Draft Guidance Novel Foods

Nutritional Information and Human Studies

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8. NUTRITIONAL INFORMATION (1)

- The applicant should demonstrate that the Novel Food (NF) is **not nutritionally disadvantageous for consumers at 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**.

- Where a **NF is intended to replace another food**, or when a novel production process is applied to a food which is a relevant source for nutrients, the applicant should demonstrate that the NF does not differ in a way that it would be nutritionally disadvantageous for the consumer at the proposed conditions of use.

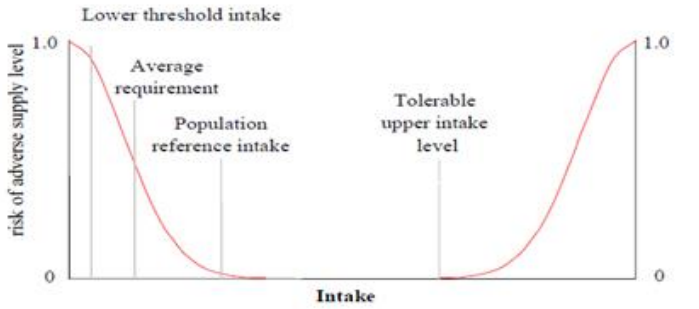
From: Health and Welfare, Canada, 1983; as adapted by Netherlands Health Council, 2000

8. NUTRITIONAL INFORMATION (2)

- Nutritional information on the NF should include **details of its nutrient composition** taking into account **influences of production, storage and further processing, handling and cooking**.
- 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.
- **Use levels and estimated intakes** for the target population should be taken into account as specified in section 6 (“Proposed uses and use levels and anticipated intake of the Novel Food”).

8. NUTRITIONAL INFORMATION (3)

- Intakes of relevant nutritional and anti-nutritional substances from the **background diet** should be considered for **establishing mean and high intake scenarios**. The estimates should be discussed in the context of **dietary reference values including tolerable upper intake**.



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

- 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.

8. 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 pharmacodynamic, mechanistic, feeding, toxicological and human studies.

9.7. HUMAN DATA (1)

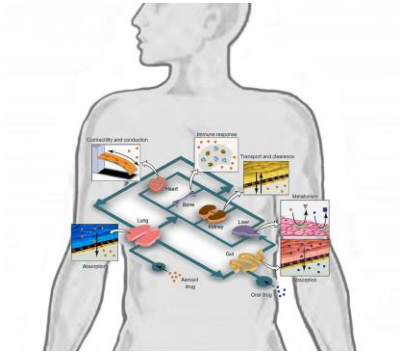
- Human studies, if available, should be provided if they contain **information relevant for the safety assessment,** such as physical examination, blood chemistry, haematology, urine analysis, blood pressure and organ function tests and/or monitoring of adverse reactions.
- Relevant data may be derived from the use of the NF for medical purposes or from epidemiological studies.
- **Additional human studies** may be needed to investigate further **potentially adverse effects**.

  In those cases where the NF may exert pharmacodynamic effects, specific studies may be required to demonstrate that the proposed consumption and use of the NF does not raise safety concerns

9.7. HUMAN DATA (2)

- The data from intervention studies and observational studies in humans should be organised according to a **hierarchy of study designs and research question**, reflecting the relative strength of evidence.
  Studies with the highest level of scientific evidence should be presented first.

  <u>Not relevant</u>:
  studies investigating supposed health benefits if they do not include endpoints relevant for the safety.



Thank you for your attention !