



# **Better Training for Safer Food** *Initiative*

**Conference on the EU Novel Food Regulation  
and the Case of Insects**

# **BTSF**

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**The dossier for the notification/application for  
authorisation of novel foods in the context of  
Regulation (EU) 2015/2283**

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## **AUTHORISATION PROCEDURES FOR A NOVEL FOOD (REGULATION (EU) 2015/2283)**

**Art. 10: application for the authorisation of a novel food**

**Art. 14: Notification of a traditional food from a third country**

**Art. 16: Application for the authorisation of a traditional food from a third country**

## SCIENTIFIC OPINION

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# **Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283**

## SCIENTIFIC OPINION

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# **Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283**

## The guidance on “traditional foods” applies to both:

- **Notification dossier pursuant to Article 14**
- **Applications concerning the data on the history of safe use in a third country pursuant to Article 16 of Regulation (EU) 2015/2283.**

## Art. 14 : Notification of a traditional food from a third country

Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to **submit a notification of that intention** to the Commission.

**The notification shall include the following information:**

- ❖ the name and address of the applicant;
- ❖ the name and description of the traditional food;
- ❖ the detailed composition of the traditional food;
- ❖ the country or countries of origin of the traditional food;
- ❖ documented data demonstrating the history of safe food use in a third country;
- ❖ a proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

## Article 16 : Application for the authorisation of a traditional food from a third country

Where the Commission, acting in accordance with Article 15(5), does not authorise the placing on the market within the Union of a traditional food from a third country or update the Union list, the applicant may submit an application including, in addition to the information already provided in accordance with Article 14, **documented data relating to the duly reasoned safety objections** submitted in accordance with Article 15(2). The Commission shall, without delay, forward the valid application to the Authority and make it available to Member States.

## Safety assessment of novel foods by EFSA

The following aspects shall be considered:

- ❖ whether the history of safe food use in a third country is substantiated by reliable data submitted 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;
- ❖ 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.



## 'History of safe food use in a third country'

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

## Detailed description of the production process

- ❖ the breeding, rearing, feeding and farming conditions for farmed animals or the hunting, catching or collecting and killing of wild living animals;
- ❖ the process by which the raw material is converted into an ingredient or a preparation intended for a food product.
- ❖ Measures implemented for production control and quality and safety assurance should be described (e.g. HACCP). A production flow chart should be provided

## Compositional data

- ❖ Information on the identities and the quantities of impurities or by-products, residues and chemical and microbiological contaminants should be provided (e.g. heavy metals, mycotoxins, PCBs/dioxins, pesticides).
- ❖ For whole foods, this should include proximate analyses (i.e. ash, moisture, protein, fat, carbohydrates).
- ❖ qualitative and quantitative data on inherent substances of possible concern to human health (e.g. toxic, addictive, psychotropic, allergenic) should be provided.

## Stability

- ❖ parameters of the traditional food which may be susceptible to changes during storage and which may directly affect its safety or serve as indicators for alterations which could have an impact on the safety of the food
- ❖ microbiological stability of the traditional food under normal conditions of storage, including the effects of packaging, the storage temperature and the environment (light, oxygen, moisture, relative humidity)

## Specifications

The specifications define the key parameters which characterise and substantiate the identity of the traditional food, as well as limits for these parameters:

- Microbiological criteria (Food Safety/Food Hygiene Criteria)
- Limits for contaminants (heavy metals, pesticides, mycotoxins,...)
- Nutrients content

**The methods to be used should be specified**

## Experience of continued food use in the third country

- ❖ Extent of use
- ❖ Characteristics of the population group(s) of consumers
- ❖ Role in the diet
- ❖ Information on the handling and preparation of the food
- ❖ Precautions for the preparation and restrictions of use
- ❖ Human data

## Proposed conditions of use for the EU market

- Target population
- Proposed uses and use levels
  - **whole food, ingredient**
- Intended role in the diet
  - **replace another food?**
- Precautions and restrictions of use
  - **allergens**

# Provisions specific for novel foods applications

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- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism and excretion (ADME)
  - **nutritional and toxicological impact**
- Nutritional information
  - **demonstrate that the novel food is not nutritionally disadvantageous**
- Toxicological information\*
  - **genotoxicity, subchronic toxicity, chronic toxicity and carcinogenicity, reproductive and developmental toxicity, human data**
- Allergenicity

## \*Specific cases

# Insects

The EFSA Scientific Committee has identified potential hazards related to the use of farmed insects as food. These should be considered in applications for novel foods which consist of, are isolated from, or are produced from farmed insects, taking into account the species and substrate to be used, as well as methods for farming and processing. Insects collected from the wild may bear additional biological and chemical hazards which should be considered and addressed.



The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.



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