



Nederlandse Voedsel- en
Warenautoriteit
Ministerie van Economische Zaken

Advice on preliminary reference doses for allergens in foods

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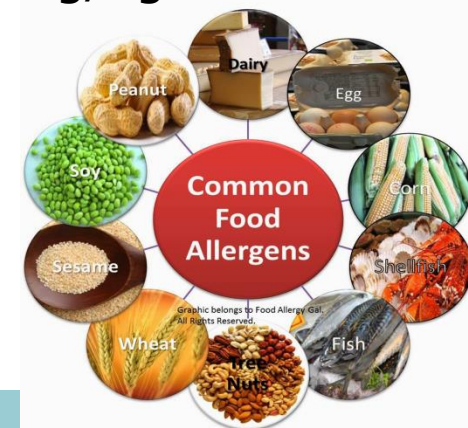
The Netherlands



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?

FR Ingrédients : pâte de cacao, sucre, beurre de cacao, menthe poivrée (2%), émulsifiant : lécithine de soja, vanille naturelle. (Cacao min : 55,9%). EN Ingredients : cocoa mass, sugar, cocoa butter, Peppermint (2%), emulsifier : soya lecithin, natural vanilla. (Min. Cocoa : 55,9%). NL Ingrediënten : cacao massa, suiker, cacao boter, Pepermunt (2%), emulgator sojalecithine, natuurlijke vanille. (Min. cacao : 55,9%). DE Zutaten : Kakomasse, Zucker, Kakaobutter, Pfefferminz (2%), Emulgator : Sojalecithin, natürliche Vanille. (Min. Kakao : 55,9%). IT Ingredienti : pasta di cacao, zucchero, burro di cacao, Menta pepata (2%), emulsionante : lecitina di soia, vaniglia naturale. (Min. cacao : 55,9%). ES Ingredientes : pasta de cacao, azúcar, manteca de cacao, Menta salpimentada (2%), emulgente : lecitina de soja, vainilla natural. (Min. Cacao : 55,9%). PO Ingredients : pasta de cacau, açúcar, manteiga de cacau, Menta salpimentada (2%), emulsionante : lecitina de soja, vanille natural. (Min. Cacau : 55,9%). SU Ingredienser : kakaomassa, socker, kakaosmör, pepparmint (2%), sojalecitin, naturligt vanilj (min kakaohalt : 55,9%). JAP 原料 : ココアのりは、ココアバター、八角、のペパーミント (2%), 乳化剤甘くなる : 大豆、自然なバニラのレシチン。(ココア分 : 55,9%). CHI 成份 : 可可粉膏, 变甜, 可可油, 柬埔寨的薄荷 (2%), 乳化剂 : 大豆, 自然香草卵磷脂。(可可粉分钟 : 55,9%).

May contain traces of nuts

WITH ...
Allergies
Contains egg, gluten and milk
May contain traces of nuts
Ingredients ...ttercream 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 contain allergenic ingredient or trace of allergen: labelling required
- Question now: how much is 'trace'?





VITAL system

- Voluntary Incidental Trace Allergen Labelling
- Developed by industry, now managed by Allergen Bureau of Australia & New Zealand
- VSEP (scientific expert panel): collaboration between Allergen Bureau, Food Allergy Research & Resource Program (FARRP) of the University of Nebraska & the Netherlands Organisation for Applied Scientific Research (TNO)
- 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} used
- 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 sensible allergic persons
- The VITAL approach is valid
- 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 that a food with an allergen that is not declared on the label, is always unsafe can be relaxed
- The VITAL database is unique. 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

- Use preliminary reference doses based on information published on ED_{01} and ED_{05} by VITAL
- Evaluate these reference doses by using cases reported to NVWA



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
- Determine threshold concentrations of each allergen in food providing an acceptable level of protection for consumers
- Harmonised rules required



Data required to determine reference doses for allergens

- Will EFSA be able to collect data?
- Clinical (double-blind, placebo-controlled) food challenges of food allergic subjects
- Data to come from EuroPrevall (?)
- Many unpublished data
- Role for Focal Points?

