



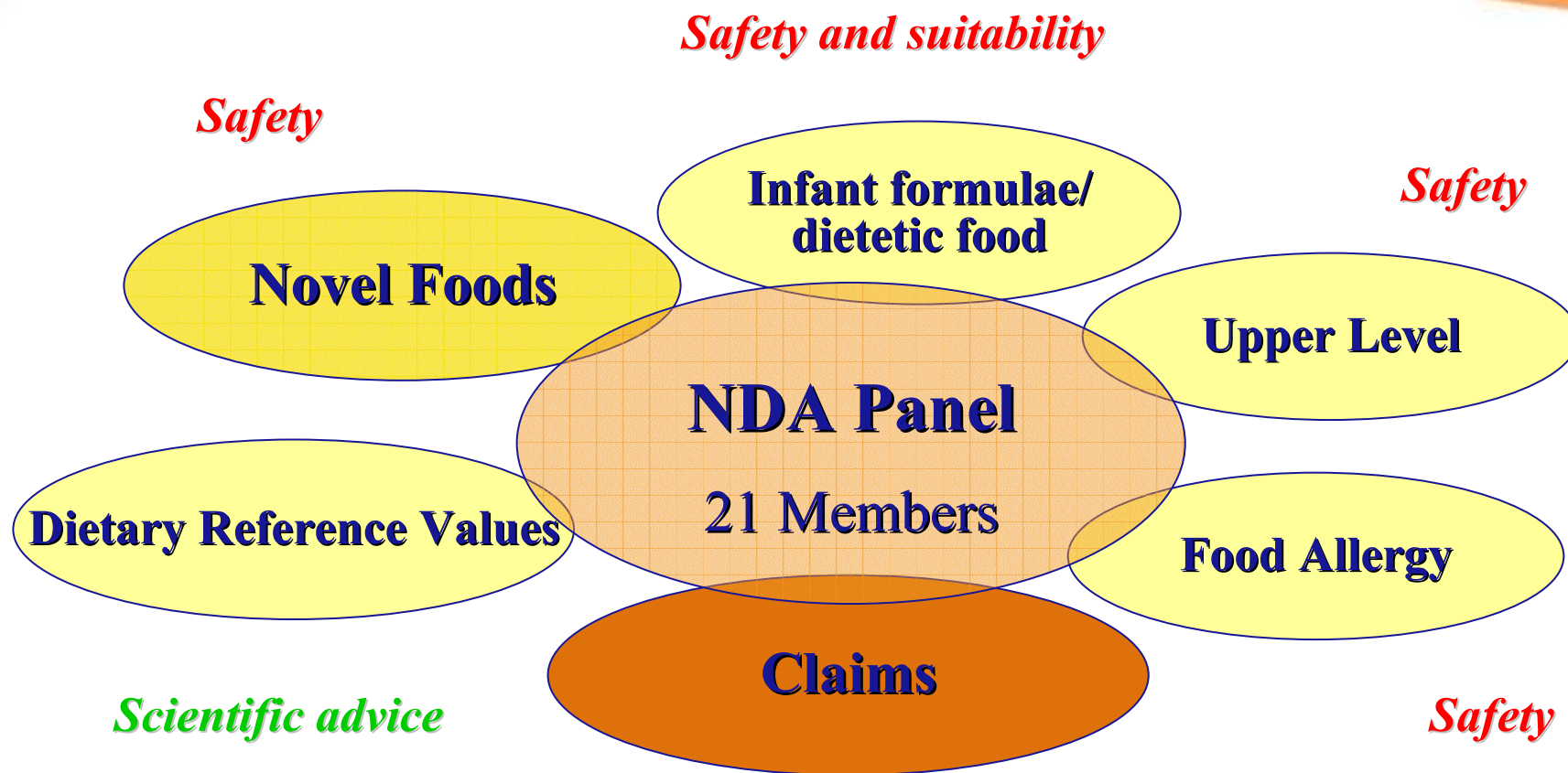
# ***The role of EFSA in the area of allergens***

