Guidance on Novel Foods

Intake Assessment

Davide Arcella
EFSA Data Unit

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.... 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 relevant safety 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.

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

- **form of uses** (e.g. as whole food, ingredient);

- **food categories** in which the NF (if an ingredient) is proposed to be used;

- whether the NF is **intended to replace another food**;

- proposed **maximum amounts** in final product(s);

- proposed **maximum daily intakes** for different age/gender groups as appropriate;

- 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 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 to be used as the starting point for the safety evaluation.

The **EFSA Comprehensive European food consumption database** contains data:

- 24-hour recall or dietary record method
- data collected at individual level
- most recent data within each country
- random sample at <u>national level</u>
  - different age classes, from infants to elderly
  - special population groups

ST photo:
Mugilan Rajasegeran

MAGNITUDE OF THE CONSUMPTION DATABASE

Number of	
Member States	23
Dietary surveys	51
Population groups	128
Subjects	94,532
Different national food codes	127,912
Different standard food codes	1,578
Consumption records	10,470,332

AGE CLASSES

Age class	Age range (years)	Number of surveys*	Number of countries*
Infants	0 – 1	6	6
Toddlers	1 – 3	11 (10)	10 (9)
Children	3 - 10	20 (18)	17 (15)
Adolescents	10 - 18	20 (17)	17 (14)
Adults	18 - 65	22 (17)	21 (16)
Elderly	65 - 75	16 (14)	15 (13)
Very elderly	> 75	14 (12)	14 (12)
Special population group		2 (2)	2 (2)

* In parenthesis only surveys with more than one day per subject

Summary food consumption statistics (chronic and acute) available for each country, survey, age group (from infants to elderly) and FoodEx food group (over 1,500) in g/day and g/kg bw per day.

Chronic food consumption statistics

Intake	All subjects	Consumers only
grams per day* (g/day)		
grams per day per kilogram of body weight* (g/kg bw per day)		

Acute food consumption statistics

Intake	All days	Consuming days only
grams per day* (g/day)		
grams per day per kilogram of body weight* (g/kg bw per day)		

http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

FoodEx

Food list: ~1,700 end-points
(food names, generic food names)
Hierarchical structure, up to 4 levels,
  not equal branching
  – 20 main food groups
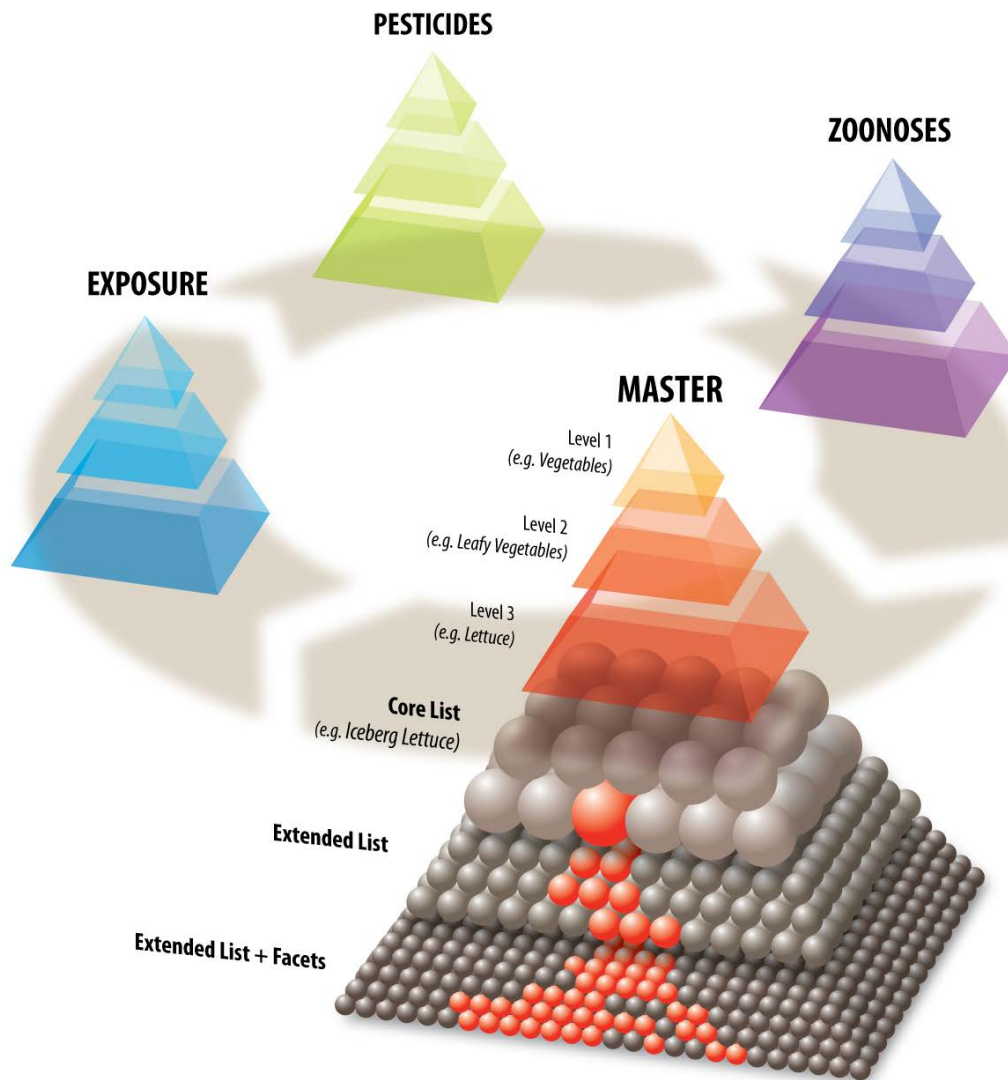 – 2nd level composed by ~160 items
Structured on child-parent relation

