



EFSA 's role, experiences with the evaluation of the applications for authorisation of **Novel Food** or notification of **Traditional Food** from the third country

Emanuela Turla
Scientific Officer
Nutrition Unit - EFSA

International Conference on Novel Foods

Prague, 20 June 2018

OUTLINE

EFSA

What is a Novel Food (NF) and Traditional Food from a Third Country (TF)?

Role of EFSA in the evaluation of NF and TF



HEADQUARTERS
in the **heart of Parma**

EFSA IS



The reference body for **risk assessment** of **food and feed** in the European Union.

Its work covers the entire food chain **from field to fork**.

A BRIEF HISTORY

EFSA was established under **EU law in 2002** following a series of food crises in order to:

- ❖ **improve** the EU food safety system
- ❖ **help ensure** a high level of consumer protection
- ❖ **restore and maintain** confidence in the EU food supply
- ❖ **clearly separate** risk assessment and risk management functions

WHAT EFSA DOES



Provides independent scientific advice and support for EU risk managers and policy makers on food and feed safety

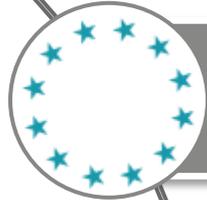


Provides independent, timely risk communication

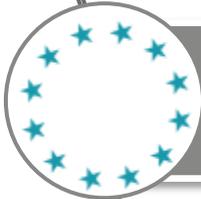


