Guidance on requirements and recommendations for the use of precautionary allergen labelling (PAL) for food products.

Preface

This guidance has been developed by the Swedish Food Retailers Federation, Menigo and Martin & Servera. The document aims to inform about requirements and recommendations to improve the scientific value of allergen warning labelling (PAL) and to increase the credibility of such warning labelling for consumers.

Swedish Food Retailers Federation (Svensk Dagligvaruhandel) is the trade organisation for the grocery trade in Sweden that works to ensure that retailers take active and shared responsibility for competition-neutral issues.

Menigo is one of Sweden's largest food distributors and delivers food, drinks, consumables, restaurant equipment and related services to private and public organisations.

The Martin & Servera group is Sweden's leading wholesaler for restaurants and catering. The companies in the group supply beverages, food, equipment, non-food, chemicals and services to hotels, restaurants, cafés, public catering establishments and shops.

Authors and reference group

Anders Nilsson (ANFC), Annika Bengtzon (ICA), Ann-Julie Johansson (Menigo), Elise Nassab (Coop), Helena Björck (Axfood/Dagab), Karin Billinger (Martin och Servera), Karin Vigerland (ICA), Mia Broden Borgvall (Lidl), and Mona Lauremann Orheden (Swedish Food Retailers Federation).

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Definitions

PAL - Precautionary Allergen Labelling

- Voluntary alert labelling (PAL), e.g., "May contain traces of .... (allergen)". Used by food producers to inform the consumer of the risk that named allergens may be present in a food product due to accidental contamination.

PAL risk assessment

- A quantitative risk assessment based on reference doses, portion size and consumption data, sampling and analysis that can serve as a basis for companies to evaluate whether or not PAL labelling is necessary.

VITAL® - Voluntary Incidental Trace Allergen Labelling

- The Australian VITAL programme is a risk-based method for food producers to use to assess the impact of cross-contact with allergens. This is to enable appropriate allergen warning labelling (PAL) as described above. For information, see www.allergenbureau.net

UAP - Unintended Allergen Presence

- Unintentional presence of allergens (UAP) can be due either to cross-contact, mistakes in food processing or mislabelling of raw materials in production.

Allergens and food allergies

- Proteins or parts of proteins in foods that can induce immunological reactions in people who cannot tolerate them. Such reactions involve IgE antibodies or certain types of cells. IgE-induced reactions are known as food allergies. The symptoms of an allergic reaction can range from mild to severe, and in the worst cases can lead to death.

Gluten/intolerance - coeliac disease

- Gluten is a protein found in wheat, rye and barley. Coeliac disease is an autoimmune disease in which gluten affects the immune system, causing damage to the small intestine. People with coeliac disease can experience stomach pain, diarrhoea and a lack of certain nutrients, which in turn can cause symptoms such as tiredness, depression or failure of children to grow properly.

Other hypersensitising foods

- Foods that can induce other non-immunological reactions. These include enzyme deficiencies defects such as lactose intolerance, pharmacological reactions (e.g., histamine) and other reactions to food that occur via as yet undefined mechanisms.

Producer

- Produces food within the EU or is responsible for imports into the EU from third countries (outside the EU), which have producer responsibility under EC Regulation 178/2002.

Supplier/distributor

- An intermediary (food company, industry or agent) that resells food products not produced by them to, for example, the Swedish Food Retailers Federation members, supermarkets and restaurants.

Reference Dose - ED=Eliciting Dose / Trigger Dose

- The amount of protein in milligrams that is estimated to induce reactions in a defined proportion (%) of the allergic population.
- The levels ED01 (1% of allergy sufferers react) - ED05 (5% of allergy sufferers react) have been recommended by the Allergen Bureau and FAO/WHO as appropriate reference doses for use in PAL risk assessment. The Swedish Food Agency does not take a position on which ED levels should be used and indicates a wide range (ED01 to ED50 (Allergen Bureau 2019 SU; FAO/WHO 20 August 2021; Livsmedelsverket 2022). See also table Annex 2.

Portion/consumption size

- As food allergy is an acute reaction to the ingestion of a food, the consumption data used should be data from one eating occasion (meal). The maximum amount of food consumed by adults in a population during a meal can be specified at different levels (e.g., 75%/90%/95% of a population)**.** Note that VITAL 3 calculations are based on the portion size indicated on the package according to the *AFGC Code of Practice for Food Labelling and Promotion* (see Allergen Bureau 2021 VI, et al.). No correction is made for those consumers who consume large quantities.

Measurement uncertainty - a specified margin of error for a measurement result.

- Accredited laboratories shall report the expanded measurement uncertainty, *U*, with an approximate 95 % confidence interval. *U* is calculated from the standard uncertainty, *u,* and a so-called coverage factor, *k*. The coverage factor for the 95 % confidence interval is normally "2". Extended measurement uncertainty is calculated as follows: $U = 2 \times u$.
  Comment: One standard deviation, *s,* describes the random errors in a measurement while a standard uncertainty, *u*, also takes into account systematic errors such as differences between different analytical methods or laboratories.

Guard band

- A safety margin is used to ensure that the reference dose is not exceeded. The reference dose is reduced by the guard band when the decision limit is set (see below).

  Guard bands are calculated with a factor of 1.64 (one-sided range, established in the references below) which provides a sufficiently safe decision limit (95% confidence). The factor 2 is also used but is not recommended by statisticians as it gives unnecessarily low decision limits in case of high measurement uncertainty and is thus costly for producers and brand owners. See references Eurachem/CITAC compliance leaflet (2021) and Guidelines from the Global Organisation for Accredited Laboratories ILAC (2019).[1]

  Guard bands are calculated from

  1. Reference dose (mg)
  2. Measurement uncertainty of the analytical method, *U* (%)

[1] In ILAC G8 a factor of 0.83 is given which is ≈ 1.64/2 for the 95 % confidence in Table 1. Confidence is given as PFA probability of false acceptance 5 %.

Example:

1. Reference dose 0.7 mg
2. Measurement uncertainty, *U* = 30 %

Guard band becomes (0.7 * 1.64 *(*U/2*) / 100 = 0.17 mg.

Decision limit

- A decision limit is compared with analytical results to assess whether PAL should be used.
- The decision limit is calculated from
  1. Reference dose
  2. Guard band
  3. Portion size

Example:

1. Reference dose (E01) 0.7 mg
2. Guard band is 0.17 mg
3. Portion size 0.35 kg

The decision limit is (0.7 - 0.17) / 0.35 ≈ 1.5 mg/kg.

Summary of the guidance

Swedish Food Retailers Federation's requirements and recommendations for the use of allergen warning labelling - PAL

Warning labels for allergens "May contain traces of..." are used to inform about the risk that an allergen may be present as a contaminant in a food product. Internationally, such warning labels are called PAL - Precautionary Allergen Labelling.

Surveys among allergic consumers show that PAL currently lacks credibility and does not help to reduce the risk of allergic reactions. Experience shows that PAL is not always linked to whether there is an actual risk of an allergic reaction. Much work is ongoing in Sweden and internationally to address this. More information on this work can be found in the guidance.

In anticipation of uniform EU legislation, the Swedish Food Retailers Federation, together with its partners, has summarised the requirements and recommendations for better use of PAL so that the labelling is of benefit to allergic consumers. Suppliers and producers of own brand products to any of the Retailers Federation's member companies are expected:

- Be certified against a food safety standard. This standard must be recognised by the Global Food Safety Initiative (GFSI, see https://mygfsi.com/).
- Have a food safety management system based on one of the established industry guidelines for managing and labelling the presence of allergens (see examples in this guidance).

