



Guidance on Novel Foods

# The relevance of Nutritional Information

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# OUTLINE

- Regulatory background (Regulation)
- The EFSA Guidance document
- Aspects raised in the public consultation
- Examples from the past and considerations of the NDA Panel.
- Requests for additional information

## REGULATION (EU) 2283/2015 (1)

- Article 3, 2 (a)

**Novel foods** include also ...

(iv) food consisting of, isolated from or produced from plants or their parts, obtained by non-traditional propagating practices not used for food production within the Union before 15 May 1997, ...

(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, ...

... **where those practises give rise** to significant changes in the composition or structure of a food, **affecting its nutritional value**, metabolism or level of undesirable substances;



## REGULATION (EU) 2283/2015 (2)

- Article 7 (c)

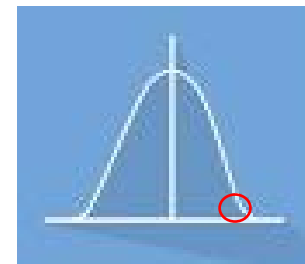
Where the food is intended to replace another food, it **shall not differ** from that food in such a way that its *normal consumption* would be **nutritionally disadvantageous** for the consumer.

This applies also to traditional foods from third countries according to Article 17(2)(c).

## GUIDANCE: 2.9. NUTRITIONAL INFORMATION (1)

- The applicant should demonstrate that the Novel Food (NF) is **not nutritionally disadvantageous for consumers under the proposed conditions of use**.
- «Nutritional information» specifically refers to the role of the NF in the diet in terms of its **contribution to or interaction with nutrient intakes**.

«*Normal consumption*» (NF Regulation) or «*under the proposed conditions of use*»: is understood as normal distribution of consumption by the target population and includes high percentile intakes.



## 2.9. NUTRITIONAL INFORMATION (2)

- Information on the NF should include details on:
  - its nutrient composition
  - influences of production and storage
  - and further processing that may be required prior to consumption.
- The content and effect of **anti-nutritional factors** in the NF (e.g. inhibiting absorption or modifying bioavailability) and other known and suspected **interactions with nutrients** should also be assessed.



General principles such as No 3 (“all available scientific data”) and No 4 (identification of data, literature review) also apply here.

## 2.9. NUTRITIONAL INFORMATION (3)

- **Levels of use and estimated intakes** for the target population should be taken into account as specified in section 2.7. (“Proposed uses and use levels...”).
- Intakes of relevant nutritional and anti-nutritional substances from the **background diet** should be considered for **mean and high intake estimates**.
- The resulting intake estimates should be discussed in the context of **dietary reference values including tolerable upper intake level**.

## 2.9. NUTRITIONAL INFORMATION (4)

- Apart from an evaluation of the compositional data and an appraisal of the relevant literature and databases, in **specific cases**, data from investigations *in vitro* and/or in animal models and/or human studies may be needed to address the interaction of the NF with the diet and nutrients.
- The **necessity for such studies** may arise from information on the source, the composition and the production, from documented experience on the uses, preparation and/or handling of the NF (e.g. foods which have been consumed in third countries), outcomes from studies on ADME, and from pharmacological, mechanistic, feeding, toxicological and human studies.



## 2.9. NUTRITIONAL INFORMATION (5)

- Intake estimates for **potentially anti-nutritional substances should be compared with health-based guidance** values (e.g. ADI).
- Vulnerable subgroups (e.g. young children, pregnant and lactating women or subjects with particular metabolic characteristics) should be specifically considered on a case-by-case basis.



## PUBLIC CONSULTATION (1)

- ◇ Comments pointed out the **challenges** related to the assessment of the influences of production, storage and further **processing, handling and cooking** on the nutrient composition of the novel food, considering that not all uses can be anticipated. It was noted that **end users** would be responsible for the nutritional information on their product.

Possible impact of the **production process** should be assessed. **Cooking** may also be relevant to reduce or inactivate anti-nutritional substances or toxins. The NF should not be nutritionally disadvantageous for the consumer. The nutritional assessment is therefore based on the intended uses and use levels.



## PUBLIC CONSULTATION (2)

- ◇ The request for data on anti-nutritional factors and possible interactions with nutrients **should be limited to NF that are intended to modify bioavailability or are known to contain physiologically relevant amounts of the respective compounds.** The difficulty in demonstrating that the in-vitro inhibitory activity of a food/ingredient is of physiological relevance was highlighted. It was stated that physiologically relevant effects of this type would most likely be revealed by **90-days oral toxicity** studies and addressed by an appropriate margin (uncertainty factor) may protect consumers.