Promotes scientific cooperation

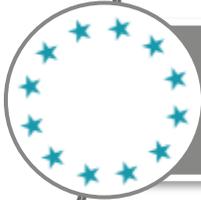
WHAT EFSA DOES **NOT** DO



Develop food safety policies and legislation



Adopt regulations

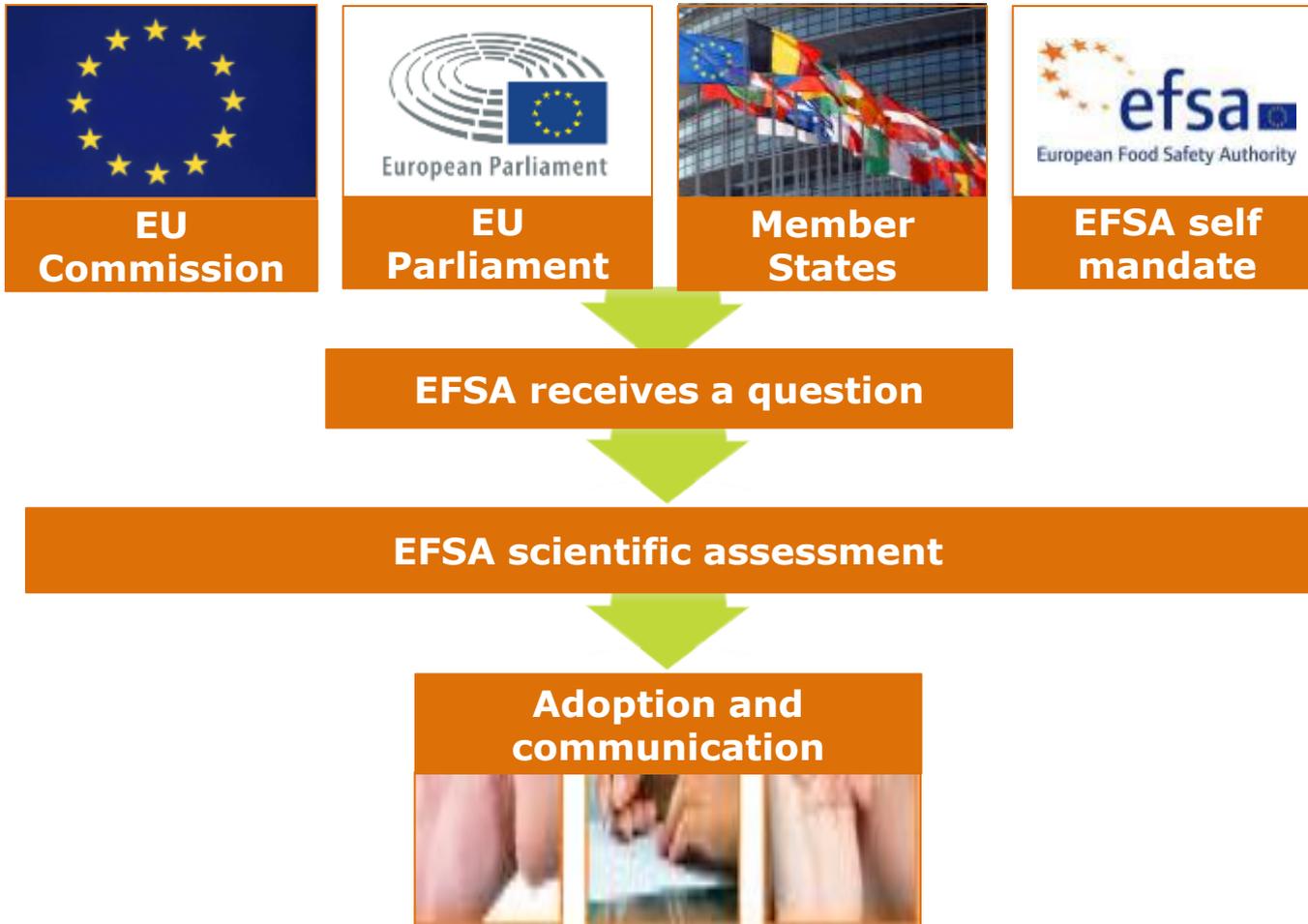


Authorise Novel Foods or health claims

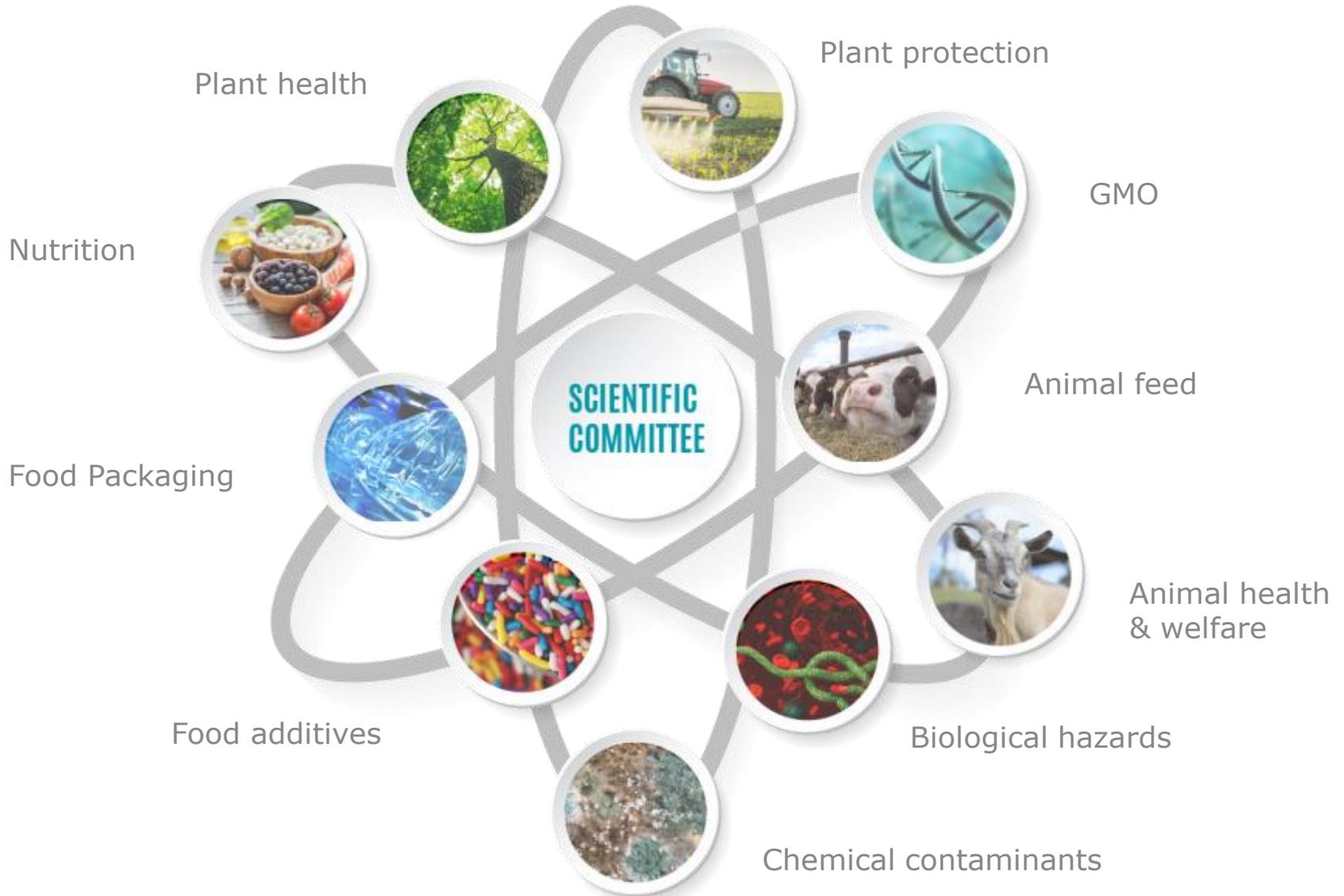


Enforce food safety legislation

QUESTIONS AND ANSWERS



THE SCIENTIFIC PANELS



WHO PRODUCES ASSESSMENT ON NUTRITION RELATED ISSUES?



Supported by EFSA Unit on Nutrition

OUTLINE

EFSA

What is a Novel Food (NF) and Traditional Food from a Third Country (TF)?

Role of EFSA in the evaluation of NF and TF

DEFINITION of NF

Regulation (EU) 2015/2283

A food that was not consumed to a significant degree by humans in the EU prior to 15/05/1997



Scope of the Regulation

It does not apply to

- ❖ **genetically modified foods** - Regulation (EC) 1829/2003;
- ❖ **foods when and in so far as they are used as:**
 - ✓ **food enzymes** - Regulation (EC) 1332/2008;
 - ✓ **food additives** - Regulation (EC) 1333/2008;
 - ✓ **food flavourings** - Regulation (EC) 1334/2008;
 - ✓ **extraction solvents** - Directive 2009/32/EC

Scope of the Regulation

It does apply to Novel Foods

- ❖ a food that was not consumed to a significant degree by humans in the EU prior to 15/05/1997

AND

- ❖ falls under at least one of the categories listed in Art. 3

DEFINITION of NF

Categories listed in Art. 3

- ❖ food with a new/intentionally **modified molecular structure**
- ❖ from **microorganisms/fungi or algae**
- ❖ from material of **mineral origin**
- ❖ from **plants or their parts**/from **animals**/ from **cell culture or tissue culture**
- ❖ from a **new production process**
- ❖ consisting of **engineered nanomaterials**
- ❖ **vitamins, minerals and other substances** from a new production process or consisting of engineered nanomaterials
- ❖ **new uses for foods** used exclusively in food supplements (<1997)

DEFINITION of TRADITIONAL FOOD (TF)

WHAT IS A 'TRADITIONAL FOOD'?

- ❖ **a food not consumed to a significant degree by humans in the EU prior to 15/05/997**
- ❖ **from microorganisms/fungi/algae/plants/animals/cell or tissue cultures**
- ❖ **from primary production**
- ❖ **processed or unprocessed**
- ❖ **'history of safe food use in a third country'**

DEFINITION of TF

'History of safe food use in a third country'

- ❖ confirmed by 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**



OUTLINE

EFSA

What is a Novel Food (NF) and
Traditional Food from Third Countries
(TF)?