For the PAL risk assessment

1. Decisions on PALs should be based on a quantitative risk assessment. The mere detection of an allergen in a food, without an evaluation of whether the detected amount could be harmful - a "zero tolerance assessment" - is not an acceptable basis for using the PAL.
2. The reference doses used in the risk assessment are recommended to be at ED01 or ED05 level (the amount at which 1% and 5% of allergic consumers react, respectively).
3. The amount of food used in the risk assessment should be based on what 75% of a population consumes at one time. Other portion / consumption sizes need to be justified.
4. The amount of allergenic protein in a food product needs to be determined (verified) by means of a sampling plan and an analysis. The number of samples is affected, for example, by whether the allergen is homogeneously or heterogeneously distributed in the food, or whether a theoretical risk assessment for particulate allergens or VITAL calculations have been carried out.
5. Analytical data should be converted (when necessary) to the total amount of protein in the allergenic ingredient. Currently, ELISA methodology is recommended to enable this, but quantitative PCR or LC-MS methods can also be used when those are developed to give reliable results.
6. Analyses should be performed by laboratories accredited for the above-mentioned methods.
7. A safety margin based on the measurement uncertainty of the analytical results shall be used in calculations to assess whether PAL should be used.

If these requirements and recommendations can be met, the PAL - the 'May contain traces of' warning label - will be more credible and will be of great benefit to allergic consumers.

Background - Allergen warning labels (PAL) lack credibility

Precautionary Allergen Labelling (PAL) is used to inform the consumer of the risk that allergens may be present in a food product. Such unintentional presence of allergens (UAP) can occur in different ways. Most commonly, it is through contamination (cross-contact) during the manufacture of either the product or one of its ingredients, including agricultural raw materials.

The current application of PAL does not help allergic consumers make safe product choices. Internal and research shows that consumers see PAL as unhelpful and confusing, and have little confidence in the rationale behind the use of PAL. Various articles describe how warnings for allergens detected analytically do not always correlate with either the absence or the concentration of the identified allergen. Consumers may face increased costs and ultimately affect their quality of life.

A lack of consensus that PAL needs to be based on quantitative risk assessments leads to increased costs for producers and brand owners. The "zero tolerance" model used by some companies and authorities can lead to increased food waste, unjustified recalls and high costs associated with these. Ultimately, unclear PAL labelling is a threat to companies' market shares, brands and profitability.

(Blom, et.al. 2018; Do, et.al. 2018; Dunn-Galvin et.al. 2015; FoodDrink Europe 2021; ILSI Europe 2022; ISSLG, 2020; Madsen et.al. 2020; Sjögren Bolin & Lindeberg 2016; Livsmedelsverket 2022; Soon et.al. 2017).

Reasons for the lack of credibility of the PAL include, for example:

- Some manufacturers, consumers and other stakeholders do not understand current strategies for managing and communicating PAL.
- A wide spread and increased use of PAL in several product categories.
- Confusing terminology that gives the impression of a risk hierarchy, unsupported by experimental evidence.
- Lack of agreed standards for the application of PAL.
- Knowledge of PAL and how to minimise the risk of allergen contamination at the farm level has only recently begun to be discussed.

This means that the PAL (labelling "May contain traces of...") is not always linked to the actual risk to the consumer.

The use of a scientific risk-based approach to PAL assessment has been prioritised in recent years by EU working groups, position papers by organisations such as FoodDrink Europe**,** FAO/WHO and the International Life Sciences Institute (ILSI). This will result in reducing "unnecessary warnings" and increasing the credibility of PAL for consumers.

Introduction

The use of PALs for allergens is unregulated in the EU and many other countries. There is also no standardised method for evaluating the need for PALs. Several EU authorities apply a 'zero tolerance' approach, so that only the detection of adventitious allergens requires PALs, regardless of the amount detected. Other EU countries, including Sweden, promote a risk-based approach using reference doses, consumption data, validated sampling and analytical methods. This lack of consensus has implications not only for PAL application, but also for

food recall from the market (Dunn-Galvin et.al. 2019; FoodEurope 2021; ILSI Europe 2022; Madsen et. al. 2020).

PAL is currently used on several different types of food and is more common in certain areas, such as chocolate products and other confectionery. There are indications of increased use of this labelling on several different types of products, not least because of the risk of contamination in the cultivation stage and early in the food chain. Work to develop and introduce national and international guidelines for PAL has been ongoing for many years (Dunn-Galvin et.al, 2019; FAO/WHO 2022, 20 August & 13 December 2021; Food Allergy Canada 2022; ILSI Europe 2022; Sjögren Bolin 2015).

The use of PAL requires that all growers, raw material suppliers and producers in the food chain have knowledge of allergens and have effective systems in place to risk assess and prevent the accidental presence of small amounts of allergens.

Senior management in companies need to support and prioritise the use of a risk-based approach (Yeung & Robert 2018). Education of consumers, caregivers, food business operators, risk assessors and risk managers is essential for PAL to achieve its purpose (FAO/WHO 13 December 2021; FoodDrink Europe 2021; Madsen et.al. 2020).

The Swedish Food Retailers Federation and its partners participate in allergen networks and closely follow the development of PAL guidelines together with representatives of consumer organisations, food producers, restaurants and Swedish authorities.

In 2022, the Swedish Food Agency updated the guidelines for risk assessment for undeclared allergens genes. In the same year, ILSI Europe published a guidance document with methods and approaches, aiming to harmonise the application of risk assessments and the use of PALs. Interestingly, the Allergen Bureau also published an updated document *Assessing Agricultural Cross Contact*. These documents are important tools, with information that has been incorporated into this version of the Swedish Food Retailers Federation and their partners' guidance (Allergen Bureau 2022 AC; ILSI Europe 2022; Livsmedelsverket 2022).

Objective

The purpose of Swedish Food Retailers Federation requirements and recommendations is:

1) To improve the scientific value of allergen warning labelling (PAL).
2) To increase the credibility of such warning labels for consumers.

The guidance summarises these requirements and recommendations for allergens and gluten in foods on the EU list (EU Regulation 1169/2011). Lactose and sulphite, which are not potentially as acutely dangerous for sensitive consumers, are not covered by the possibility of labelling with PAL.

Application

The requirements and recommendations set out in this guidance need to be fulfilled in order to justify the warning label 'May contain traces of' for foods.

A Risk Assessment Evaluation Guide for Traces of X (PAL) *labelling* has been developed to summarise the requirements and recommendations, and to assist in evaluating compliance and use where appropriate (see Annex 3).

The compilation of the requirements and recommendations and the related guidance document will be updated as new knowledge becomes available on risk assessments on

allergens, reference doses, portion/consumption sizes, sampling and analytical methods (including certified reference materials) and any legislation that may regulate this.

Prerequisites for the use of PAL

Suppliers and producers of own-brand products to any of the Swedish Food Retailers Federation members must, as a basic requirement, be certified against a food safety standard recognised by the Global Food Safety Initiative (GFSI, see https://mygfsi.com/).

A PAL label highlighting the risk of contamination should never be used as an excuse for poor control and hygiene management practices. The EU Regulation 852/2004 states that food business operators shall establish, maintain and demonstrate an appropriate food safety culture that emphasises, among other things, a committed management and staff to ensure the safe production and distribution of food.

