

# REVISION OF THE GUIDANCE ON TRADITIONAL FOODS

OUTCOME OF THE PUBLIC  
CONSULTATION

Emanuela Turla  
Senior Scientific Officer

# OVERVIEW

- ❖ 48 comments received
- ❖ 7 interested parties: 4 food industry associations/organisations, 2 national authoritative bodies, and 1 person in her/his personal capacity

Interested party	Country
Atova Regulatory Consulting SL	Spain
Food Supplements Europe	Belgium
German Federal Institute for Risk Assessment (BfR)	Germany
Ministry of Regional Affairs and Agriculture	Estonia
Nutraveris - A FoodchainID company	France
Pen & Tec Consulting S.L.U. (trading as Argenta®)	Spain
Submission on personal capacity	Belgium

- ❖ Comments were discussed with the Working Group on Traditional Foods (TF) on 28 May 2024
- ❖ Replies to comments are provided in Annex E to the guidance on TF
- ❖ Guidance on TF has been amended in the light of comments received, when appropriate



# OVERVIEW

## Guidance on TF

- ❖ TF are Novel Foods (NF), restricted to some categories (e.g. derived or consisting of microorganisms, plants, animals, cell culture) and from primary production
- ❖ **'History of safe food use in a third country'** => compositional data and experience of continued use for at least 25 years in the diet in at least one third country
- ❖ **Many requirements are in common with NF** => many sections in the Guidance on TF are taken from the Guidance on NF (identity, production process, compositional data, specifications, intended uses)



# OVERVIEW

## Type of comments received

❖ Editorial comments: 13

❖ **Comments overlapping with Novel Foods:** 21

Reply to these comments:  
reference to the guidance  
on novel foods

**Identity:** methods to verify identity of botanicals and animals; non-GMO statement

**Production process:** description of feed, HACCP plan

**Compositional data:** accreditations of laboratories; principles for sampling protocols; list of impurities and by-products to be analysed; unidentified components in complex mixtures; number of batches of TF when investigating impact of processing; conditions in which no need to perform a nano-specific risk assessment

**Specifications:** reference to EU regulatory limits; add fibre in the proximate analysis

**Conditions of use in EU:** target population

❖ **Comments specific for Traditional Foods:** 14



# COMMENTS ON TRADITIONAL FOODS

## GENERAL PRINCIPLES

- ❖ **“Enforcement date” of the guidance on TF** (comment 4)
  - Enforcement will be indicated in the EFSA guidance.
- ❖ **Since TF derives from primary production, requirements can be reduced** (comments 4, 8)
  - Depending on the origin of the TF (microorganism, plants, animals), applicants should provide the relevant information pertaining to it. Deviations can be justified.
- ❖ **New approach methodology (NAM) needs more explanation and proper applicability recommendations** (comment 5)
  - Reference to NAM has been deleted as the assessment of TF rely on compositional data and history of safe food use in a third countries and not on toxicological studies.



# COMMENTS ON TRADITIONAL FOODS

## IDENTITY

- ❖ **Microorganism category: waiver for whole genome sequence (WGS) for TF** (comment 11)
  - Comment declined as WGS is the most reliable way to unequivocally identify a microorganism.

## PRODUCTION PROCESS

- ❖ **Waiver for HACCP plan** (comments 19, 21)
  - Comments declined as HACCP plan is a requirement for foods placed on the EU market, covering all sites mentioned in the TF notification.

## COMPOSITIONAL DATA

- ❖ **The applicant should describe and discuss significant differences between compositional data from TF batches and from the literature** (comment 23)
  - Comment accepted. Guidance has been changed.



# COMMENTS ON TRADITIONAL FOODS

## COMPOSITIONAL DATA

- ❖ **Suggestions on the paragraph which refers the 'comparator'; confusion with the term 'comparator' mentioned in the stability section** (comment 24)
  - Comment accepted:  
the paragraph referring to comparator has been revised;  
the term 'comparator', which was incorrectly mentioned in the stability section, has been replaced with 'control'.
- ❖ **Waiver to provide 5 batches of the TF covering the whole spectrum of production parameters applied (as TF are often produced on pilot scale)** (comment 28)
  - Comment declined. Flexibility to deviate from the requirements, as long as a rationale is provided.



# COMMENTS ON TRADITIONAL FOODS

## COMPOSITIONAL DATA

- ❖ **Specify qualitative and quantitative data regarding allergenic substances** (comment 32)
  - No experimental data are required regarding allergenicity of the TF. Data from the literature are sufficient. Section 5.7 'Other information' already indicates that publications on studies which could indicate allergenic potential of the TF should be provided. No need to change the guidance.

## STABILITY DATA

- ❖ **Stability tests should be provided for each form of the TF (e.g. dried, frozen, powder)** (comment 34)
  - Comment accepted. The guidance has been changed.





# COMMENTS ON TRADITIONAL FOODS

## DATA from EXPERIENCE OF CONTINUED USE IN A THIRD COUNTRY

- ❖ **The guidance requests to provide reports on human studies. However, since human studies are mostly retrieved from the literature, study reports are not always available** (comment 40)
  - Comment accepted. The guidance has been amended to indicate that human study reports should be provided if available.
- ❖ **Clarifications on the meaning of 'grey literature' and whether references should be provided in English** (comment 41)
  - The definition of 'grey literature' is reported in the EFSA guidance cited. Documents should be provided in English as indicated in the Administrative guidance on TF.

## PROPOSED CONDITIONS OF USE IN THE EU

- ❖ **If a TF is proposed to be placed in the EU market in different forms (e.g. dried, frozen, powder), applicants should indicate the maximum use levels of the TF in each of the proposed form** (comment 44)
  - Comment accepted