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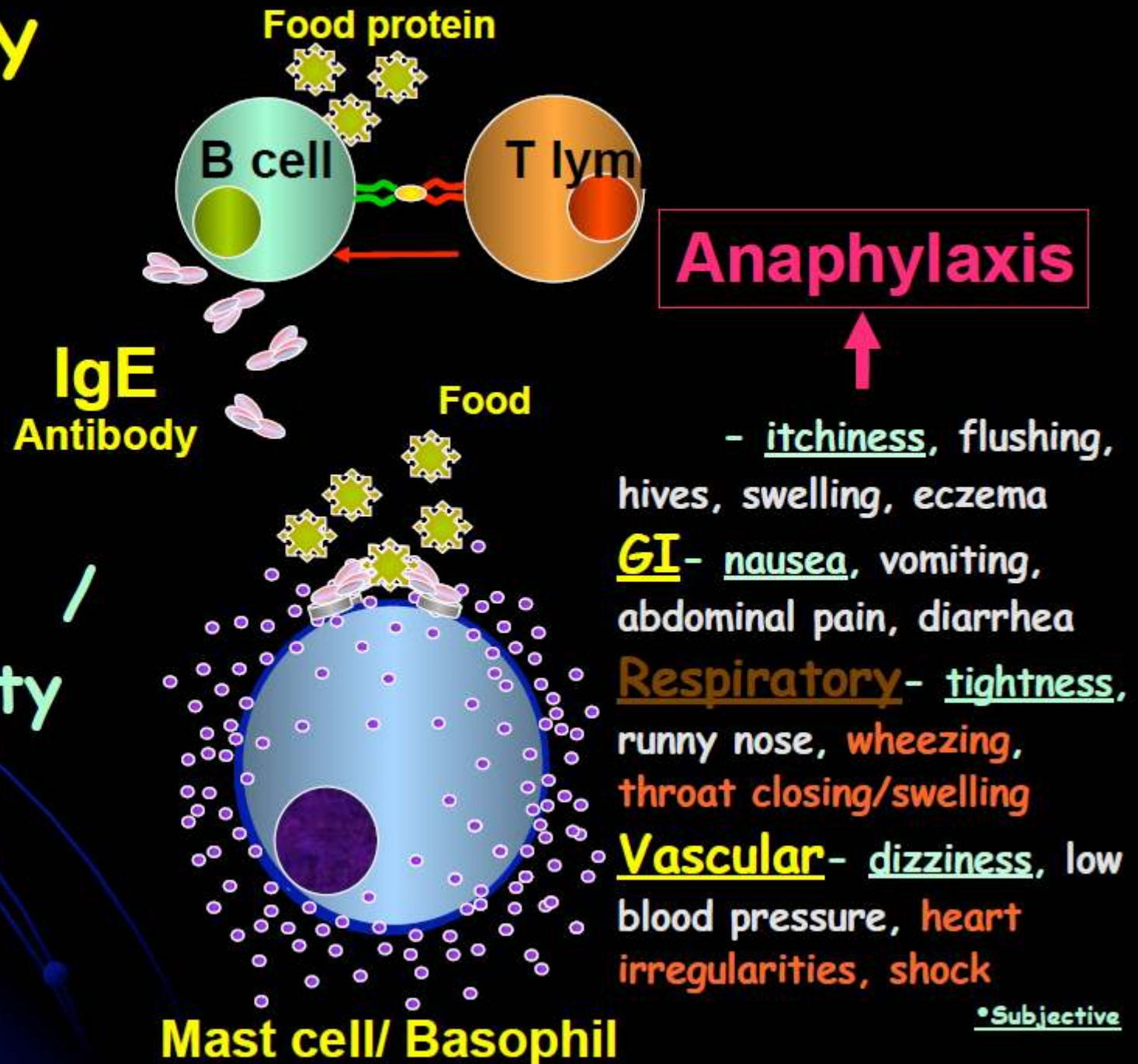
# NDA Panel & Working Groups



Supported by the EFSA Secretariat (NDA Unit)



# ALLERGY



- **NZ & Australia:** Australia NZ Food Standards code (**the code**) Standards 1.2.3 Dec 2002
- **EU:** Directive 2003/89/EC – Dec 2004
- **USA:** Food Allergen labelling & consumer protection Act (**FALCPA**)- 1 Jan 2006
- **Canada:** Part of Food & Drug Act – 2004
- **Japan:** Food Sanitation Law – April 2002

- Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs
  - Specific provisions on food allergen labelling
  - Establishment of a list of foods / ingredients known to trigger allergic reactions or intolerances (Annex IIIa)
  - Whenever the listed ingredients are used in the production of foodstuffs they must be labelled

# Annex IIIa of Directive 2000/13/EC

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

*...and products thereof*

# Selection of allergenic foods for labelling purpose

- Propose criteria
  - Food cause anaphylaxis proven by DBPCFC
  - Published in peer review journal
- **Does severity of reaction matter or frequency?**
- **Major or minor allergens i.e causing allergy in more or less than 50% of sensitized individuals**
- Evaluate criteria based on scientific literature on food allergy
- Determine which foods meet criteria

# **REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 25 October 2011**

**on the provision of food information to  
consumers**

**Applies after 13 December 2014**

- (48) ...information on potential allergens is considered very important. Evidence suggests that most food allergy incidents can be traced back to **non-prepacked** food. Therefore information on potential allergens should always be provided to the consumer.

