

# Mandatory risk assessment and the use of Precautionary Allergen Labelling in the Netherlands

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22 May 2025



## Introduction

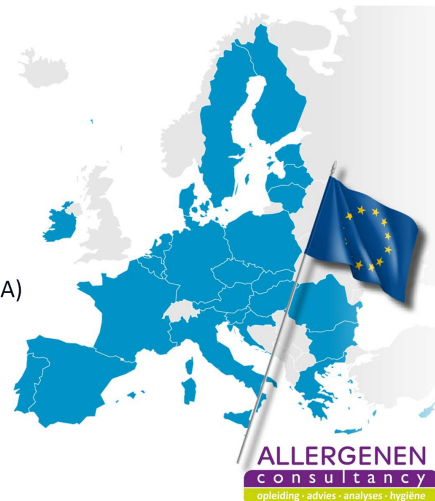
- Food technologist (QA manager, auditor)
- Allergen specialist for the food industry since 2003:
  - Risk assessment
  - Recall support
  - Advice labelling and legislation worldwide
  - Training, courses and e-learning (first European VITAL trainer)
  - Allergen analysis (a.o. ELISA, PCR, LC-MS, rapid tests)
- Food allergic consumer, affiliated with Dutch patient organisation



## Legal framework and enforcement Europe

### European Union:

- 27 nations
- 24 official languages
- Free movement of goods, cross-border sales
- Current legal framework PAL Europe:
  - Hygiene Regulation 2021:
    - Cleaning after production of allergens
    - Commission Notice 2022 (elements of QRA)
  - Labelling Regulation 2011:
    - PAL is voluntary information
    - Implementing act will be provided.....
  - European Parliament:
    - Awaiting developments Codex
    - Court of Auditors: 2027 deadline



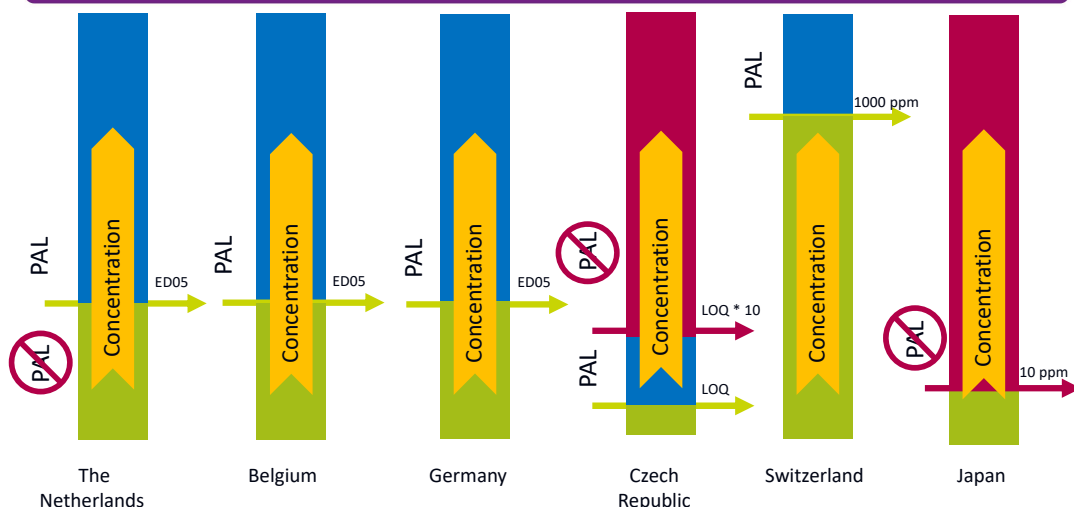
## National legislation/ guidelines within Europe on PAL

### Member States:

- Some: interpretations on voluntary use of PAL (eg wording) for FBO
- Some: national monitoring plans (indirect), including reference doses
- Most: no requirements on PAL or risk assessment
- The Netherlands:
  - In 2016 temporary RfD established but PAL was not acknowledged
  - Court case in 2022 for products with cross-contact (but having a PAL)
  - Multi-stakeholder platform developed new policy
  - Policy rule on PAL per 1-1-2026



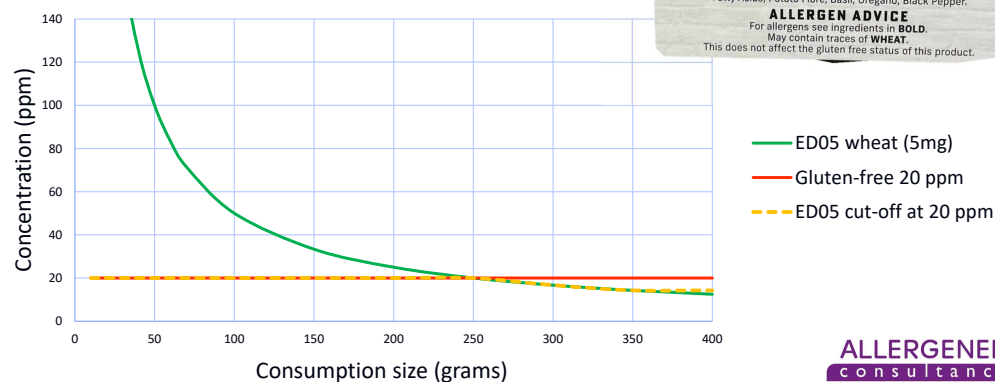
## Legal framework and enforcement in Europe (and Japan)