In order to justify the use of PAL, companies need to have a food safety management system that is also based on one of the following sectoral guidelines:

- Food industry and retailers' food sector guidelines for Management and labelling of food products - Allergy and other intolerance (April 2015) (Swedish national guidelines approved under Article 7 of EC Regulation 852/2004) - www.livsmedelsverket.se
- Guidance on Food Allergen Management for Food Manufacturers Version 2, FoodDrinkEurope (2022) - www.fooddrinkeurope.eu
- Food Industry Guide to Allergen Management and Labelling, Allergen Bureau (2021) - www.allergenbureau.net
- Assessing Agricultural Cross Contact, Allergen Bureau (2022) - www.allergenbureau.net
- Components of an Effective Allergen Control Plan, A framework for food processors, Food Allergy Research & Resource Program (2008) - www.farrp.org
- Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment within Food Operations (ILSI Europe 2022). https://ilsi.eu
- Allergen management guidelines for food manufacturers, Food Allergy Canada (September 2022) - https://foodallergycanada.ca/
- Other national or international guidelines for "Allergen management" that are equivalent in scope to those above can be accepted, provided that the Swedish Food Retailers Federation members and owners of their own branded products have been informed and approved.

GFSI-recognised standards such as BRCGS, FSSC 22000 and IFS require certified companies to meet legal and customer requirements also in the country where the food is to be sold. For such certification, the company must be able to demonstrate, among other things, that it knows and uses industry guidelines and new scientific findings that are relevant to its food safety work.

The food safety management of suppliers and producers should address the entire food chain including agricultural practices, storage, transport and production processes, as described for example in the *Code of practice on food allergen management for food business operators* and introduced as a legal requirement in the EU hygiene regulation (Allergen Bureau 2022 AC; Codex Alimentarius 2020; EC Regulation 852/2004; ILSI Europe 2022).

Some producers have achieved gluten-free certification according to an international standard (AOECS 2016; BRCGS 2019; BRCGS 2022). These do not address PAL risk assessment per se, but demonstrate an active and good work with the management of allergens.

The Swedish Food Retailers Federation assumes that companies' top management supports and prioritises the use of a risk-based approach (Yeung & Robert 2018).

All producers and suppliers of food products that sell to the Swedish Food Retailers Federation members' stores are expected to continuously update their expertise on allergens and other hypersensitivity-inducing foods and requirements and recommendations on the application of PAL.

Formulation of warning labelling

According to Swedish food sector guidelines for Allergy and other intolerance (2015), warning labelling (PAL) should be written "May contain traces of (allergen X)". The Swedish Food Retailers Federation also accepts the formulation "May contain (allergen X)" used by some producers and suppliers.

Labelling should be designed for each specific allergen, and group names should be avoided. For example, "May contain traces of nuts" should not be used but each specific nut variety should be indicated (Allergen Bureau 2021 FI; FoodDrink Europe 2021; Li&SvDH 2015; Sjögren Bolin & Lindeberg 2016; Svinddal 2012).

PAL may not be applied to food products specifically designed for, and declared as "Free from (allergen)" (EU Regulation 1169/2011, FAO/WHO December 2021 and other sources).

Vegan labelling does not guarantee that the food is completely free of eggs, milk, fish or shellfish. A person with a severe allergy cannot be sure that they can eat vegan labelled products. The Swedish Food Retailers Federation follows the recommendations of the Swedish Food Agency and the European Food & Drink Federation to accept the use of PAL on products labelled and marketed as "vegan". Production of such products does not guarantee that they fulfil the requirements to be "free from" milk, fish, crustacean, mollusc and/or egg contaminants (Food&Drink Federation 2020).

An alternative form of warning labelling that has been legislated in the EU is that certain 'novel foods' must carry information that they may be allergenic. For example, EU Regulation 2017/2470 requires that foods containing;

- rapeseed protein shall be labelled with a statement that this ingredient may cause an allergic reaction in people who are allergic to mustard and its products.

Similar labelling shall also be provided for foods based on

- partially defatted rapeseed powder
- extracts of three plant roots used in dietary supplements (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz, and *Angelica gigas* Nakai).
- mealworm (*Tenebrio molitor* larva), house cricket (*Acheta domesticus)* and European *locust* (*Locusta migratoria)* in frozen, dried and powdered form.

See the Novel Foods Regulation for more details and possible updates with novel foods. Please note that the potential allergens mentioned in the Novel Foods Regulation are not currently listed in Annex II of the Information Regulation on substances or products causing allergy or intolerance (EU Regulation 1169/2011).

The warning for these allergens in Novel Food should be placed near the list of ingredients (EU Regulation 2017/2470; IPIFF 2021). There is no information by March 2023 whether PAL may be used or has been used for allergens under the Novel Food Regulation. SvDH's view is that this should not happen.

Allergens that can be warned for

At present, Swedish food authorities and Swedish Food Retailers Federation accept the use of PAL only for the allergens listed in the EU regulation 1169/2011. Note that, for example, wheat (proteins) causes allergy and needs to be assessed separately from gluten which is found in several different types of cereals. PAL should not be used for other over sensitisation inducing substances such as lactose and sulphite (these two are included in the "EU list").

There are a large number of foods/ingredients that can induce allergic reactions and are not currently covered by the EU Information Regulation. Other examples include various pea plants, kiwi and insect proteins (FAO/WHO 2022; Li&SvDH 2015; Li&SvDH 2021). Companies' hazard analyses (HACCP plans, or equivalent) need to address these allergens as well. Management systems for food safety at producers, raw material and other suppliers of EVM products to the Swedish Retailers Federation need to be continuously updated with new knowledge and also include these other allergens.

Risk assessment that can justify the use of PALs

Article 36 of the EU Information Regulation (EU 1169/2011) states, among other things, that voluntary food information:

a) should not mislead the consumer.
b) should not be ambiguous or misleading.
c) should be based on relevant scientific data.

Article 36 also allows the EU to develop rules on voluntary information on the possible and unavoidable presence of allergens. There is no deadline set for this to be finalised.

Pending uniform EU rules, the Swedish Food Retailers Federation requires a decision on whether PAL labelling should be used based on a quantitative risk assessment. Documentation presented to the owner of own-brand products should describe reference doses, portion sizes, analysis and sampling methods, and results used in the assessment. A "zero tolerance assessment" where PAL is based on the sole detection of an allergen without evaluation of the impact on the final consumer is not accepted (Dunn-Galvin et.al. 2019; FAO/WHO 13 December 2021; Food Allergy Canada 2022; FoodDrink Europe 2021; ILSI Europe 2022).

The form and solubility of allergens and whether they are homogeneously (evenly) distributed or heterogeneously (unevenly) distributed (e.g., particulate allergens) in the food affects how and when the use of PAL can be justified (see section below *on Sampling*). The probability of accidental presence of allergens (UAP) and the heterogeneity determine the sampling plan.

There are few publications on assessing the risk of contamination by particulate allergens. The fear of severe outcomes has led to the use of PAL with particulate allergens (a recommendation given in the VITAL guides). ILSI Europe (2022) describes how risk can be assessed based on three different variables:

Particles:

- Size (volume) and mass.
- Composition.
- Distribution.

