Risk Assessment on Food Allergy

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• Mission and structure of EFSA
• EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel)
• Background (Labelling Directive)
• Risk assessment of food allergens for labelling purposes
EFSA’s Mission

• Provision of scientific advice and scientific and technical support for the Community’s legislation and policies in all fields which have a direct or indirect impact on food and feed safety, including nutrition;

• High level of scientific excellence, independence and transparency

• Risk communication
**NDA Mandate:**
Questions on human nutrition, dietetic products and food allergy, and other associated subjects such as novel foods.
Risk Assessment on Food Allergy

Legal background:

- New Labelling Directive* - November 2003
  (entered into force - November 2005):
  - Abolishment of the “25% rule” - all ingredients must be listed on the label
  - List of allergenic foods (Annex IIIa) - no labelling exemptions for these ingredients and their derivatives
  - Procedure to update Annex IIIa

Annex IIIa
(Directive 2003/89/EC as amended by Directive 2006/142)

- Cereals containing gluten
- Crustaceans
- Eggs
- Fish
- Peanuts
- Soybeans
- Milk (including lactose)
- Nuts
- Celery
- Mustard
- Sesame seeds
- Sulphites (>10 mg/kg or 10 mg/L)
- Molluscs
- Lupin

... and products thereof
Opinion of the NDA Panel on an evaluation of allergenic foods for labelling purposes (Feb 04)*

• Review of scientific basis of 12 food allergens listed in Annex IIIa

• Scientific evidence available shows that the 12 food ingredients in Annex IIIa have the capacity to trigger adverse health effects (i.e. allergic reaction/intolerance)

• Scientific evidence is insufficient to establish for any of these ingredients an intake threshold below which an allergic reaction does not occur

Opinions of the NDA Panel on evaluation of (2006)*

- Fructose
- Molluscs
- Lupin

Allergen derivatives:

- EU Labelling Directive specifies a procedure for exemption from mandatory labelling (for ingredients derived from allergens listed in Annex IIIa)
- 2-step procedure:
  A) Temporary labelling exemptions - granted in 2006
    - Industry notified the European Commission (29 dossiers)
    - Evaluation of dossiers by EFSA (NDA Panel) - delivering of 29 scientific opinions
    - European Commission adopted a list of derived ingredients that were temporarily "deleted" from Annex IIIa
  B) Permanent labelling exemptions - granted in Nov 2007
    - Evaluation of 22 dossiers by EFSA - issuing 22 opinions
    - European Commission adopted a list of derived ingredients that are permanently "deleted" from Annex IIIa
EFSA Opinions on allergen derivatives for labelling exemption (n=51)

- Wheat-based glucose syrups
- Wheat-based maltodextrins
- Barley-based glucose syrups
- Fully refined peanut oil and soybean oil (N/RBD oils)
- Soybean oil-derived phytosterols
- Soybean-derived tocopherols
- Celery-derived oils
- Mustard-derived oils
- Distillates from cereals, whey and nuts
- Nut extracts used as flavours in distillates
- Isinglass used as clarifying agent in brewing
- Fish gelatine (all uses and as carrier for flavour)
- Milk, egg and fish products used in wine and cider manufacture
- Hydrolysed wheat gluten used as fining agent in wines
- Wheat- and soy-derived acid hydrolysed vegetable protein
- Egg lysozyme as food additive
- Lactitol
EFSA Opinions on allergen derivatives
Risk Assessment Process

- **Summary**
- **Background**
- **Terms of Reference**
  - Likelihood of adverse reactions in susceptible individuals by consumption of derivative & under the conditions of use specified by manufacturer
- **Assessment**
  - Manufacturing process
  - Characterization of the product and its use
  - Conditions of use
  - Residual amounts of allergen derivative & exposure levels
  - Evidence of non-allergenicity
    - History of non-allergenicity of the product
    - Preclinical studies on allergenicity
    - Clinical studies on allergenicity
- **Conclusions**
“On the basis of the data provided, the Panel considers that:
  - it is unlikely
  - it is not very likely
  - may trigger
  - do not allow the Panel to assess the likelihood

that the derivative ...(e.g. isinglass)...

used as ...(e.g. clarifying agent in beer)... will trigger an allergic reaction in susceptible (e.g. fish allergic) individuals...

under the conditions of use specified by the applicant.”
Thank you for your attention