The request for data on anti-nutritional factors and possible interactions with nutrients refers only to those instances where there is indication of the presence of such substances in a Novel Food (e.g. based on the composition or nature of the novel food, ADME data, animal data or literature).

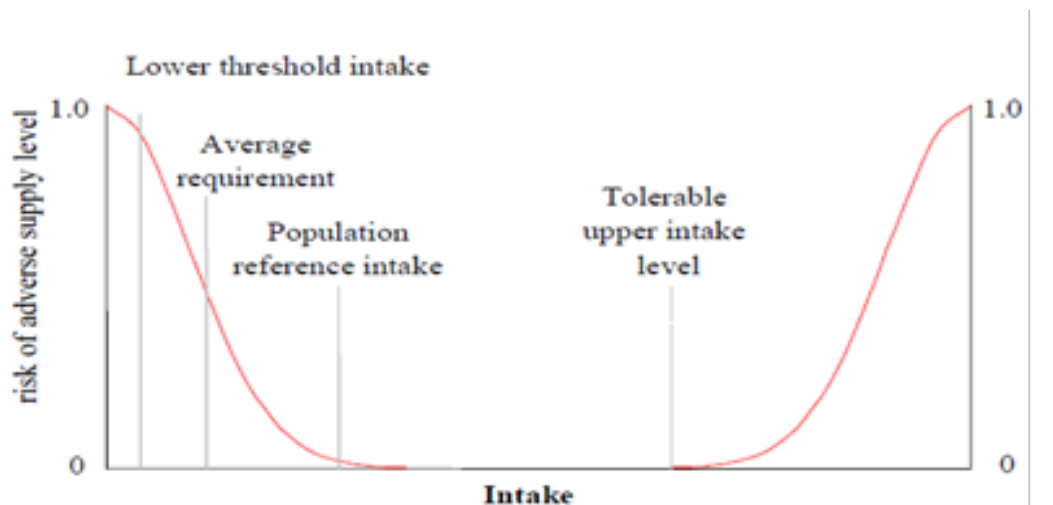
## PUBLIC CONSULTATION (3)

- ◇ It was proposed to indicate that new **animal testing should be kept to the minimum** and should not be carried out when alternative validated methods and recognized risk assessment models are available.



Animal testing is **normally not required for the evaluation of the nutritional impact of the NF**. As outlined at the end of this section, **only in specific cases** data from investigations in vitro and/or in animal models and/or human studies may be needed to address the interaction of the novel food with the diet and nutrients. **The Panel notes general principle No 12 which stresses that unnecessary use of animals should be avoided.**

## 2.9. NUTRITIONAL INFORMATION - EXAMPLES

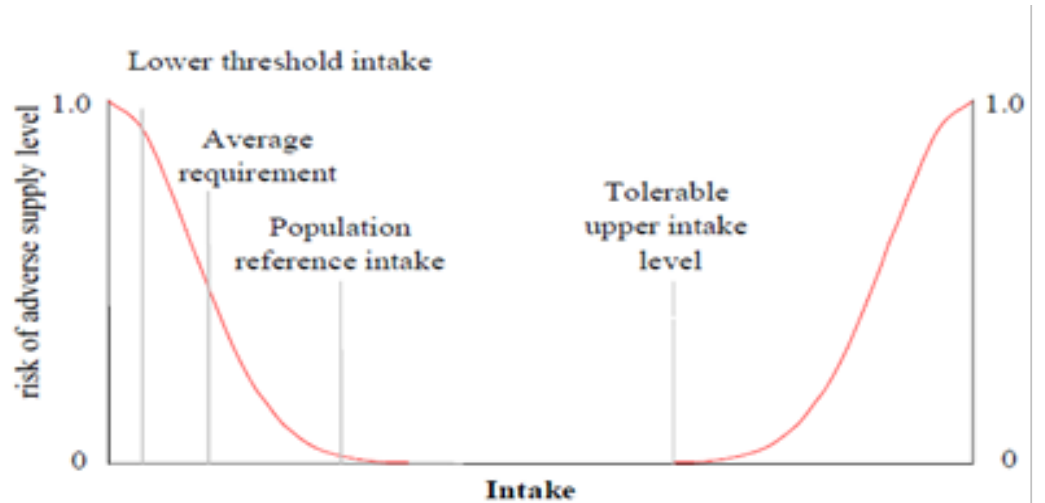


From: Health and Welfare, Canada, 1983; as adapted by Netherlands Health Council, 2000