Some allergens can adhere very strongly to the substrate (e.g., production equipment). Whether water cleaning can be used or only dry cleaning (e.g., for muesli production) is possible also has a major impact. Cleaning needs to be adapted to the allergen and equipment and cleaning methods, and needs to be validated before they are put into use (see References for examples of guides from Dairy Food Safety Victoria (DFSV) and ILSI Europe). A good hygienic design of the equipment under helps. Production planning also has a major impact. By planning production sequencing so that allergen-free products are produced only after effective 'allergen cleaning' if allergens were used in previous production. This also reduces the need to label with PAL (DFSV 2018; ILSI Europe 2022; Li&SvDH 2021).

If an allergen is homogeneously distributed, it is possible to estimate its amount and concentration in the food and to assess whether or not a PAL can be justified on the basis of a reference dose. Particulate allergens are usually unevenly distributed in the food and even small pieces may individually contain an amount equal to or greater than the relevant reference dose. Where the unintentional presence of allergens (UAP) with particles cannot be eliminated by systematic food safety work, PAL can in many cases be justified (see discussions under the sampling section below). This also applies to warning labelling for gluten, if for example contamination with whole wheat grains may be present in other raw material from primary production.

The maximum amount (consumption dose) of homogeneously distributed allergens (expressed as total allergenic protein) in a portion of the food needs to be determined. Different methods can be used for this (see examples below).

The Swedish National Food Agency's reports No. 17 from 2015 and No. 13 from 2022 provide examples of food sampling and analytical results (Sjögren Bolin 2015; Livsmedelsverket 2022). Allergen Bureau's VITAL 3 model is based on a documented theoretical calculation of the amount of allergens that may be present in used raw materials (materials and ingredients) and that may remain in a production line's "hang-up points" after a validated allergen cleaning. The estimated amount of cross-contact allergens (UAP) can be verified by sampling and analysing the final product, but this is not a mandatory step in the VITAL methodology (Allergen Bureau 2021 VI).

The methodology chosen for a PAL risk assessment, and the results of these, need to be documented with information including

- concentration of the allergen in the food (estimated, analysed).
- an estimate of how much food a consumer eats of the food in question at any one time.
- the total amount (dose) of the allergen present in what the consumer ate.
- comparison between the amount and the reference dose for this allergen.

A VITAL® Standard Version 1 has started to be used for certification in Asia, Australia and New Zealand. This is to be combined with e.g., BRCGS Food Safety certification and is proof of good PAL assessments (Allergen Bureau 2019 ST). The Swedish Food Retailers Federation

recommends that VITAL certified producers need to show that food consumption data used for calculation of PAL is based on 75% (percentile) data as discussed below.

The company should demonstrate effective preventive measures

The PAL should not be used or seen as a substitute for implementing effective food safety work based on hazard analysis ("HACCP"), implementation of prerequisites programmes (Prerequisites programmes/PRPs, Good Hygiene Practice/GHP, equivalent), or as a generic disclaimer by "over-declaring" with the PAL.

All measures must be taken to eliminate or minimise allergen contamination by following the requirements of GFSI recognised standards and the industry guidelines described in this document before conducting a PAL risk assessment for allergens.

Methodology based on analyses or theoretical calculations

The Swedish Food Retailers Federation recommends that the use of PAL is based on results from quantitative analyses of foodstuffs. If VITAL's theoretical evaluation model is used, the results from this model should be validated by sampling and quantitative analysis of allergens (Allergen Bureau 2021 VI). The different analytical methods used by producers and suppliers to Svenk Dagligvaruandel to evaluate the need for PAL need to be documented in the company's risk assessment. The PAL risk assessment needs to be continuously updated as new knowledge emerges and globally accepted reference methods have been established.

Laboratories performing the analyses should be competent, and if possible, accredited for the method used according to the ISO/IEC 17025 standard (a requirement for official food control). Laboratories need to be able to demonstrate that the reporting limit is sufficiently low. Have a dialogue with the laboratory about processing and ingredients.

- Can the method also detect allergens in heated products (e.g., when proteins have been altered or denatured)?
- Is there any ingredient in food that the method can cause a cross-reaction? (e.g., pea protein may give a false positive result in a method for peanuts or soya).
- Avoid analysing pooled samples as this leads to dilution and uncertain assessment against reference doses.
- Pay attention to the unit in which the allergen is expressed, such as mg peanut protein/kg or mg peanut/kg (reference doses are given as mg protein/kg).

When performing a PAL risk assessment, decision limits need to be established based on established reference doses and the measurement uncertainty of the analytical result - see below and Appendix 1 for examples. Be aware that laboratories may report uncertainty in different ways. Accredited laboratories normally report the expanded uncertainty, *U* (95% confidence interval).

If discussions or disputes arise about the analysis results that form the basis for PAL on products, it is recommended that the methods and laboratories designated by the members of the Swedish Food Retailers Federation be considered as references and used for decisions on labelling, etc.

On reference doses for allergens and gluten

For allergens

The FAO/WHO expert group recommends that the decision whether to use PAL labelling should be based on a PAL risk assessment. Food Allergy Canada, FoodDrink Europe and ILSI Europe note that PAL should be applied based on well-documented reference doses derived using the most up-to-date, relevant, peer reviewed and robust scientific data (FAO/WHO 13 December 2021; Food Allergy Canada 2022; FoodDrink Europe 2021; ILSI Europe 2022).

Common, globally accepted reference doses are not yet available but various initiatives exist and are used in PAL evaluations. Reference doses at levels ED01 - ED05 (where 1 and 5% of allergy sufferers react, respectively) have been recommended by the Allergen Bureau and FAO/WHO as suitable for use in PAL risk assessment. The Swedish Food Agency does not take a position on which ED levels should be used and indicates a wide range (ED01 to ED50; doses where 1-50% of allergy sufferers react) (Allergen Bureau 2019 SU; FAO/WHO 20 August 2021).

The Allergen Bureau's VITAL 3 documentation uses ED01 values for 14 different allergens, developed and updated by the organisation's scientific panel (Allergen Bureau 2019 SU).

The FAO/WHO working group "Expert Consultation on Risk Assessment of Food Allergens" has reviewed and established reference doses in food for 13 priority allergens. The doses are given at a level just below ED05. Belgian authorities recommend using the FAO/WHO choice of reference doses (FAO/WHO 20 August 2021; FAO/WHO 4 April 2022; SciCom 2022).

In the Swedish Food Agency's latest risk assessment guide for undeclared allergens Report No. 13 from 2022, reference doses are given for milk, peanut, hazelnut, egg, cashew nut, walnut, soya, wheat, crustaceans, fish and celery. The Swedish Food Agency does not take a position on which ED levels should be used and gives a wide range (ED01 to ED50). The ED01 and ED05 values given are the same as in VITAL 3 with the exception of shrimp (26.3 mg instead of 25 mg). Reference doses from FAO/WHO are also given (slightly different for a number of proteins compared to VITAL's ED05 values) (Allergen Bureau 2019 SU; FAO/WHO 21 August 2021; FAO/WHO 4 April 2022; Livsmedelsverket 2022).

The accepted reference doses may vary by country or region and may be subject to (rapidly) changing views of the relevant authorities. For example, the Dutch NVWA has published its own reference doses at ED01 and ED05 level for several allergens. These doses are lower than those indicated by FAO/WHO and VITAL 3. Another example is the reference doses published by the FDA for ED01 and ED50 (FDA Draft Guidance 2022; NVWA 2016).