**Role of EFSA in the evaluation of
NF and TF**

EFSA'S ROLE in NF

NOT



- ❖ **Legislation**
- ❖ **Regulatory decisions**
 - classifications
 - authorisations
 - conditions of authorisations
 - labelling, post monitoring
 - food inspections
 - sanctions

YES



- ❖ **Safety assessment**
- ❖ **Communication**
- ❖ **Guidelines**
- ❖ **Collaboration**

What is NEW in Regulation 2015/2283?

- ✓ **Applications on NF/Notifications on Traditional Foods (TF)** submitted to the Commission
- ✓ **Assessment by EFSA**
 - ❖ **NF applications: 9 months**
 - ❖ **Notifications on TF:**
EFSA and Member States
4 months for 'duly reasoned safety objections'

ASSESSMENT of TF

Art. 14 Notification on TF

European Commission

EFSA and Member States

4 months for 'duly reasoned safety objections'

Yes objections

No objections

**Art. 16 application to EFSA
(6 months)**

Initial TF
notification

Responses
to safety
objections

Authorisation (if positive assessment)

Authorisation

EC MANDATE FOR EFSA GUIDANCE

EFSA was asked to prepare two guidance documents for:

- ❖ **applications for novel foods**
- ❖ **notifications of traditional foods from third countries**

Do composition and conditions of use **pose a safety risk?**

Nutritionally disadvantageous
for the EU consumer?

Is **history of safe food use** in a third country substantiated?

EFSA GUIDANCE on NF/TF

OBJECTIVES

- ❖ assist applicants with a **common format** in the preparation of a well-structured notification on TF/applications on NF
- ❖ support applicants in providing the **type and quality of information** needed for notifications/applications



 Open Access   Creative Commons

Scientific Opinion

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



 Open Access   Creative Commons

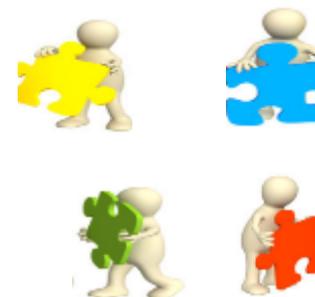
Scientific Opinion

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

<http://www.efsa.europa.eu/en/topics/topic/novel-food>

EFSA GUIDANCE on NF

- 1 Administrative data
- 2.1 Introduction
- 2.2 Identity of the NF
- 2.3 Production process
- 2.4 Compositional data
- 2.5 Specifications
- 2.6 History of use of the novel food and of its source
- 2.7 Proposed uses and use levels and anticipated intake
- 2.8 Absorption, distribution, metabolism, and excretion
- 2.9 Nutritional information
- 2.10 Toxicological information
- 2.11 Allergenicity
- 2.12 Concluding remarks
- 3 Annexes, References



INTRODUCTION and IDENTITY

Introduction

Brief description of the NF (the source, production process, compositional, intended uses of the NF)

Identity of the NF

Chemical substances (chemical name, CAS number, etc.)

Foods consisting or produced from:

- microorganisms, fungi or algae (e.g. name of the organism, origin)
- plants or their parts (e.g. scientific name, taxonomy part used, geographical origin)
- animals or their parts (e.g. name, zoological family, parts used, geographical origin)
- cell or tissue cultures derived from animals, plants, fungi, algae (e.g. biological source, substrate, type of cultures)

PRODUCTION PROCESS

- Detailed description of the **process to produce** the NF (e.g. chemical synthesis, fermentation, isolation from natural sources), including information on substances used (e.g. extraction solvents)
- **Flow-chart** of the production process
- Potential by-products, impurities, contaminants
- **Handling of sources**
 - plants: cultivation practice, time of harvest, etc.
 - animals: breeding, farming, hunting conditions, etc.
 - microorganisms: culture conditions, etc.
- Measures implemented for **production control** and **quality and safety assurance** should be described (e.g. HACCP, GMP, ISO).

