



Guidance on Novel Foods

# History of consumption and dietary intake from other sources

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# OUTLINE

- **Guidance:** History of use
  - of the SOURCE and of the NOVEL FOOD
- **Dietary background intake**
- **Comments received from public consultation**
- **Requests for additional information**

## 2.6. HISTORY OF USE OF THE NF AND ITS SOURCE

### 2.6.1 History of use of the **SOURCE**



### 2.6.2 History of use of the **NOVEL FOOD**



## 2.6.1 HISTORY OF THE SOURCE

**Relevant aspects** for further consideration may come from available information on the **source**, related to its:

- composition
- production
- experience from use of products from the source (other than the NF itself),

...regarding critical substances, potential hazards or precautions.

With respect to foods derived from plants, relevant information may be found in EFSA's Compendium on botanicals (EFSA Scientific Committee, 2012).


## 2.6.1 HISTORY OF THE SOURCE: **SARDINE PEPTIDES**

- A peptide mixture obtained by an alkaline protease-catalysed hydrolysis of the muscle of sardine (*Sardinops sagax*).
- Sardines have been consumed to a significant degree in Europe. Sardine peptide isolates have not been used as a food ingredient in Europe (and outside).
- Source, composition and production process of the NF of no concern.
- Low intake estimates: Highest 97.5<sup>th</sup> percentile intake: 2.4 g/day (male teenager).

**No 90 d study, but human data from literature, mainly focusing on blood pressure, were assessed.**



## 2.6.1 HISTORY OF THE SOURCE: **RAPSEED PROTEIN ISOLATE**

- Products (oil, spreads) derived from its source (rapeseed) with a significant history of consumption. The source of the NF is well characterised; much information in the literature.
- Rapeseed protein itself has no history of consumption. 
- Available literature provides important information on undesirable substances (such as erucic acid, glucosinolates and phytates) contained in rapeseed, and on health outcomes in humans.
- Specification limits (glucosinolates, phytates) and information on the source (erucic acid  $\leq 2$  % by mass in the oil) provide assurance regarding these substances.
- Two 90 d studies published with comparable products.

**Safety was established without 90 d study with the NF.**

## 2.6.1 HISTORY OF THE SOURCE: 'YEAST *BETA*-GLUCANS'

- Products (bread, wine, beer and other) produced with its source (bakers' yeast), and thus also containing yeast *beta*-glucans, have a significant, long history of use.
- The source of the NF is well characterised, with much information in the literature. QPS (Qualified Presumed Safety) status assigned by EFSA.
- Biologically the yeast *beta*-glucans are expected to be comparable with cereal *beta*-glucans (undigestible by human enzymes, but fermented by colon microbiota).
- Intake assessment: intakes comparable with background dietary intake levels.



**Safety was established despite a 90 d study providing a Margin of Exposure of 1 (NOAEL = the highest dose).**

## 2.6.1 HISTORY OF THE SOURCE: "BOTANICALS" (1)

### The EFSA Compendium of Botanicals:

<https://www.efsa.europa.eu/en/data/compendium-botanicals>

- Database of botanicals that are reported to contain naturally occurring substances of possible concern.
- Not intended to conclude on the safety but to support the safety assessment of botanicals and botanical preparations including supplements by facilitating hazard identification.
- Presence of a substance of concern in a botanical does not necessarily mean that the substance will also be present in a botanical preparation and, if so, at a dosage that could cause a health concern, which depends also on the plant part used, the preparation method and the conditions of use.
- It does not list all bioactive substances present in a given botanical or all potential health effects.





## 2.6.1 HISTORY OF THE SOURCE: "BOTANICALS" (2)

- If a specific species shows an adverse health effect, other closely related species in terms of botanical taxonomy and chemical composition profile should also be considered ("read-across") – EFSA Opinion on a qualified presumption of safety (QPS) approach for the safety assessment of botanicals (2014).
- The absence of a botanical species from the compendium does not mean that it is devoid of hazardous compounds.
- Similarly, if a specific part of a plant is not mentioned, this does not mean that substance(s) of concern are absent from this part.
- The compendium currently does not include algae, cyanobacteria and fungi; they will be considered for possible inclusion in the future.