SvDH recommends that published reference doses in the range ED01 - ED05 are used. However, the Swedish Food Retailers Federation shall accept reference doses applied by local authorities in other countries.

For conversion to the decision threshold, see below under the section *Assessment of whether to use PAL*.

For gluten

Reference doses are missing for gluten. The "may contain traces of gluten" labelling used on products today cannot therefore be based on FAO/WHO and other organisations' recommendations on PAL risk assessments. More research is needed to increase the credibility of. PAL labelling for gluten.

The limit for gluten-free is 20 mg/kg and is based on total daily intake (not per meal as for allergens). Current research focuses on damage to the gut, not symptoms. A systematic review term 2008 suggests that although the amount of tolerable gluten varies between people with coeliac disease, a daily gluten intake of <10 mg is unlikely to cause problems. A daily intake of 500 mg of gluten is reported to cause great harm and observable changes are obtained with 100 mg. The European Society for the Study of Coeliac Disease (ESsCD) suggests in 2019 that a safe limit is currently set between 10 and 100 mg (Akobeng & Thomas 2008; Abdulbaqi et.al. 2019). Recently published information assesses that a daily gluten intake around 10 mg may cause an adverse effect and contribute to the increase in risk (in contrast to previous data that 10 mg is a no-effect level in the intolerant) (Rasmussen et.al. 2022).

Until ED values, and recommendations on PAL for gluten are developed, the following is suggested.

1. If the gluten content is below 20 mg/kg in all samples taken according to a sampling plan (see below), PAL should not be indicated.
2. If the gluten content in one of several samples taken according to the sampling plan has a gluten content above 20 mg/kg, PAL for gluten can be justified.

When assessing whether PAL should be used, the result's measurement uncertainty (*U*) needs to be taken into account - see Appendix 1 for an example of soft bread, the decision limit is 15 mg gluten/kg. The limit values and alternative assessment criteria for gluten used by producers and suppliers to the Swedish Retailers Federation in a PAL risk assessment must be documented. This documentation needs to be updated when new knowledge emerges and global reference doses have been established.

On portion/consumption sizes

Food consumption data is an important aspect of food allergen risk assessment. As allergic reactions to food generally develop more or less acutely, the risk assessment should be based on what is consumed on a single occasion.

There is currently no EU-wide model or database for food consumption data. The Swedish Food Agency's report 13 (2022) recommends using data based on the largest amount of food consumed during a meal by 75% of adults or teenagers (see Table 5 in the report and Appendix 2 below). This level is also recommended by, for example, the Danish Veterinary and Food Administration and ILSI Europe.

The Swedish Food Agency encourages the use of country-specific consumption data whenever possible. Alternatively, other credible food consumption data can be used (Birot et.al. 2018; ILSI Europe 2022; Livsmedelsverket 2022).

VITAL 3 calculations are based on principles for portion size indicated on the packaging according to the AFGC Code of Practice for Food Labelling and Promotion (for details, see Allergen Bureau 2021 VI). If the VITAL model is used, The Swedish Food Retailers Federation assumes that the consumed amount (reference amount) is based on food consumption data at the 75% level (p75) according to the Swedish Food Agency's recommendation.

The Swedish Food Retailers Federation recommends that the consumption data used to evaluate the need for PAL for EVM products needs to be documented in the risk assessment. This should be updated when new knowledge emerges.

About analysing allergens and gluten

As mentioned earlier, the Swedish Retailers Federation recommends that PAL is based on the results of food analyses.

The scientific value and credibility of the PAL depends on addressing weaknesses in current analyses and developing it:

1. recognised standard reference materials for certain allergens.
2. a recognised standard sampling plan.
3. a recognised reference method (although one exists for gluten).

To address the gaps in analytical methodology, the FAO/WHO Expert Group recommended the development of method performance criteria and reference materials (Cordeiro et.al. 2021; FAO/WHO 20 August 2021; FoodDrink Europe 2021; Yeung & Robert 2018).

An understanding of the nature of the allergen, its form (e.g, powder, liquid, homogeneous or particulate), its behaviour in the food in which it is used, and whether it is heated or not, is of great importance for the choice of sampling and analytical method. More information on analytical methods for the determination of allergens can be found in, for example, the Swedish Food Agency's report no. 13 (2022), the ILSI Europe and Food Allergy Canada guides, and at https://allergenbureau.net/food-allergens/food-allergen-analysis.

The most common methods today are based on ELISA (Enzyme Linked Immuno-Sorbent Assays) and detect the presence of allergenic proteins. The methods often fulfil requirements for detection limits and selectivity, and are simple and economical to use. However, there are reports that ELISAs have given erroneous results when used on highly processed foods (so-called matrix effects). False positive results can also arise from cross-reactions with similar allergens. For example, rapeseed and mustard protein can lead to incorrect decisions and product recalls (Canada 2019; FoodDrink Europe A3 2022; ILSI Europe 2022).

Polymerase Chain Reactions (PCR) based assays are indirect tests that detect DNA but not the allergenic protein. These can be used to confirm results from ELISA tests if they are non-specific. DNA assays should be used in PAL risk assessment only when protein quantification assays are not available (it should be noted that DNA assays can also be non-specific; ILSI Europe 2022).

Methods combining mass spectrometry (MS) and liquid chromatography [LC-tandem MS (MS/MS)] are promising non-immunological methods for the quantification of allergens and gluten. However, the technology is new and potential weaknesses need to be evaluated and addressed. Expensive analytical equipment, skill requirements and time to obtain results mean that these methods are not used for routine analyses today (Yeung & Robert 2018; FoodDrink Europe 2022).

The analytical methods used to inform the risk assessment process and validate/verify cleaning processes and presence in food need to have a demonstrated fitness for purpose. This includes accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), recovery, selectivity (specificity), sensitivity and linearity. Regardless of the technology used, the results always need to be evaluated taking into account the measurement uncertainty of the method in question. Results should be reported in units of mg of total protein from the allergenic source per kg of food. Conversion factors are published both from amount of raw material to amount of protein therein (see for example ILSI ANNEX 7.8 protein content table...) and detected amount of allergenic protein (Table 2 in the Swedish Food Agency's

report 13). Note that laboratories need to be able to provide up-to-date information on any conversion factors, so that analysis results can be used in PAL risk assessment (FAO/WHO 13 December 2021; ILSI Europe 2022; Livsmedelsverket 2022).

About sampling

It is of great importance that a risk-based sampling plan is developed for a PAL risk assessment. The "Allergen sampling and analysis" section of the ILSI Europe guide provides good information on sampling and analysis to facilitate harmonisation of practices throughout the food chain. Advice is given on evaluating risks in the supply chain, in production and in distribution, Other sources provide more general guidance (FoodDrink Europe 2022; ILSI Europe 2022; Livsmedelsverket 2022; Yeung & Robert 2018).

For example, samples can be taken from the finished product, composite sub-components or ingredients. Analytical results, after correction for any dilution in the finished food, can provide a direct measure of the amount of allergen to which the consumer is exposed. Indirect sampling of rinse water, air samples and swabbing of surfaces can be difficult to use as a basis for quantitative risk assessments.

This guidance proposes a simple sampling plan for homogeneously distributed allergens based on Dairy Food Safety Victoria "A guide to managing allergens in the dairy industry" (DFSV 2018). It describes a sampling plan for analytical validation of the effectiveness of an allergen cleaning method. This is based on taking five samples from three different production events. FoodDrink Europe (2022) states that sampling for validation should take place on at least three production occasions. It also states that the number of samples per occasion should be increased for allergens that are heterogeneously distributed in the food.

