Ministerie van Volksgezondheid,
Welzijn en Sport

Regulation of the State Secretary for Health, Welfare and Sport, of [date, No], laying down policy rules on cross-contamination with allergens and precautionary labelling (Policy Rule on Precautionary Labelling)

The State Secretary for Health, Welfare and Sport,

Having regard to:
- Article 14(1) and (2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31);
- Annex II, Chapter IX, point 9 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on food hygiene (OJ 2004 L 139);
- Article 36(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) 1924/2006 and (EC) 1925/2006 of the European Parliament and of the Council and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304);
- Article 4:81(1) of the General Administrative Law Act [Awb];

Hereby decrees as follows:

Article 1

In this Policy Rule, the following terms and definitions shall apply:
- *artisan food products*: food products supplied directly by the producer in small quantities to the final consumer, or to local retail establishments directly supplying the final consumer;
- *precautionary allergen labelling*: information on the possible unintended presence in food of substances or products that may cause allergies or intolerances.

Article 2

1. Precautionary allergen labelling is based on findings of a risk assessment carried out by food-business operators.
2. Precautionary allergen labelling shall only be applied if the risk assessment referred to in paragraph 1 reveals that one or more of the reference values set out in the Annex have been exceeded.
3. By way of derogation from paragraph 2, allergen labelling may be applied as a precautionary measure to artisan foods if the risk assessment shows that cross-contamination with one or more of the allergens listed in the Annex is possible in practice.
4. The wording ‘May contain xxx’ or ‘Not suitable for xxx’ shall be used when precautionary labelling is applied.

Article 3

This Policy Rule shall come into force on 1 January 2026.

Article 4

This Policy Rule shall be cited as the: Precautionary allergen labelling.

This Policy Rule, along with its explanatory notes, shall be published in the Government Gazette.

The State Secretary for Public Health, Welfare and Sport,

Annex to Article 2

Annex Reference values for risk assessment
(Annex as referred to in Article 2(2) and (3) of the Policy Rule on Precautionary Labelling)

Allergen	**Recommended reference dose on the basis of ED_{05} (mg of total protein of the allergen)**
Egg	2.0
Lupin	15.0
Milk	2.0
Mustard	0.40
Nuts:	
- Almond	1.0
- Cashew nut	1.0
- Hazelnut	3.0
- Macadamia nut	1.0
- Brazil nut	1.0
- Pecan nut	1.0
- Pistachio nut	1.0
- Walnut	1.0
Peanut	2.0
Crustaceans	200.0
Celery	1.0
Sesame	2.0
Soybean	10.0
Wheat / Cereals containing gluten	5.0*
Fish	5.0
Molluscs	20.0

* For cereals containing gluten, the reference value of wheat shall be 5.0 mg unless the final product exceeds the concentration of 20 mg/kg gluten. In that case, this applies as a boundary.

Conversion of reference dose (RfD) to action limit
This reference dose should be converted into a concentration in mg/kg (ppm), known as the action limit. The conversion of the absolute amount of the reference dose to an action limit is set out below.

The reference dose is an absolute protein amount of an allergen (mg) per dosage/meal. This is not equal to a concentration (mg of protein of an allergen / kg product = ppm). To convert the RfD into an action limit, the following formula is used:

$$Actielimiet\ (ppm) = \frac{referentiedosis\ (in\ mg)}{consumptiegrootte\ (in\ kilo)}$$

Actielimiet (ppm)	Action limit (ppm)
Referentiedosis (in mg)	Reference dose (mg)
Consumptiegrootte (in kilo)	Consumption size (in kilos)

Explanatory Notes

I. General

1. Introduction

This Policy Rule specifies the use of allergen labelling as a precautionary measure, also known as precautionary allergen labelling (hereinafter: PAL). The purpose of this Policy Rule is to clarify when there is cross-contamination with allergens and when allergen labelling should be applied as a precautionary measure.

Substances or products that cause allergies or intolerances (hereinafter: allergens) may inadvertently become present in food as a result of cross-contamination. Cross-contamination occurs when an allergen inadvertently becomes present in a food at a low concentration. This can occur due to contamination of the raw material used or contamination during production. The possible and unintended presence of allergens in food poses a health risk to consumers with food allergies. Therefore, it is first and foremost important to prevent or to minimise the risk of cross-contamination by taking preventive measures. A risk assessment must reveal whether the preventive measures have been sufficiently effective. Only if this risk assessment reveals that the product in question can pose an actual risk to consumers with a food allergy should allergen labelling be applied as a precaution.