Allergen	FAO/ WHO	VITAL 4.0	NL	BE	Germany	
Reference doses in allergen protein	mg	mg	mg	mg	mg	calculated to max. analytical result at 100 grams (ppm)
Peanut	2	2	2	2	2	20
Milk	2	2	2	2	2	20
Egg	2	2	2	2	2	20
Nuts (hazelnut)	3	3	3	3	3	30
Nuts (other)	1	1	1	1	1	10
Soy	10	10	10	10	10	100
Gluten containing cereals	5 (wheat)	5 (max 20ppm)	5 (max 20ppm)	5	5	50
Mustard	1	1	0,4	1	1	10
Lupin	10	10	15	10	10	100
Sesame	2	2	2	2	2	20
Crustaceans	200	200	200	200	200	250 should be 2000 mg, but considered too high
Molluscs	-	20	20	200	-	-
Fish	5	5	5	5	5	50
Celery	1	1	1	1	1	10

## Wheat and gluten

$$\text{Action level (ppm = mg/kg)} = \frac{\text{reference dose (in mg)}}{\text{consumption size (in kilo)}}$$



A THIN GLUTEN FREE STONEBAKED PIZZA BASE  
TOPPED WITH TOMATO SAUCE, MOZZARELLA  
CHEESE & SMOKED PEPPERONI.

**INGREDIENTS**  
Water, Mozzarella Cheese (**MILK**) (19%), Cornflour, Tomato Purée, Smoked Pepperoni (10%) (Pork, Pork Fat, Salt, Dextrose, Smoked Salt (Salt, Smoked Salt), Antioxidants: Sodium Ascorbate, Extracts Of Rosemary; Paprika, Paprika Extract, Coriander, Oregano, Garlic, Pepper Extract, Preservative: Sodium Nitrite), Rice Flour, Tapioca Starch, Potato Starch, Rapeseed Oil, Dried Yeast, Potato Flakes, Dried Rice Sourdough, Sugar, Psyllium Husk Powder, Thickener: Xanthan Gum; Brown Rice Flour, Raising Agents: Diphosphates, Sodium Carbonate; Fructose, Garlic Purée, Salt, Emulsifier: Mono And Diglycerides Of Fatty Acids; Potato Fibre, Basil, Oregano, Black Pepper.

**ALLERGEN ADVICE**  
For allergens see ingredients in **BOLD**.  
May contain traces of **WHEAT**.  
This does not affect the gluten free status of this product.

## Policy rule the Netherlands

### Policy:

- Basis Commission Notice
- Recommendations of FAO/ WHO applied
- 3 different documents:
  - Allergen policy in [Government Gazette](#)
  - [Guidelines](#)
  - Q&A document (in draft)

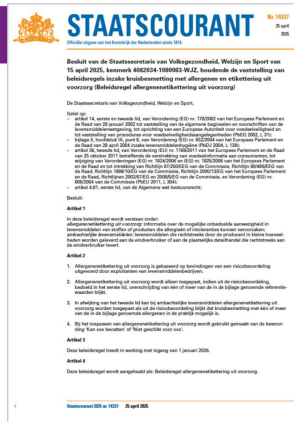


Ministerie van  
Volksgezondheid,  
Welzijn en Sport

## Policy rule the Netherlands

### Requirements:

- Risk assessment based on reference doses (RfD)
- PAL shall only be used if cross-contact is above RfD
- Qualitative risk assessment for artisan foods
- Wording “May contain XX” or “Not suitable for xxx”.
- In force 1-1-2026 (production date)



<https://zoek.officielebekendmakingen.nl/stcrt-2025-14337.html>

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## Policy rule in the Netherlands/ Europe



RASFF Window

SEARCH CONSUMERS

### NOTIFICATION 2024.3276

Prodotto alimentare ottenuto con ingrediente inquinato da allergene non dichiarato in etichetta/ allergen (peanuts) not declared on the label of fresh vegan pasta filled with spinach and cashew cream

notified 24 APR 2024 by Italy | last update 16 MAY 2024 EC validated

Reference	2024.3276	
Subject	Prodotto alimentare ottenuto con ingrediente inquinato da allergene non dichiarato in etichetta/ allergen (peanuts) not declared on the label of fresh vegan pasta filled with spinach and cashew cream	
Notification type	Food	Risk
Notification basis	Company's own check	Risk decision Potential risk
Classification	Alert notification	Hazards observed Not defined
		Nb. persons affected ---
Organisations		Symptoms / Illness Unknown

