

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
- 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: cacaomassa, suiker, cacaoboter, Pepermunt (2%), emulgator sojalecithine, natuurlijke vanille. (Min.cacao: 55,9%). DE Zutaten: Kakomasse, Zucker, Kakaobutter, Pfefferning (2%), Emulgator: Sojalecithin, natürliche Vanille. (Min. Kakao: 55,9%). IT Ingredienti pasta di cacao, zucchero, burro di cacao, Menta pepata (296), emulsionante: lecitina di sola, vaniglia naturale. (Min. cacao:55,996). ES Ingredientes: pasta de cação, azúcar, manteca de cação, Menta salpimentada (296), emulgente: lecitina de soja, vainilla natural. (Min. Cacao: 55,9%). PO Ingredientes: pasta de cacau, açucar, manteiga de cacau. Menta salpimentada (296), emulsionante : lecitina de soja, vanille natural. (Min. Cacau: 55,996). SU Ingredienser: kakaomassa, socker, kakaosmör, pepparmint (2%), sojalecitin, naturlig vanilij (min kakaohalt: 55,9%). JAP 原料: ココアのりは、ココアバター、八角、の ベバーミント (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: 可可粉酱, 变甜, 可可油, 東埔寨的薄荷(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 Allergies

Contains egg, gluten and milk

Contains egg, gluten and milk

May contain traces of nuts

May contain traces of nuts

Allergies

All









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



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