The correct application of allergen labelling as a precaution is important, on the one hand, because very low concentrations of an allergen can lead to very serious reactions and consequences in some consumers with a food allergy. On the other hand, the unnecessary and/or excessive use of allergen labelling as a precautionary measure may limit the food choice of consumers with food allergies and increase the risk of developing nutrient deficiencies. Finally, there is a possibility that consumers with allergies may take the PAL indication less seriously, resulting in health risks.

Consumers are partially protected in the field of allergens by Regulation (EU) No 1169/2011[1], which requires the indication of 14 allergens when they are present as ingredients in prepacked or non-prepacked foods. Mandatory indication of food allergens in accordance with this Regulation shall not be required where a food allergen is present in a food as a result of cross-contamination. For this purpose, this Regulation defines a voluntary warning (PAL). Due to the absence of European regulations on PAL, in 2016 the Risk Assessment & Research Office (hereinafter: BuRO) of the NVWA (Netherlands Food and Product Consumer Safety Authority) proposed reference values for the possible presence of a certain allergen in a product that may trigger an allergic reaction.[2] The proposed reference values were

[1] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 2011).

[2] BuRO, 2016. Opinion on provisional reference doses for allergens in foods. Utrecht.

provisional, as the availability of information was limited and there was uncertainty regarding the calculation of the available reference values and the possible health effects when choosing a certain threshold.

In 2021, the Ministry of Health, Welfare and Sport requested BuRO to evaluate the 2016 Opinion on reference values in response to various concerns from the field and lawsuits against the NVWA's actions. These reference values were based on the information publicly available underlying the Voluntary Incidental Trace Allergen Labelling (VITAL) system developed by the Allergen Bureau of Australia and New Zealand.
Meetings of the Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens (hereinafter: FAO/WHO Expert Committee) took place in 2020 and 2021. The purpose of those meetings was, inter alia, to establish reference values. BuRO has examined whether the reference values proposed by the FAO/WHO Expert Committee lead to a different level of public health protection.

BuRO's assessment led to a new opinion in 2022.[3] In summary, BuRO recommends setting reference values at national level until European rules are in place. These reference values are used to determine whether or not PAL should be used. It is important that the PAL wording is informative, and offers the allergic consumer a perspective for action.
Based on BuRO's advice, it was decided to use the reference values proposed by the FAO/WHO Expert Committee as a starting point. These reference values are to be discussed by the Food Labelling Committee within the framework of Codex and are to be established in a Codex standard. The reference values proposed by the FAO/WHO Expert Committee are based on the ED_{05} values[4] which are considered a safe starting point. This differs from the reference values chosen in 2016 in the Netherlands based on the ED_{01} value. BuRO advised these values at the time on the basis of precaution, and the limited publicly available information on the ED values. The new choice of the ED_{05} as a reference value means accepting that the probability of allergic patients having an allergic reaction is increased from 1 % to 5 % of the population with allergies. This is by definition a higher number of allergic reactions, which is acceptable in the eyes of the patient organisations. The current use of ED_{01} does not provide a significant health benefit over ED_{05}, as with ED_{05} almost only mild or moderate reactions will occur. The use of ED_{01}, on the other hand, reduces the food choice of patients with allergies, which is why the use of ED_{05} is seen as an optimal balance. Ultimately, the new allergen policy will ensure that the presence and absence of a warning for consumers with allergies become significantly more reliable.

For a number of allergens, such as lupin and celery, the FAO/WHO Expert Committee did not propose any reference values at the time of drafting the new allergen policy. This is because there is a difference between Regulation (EU) No 1169/2011, which lists 14 substances as allergens, and the food allergens in the Codex Standard (GSLPF). Since then, a publication has been issued with reference

[3] BuRO, 2022. Opinion on reference values for allergens in foods. Utrecht.

[4] Eliciting dose (ED) is the dose at which an allergic reaction is induced. Eliciting doses (EDs) of allergenic foods can be defined by the distribution of threshold doses for individuals within a specific population. The ED_{05}, for example, means a residual risk of 5 %, meaning the dose at which a reaction can be expected in 5 % of the population with allergies. Or, in other words, ED_{01} and ED_{05} values predict the occurrence of objective allergic symptoms in 1 % and 5 % of the with allergies, respectively (Houben et al., 2020).

values for lupin and celery.[5] These reference values have not yet been established in the context of Codex, which is why these values have not been included in the current policy. It is to be decided at a later stage whether these reference values are to be included in the Policy Rule.
Reference values for allergens listed in Regulation (EU) 1169/2011 but not in the FAO/WHO proposal are based on the ED_{05} from underlying documents, such as the BuRO Opinion. These reference values are based on an analysis of the scientific data available.