Austria (d)(ffup) Belgium (d)(ffup) Denmark (d)(ffup) Greece (d)(ffup)  
 Hungary (ffup) Italy (n)(o)(op)(ffup) Netherlands (d)(ffup)  
(n) Notifying | (o) Origin | (d) Distribution | (op) Operator  
(ffup) Flagged for Follow-Up | (ffa) Flagged For Attention

### Data:

- 135 mg/ kg peanut in cashew flour
- Protein conversion factor 26% = 35 mg/ kg
- 7,2% cashew flour in end product
- 7,2% of 35 mg/ kg = 2,52 mg/ kg
- Consumption size end product 125 grams
- RfD peanut 2 mg

$$\text{Action limit} = \frac{\text{reference dose (in mg)}}{\text{consumption size (in kilo)}}$$

$$\text{Action limit} = \frac{2}{(125/1000)}$$

= 16 mg peanut protein/ kg vegan pasta

No recall Belgium and The Netherlands

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## Policy rule the Netherlands

### Guidelines (17 pages)

1. 10 key elements (between blue lines)
2. Focus areas:
  - Raw material information
  - Preventive segregation, cleaning, validation, analysis
  - Risk assessment (QRA)
  - Risk communication (PAL)
3. Many worked-out examples (in orange)

### Guidelines on cross-contact of allergens FNLI - CBL - NVWA - version April 2024

#### Introduction

Following amendment 1 of Regulation (EC) No 853/2004 on food hygiene in 2013, specific requirements for cleaning after processing allergens are in force. The European Commission clarified these requirements with the publication of a Commission Notice in 2012. The Notice explains that these requirements are a best efforts obligation to prevent cross-contact and that in all cases preventing cross-contact in the first step that food business operator should focus on, after that, if real risks to food allergic consumers remain, precautionary labelling is important.

Advisory labelling, or Precautionary Allergen Labelling (PAL), is only possible based on the following two steps according to the Notice:

1. Taking preventive measures to prevent or minimise cross-contact as much as possible, with raw material information and cleaning being important measures.
2. A risk assessment to identify a real risk and -where possible- quantify risk it when preventing cross-contact is not possible.

Risk communication through PAL is subject to conditions so that the labelling statement is as clear and unambiguous as possible.

#### Practical translation into key elements

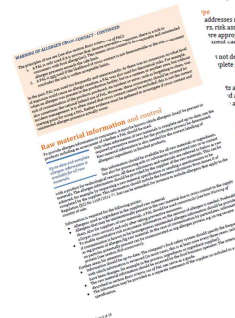
This document converts the Commission Notice guidance into key elements to be adopted in a Food Safety Management System. These key elements give further interpretation to the basic obligations in the Notice. Each key element is identified as a section in italics in the margin, marked as at the top and bottom of the box.

Address management of cross-contact with allergens in the whole food chain. This is a risk assessment of products and raw materials having potential cross-contact cross-contamination - one of a PAL on pre-packed food products on the Dutch market. Its content can be used as a basis for a risk assessment.

Not describe all possible options and measures to prevent cross-contact. Nor is it possible to design and implementing an allergen management system.

Are regulated by the Dutch Commodities Act Regulation allergen information for foodstuffs outside the scope of this document. These are products sold as foodstuffs - or products packaged for direct sale (including 'bakery' products).

No 1149/2011 lists the allergens that are subject to legislation ('regulated allergens'). These substances, derived from certain regulated allergen sources, are listed in the list of products. For this reason, they are not subject to the requirements of this document. For this reason, they are not subject to the requirements of this document. For this reason, they are not subject to the requirements of this document.



<https://www.allergenenconsultancy.nl/en/nieuws/richtlijnendocument-kruisbesmetting-allergenen-nederland>

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## Policy rule the Netherlands: steps



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## Learnings

- Stakeholder commitment is important
- Positive feedback in the Netherlands
- Clearly indicate when no PAL is allowed
- Proof of UAP and use of PAL needed (e.g. visual presence, analytical data)
- Guidelines on QRA/ RA needed
- Input/ data for QRA needs to be specified
- QRA as calculation (like VITAL) is difficult for many FBO
- “May contain” is preferred above “Not suitable for”
- Q&A for questions that will arise during implementation



## Questions

- How and why specify cereal or just mention “gluten”?
- Is it necessary to specify nuts (breakdown all 8) or just mention “nuts”?
- Scope and definitions:
  - pre-packed foods and foods prepacked for direct sale (PPDS)
  - artisan products pre-packed and non prepacked foods
- How to perform a *qualitative* risk assessment (artisan products)?
- Supply chain needs to pass through cross-contact amounts and can not perform QRA themselves. When is cross-contact not relevant (<x ppm?)
- European harmonization/ free movement of goods (multi-lingual labels)



## Count down – only half a year to go

Food industry is preparing themselves

- Waited (too long) for official publication policy/ Q&A document
- Fear of removing PAL
- Despite GFSI certification
  - No complete and up-to-date raw material information
  - Cross-contact information in supply chain is difficult to obtain (no PIF)
  - Cleaning validation is often lacking or no worst-case design
- From “I can not exclude” to “I know” is difficult transition
- Big need for European and global harmonization

