of an application for authorisation of a Novel Food**

# GENERAL PRINCIPLES (1)

1. This document should be read in conjunction with **Regulation (EU) 2015/2283 on NF**, and with current and future EU guidelines and provisions, as well as with **relevant up-to-date EFSA Guidance documents**.
2. **Stand-alone dossier** refers to both, “notification” (Art. 14) and Art. 16 applications.
3. **All of the available data** (**data in favour** and **not in favour**) that are pertinent to the safety of the TF should be provided (comprehensive, complete); **full study reports**.
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.

## GENERAL PRINCIPLES (2)

5. Common format to assist applicants in the preparation of **well-structured applications**, and to assist EFSA in assessing the data and delivering its scientific opinion.
6. Reliable data on its **composition**, its **experience of continued use**. In addition, its normal consumption should not be nutritionally disadvantageous. According to the Regulation, also the **specifications** of the traditional food and **conditions of use** must be provided.
7. 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.

## GENERAL PRINCIPLES (3)

8. 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.
9. **Deviations** should be justified.
10. The decision on **confidential treatment** of information submitted under Article 23 of Regulation 2283/2015 falls under the responsibility of the European Commission. EFSA shall take necessary measures to ensure appropriate confidentiality, except for information which is required to be made public in order to protect human health.



# DATA REQUIREMENTS - OVERVIEW

- 2.1 Introduction
- 2.2 Identity
- 2.3 Production process
- 2.4 Compositional data
- 2.5 Specifications



**'HISTORY  
OF SAFE  
FOOD USE'**

## 2.6 Data from experience of continued use

### 2.6.1. Experience of continued food use in the third country

2.6.1.1 Extent of use

2.6.1.2 Characteristics of the population group(s)

2.6.1.3 Role in the diet

2.6.1.4 Information on the handling and preparation

2.6.1.5 Precautions for the preparation and restrictions of use

2.6.1.6 Human data

### 2.6.2. Other information (from non-food uses)

# TRADITIONAL FOODS – TYPE OF DATA

*include:*

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



**25 years  
(1992)**

## EXPERIENCE OF USE (1)

### 2.6.1. Experience of continued food use in a third country

#### 2.6.1.1 Extent of use

- Place of production and volume produced per year,
- the geographical areas (e.g. region, country) where it has been consumed;
- the quantity of consumption, serving size(s), average, high and if available maximum intake levels per person; if available, intake estimates based on food consumption surveys or other estimates should be provided;
- clear distinction should be made between the intakes of a part of a botanical as such, preparations made of it (e.g. tea), or, for example, an intake of essential oil;
- the length and continuity of its use over time.

## EXPERIENCE OF USE (2)

### 2.6.1.2 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).

### 2.6.1.3 Role 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 (3)

### 2.6.1.4 Information on handling and preparation

Documentation concerning handling, including storage, and 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 (cooking method), or any other type of treatment.



## EXPERIENCE OF USE (4)

### 2.6.1.5 Precautions for preparation and restrictions of use

- Information on any prohibition or restrictions imposed in respect of the food in the third countries
- Precautions to be taken during its preparation, any kind of treatment or methods to reduce levels of toxic, allergenic or antinutritional substances or to improve digestibility
- Information on reported limitations and restrictions for sensitive/specific population groups.



## EXPERIENCE OF USE (5)

### 2.6.1.6 Human data

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

### 2.6.2. Other information (from non-food uses)

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

## 2.7 PROPOSED CONDITIONS OF USE FOR THE EU MARKET

2.7.1 Target population

2.7.2 Proposed uses and use levels

2.7.3 Intended role in the diet

2.7.4 Precautions and restrictions of use



**Concluding remarks**