DESCRIPTION WITH FACETS

The information we have on a specific food item may be split into a series of structured 'points of view'. Each of them has a choice of standard descriptors from that point of view.

Sugars and similar [A0BY6]
- Sugars (mono- and di-saccharides) [A032G]
  - Sucrose (common sugar) [A032H]
  - Mono- di-saccharides other than sucrose [A032S]
- Honey [A033J]
- Syrups (molasses and other syrups) [A033R]
- Polyols [A032Z]
- Artificial sweeteners (e.g., aspartam, saccharine) [A046M]
  - Saccharine [A046N]
  - Aspartame [A046P]
  - Acesulfame k [A046Q]
  - Sucralose [A046R]
  - Cyclamate [A046S]
  - Neo-hesperidine [A046T]
  - Thaumatine [A046V]
  - Neotame [A046X]
  - Steviol glucoside [A046Y]
  - Advantame [A046Z]

- [F01] Source
- [F02] Part-nature
- [F03] Physical-state
- [F04] Ingredient
- [F06] Surrounding-medium
- [F07] Fat-content
- [F08] Sweetening-agent
- [F09] Fortification-agent
- [F10] Qualitative-info
- [F11] Alcohol-content
- [F12] Dough-Mass
- [F17] Extent-of-cooking
- [F18] Packaging-format
- [F19] Packaging-material
- [F20] Part-consumed-analysed
- [F21] Production-method
- [F22] Preparation-production-place
- [F23] Target-consumer
- [F24] Intended-use
- [F25] Risky-Ingredient
- [F26] Generic-term
- [F27] Source-commodities
- [F28] Process
- [F29] Purpose-of-raising
- [F30] Reproductive-level
- [F31] Animal-age-class
- [F32] Gender
- [F33] Legislative-classes

- For the intake assessment on the basis of 'per kg body weight'.

- **Chronic intake** estimates should be provided by default, **acute** intake estimates in case the available (animal or human) data raise concerns regarding an acute effect(s).

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

- the <u>sources</u> of data used (sources of food consumption data and food composition data),

- the <u>scientific principles</u> and methods applied,

- the <u>assumptions</u> made and their rationale; in particular with respect to the assignment of a food to a particular food category, or for the model used for the calculation of high intakes.

2.7.3 ANTICIPATED INTAKE – TIERED APPROACH

- **Summary statistics** from the EFSA Comprehensive European Food Consumption Database (incl. FAIM tool) provide valuable screening estimates of intake:

  - ➤ Spreadsheets: Detailed information on the database and guidance on its use have been published by EFSA (2011). Anticipated daily intakes for mean and high-percentile consumers can be calculated through the combination of the intended use level in each food category with mean and high chronic consumption values from the database.

  - ➤ The Food Additive Intake Model (FAIM) Tool

- In cases where **more refined estimates** are needed, more detailed assessments should be considered, such as calculations based on **individual data from national food consumption surveys.**

EFSA **Food Additive Intake Model (FAIM)** tool was 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 NF used as ingredients to be added in several food categories.

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.

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

Where a novel food is **intended to replace another food** (in the sense of an alternative choice, option) already existing on the market, the applicant should provide their considerations and explanations why it is reasonable to expect that the novel food would replace that food.

In such cases, estimates of the consumption of the food that is intended to be replaced could be used for estimating consumption of the novel food.

Examples:

- Rapeseed protein isolate - alternative to soy protein
- Starch-rich root from other countries - potatoes
- Chia seeds to replace 5 % of „traditional grain" for bread

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

- 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 consumers to these constituents for the relevant population groups.

- Unclear or contradictory information on the intended food categories (to which the NF is intended to be added), use levels, and target population.

- Population groups considered in the intake estimate did not match or fully cover the intended target population.

- Anticipated intake exceeds safe levels deriving from the animal studies (insufficient margin of exposure). EFSA asked if applicants intend to reduce proposed uses and/or lower use levels.

- Insufficient description of the database used and underlying assumptions.

- Intake estimate based on a publication without providng information on the underlying methodology.

- The assumption that 2 x the mean could be considered as high intake percentile was not accepted.

- Use level was given for a "portion size" without specifying it (in ml, g).

- Proposed intake per serving was given, but without specifying the maximum number of servings per day.

- Intake estimate is based on „old" consumption data from countries for which more recent surveys exist.

- Intake estimate based on only one country (maybe acceptable in some cases, in others not sufficient).

Thank you for your attention !