Guidance on Novel Foods

Human studies pertinent to the safety assessment

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Info-session
06 March 2017
Parma

efsa
European Food Safety Authority

THE NF GUIDANCE ON HUMAN DATA (1)

- **2.6.2. History of use of the NF**

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

- **2.8. Absorption, distribution, metabolism, excretion**

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

- **2.9. Nutritional information**

In specific cases, data from investigations in in vitro and/or in animal models and/or human studies may be needed to address the interaction of the novel food.

THE NF GUIDANCE ON HUMAN DATA (2)

- **2.10. Toxicological information - General considerations**

Additional studies may be needed to examine specific biological processes which may not be fully considered in the core areas for evaluation. Other studies that may be relevant include, for example, immunotoxicity, hypersensitivity and food intolerance, studies on neurotoxicity, endocrine activity and mode of action. *(May need to be studied in humans)*.

- **2.10.6. Human data** ⟵

- **2.11.2. Allergenicity – Human testing**

2.10.6. 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.**

2.10.6. HUMAN DATA (2)

- **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 do not raise safety concerns.

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

EXAMPLES (1) – NO HUMAN STUDIES WITH THE NF

Application	Key data
Baobab fruit pulp, Allanblackia seed oil,	Compositional data and history of use of the NF (or its source)
UV treated bread, milk, yeast, milk fermented with *B. xylanisolvens*	Compositional data and effect of the production process on the composition.
Alfaalfa protein concentrate, rapeseed protein isolate	Compositional data and effect of the production process on the composition, data from literature (regarding anti-nutritional factors)
Lycopene (tomato oleoresin; from *Blakeslea trispora*)	Composition, production process, toxicological data, data from literature
Taxifolin from Dahurian Larch	Composition, production process, toxicological data
Chewing gum base ingredient (synthetic polymer)	Composition, production process, toxicological data, (+ data from literature on low molecular weight components)

EXAMPLES (2) – HUMAN STUDIES NEEDED

Application	Objective
Conjugated linoleic acid (CLA)	The extent of the effects of CLA on insulin resistance and also on markers of cardiovascular risk (lipid peroxidation, inflammatory markers, vascular function, blood lipids) appears to be species-dependent; difficult to extrapolate from animal studies to humans. Safety assessment relied mainly on human studies and including those parameters which were most affected in animal studies.
2'-O-fucosyllactose , lacto-N-neotetraose (intended uses included infant formula)	Double-blind, randomised, controlled clinical trial with infants to study non-inferiority to infant formula without the NF (endpoints: weight gain, body weight, body length, head circumference, 'digestive tolerance', stool characteristics, behaviour patterns, formula intake, use of concomitant medications and adverse events; comparison with WHO growth curves).

EXAMPLES (3) – HUMAN STUDIES SUPPORTIVE EVIDENCE

Human studies with the NF and/or from literature

- Glucosamine (from literature)
- Citicoline (from literature and studies with the NF)
- Synthetic resveratrol
- Sardine peptides (blood pressure, adverse effects)
- Bovine lactoferrin

HUMAN STUDIES SUPPORTIVE EVIDENCE

Criteria:

- Test material representative for the NF or its main component(s)
- Study population relevant for the target population
- Number of subjects
- Studied dose relevant for the intended uses and use levels
- Duration (short duration may be sufficient for addressing acute effects such as blood pressure).
- Safety-relevant endpoints studied and reported
- Power
- Study design

The majority of human studies provided in NF dossiers are not pertinent to provide supportive evidence.

REQUESTS FOR ADDITIONAL INFORMATION

- Information on the identification and selection of human studies
- Human studies available in literature not provided
- Human studies cited in the dossier, but references not provided
- Study report of proprietary human study with the NF
- Human study needed (2'-O-fucosyllactose, lacto-N-neotetraose for infant formula)

Thank you for your attention !