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# May contain **allergens!**

On January 1, the Dutch Ministry of Health instituted a new allergen policy using precautionary allergen labeling (PAL). For consumers with food allergies, this means more clarity around products where allergens may be unintentionally present.

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bout 3% of the population has a food allergy; in the Netherlands, this equates to over half a million people. Ingesting an allergen can be hazardous to their health. European legislation requires that allergens in ingredients used in food must be clearly stated on the label. This obligation also applies to nonprepackaged products used in catering and specialty stores.

#### Unintentionally present

Allergens can also get into food unintentionally, for example through raw materials contaminated with allergens or cross-contamination in the factory or supply chain . For these "unintentionally present allergens," there were no rules for labeling the possible presence of allergens, or precautionary allergen labeling (PAL), until this year. This caused confusion. For example, to be on the safe side producers warned of the possible presence of allergens when there was none. As a result, consumers with allergies were unnecessarily limited in their food choices. It would also be the case that producers did not warn of an allergen, unaware of a cross-contamination.

#### New policy

The new Dutch allergen policy came about after intensive consultations between the Ministry of Health, Welfare and Sport, the Netherlands Food and Product Safety Authority (NVWA), the food industry and patient organizations, which established reference doses, wording and allergen status. The starting point for the new policy was that PAL warnings may only be issued if an assessment shows an actual risk. The new policy will ensure fewer warnings. Not only will consumers have more clarity, but producers and authorities will also know how a risk should be determined.

#### **Reference doses**

With the new policy, the 2016 thresholds were dropped. Previously, the NVWA's Office for Risk Assessment & Research determined preliminary reference doses which food producers could use to conduct their own risk assessments. These reference doses were based on a reaction in 1% of people with allergies. The new reference doses [Table 1] for PAL are set based on the FAO-WHO standard, whereby a maximum of 5% of people with allergies may have a (mild) reaction when eating a product with an allergen content below the threshold. This means that if there is no mention of allergens on the package, there is no warning of an allergen and >

### Guidelines for producers

To help companies with the new allergen policy, the trade associations for the Dutch food industry and retail, FNLI and CBL, have jointly written guidelines on what measures companies should take to prevent cross-contamination, such as cleaning the production process, risk assessment, risk communication, and being able to analyze allergens and different types of contamination. The contents of the guidelines are endorsed by the NVWA and can be used as a starting point for monitoring.

thus 95% people allergic to that allergen can safely eat the product. The advantage of increasing the reference doses is that warnings are not required for numerous products that previously had them. The patient organizations involved in drafting the new policy therefore found the increase from 1% to 5% acceptable.

#### Wording

In addition to the thresholds, the new policy also updates the food label. If a risk assessment shows that the reference dose may be exceeded, PAL is mandatory. If the reference dose is not exceeded, PAL is not allowed. Warnings about the possible presence of allergens are allowed in only two ways: "May contain X" and "Not suitable for X", where X stands for one or more allergens.

#### The Netherlands and Europe

In the Netherlands, PAL has a legal status and will be converted into an official policy once published in the Dutch Government Gazette ("Staatscourant"). Food producers have two years to implement the policy and, if necessary, adjust PAL on their

## Key definitions

#### Reference dose:

The absolute amount of allergenic protein (mg) that entails an acceptable risk of reaction in an allergic consumer and can thus be considered a safe limit. Acceptable means that no serious symptoms occur.

#### Threshold value:

The concentration of an allergen in a product at which a proportion of allergic consumers may have a (mild) reaction when eating a product with protein values below the threshold. The new policy applies a value of 5% of allergic consumers.

#### Action level:

Conversion of the reference dose to an action level requires a serving size. The serving size is the amount of product consumed in one sitting (within about half an hour).

food products. As of a production date of January 1, 2026, all labels must comply with this policy. The new policy applies only to pre-packaged foods and not to non-prepackaged products such as those sold in catering and specialty stores. With the rules for PAL, the Netherlands is leading the way in Europe and the rest of the world. It is expected that the new threshold values will be adopted at the European and international levels (the Codex Alimentarius).

1. Nuts (cashews, almonds, walnuts, pecans, pistachios, Brazil nuts, macadamia nuts)	1.4 (cashews)	1.0
2. Hazelnuts	0.011	3.0
3. Celery	-	1.0
4. Egg	0.0043	2.0
5. Fish	-	5.0
6. Peanuts	0.015	2.0
7. Lupin	0.83	15.0
8. Milk	0.016	2.0
9. Mustard	0.022	0.40
10. Sesame	0.1	2.0
11. Crustaceans	3.7	200.0
12. Soy	0.078	10.0
13. Gluten-containing grains/wheat	0.14	5.0 (maximum action level: 20 mg gluten/kg*)
14. Molluscs	-	20.0

\* An action level has only been set for wheat. Because the action level for gluten-free products may be higher than the maximum level, the action level is capped at 20 parts per million. www.allergenenconsultancy.nl

Table 1. Allergens for which a warning on the label is mandatory and corresponding reference doses according to the NVWA (2016) and the Dutch Ministry of Health (2024).

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