COMPOSITIONAL DATA and SPECIFICATIONS

Compositional data

- qualitative and quantitative data on composition, physico-chemical, biochemical and microbiological properties
- impurities, nutrients and antinutrients, substances of possible concern
- use of validated methods (preferably nationally or internationally-recognised methods)
- certificates of analyses, information on accreditation

Specifications

- Proposed by the applicant
- key parameters for characterisation/identity of the NF
- set limit regarding minimal purity
- limits for substance of concerns/contaminants
- a table: key parameters, limits and methods used

PROPOSED USES, USE LEVELS, ANTICIPATED INTAKE

- Target population
- Proposed uses and use levels
- Anticipated intake of the NF
- Combined intake from the NF and other sources
- Estimate of exposure to undesirable substances
- Precautions and restrictions of use



ADME and NUTRITIONAL INFORMATION

Absorption, distribution, metabolism and excretion (ADME)

- Critical for the development of appropriate toxicity testing (e.g. *Negligible absorption*: may justify not undertaking higher tiered toxicological studies; the same principles as applied to food additives are used for NF)

Nutritional information

- Should not be nutritionally disadvantageous
 - Novel food is intended to **replace another food**
 - Novel production process** is applied
- Nutrients, anti-nutrients, interaction with nutrients

TOXICOLOGY and ALLERGENICITY

Toxicological information

➤ **Tiered toxicity testing approach** as the default approach

- ✓ genotoxicity
- ✓ repeated dose toxicity testing
- ✓ reproductive and developmental toxicity



➤ **Additional studies** may be needed (e.g. immunotoxicity, neurotoxicity, endocrine activity, mechanisms and modes of action)

Allergenicity

➤ **Protein content**

No protein → very low allergenic potential

Contains proteins → have allergenic potential (default assumption). Further testing is needed

Data requirements

- 2.1. Introduction**
 - 2.2. Identity of the TF**
 - 2.3. Production process**
 - 2.4. Compositional data**
 - 2.5. Specifications**
 - 2.6. Data from experience of continued use for at least 25 years**
- 'History of safe food use'**
- 2.7. Proposed conditions of use of the TF for the EU market**

EFSA GUIDANCE ON TF

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



2.6 Data from experience of continued use

2.6.1. Experience of continued food use in the third country

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

2.6.2. Other information (from non-food uses)

EXPERIENCE of CONTINUED USE

TYPE OF DATA

- ❖ 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

EXPERIENCE of USE

Experience of continued food use in a third country

❖ Extent of use

- place of production and volume produced per year
- geographical areas (e.g. region, country) where the TF has been consumed
- quantity of consumption, serving size, 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

❖ **Characteristics of the population group(s) of consumers**

General population or limited consumption by a specific sub-populations.

❖ **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 was used



EXPERIENCE of USE

❖ 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

- ❖ **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

❖ **Human data**

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

❖ **Other information (from non-food uses)**

If available, other data (e.g. cosmetic, medical, feed) and animal studies (e.g. toxicity studies)

PROPOSED CONDITIONS of USE of the TF in the EU

❖ Target population

❖ Proposed uses and use level

- form of uses (e.g. as whole food, ingredient)
- food categories in which the TF is proposed to be used
- whether the TF is intended to replace another food
- proposed maximum use level(s) in final product(s)
- proposed daily intakes for different age/gender groups as appropriate

❖ Intended role in the diet

- Where the TF is intended to replace another food

❖ Precautions and restrictions of use

UNION LIST of NOVEL FOODS

- ❖ List of all Novel Foods/Traditional Foods authorised in the EU
- ❖ It includes **conditions of use, labelling requirements and specifications**
- ❖ **'Generic list'** unless data protection is requested by the applicants (applicable only to NF and **NOT** to TF)
- ❖ Available in the EC web-site:
https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en

