Draft Guidance Novel Foods

Allergenicity and Concluding Remarks

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Allergenicity (1)

- Food allergens are mostly (glyco)**proteins**, and thus the allergenic potential of a Novel Food (NF) containing no protein (or protein fractions) is very low.
- The default assumption for **NF containing proteins** is that such Novel Foods have allergenic potential.
- **Methods of analysis for protein** (including the LOD, LOQ) and the results should be provided in section 2.
- The allergenic potential of the NF should be explored by considering its **composition, particularly its protein(s), its source, the production process, and available experimental and human data**. This comprises a **comprehensive literature review** in order to retrieve available information on sensitisation, and on case reports of allergic reactions and/or allergenicity studies (*in vitro*, in animals, in humans) of the NF and/or its source.

10. Allergenicity (1)

Information on **appropriate methods** to further investigate the potential allergenicity of foods is provided by the NDA Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes (EFSA, 2014). Such methods include:

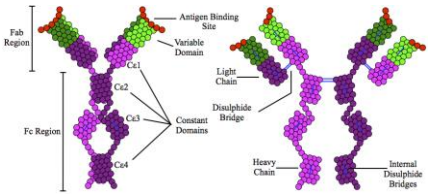
10.1 Protein analysis

- Protein content in the Novel Food
- Immunological tests (e.g. Western blotting)
- Molecular weight of potentially allergenic protein, heat stability, sensitivity to pH, digestibility by gastrointestinal proteases,
- Degree of sequence homology with known allergens.

10. Allergenicity (2)

10.1 Human testing

- Detection of specific IgE antibodies
- Skin prick testing
- Double blind placebo controlled food challenge studies



https://en.wikipedia.org/wiki/Immunoglobulin_E

10. Allergenicity (3)

- **If an applicant wishes to demonstrate that the NF is unlikely to trigger adverse reactions** in sensitive individuals under the proposed conditions of use, he should follow the approach outlined in the EFSA Guidance on the preparation and presentation of applications pursuant to Article 6 Paragraph 11 of Directive 2000/13/EC, as amended (EFSA, 2013).

- Applicants for **NF which potentially contain allergens listed in Annex II of Regulation (EU) No 1169/2011** and who seek exemption from mandatory labelling are advised to file an application pursuant to Article 21 paragraph 2 of Regulation 1169/2011 (previously Article 6 Paragraph 11 of Directive 2000/13/EC) by using the afore-mentioned guidance document (EFSA, 2013).

ConcluDING Remarks (1)

The applicant should **integrate the data presented in the previous sections to provide their overall considerations** on how the information supports the safety of the NF under the proposed conditions of use.

Where **potential health hazards** have been identified (e.g. on the basis of the composition of the NF, its production process, its history of use, results from animal or human studies), they **should be discussed** in relation to the anticipated intakes of the NF and proposed target populations.

ConcluDING Remarks (2)

In particular, the applicant should address:

- The relevance of toxicologically relevant components (e.g. impurities, by-products, residues, chemical or microbiological contaminants) in relation to their estimated intakes, possible background exposure and their health-based guidance values (e.g. tolerable daily intakes), when applicable.
- The results of toxicity studies.
- Any adverse effects identified through the human data.
- Sources of uncertainties.

Thank you for your attention !