Homogeneously distributed allergens

If the product is homogeneous or mixable (a free-flowing powder or liquid), a relatively small number of samples may be representative. As a starting point for risk assessment in smaller food industries, the Swedish Food Retailers Federation recommends the following (partly based on the validation of allergen cleaning in DFSV 2018):

- The planning and implementation of a sampling should only take place when all the measures according to "prerequisite's for PAL" above are effectively implemented (including a validated allergen cleaning).
- For an allergen judged to be homogeneously distributed in the food;
    - sample five packs (that do not have the allergen as an ingredient) at the beginning of a production run (after validated allergen cleaning), e.g., after a production run in the same line where the allergen was included as an ingredient.
    - samples are recommended to be taken at different times at the beginning of a new production (e.g., spread over the first 15 minutes).
    - repeat this in three different productions (giving a total of 15 samples).

See also ILSIS Europe's guide (2022) on PAL, section 3.2.1 "Case study - Example Foods - Case description of a process with homogenous cross-contact".

Heterogeneously distributed (particulate) allergens

If the company wants to perform a PAL assessment for hard-to-clean allergens or allergens that are more heterogeneously distributed, more samples need to be taken on each occasion.

Inhomogeneity, with "hot spots" of allergenic clumps or particulate allergens found in unpredictable locations in a bulk volume or batch of packaged food, is more of a problem.

When sampling from a large number (N) of packaged units, several "rules of thumb" have been developed.

Examples include the square root of N plus 1 (√(N) + 1) rule and the cube root of N ($\sqrt[3]{N}$, or N^(1/3). As an illustration, for N = 10,000 packaged units, (√(N) + 1) = 101 samples or steps and $\sqrt[3]{N}$ = 22 samples or steps. Another option is an approach based on the sampling of pathogenic microorganisms in food (risk, without growth). ICMFS recommends taking between 10 and 30 samples per batch to evaluate whether a product is unsafe.

ILSI Europe describes in section 5.1.2.4 "Particulate allergen cross-contact" how risk assessment can be done based on model particles such as mustard and sesame seeds, pieces of hazelnuts and walnuts. If such particles are repeatedly found in the production lines after validated allergen cleaning, it is likely that one such particle corresponds to more than one reference dose. ILSI recommends that a "visual-based sampling programme" be used to determine how many "defective" packages or products are present. Based on this, it may be possible to estimate and calculate the protein concentration and dose of protein in a portion of the specific food (Andersson 2018; ICMSF 2011; ILSI Europe 2022).

When PAL is used for heterogeneously distributed allergens, it should be stated in the risk assessment report whether, for example, ILSI's guidelines for this have been used. The Swedish Food Retailers Federation assumes that the sampling model is based on a "worst-case scenario" where the risk of contamination (UAP) is greatest when switching from production with an allergen to production without this allergen as an ingredient.

Sampling plan

The chosen sampling plan needs to be justified and documented. The plan can, for example, specify how samples are to be taken, the number of samples, the sample weight of each sample and the number of batches to be sampled. The plan is based on requirements and knowledge of inhomogeneity and how the allergen is present in the sample. ILSIS Europe (2022) Guidance on the Application of Food Allergen Quantitative Risk Assessment within Food Operations provides extensive advice on the preparation of sampling plans and also suggests forms for documenting such plans (see e.g. 7.7. ANNEX for sampling and analysis).

Assessment of whether to use PAL

The result of the analysis is compared with a decision limit. If the result is below the decision limit, it is recommended not to use PAL. If the result is equal to or above the decision limit, PAL should be used. Below is an example with wheat protein in lunch soup. See Appendix 1 for more examples.

To calculate a decision limit in mg/kg is needed:

- Reference dose (mg)
- Guard band (mg) (a safety margin)
- Portion size (kg)

$$\boldsymbol{Decision\ limit\ (mg/kg)} = \frac{\boldsymbol{(reference\ dose - guard\ band)}}{\boldsymbol{portion\ size}}$$

Example: A lunchtime soup contains 1,4 mg wheat protein/kg, portion size is 0,35 kg (*p75*). Reference dose is 0,7 mg (ED01); guard band is 0,17 mg (guard band calculation, see below).

The decision limit for wheat protein in lunchtime soup will be $\frac{(0.7-0.17)}{0.35}$ ≈1.5 mg/kg.

PAL should not be used as the analytical result of 1.4 mg/kg is below the decision limit.

Reference dose for food

Reference doses in the range ED01 to ED05 have been recommended by the Allergen Bureau and FAO/WHO as suitable for use in PAL risk assessment. The Swedish Food Agency specifies a wide range (ED01 to ED50, see also the section *on reference doses for allergens and gluten* (see below and Appendix 2).

Analysis results can be expressed as a total amount of protein per kilo of consumed food (e.g., mg milk protein/kg and mg egg protein/kg) and as an amount of a specific allergenic protein per kilo (e.g., mg casein/kg and mg egg white protein/kg). When assessing whether or not to use PAL labelling, the reference dose needs to be selected or a conversion factor applied accordingly. The Swedish Food Agency and ILSI Europe have published examples of conversion figures from amount of allergenic protein to total amount of protein. An example of a protein content table that can be used for data conversion from total amount of product has been published by the organisation Allergen Consultancy (ILSI Europe 2022; Livsmedelsverket 2022; see also Appendix 2).

Guard band based on the measurement uncertainty of the analysis method.

Guard bands are used to ensure that the reference dose is not exceeded. The guard band is calculated from the reference dose, the measurement uncertainty of the analytical result, *U,* and a factor of 1.64 (one-sided interval) which gives a sufficiently safe decision limit (95 % confidence).

$$\boldsymbol{Guard\ band} = \frac{\boldsymbol{Reference\ dose} \times \boldsymbol{factor} \times \left(\frac{\boldsymbol{U}}{\boldsymbol{2}}\right)}{\boldsymbol{100}}$$

Example for lunchtime soup and wheat protein

1. Reference dose ED01: 0,7 mg
2. Measurement uncertainty: *U* = 30 per cent
3. Factor: 1.64

$$\boldsymbol{Guard\ band} = \frac{\boldsymbol{0,7} \times \boldsymbol{1,64} \times \left(\frac{\boldsymbol{30}}{\boldsymbol{2}}\right)}{\boldsymbol{100}} = \boldsymbol{0,17\ mg}$$

Portion size

Portion size is the amount of food consumed (portion size based on food consumption data *p75*). For lunchtime soup, the portion size is 0.35 kg (Livsmedelsverket 2022).

Calculation according to the Swedish Food Agency

An alternative proposal for calculating the decision limit is given in the Swedish Food Agency report *Undeclared allergens in food - guide on how to assess the risk of allergic reactions in the population* (Livsmedelsverket 2022). This proposal is being discussed internationally but is not yet finalised. Table 6.1 in this report gives decision limits according to the formula

Decision limit (mg/kg) = Reference dose (mg) / (1 + *U/100*) / portion size (kg)

With the example of lunch soup above, the decision limit = 1.5 mg/kg, i.e., the same limit as calculated above. With higher measurement uncertainty, the difference is greater and the decision limit is slightly higher with the Swedish Food Agency's proposal.