UV treated milk (Vit D content ↑)  
 intake assessment on the basis of Vit D  
 content, consumption of milk, intake from  
 background; > *unlikely that tolerable  
 upper intake levels will be exceeded.*

## 2.9. NUTRITIONAL INFORMATION - EXAMPLES



From: Health and Welfare, Canada, 1983; as adapted by Netherlands Health Council, 2000



### Milk fermented with *B. xylanisolvens*

(includes post-fermentation pasteurisation for 1 h at 75°C)

Effects on nutrients for which fermented milk products are a relevant source? Panel asked for vitamins B2, B12 and lysine contents and furosine as marker for Amadori products.

No nutritionally relevant effects.

## EXAMPLE FROM THE PAST – RAPESEED PROTEIN ISOLATE (1)


- Well characterised **source** with a history of food use.
- **Compositional data**  $\geq 90\%$  protein,  $\leq 7\%$  fat,  $\leq 7\%$  carbohydrates; protein: 60-65% globulin and 30-35% albumin and other minor proteins; *glucosinolates* below detection limit, *erucic acid*  $\leq 2\%$  by mass in oil fraction, *phytates*  $< 1.5\%$ .
- Sufficiently described **production process**.
- **Proposed uses**: alternative to the use of soy protein products in meal replacements, protein drinks, meat analogues ...
- General population: **DRV protein Opinion (EFSA 2012)**: about 18% of protein intake from processed foods. For vegans there may be a higher proportion of consumed protein from plant-derived protein added to processed foods.
- For the nutritional assessment a comparative approach was taken:

## EXAMPLE FROM THE PAST – RAPESEED PROTEIN ISOLATE (2)

- **Rat** study: fecal nitrogen digestability of  $\approx 93\%$ . Other rat study:  $\approx 92\%$  vs.  $\approx 95\%$  for soy protein isolate and  $\approx 97\%$  for casein.
- Two **human** studies: ileal protein digestibility  $\approx 84\%$  and  $87\%$ .
- **4 batches analysed for the amino acid (AS) composition:** lysine content about 15% higher in soy protein, cysteine/cystine plus methionine about 65% higher in the rapeseed protein. Values for other AS were comparable.
- **Data from literature** on protein digestibility and protein-digestibility corrected amino acid scores (PDCAAS) of rapeseed and soy protein were provided.
- Using the most recent amino acid scoring pattern (EFSA NDA Panel, 2012) and a digestibility of 85 % from human studies, the **PDCAAS of five batches of the NF** was calculated. The mean and the range of the PDCAAS of the five batches were 0.98 and 0.92-1.00, respectively, with mainly lysine (in four batches) or leucine (one batch) as potentially limiting amino acids.



## OTHER EXAMPLES

Application	Key issues and approach
<b>UV treated bread, yeast</b>	Effect on vitamin D content and other relevant nutrients to be explored
<b>Plant sterols</b>	Effect on $\beta$ -carotene plasma levels at dose > 3 g/day
<b>Ice structuring proteins</b>	To be added at max 0.01% to ice products, no nutritional implications at such small intakes.
<b><i>Alfalfa protein concentrate</i></b> 	Nutritional assessment focused on substances like saponins, phytates, L-canavanine at the intended use levels (max. 10 g of the NF per day), heat treatment inactivates antitrypsin, feeding studies.
<b>Allanblackia seed oil</b>	For use in spreads (up to 20%), focus on fatty acid profile and compared with fatty acid in the diet.
<b><i>Novel Foods for supplement use</i></b> (if not vitamins or minerals)	Usually no relevance as nutrients. At least available data of the literature should be reviewed regarding possible interaction with ADME of nutrients.

## REQUESTS FOR ADDITIONAL INFORMATION

- Data on composition and production process insufficient to assess whether a NF may be nutritionally disadvantageous.
- Available data on anti-nutritional effects from the literature not provided and not considered.
- Effects of the production process not sufficiently evaluated, e.g. impact on nutrient's content.
- Possible effects not evaluated by considering the high percentile intake estimates deriving from an appropriate intake estimate.



# Thank you for your attention !

