Industry perspective on assessing allergenicity in novel foods

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Novel Foods

- What’s a novel food?
- Why assess allergenicity?
- How can we assess allergenicity?
Novel Foods: what are they?

- Originally defined by Regulation 258/97, now replaced by Regulation 2015/2283:

  - ‘Novel Food’ means any food that was not used for human consumption to a significant degree within the European Union before 15 May 1997 ...
Novel Foods: what are they?

... and that falls under at least one of the following categories:

- new or intentionally modified molecular structure
- isolated from or produced from microorganisms, fungi or algae
- isolated from or produced from material of mineral origin
- plants or their parts, unless they have a history of safe use
- animals or their parts (history of safe use excluded)
- cell or tissue culture
- novel production process (for the EU)
- engineered nanomaterials
- Vitamins (where any of the above apply)
- Food supplements (where intended to be used other than as supplements)
Novel Foods: what are they (not)?

- Out of scope
- Genetically modified foods
- Foods used as
  - Food enzymes
  - Food additives
  - Food flavourings
  - Extraction solvents

all the above are covered by different Regulations
Novel Foods: what is required of them?

- Novel foods, in common with all foods must be safe:
  - “Food shall not be placed on the market if it is unsafe
    “Food shall be deemed to be unsafe if it is injurious to health”
  - Regulation 178/2002 (The Food Law)
  - “The food does not, on the basis of scientific evidence that the food
    does not pose a risk to human health” Regulation 2015/2283
  - EFSA Guidance on the preparation and presentation of an application for
    authorisation of a Novel Food
    - This includes allergenicity (Section 10)
      “The default assumption for Foods containing proteins si that such Novel
      Foods have allergenic potential. The allergenic potential of the Novel Food
      should be explored....”
Novel Foods: Allergenicity assessment

From EFSA Guidance document

10. Allergenicity

10.1 Protein analysis

- Protein content
- Immunological tests (e.g. Western Blotting)
- Molecular weight of potentially allergenic protein, heat stability, sensitivity to pH, digestibility
- Degree of sequence homology with known allergens

10.1 Human studies

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

Ultimate conclusion is based on Weight of Evidence
Ice Structuring Proteins: a case study

ISPs protect organisms from the damage caused by freezing and are found widely in nature.

First discovered by De Vries (1969) in the blood of arctic fish.

Now identified in >200 organisms: fish, insects, bacteria, plants & lichen.
Unilever and ISPs

• Unilever saw an opportunity to use ISPs to improve ice cream:
  • ISP remains in the ice because the product is frozen
  • The resulting ice structure is totally NEW
  • This allows for products with better physical and nutritional attributes
  • Another bonus: improved sustainability (keep at higher freezer temperatures – less energy required)
Unilever’s ISP Preparation

- Active component: ISP type III HPLC 12, originally identified in the Ocean pout
- Not sustainable to produce from fish
- Uses Baker’s yeast (*S. cerevisiae*) containing copies of the ISP gene
- The technology used is very similar to that used for the production of Chymosin (microbial rennet) and other enzymes used in food production
Allergenicity Assessment

- Based on a **weight of evidence** approach, in accordance with FAO-WHO (2001) consultation and Codex Alimentarius guidelines (2003) - *Also in line with current EFSA guidance*

- Used sources of evidence of different types, to provide different information about the protein and its potential allergenicity

- 4 main areas of testing
  - Bioinformatics – amino acid sequence analysis
  - Resistance to pepsin hydrolysis
  - Serological analysis – IgE binding
  - Confirmatory tests in man
An intensive & comprehensive allergenicity assessment was undertaken as part of the overall safety programme. Results published in peer-reviewed journals.
Summary of Allergenicity assessment

- History of safe use: *no history of allergic reactions to ISP from human consumption*
- Sequence analysis: *no similarity to known allergens*
- Pepsin resistance: *ready hydrolysis by pepsin*
- Clinical studies:
  - *ISP does not bind to IgE*
  - *SPT negative to ISP*
  - *No antibody response to ISP after consuming ISP daily for two-months*
Thank you for your attention
Any questions?