Comment: Before general recommendations are established by the Swedish Food Agency, we recommend using the guidance of the International Laboratory Accreditation Centre (ILAC) to establish decision limits. See the examples in Annex 2 of this report.

About PAL at the farm level

Contamination of allergens from the farm level is a major factor in deciding whether or not to use PAL. Contamination can occur if different crops are grown in close proximity, share the same field due to crop rotation and/or share the same equipment/facilities for harvesting, transport and storage. There are many reports of cereals, dried garlic, spices and other agricultural products containing e.g. gluten, peanuts, mustard, soya and lupin coming from the cultivation stage. Although it is possible to mitigate such contaminants and reduce the concentration of all genes, it may be difficult to eliminate them (Allergen Bureau 2022 UA; Allergen Bureau 2022 AC; Codex Alimentarius 2020).

Since 4 March 2021, EC Regulation 852/2004 on food hygiene includes Codex requirements for allergen management at the farm level. The regulation states that:

'Equipment, vehicles and/or receptacles/containers used in the harvesting, transport or storage of one of the substances or products causing allergies or intolerances referred to in Annex II to Regulation (EU) No 1169/2011 shall not be used in the harvesting, transport or storage of foodstuffs not containing that substance or product, unless the equipment, vehicles and/or receptacles/containers have been cleaned and checked at least to ensure that no visible residues of the substance or product remain'.

The Allergen Bureau (2022) guide Assessing Agricultural Cross Contact provides information on allergens that may be present as a contaminant from agriculture, situations that contribute to the mixing of allergens in agriculture and measures used to reduce this.

Examples are given of key questions that can be used in PAL risk assessment for raw materials:

- What other crops are grown and possible to grow in the neighbourhood?
- What other crops are used for crop rotation by the farmer?
- In which seasons are the crops harvested? This provides information about other farms in the neighbourhood and shared equipment.
- What measures are in place to effectively reduce physical residues of other crops?
- Which crops are purchased from contract farms or wholesalers?
- What effective measures are in place to minimise potential cross-contact with allergens from maintenance machinery and harvesting equipment?
- What effective measures are in place to minimise potential cross-contact with allergens from shared storage equipment and facilities and/or transport?
- Does the primary and secondary processor have allergen controls within their facility?
- What is the shape of the crop or processed crop? Is the cross-contact allergen similar in appearance?

Producers and suppliers of EVM products need to focus particularly on the fulfilment of the requirements of the EU hygiene regulation 852/2004.

The Swedish Food Retailers Federation assumes that the use of PAL on agricultural products is based on a risk assessment as described above.

When can PAL information for raw materials be transferred and used on product

Suppliers of raw materials (ingredients sometimes indicate that they may contain traces of an allergen). In order to use this information, open and honest communication between producers and suppliers is needed so that quantitative PAL risk assessment can be made. ILSI Europe (2022) provides the following advice (see the guide for more details):

1. Ensure that business partners are aware of the globally diverse legal requirements for allergens and their labelling. This is so that no mistakes are made by not knowing which allergens are relevant in a geographical area you are importing from or exporting to.
2. Define the level of detail of the information needed from an ingredient supplier to support quantitative risk assessments.
3. Understand the key questions to ask suppliers to get the information required for your allergen assessment and management programme.

ILSI also provides examples of questions that can be used in supplier surveys:

- Which food allergens are present in the ingredient formulation?
- What food allergens are present in the establishment/site?
- Which food allergens are present on the same production line? Could these food allergens cause residues that could cause UAP from cross-contact in the following product?
- Which food allergens are present on the neighbouring production line? Could these food allergens cause residues that could cause UAP from cross-contact in the following product on the production line in question?
- How does the supplier deal with food allergens?
- What allergen control programmes and other effectively implemented PRPs are in place?
- How does the supplier manage its upstream supply chain?
- How will any changes to formulations or allergen controls be communicated to customers?
- How will any changes to the precautionary labelling of allergens be communicated to customers and consumers?

ILSI also recommends checking whether the right person with knowledge of the food allergen has answered the different questions.

A PAL information on raw materials can be used by producer and transferred to finished product only if:

1. A PAL risk assessment has been performed by the raw material supplier according to SvDH's requirements and the producer of the EVM product has evaluated that this justifies the use of warning labelling.
2. The level of the allergen (gluten) is not diluted so that the dose in the final product can justify the use of a warning label (PAL).

Author

Anders Nilsson
070 6431582
anders.nilsson@anfc.se
Anders Nilsson Food Sector Consulting AB

Statistical consultant

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Reference group at the Swedish Food Retailers Federation

- Annika Bengtzon - annika.bengtzon@ica.se;
- Karin Vigerland - karin.vigerland@ica.se;
- Elise Nassab - elise.nassab@coop.se;
- Helena Björck - helena.bjorck@dagab.se;
- Mia Broden Borgvall - mia.broden_borgvall@lidl.se;
- Ann-Julie Johansson - ann-julie.johansson@menigo.se;
- Karin Billinger - karin.billinger@martinservera.se;
- Mona Lauermann Orheden - mona.lauermannorheden@svdh.se;

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Annex 1 - Example - assessment of whether PAL should be used

In order to be able to assess whether PAL should be used or not, analysis results must always be expressed as mg protein/kg food, taking into account any conversion factors (see section on Assessing whether PAL should be used and Appendix 2).

The examples used below are intended as the highest result of the samples taken according to the sampling plan. This example is based on 15 samples taken on three different production occasions as described in the section *on sampling*.

Reference doses:

- ED01 according to Swedish Food Agency report No 13 (2022) and Allergen Bureau (2019 SU).
- Reference dose (RfD) according to FAO/WHO (20 August 2021; 4 April 2022).

The portion size used is based on Swedish nutrition data according to table 5 in report 13 (Livsmedelsverket 2022) and is the largest amount of food consumed during a meal by 75% (p75) of adults or teenagers. Producers and suppliers can use other data for portion size as described above; use these portion sizes in the calculation below.

The measurement uncertainties used are examples from Annex 2; it is important to use the value reported by the contracted laboratory for the method used and the food analysed.

For an explanation of the formulae used in the examples below - see under the section *Assessing whether to use PAL* in the earlier part of the guidance.

Hard bread

The allergen milk protein (casein) is considered to be homogeneously (not particulate) distributed in the food. Factor 1.2 is used for conversion from casein to protein content in milk (Livsmedelsverket 2022).

- Analytical results: The highest result of 15 samples analysed is 4.4 mg milk protein/kg (converted from 3.5 mg casein/kg).
- Reference doses
    - ED01: 0.2 mg of milk protein
    - FAO/WHO RfD: 2.0 mg milk protein
- Portion size (p75): 0,024 kg.
- Extended measurement uncertainty *U* = 45 per cent

$$\boldsymbol{Guard\ band\ (ED01) = \frac{0,2\ \times 1,64 \times \left(\frac{45}{2}\right)}{100} = 0,074\ mg}$$

$$\boldsymbol{Guard\ band\ (FAO/WHO) = \frac{2,0\ \times 1,64 \times \left(\frac{45}{2}\right)}{100} = 0,74\ mg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (ED01) = \frac{(0,2 - 0,074)}{0,024} = 5,25\ mg/kg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (FAO/WHO) = \frac{(2,0 - 0,74)}{0,024} = 52,5\ mg/kg}$$

Conclusion: The highest concentration of *4.4 mg* milk *protein/kg* in the 15 samples taken is at a level below both ED01 and *FAO/WHO* decision limits - PAL should not be used.