- Art.21. **The name of the substance** or product as listed in Annex II **shall be emphasised through a typeset that clearly distinguishes it** from the rest of the list of ingredients, for example **by means of the font, style or background colour**.
- In the absence of a list of ingredients, the indication of the particulars referred to in point (c) of Article 9(1) shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II.
- Where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned.
- The indication of the particulars referred to in point (c) of Article 9(1) shall not be required in cases where the name of the food clearly refers to the substance or product concerned.

- Art. 21.2.
- In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the Commission shall systematically re- examine and, where necessary, update the list in **Annex II** by means of delegated acts, in accordance with Article 51.

# Annex II of Regulation 1169/2011/EC

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

*...and products thereof*

- If the food / ingredient listed in Annex IIIa or a product thereof
  - is used in the production of a foodstuff and still present in finished product (even in altered form) or
  - is used as an ingredient
- ➔ it needs to be indicated on the label with a clear reference to the name under which the allergen is known

# Other (not listed) allergens

- There are no specific regulations covering such claims for any of the other listed allergens, but labelling, advertising and presentation of food, including the information made available, should not mislead consumers.
- In addition, claims must not be false or mislead as to the nature, substance or quality of the food. Manufacturers should ensure that they have adequate Quality Assurance and Good Manufacturing Practice systems to back up any such claims that are made.

- Declaration is not specifically required where one of the 14 ingredients is found in low levels as a result of cross-contamination in the food, though the management of this situation is not harmonised throughout EU MS and therefore is handled in accordance with risk assessment in each individual jurisdiction.

- Food processing can alter the epitopes (parts of the proteins responsible for IgE cross-linking) and thus alter the allergenicity of foods.
- Epitope may be destructed, modified, masked or unmasked
- High temperature can lead to epitope destruction
- The allergenicity of boiled peanuts is lower than roasted peanuts (because of loss of low molecular weight allergens into the water)
- Interaction with **food matrix**. In milk, the interaction between the protein beta-lactoglobulin and the sugar lactose increases allergenicity
- **Proteolysis** (breakdown of proteins). Proteases added to milk followed by ultrafiltration are used to prepare hypoallergenic products such as infant formulae.

- GMO foods undergo a safety assessment by EFSA which includes an assessment of allergenicity of the new trait.
- e.g. GM technology may remove allergens from soy products

- **Adverse immune responses to foods**

- **Prevalence of Food Allergy**

- *Public perception is 20 – 25%*
- **Confirmed FA from oral challenges:**
  - Adults: 3-4 %
  - Infants / Children: 6 – 8%
- **Fruit and tree nuts 0.1% - 4.3%**
- **Vegetables : 0.1% - 1.4%**
- **Food Additives / Dyes / preservative allergy very rare**

# EFSA's role – NDA Panel

Upon request of risk managers (EC, Member States), EFSA (NDA Panel) provides advice on the allergenicity of foods and products thereof i.e, the likelihood of triggering (severe) allergic reactions in susceptible individuals upon consumption of the foodstuff.



# EFSA's work on food allergy for labelling purposes

- Exemptions from labelling (Directive 2003/89/EC)
  - Notification process: initial evaluation of data by EFSA (29 opinions)
  - Establishment of a temporary list for labelling exemption (Directive 2005/26/EC)
  - Submission of full dossiers for obtaining a permanent labelling exemption, evaluation by EFSA (22 opinions)
  - Establishment of a list for permanent labelling exemption (Directive 2007/68/EC)
- Inclusion of additional allergens
  - Evaluation of the allergenic potential of lupin and molluscs (EFSA)
  - Inclusion in Annex IIIa (Directive 2007/68/EC)

# Permanent exemptions as laid down in Directive 2007/68/EC

Ingredients	Products thereof excluded
Cereals containing gluten	(a) wheat-based glucose syrups including dextrose [1]; (b) wheat-based maltodextrins [1]; (c) glucose syrups based on barley; (d) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.
Fish	(a) fish gelatine used as carrier for vitamin or carotenoid preparations; (b) fish gelatine or Isinglass used as fining agent in beer and wine.
Soy	(a) fully refined soybean oil and fat [1]; (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; (d) plant stanol ester produced from vegetable oil sterols from soybean sources.
Milk	(a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; (b) lactitol.
Nuts	(a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

[1] And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

“Scientific Opinion related to a notification from the International Organisation of Vine and Wine (OIV) on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC - for permanent exemption from labelling”

- “ovalbumin/egg white” fining agents have not been sufficiently characterised in the application regarding their content of egg proteins other than ovalbumin
- Ovalbumin residues found in wines under standard manufacturing conditions as stated by the applicant.
- No quantitative assessment of other milk proteins than ovalbumin in fined wines
- the lowest dose of egg white proteins capable of triggering an allergic reaction in a sensitive individual **highly uncertain**