2. Legal framework

Regulation (EG) 178/2002:
Pursuant to Article 14 of Regulation (EC) No 178/2002[6], food shall not be placed on the market if it is unsafe. When assessing whether a food is unsafe, account shall be taken, inter alia, of the information provided to the consumer, including the information on the label, or other information generally available to consumers regarding the avoidance of specific adverse health effects of a particular food or category of food. For consumers with allergies, it is important that the information on the label warns if an allergen is present in quantities that may pose an actual risk. A PAL should therefore only be used if it appears that, despite preventive measures, there is a risk to consumers with allergies. In that case, cross-contamination exceeds the safe limit.

Regulation (EU) 1169/2011:
Pursuant to Article 9(1)(c) of Regulation (EU) No 1169/2011, certain allergens that are intentionally used in the manufacture or preparation of a food and are still present in the final product must be indicated on the label of that food.
Information on the possible unintended presence of allergens in food may be provided on a voluntary basis.[7] To date, the European Commission has not established any requirements for this information. Until such harmonised rules are adopted, it is the responsibility of food-business operators to ensure that, where such information is provided, it is not misleading, ambiguous or confusing for consumers.[8] Therefore, a PAL shall not be used if the risk assessment reveals that the safe limit is not exceeded or the risk of cross-contamination is not demonstrable.
This Policy Rule shall be repealed when the Commission has established rules.

Regulation (EC) 852/2004

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[5] FAO/WHO, 2023. Risk assessment of food allergens: Part 5: review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats: meeting report.

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 2002)

[7] See Article 36(3)(a) of Regulation (EU) No 1169/2011.

[8] See Article 36(2) of Regulation (EU) No 1169/2011 and Annex I, point 3.7 of the Communication from the Commission on the implementation of food safety management systems consisting of good hygiene practices and procedures based on the HACCP principles, including the promotion/flexibility of implementation in certain food businesses (2022/C 355/01) (OJ 2022, C 355).

In 2021, Regulation (EC) No 852/2004 was amended.[9] The amendment includes the introduction of hygiene rules to prevent or minimise cross-contamination of food with allergens, both during primary production and at subsequent stages in the food chain.[10] It lays down rules at European level to prevent or reduce the unintended presence of allergens in food. In a 2022 Commission Communication[11], further details are provided on the implementation of good hygiene practices required to prevent or reduce the presence of allergens due to food contamination. The Commission emphasises that preventive measures are the starting point for safe food, and that allergen labelling should never be used as a precautionary alternative to preventive measures.
Precautionary allergen labelling is a statement separate from the list of ingredients, and must be based on the findings of an appropriate risk assessment conducted by the food producer, in which the possible and unintended presence of allergens is evaluated.

3. Impact on regulatory burden

This Policy Rule does not lead to changes in the regulatory burden on citizens. However, consequences for the regulatory burden on businesses are to be expected. The main burdens for them are related to substantiation and quantification of cross-contamination, and the adaptation of labels. A rough estimate of the administrative tasks for substantiating cross-contamination is:

- Contacts with raw material suppliers to receive quantitative data
- Conversion and entry of allergen levels into specification and other business systems
- Keeping data and specifications up to date
- Analysis costs
- Adaptations to work processes and administration

For the adjustment of the labels, tasks and costs are mainly expected in the area of wording adjustments in systems and label design & control, as well as lithography and printing costs. The costs related to this are estimated at EUR 200 000 for multinationals and EUR 50 000 for SMEs.