## WEIGHT OF „HISTORY OF THE SOURCE“

- ✓ Extent of its characterisation
- ✓ Available data on undesirable substances and related health outcomes and/or toxicological data
- ✓ Extent of use for food production (source itself or products)
- ✓ Quantity of the source needed to produce the daily anticipated intake of the NF
- ✓ Degree of processing of the NF



## 2.6.2 HISTORY OF USE OF THE NOVEL FOOD (1)

- Use of the NF as **food in countries outside of the EU** and **non-food uses**.
- Description of the **extent of use** as a food and/or for non-food purposes.
- **The population group** for which the food has been a part of the diet.
- **Its role in the diet**, the **handling and preparation** of the food.
- **Precautions** (processing, handling, preparation, interactions...).



## 2.6.2 HISTORY OF USE OF THE NOVEL FOOD (2)

A comprehensive literature **review of human studies** reporting on relevant safety outcomes should be performed:

- on the NF itself,
- consider also studies with **specific and safety-relevant components** of the NF (e.g. data on resveratrol from Japanese knotweed for synthetic resveratrol),
- and studies with similar foods from the same or other **closely related sources** (e.g. other varieties, related species of the same genus or family).

**More guidance on the history of use is provided in the guidance for Traditional Foods from Third Countries.**

## WEIGHING OF THE HISTORY OF FOOD USE

- **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.
- **Intake data** on historical consumption (relevant target population, analytical issues...).
- **Historical intake versus intended intake**, e.g. plant sterol intake from plant sources only about 10 % of the intended intake → little, if any weight for the assessment.
- **Consideration of possible matrix effects** (historical intake versus intended uses).




# DIETARY INTAKE FROM **OTHER** SOURCES



## Relevance for the safety assessment

- Background dietary intake may be supportive for the safety of the NF on the basis of “history of use” (2.6).
  - Data from literature
  - Data generated by using food consumption data and occurrence data of a concerned substance in food.
- May also require consideration of the total exposure (NF Guidance intake from the NF and from other sources, 2.7.4) to estimate the MoE on findings in animal toxicity studies.

# DIETARY INTAKE FROM **OTHER** SOURCES

Application	Intake from sources other than the NF
<b>Yeast <i>beta</i>-glucans</b>	Bread, other bakery products, wine, beer....
<b>Lycopene</b> (synthetic; tomato oleoresin; from <i>B. trispora</i> )	Tomato products, water melons, other fruits and vegetables
<b>Taxifolin from Dahurian Larch</b>	Apple, onion, many other fruits, and vegetables
<b>Synthetic resveratrol</b>	Grapes, wine and other
<b>Synthetic zeaxanthin</b>	Fruits, vegetables
<b>DHA and EPA-rich algal oil</b>  <b>DHA and EPA-rich krill oil</b> 	Marine fish 
<b>Glucosamine produced with <i>Aspergillus niger</i></b>	Crustacea, grains
<b>Plant sterols</b>	Plants

## DIETARY INTAKE FROM **OTHER** SOURCES

Information should be provided on:

- mean and high daily intakes of the NF from its proposed uses and maximum use levels;
- mean and high daily intakes from natural sources (i.e. from the background diet);
- daily intake from food fortification and supplements;
- daily intake from other uses.

Other potential non-dietary sources (e.g. cosmetics, and from pharmaceuticals) should also be considered and taken into consideration in the total exposure assessment, where relevant.



## PUBLIC CONSULTATION

❖ *Clarification was requested on the type of documentation that can be submitted in support of the history of use of a novel food or its source; flexibility was requested. Information was also requested on the appreciation of data on the history of use of the NF and/or its source.*

The Panel considers that the guidance is sufficiently flexible. The types of documents are not limited to peer-reviewed scientific publications, although it is considered that anecdotal and grey literature are usually of lower relevance. The weighing of the evidence is carried out on a case-by-case basis.



## REQUESTS FOR ADDITIONAL INFORMATION

- Total intake (from the NF and dietary background intake) not considered when discussing the MoE.
- MoE too low when considering the potential intake from all sources.
- Insufficient data to give weight to the claimed “history of safe use”. EFSA requested qualitative and quantitative information on previous use (e.g. marketing authorisation, extent of consumption, kind of products, dosage (including supplements) and an indication of the respective countries), and on reported adverse effects.
- For a NF with has been used as a pharmaceutical in some countries, the summaries of the product characteristics (SPC) of the relevant pharmaceutical (requested for citicoline) was requested.



Thank you  
for your  
attention!