# Recent labelling exemption requests

- Based on new dossiers submitted, EFSA concluded the following evaluations for permanent labelling exemption in 2011:
  - Casein/caseinate/milk products to be used in the manufacture of wine as clarification processing aids
  - Ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids
  - Lysozyme from hen's egg used in the manufacture of wine as an anti-microbial stabiliser/additive
- Barley beta-amylase from unmalted barley to be used in starch degradation to produce glucose syrups rich in maltose

# Work in the area of allergens not related to labelling exemptions

- Potential of specific food azo-colours to cause intolerance and/or allergic reactions in humans after oral exposure
- Scientific Opinion on the effect on public or animal health or on the environment on the presence of seeds of *Ambrosia* spp. in animal feed (joint opinion of the CONTAM, NDA and PLH Panel)
  - Task of the NDA Panel: to evaluate human health risks of the contamination of food with *Ambrosia*

# Allergen risk assessment (currently ongoing)

- Request from the Food safety Authority of Ireland to:
  - Review the prevalence of food allergy in Europe
  - Recommendations on threshold concentrations of each allergen in food that would provide an acceptable level of protection for at-risk consumers
  - Assessment of “new” methods for the detection and quantification of food allergens
- Task focused on foods/ingredients listed in Annex IIIa (Annex II of Regulation (EU) No 1169/2011)
- Possibility of identifying “emerging” allergens
- Deadline: mid 2014

- Labelling exemption for food allergen – derived preparations/foodstuffs
- It appears useful to provide guidance as to which type of scientific data and information could be expected to substantiate the unlikelihood of adverse reactions triggered in susceptible individuals by the consumption of food ingredients or substances with known allergenic potential

It outlines:

- The information and scientific data which must be included in the application
- The hierarchy of different types of data and study designs, reflecting the relative strength of evidence which may be obtained from different study types
- The key issues which should be addressed in the application

- The NDA Panel evaluates the likelihood of adverse reactions in sensitive individuals after oral consumption of the food allergen-derived preparation according to the nature and quality of the totality of the evidence provided.
- This includes information about the characteristics of the food allergen-derived preparation, its intended use, and the residual allergenic proteins it contains, as well as information on its residual allergenicity.
- There is no pre-established formula as to how much or what type of information is required to conclude on non-allergenicity.

- The application should contain an analysis of all residual major allergenic proteins (e.g. for the food allergen-derived preparation egg white, the major allergenic proteins ovomucoid, ovalbumin,  $\alpha$ 3-casein and  $\kappa$ -casein) and, if appropriate, of all residual major allergenic proteins in the food which has been manufactured from it as consumed. The protocol used to obtain the samples for analysis and the analytical methods used for the detection of allergenic proteins should be adequately described. Analytical methods need to be standardised and validated. If no allergenic proteins are detected, this information on its own does not necessarily imply the non-allergenicity of the preparation.

- Data from food challenge studies in humans addressing the presence/absence of adverse reactions in susceptible individuals while ingesting the food allergen-derived preparation, whichever is intended for human consumption as prepared, may provide important information regarding its allergenicity. DBPCFC are less subject to bias than single-blind challenges or open challenges. Sufficient characterisation of the study population is important. The selected sample size should be justified. Other human studies which do not entail oral consumption of the preparation (e.g. skin-prick testing studies) can be used as supportive evidence of non-allergenicity. Observational studies in humans (e.g. case-reports) consuming the food allergen-derived preparation, if available, should also be provided.

- Data from studies in animals or other model systems alone cannot substitute for human data as evidence of non-allergenicity, but may be included as supporting evidence.
- A comprehensive review of published human studies reporting on adverse reactions to the food allergen under the proposed use is required.
- Data from studies in humans should be organised according to a hierarchy of study designs, and should reflect the relative strength of evidence which may be obtained from different types of studies.

- Precautionary labelling such as ‘may contain...’ is sometimes used by the manufacturers if they consider that unintended allergens may be present in amounts that could pose a risk.
- This labelling should be used in situations where the risk of unintended presence is real and cannot realistically be expected to be kept under control.
- No specific legislation currently exists on precautionary labelling

- Allergen safety thresholds (i.e. the minimum dose that can elicit a reaction in a substantial proportion of vulnerable consumers) and labelling thresholds (i.e. the level above which requires a specific declaration on the product packaging) are absent.
- The unwarranted use of precautionary labels can result in the unnecessary elimination of healthy options from the diet of allergic consumers

- Individual threshold – the maximum amount of an allergen that can be tolerated by an allergic individual
- Population threshold – the maximum amount of an allergen that can be tolerated by the entire population of individuals with food allergy.
- The establishment of population thresholds which protects all sensitive individuals is virtually impossible.

THANK YOU FOR YOUR KIND ATTENTION