4. Consultation

In terms of content, this policy was drawn up in collaboration with the NVWA and various stakeholders from the field, including the Dutch Food Industry Federation (FNLI), the Central Food Trade Office (CBL), the Dutch Celiac Association and the Food Allergy Foundation. The draft of this Policy Rule has therefore been submitted for consultation and discussed with these parties. In addition, the draft of this Policy Rule has been submitted to the participants in the Regular Consultation on the Commodities Act (ROW) for consultation.[12] As a result of this consultation,

[9] Commission Regulation (EU) 2021/382 of 3 March 2021 amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, food redistribution and food safety culture (OJ L 74, 2021).
[10] See Annex I, Part A, point 5bis and Annex II, Chapter IX, point 9 of Regulation (EC) No 852/2004.
[11] Communication from the Commission concerning the implementation of food safety management systems consisting of good hygiene practices and procedures based on the HACCP principles, including the promotion/flexibility of implementation in certain food businesses (2022/C 355/01) (OJ 2022, C 355).
[12] The ROW includes representatives from businesses (industry and trade), consumers, Ministries (in particular the Ministry for Health, Welfare and Sport and the Ministry for

adjustments have been made to the Policy Rule. A provision relating to artisan foods has been added to Article 2 of this Policy Rule. These foods are already subject to an exception for nutrition labelling under Regulation (EU) No 1169/2011. For the purpose of the risk assessment of the artisan food, a precautionary warning for a particular allergen may be issued without it being demonstrated that the possibility of exceeding the reference value exists. The company responsible shall have to be able to demonstrate with a risk assessment that cross-contamination with the relevant allergen is possible in practice. A precautionary warning may only be given for the allergens listed in the Annex.
Finally, the explanatory memorandum has been clarified on a number of points.

5. Enforceability and feasibility

The design of this Policy Rule has been assessed by the NVWA in terms of enforceability, enforceability and fraud-proofing. The NVWA is of the opinion that the proposed amendments are enforceable, practicable, and fraud-proof after clarification of a number of points. The required
inspection capacity of the NVWA shall be taken into account in the next annual plan process.

This Policy Rule clarifies when there is cross-contamination with allergens and when allergen labelling should be applied as a precaution. If allergen labelling is wrongly not applied as a precautionary measure,, the NVWA may take enforcement action on the basis of Article 14 of Regulation (EC) No 178/2002. If, as a precautionary measure, allergen labelling is applied incorrectly, the NVWA may take enforcement action on the basis of Article 36(2) of Regulation (EU) No 1169/2011.

6. Notification

The draft of this Policy Rule was notified on [date] to the European Commission in order to comply with Article 5(1) of Directive (EU) 2015/1535.[13] Notification to the European Commission is required, as Article 2 may contain technical regulations within the meaning of Directive (EU) 2015/1535. [PM]

II. Article by article

Article 2 and the Annex

Precautionary allergen labelling is only applied to food or beverages that, despite preventive measures, may pose an actual risk to consumers with a food allergy.

The starting point when using allergen labelling as a precautionary measure is that food-business operators are obliged to provide consumers with clear and fair food information. This means that this information should not mislead or confuse consumers and should be based, where necessary, on scientific data. A risk assessment will be conducted in order to determine whether allergen labelling is necessary as a precaution and not misleading. A directive has been drawn up

Agriculture, Nature and Food Quality) and the Netherlands Food and Consumer Product Safety Authority [NVWA].

[13] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 concerning an information procedure on technical provisions and rules regarding the services of the information society (codification) (OJ 2015, L 241).

outlining the requirements for a risk assessment.[14] A risk assessment establishes whether there is an actual risk to the allergic consumer in case of cross-contamination. Reference doses based on scientific data will be used for the risk assessment.

If all preventive steps have been taken and the validation and risk assessment subsequently reveal that the reference value has been exceeded and unavoidable cross-contamination may pose a risk to the allergic consumer, the use of allergen labelling is in that case necessary as a precaution to inform consumers.

Where allergen labelling is used as a precaution, it is to be supported by:
- information demonstrating that cross-contamination can actually occur in practice;
- a risk assessment (see above) revealing that the amount of allergen exceeds the safe limit; and
- documentation revealing that preventive measures have been taken, and allergen labelling is not used as a precaution instead of taking preventive measures.

An allergen mentioned in allergen labelling as a precaution should not already be listed in the list of ingredients. With the exception of assortment packaging, where several variants are packaged, such as mixed chocolates, ice creams or snacks. The list of ingredients may be summarised for all products in the packaging. This also applies to allergen labelling as a precaution.

The wording ‘May contain xxx’ or ‘Not suitable for xxx’ shall be used when precautionary labelling is applied. This wording makes it clear to the consumer that for the food in question, there is a real risk of the presence of a (certain amount of) allergen.

The State Secretary for Public Health, Welfare and Sport,

[14] Guidelines on cross-contamination of allergens. FNLI, CBL and NVWA. April 2024 version.