Draft Guidance Novel Foods

History of Use, Intake Assessment and Restrictions of Use

Wolfgang Gelbmann

Scientific Officer, EFSA Nutrition Unit

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5. History of Use of the NF and its Source

5.1 History of the source

5.2 History of the novel food

5.1 History of the source

Relevant aspects for further considerations may come from available information on the source, from its:

- composition
- production
- experience from use of products 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, 2012a).

5.2 History of USE of the Novel Food

- Data may be available on the use of the NF as **food in countries outside of the EU** and on **non-food uses**.
- Such information could include a 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 their diet, **its role in the diet**, the **handling and preparation** of the food and on **precautions**.
- A comprehensive literature **review of human studies** reporting on relevant safety outcomes should be performed.
- Consider also studies with **specific and typical components** of the NF and studies with similar foods from the same or other **closely related sources** (e.g. other varieties or subspecies or related species of the same genus or family).

6. Proposed Uses and Use levels

.... and anticipate intake of the NF

- Needed to evaluate **its dietary and nutritional significance** and carry out the **risk characterisation**. Intakes are estimated based on the proposed use levels and data on actual food consumption.
- A **rationale** for the target population, proposed uses and use levels, precautions and restrictions of use should be provided with cross-referencing to safety relevant data.
- **Identified potential health hazards** should be discussed and adequately addressed in the proposed conditions of use for the target population.
- Information provided in this section is **precise, complete, and free of any ambiguity**, because the safety of the NF will be assessed at the proposed conditions of use.

6.1 Target Population

- The applicant should specify the intended target population, e.g. adults, the general population or certain defined population sub-groups.

6.2 Proposed USES and USE Levels

- The form of uses (e.g. as whole food, ingredient, food supplement);
- The food categories in which it is proposed to be used;
- Whether the Novel Food is intended to replace another food;
- The proposed maximum amounts in final product(s);
- The proposed average and maximum daily intakes for different age/gender groups as appropriate;

6.3 Anticipated intake of the NF (1)

- For each **target population group** (including, where relevant vulnerable groups such as children, pregnant and lactating women) anticipated intake are requested per kg body weight and in absolute amounts, mean and high (at least 95th percentile).
- The **concurrent consumption of all food categories** in which a NF ingredient is proposed to be used, including food supplements, should be addressed in the estimations, possibly considering different consumption scenarios.
- The highest estimated intake (i.e. at least the 95th percentile) among the population groups from a **representative database** (e.g. EFSA Comprehensive European Food Consumption database or national dietary surveys) is recommended be used as the starting point for the safety evaluation.

6.3 Anticipated intake of the NF (2)

- EFSA **Food Additive Intake Model (FAIM)** tool developed to support the calculation of chronic exposure to food additives.

  Thus, the FAIM tool may be used by applicants for the intake assessment of Novel Foods used as ingredients.

  Allows to estimate the mean and high exposure to food ingredients for different population groups throughout several European countries by means of **pre-defined exposure calculation** worksheets (Excel template).

  For the calculation of high percentiles of intake, the model assumes that an individual might be a high-level consumer of one food category (that provides the highest intake) only and would be an average consumer of all the remaining food groups.

6.3 Anticipated intake of the NF (3)

Summary statistics from the EFSA FAIM tool or the EFSA Comprehensive European Food Consumption Database provide valuable screening estimates.

In cases some cases more refined estimates are needed, based on individual data from national food consumption surveys.

The application should document the methodological aspects of the intake assessment; in particular:

- the sources of data used (sources of food consumption data and food composition data),
- the scientific principles and methods applied,
- the assumptions made and their rationale; in particular with respect to the assignment of a food to a particular food category,
- discussion of uncertainties regarding under- or over-estimations.

6.4 Combined intake from multiple sources

For the estimation of the total intake of the NF, data are requested on the combined intake of the NF from all sources. Combined intake is the sum of:

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

6.5 exposure to undesirable substances

- Exposure estimates are also to be provided for relevant **undesirable substances** identified in the compositional analysis, for example potential secondary plant metabolites, residues, contaminants, or degradation products. These may be present in the NF due to its source or the manufacturing process, as well as due to its use and storage.
- The same approach as that used for the intake estimate of the NF should be followed, in order to describe the anticipated exposure for average and high (typically, 95th percentile) consumers to these constituents for the relevant population groups.

6.6 Precautions and restrictions of uSe

- When proposing precautions (including directions for its preparation and/or use) and restrictions of use, **all available information** on safety should be taken into consideration.

- The applicant should **specify the population** (sub)groups (including population groups with certain physiological conditions) which should avoid consumption of the Novel Food and include the rationale.

Thank you for your attention !