



Nederlandse Voedsel- en
Warenautoriteit
Ministerie van Economische Zaken

Advice on preliminary reference doses for allergens in foods

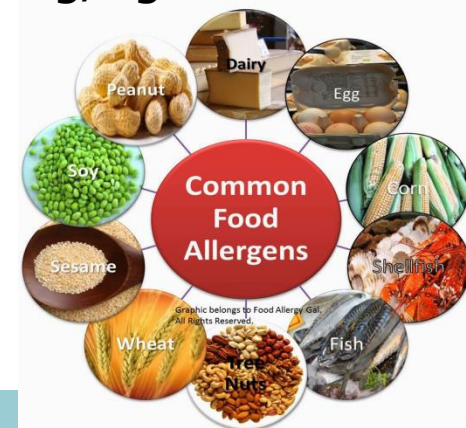
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Regulation EU no 1169/2011 on the provision of food information to consumers

Annex II: substances or products causing allergies or intolerances

1. Cereals and products thereof
2. Crustaceans
3. Eggs
4. Fish
5. Peanuts
6. Soybeans
7. Milk
8. Nuts namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia
9. Celery
10. Mustard
11. Sesame seeds
12. Sulphur dioxide and sulphites >10 mg/kg or l
13. Lupin
14. Molluscs



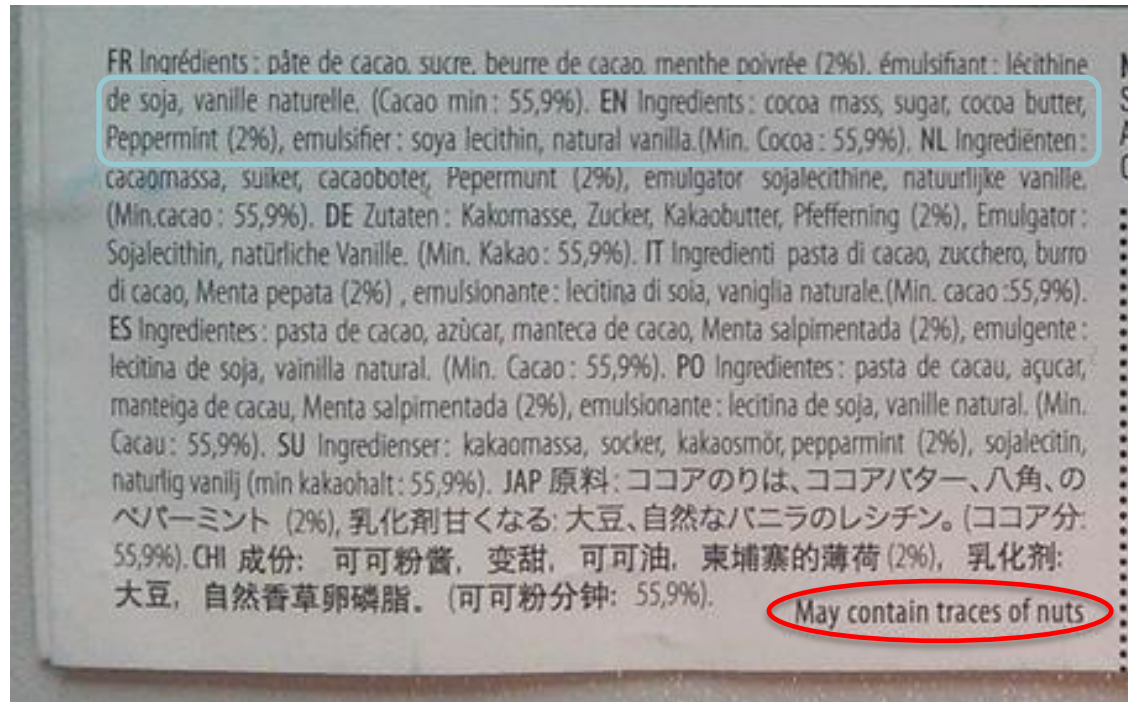


Ingredients

- Regulation aims “to enable consumers, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them.”
- ... any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form



In practice: what to do with traces of allergens?



Allergies
Contains egg, gluten and milk
May contain traces of nuts
Ingredients Buttercream filling (15% (9%), swe





Health problem?

- Up to 25% of European population reacts to food (allergy, hypersensitivity, intolerance)
- 2-3% of population have diagnosed food allergies: 17 million Europeans (in EU with population of 508 million: 13 million allergic consumers)
- DALYs: estimated for NL for peanut: 12,450 per year; cow milk: 5178 (Campylobacter: 635) → substantial burden



Adapt enforcement strategy?

Can we use the VITAL system?

- When foods contains allergenic ingredient or trace of allergen: labelling required
- Question now: how much is 'trace'?

VITAL system

- Developed by industry
- Developed reference doses considered to be safe for allergic consumers
- Number of publications





Results NVWA-BuRO

- Various analytical techniques; no reference material available
- Chance on extensive use of 'may contain' labelling is present; no guidelines
- VITAL uses reference doses based on threshold values. Threshold values are determined by using NOAELs and LOAELs of clinical provocations of allergic persons: ED_{01} and lowest 95% confidence interval of ED_{05} calculated
- EFSA described minimal (observed) eliciting doses (opinion 2014)



Conclusions

- Foods can contain traces of allergens
- There will always be a small (remaining) risk for very sensitive allergic persons
- The VITAL approach is valid. However, we were not granted access to the database or provided with additional analyses/calculations
- Main question: how did the VITAL expert panel derive the reference doses from the threshold values?
- There is no European reference laboratory for allergens in foods



Thus

- The policy can be relaxed that a food with an allergen not declared on the label is always unsafe
- The VITAL database is unique but not accessible. How VITAL reference doses were determined is not clear; thus we will not use these values



Advice

- Strive towards a harmonised approach within Europe for foods that contain traces of allergens
- If this cannot be achieved, adapt national food law
- Make available a database to enable determining reference doses for allergens
- Establish a European reference laboratory



Future actions

- NL will ask EFSA to write an opinion on reference doses for allergens
- No cure for food allergy; protection = abstention; consumers must be able to identify the ingredients they are sensitive to
- Precautionary labelling → not trustworthy, limitations to diet
- Threshold concentrations of each allergen in food providing an acceptable level of protection for consumers
- Harmonised rules required