Chocolate cake

The allergen milk protein (casein) is considered to be homogeneously distributed in the food.

- Analytical results: The highest result of 15 samples analysed is 300 mg milk protein/kg (converted from 240 mg casein/kg).
- Reference doses
  - ED01: 0.2 mg of milk protein
  - FAO/WHO RfD: 2.0 mg milk protein
- Portion size (p75): 0,100 kg.
- Extended measurement uncertainty *U* = 45 %.

$$\boldsymbol{Guard\ band\ (ED01) = \frac{0,2\ \times 1,64 \times \left(\frac{45}{2}\right)}{100} = 0,074\ mg}$$

$$\boldsymbol{Guard\ band\ (FAO/WHO) = \frac{2,0\ \times 1,64 \times \left(\frac{45}{2}\right)}{100} = 0,74\ mg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (ED01) = \frac{(0,2 - 0,074)}{0,100} = 1,26\ mg/kg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (FAO/WHO) = \frac{(2,0 - 0,74)}{0,100} = 12,6\ mg/kg}$$

Conclusion: The highest concentration of *300 mg* milk protein*/kg* in the 15 samples taken is at a level *above* both ED01 and *FAO/WHO* decision limits - PAL *should be* used.

Dessert pie

The allergen egg white is considered to be homogeneously distributed in the food. Factor 1.25 used for conversion from egg white to egg protein.

- Analytical results: The highest result of 15 samples analysed is 30 mg egg protein/kg (converted from 24 mg egg white/kg).
- Reference doses
  - ED01: 0.2 mg egg protein
  - FAO/WHO RfD: 2.0 mg egg protein
- Portion size (p75): 0,150 kg.
- Extended measurement uncertainty *U* = 50 per cent

$$\boldsymbol{Guard\ band\ (ED01) = \frac{0,2\ \times 1,64 \times \left(\frac{50}{2}\right)}{100} = 0,082\ mg}$$

$$\boldsymbol{Guard\ band\ (FAO/WHO) = \frac{2,0\ \times 1,64 \times \left(\frac{50}{2}\right)}{100} = 0,82\ mg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (ED01) = \frac{(0,2 - 0,082)}{0,150} = 0,79\ mg/kg}$$

$$\boldsymbol{Decision\ limit\ \ (mg/kg)\ (FAO/WHO) = \frac{(2,0 - 0,82)}{0,150} = 7,9\ mg/kg}$$

Conclusion: The highest concentration of *30 mg* egg *protein/kg* in the 15 samples taken is at a level *above* both ED01 and *FAO/WHO* decision limits - PAL *should be* used.

Dessert pie - alternative (analysis results with lower allergen concentration)

The allergen egg white is considered to be homogeneously distributed in the food.

- Analytical results: The highest result of 15 samples analysed is 0,63 mg egg protein/kg (converted from 0,5 mg egg white/kg).
- Reference doses
    - ED01: 0.2 mg egg protein
    - FAO/WHO RfD: 2.0 mg egg protein
- Portion size (p75): 0,150 kg.
- Extended measurement uncertainty *U* = 50 per cent

$$\boldsymbol{Guard\ band\ (ED01) = \frac{0,2\ \times 1,64 \times \left(\frac{50}{2}\right)}{100} = 0,082\ mg}$$

$$\boldsymbol{Guard\ band\ (FAO/WHO) = \frac{2,0\ \times 1,64 \times \left(\frac{50}{2}\right)}{100} = 0,82\ mg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (ED01) = \frac{(0,2 - 0,082)}{0,150} = 0,79\ mg/kg}$$

$$\boldsymbol{Decision\ limit\ (mg/kg)\ (FAO/WHO) = \frac{(2,0 - 0,82)}{0,150} = 7,9\ mg/kg}$$

Conclusion: The maximum concentration of *30 mg* egg *protein/kg* in the 15 samples taken is at a level *below* both ED01 and *FAO/WHO* decision limits - PAL *should not be* used.

Soft bread - gluten contamination

Gluten is considered to be homogeneously distributed in the food.

- Analysis results: The highest result of 15 samples analysed is 19 mg gluten/ kg.
- Daily consumption limit 20 mg gluten/kg
- Measurement uncertainty (example): 30 % (0,30)
- Decision limits - calculated as total daily intake minus guard band
    - Decision limit ("gluten-free"): 20 mg/kg - (1.64 x 0.30 / 2) x 20 mg/kg = 15.1 mg/kg.

Conclusion: Analysed level of gluten 19 mg/kg allergen is above decision limit - PAL should be used.

Annex 2 - Evidence for assessment from various publications on PAL

This annex presents information on different alternative reference doses, portion sizes / serving sizes, analytical methods, etc. that can be used to evaluate the risk analysis of producers and suppliers for the labelling "May contain traces of allergen x".

About reference doses

Information from the report *Undeclared allergens in food - guide on how to assess the risk of allergic reactions in the population. Swedish Food Agency report series. Uppsala*. The data in the table is based on Houben et. al. 2020* and publications from FAO/WHO (FAO/WHO 20 August 2021; FAO/WHO 4 April 2022).

Protein (mg)	**ED01**	**Reference dose FAO/WHO**	**ED05**	**ED10**	**ED15**	**ED20**	**ED25**	**ED50**
Milk	0,2	2,0	2,4	7,1	13,8	22,2	32,7	125
Peanut	0,2	2,0	2,1	7,1	14,6	24,7	37,7	165
Hazelnut	0,1	3,0	3,5	14,1	32,4	59,2	95,5	489
Eggs	0,2	2,0	2,3	6,3	11,8	18,5	26,7	94,5
Cashew nuts	0,05	1,0	0,8	3,4	7,8	14,5	23,9	139
Walnut	0,03	1,0	0,8	3,8	9,7	19,3	33,5	235
Soya	0,5	-	10,0	41,9	99,1	186	308	1780
Celery	0,05	-	1,3	5,4	13,0	23,3	36,9	180
Wheat	0,7	5,0	6,1	15,4	26,9	40,3	55,9	174
Shrimp	26,2	200	280	723	1260	1880	2580	7910
Fish	1,3	5,0	12,1	26,7	45,5	69,2	99,1	418

The Swedish Food Retailers Federation recommends using the Swedish Food Agency's and VITAL 3's ED01, ED05 or FAO/WHO's reference doses in PAL risk assessments (marked in red in the table above and below).

About reference doses, information from the publication: Summary of the 2019 VITAL Scientific Expert Panel Recommendations, Allergen Bureau 2019.

Allergen	No. of individuals	VITAL 2.0 Ref Dose (mg protein)	2019 VSEP Ref Dose (mg protein) [ED_{01}]	Change	2019 VSEP ED_{05} (mg protein)
Egg	431	0.03	0.2	↑	2.3
Hazelnut	411	0.1	0.1	✓	3.5
Lupin	25	4.0	2.6	↓	15.3
Milk	450	0.1	0.2	↑	2.4
Mustard	33	0.05	0.05	✓	0.4
Peanut	1306	0.2	0.2	✓	2.1
Sesame	40	0.2	0.1	↓	2.7
Shrimp	75	10.0	25	↑	280
Soy (milk + flour)	87	1.0 (soy flour)	0.5	↓	10.0
Wheat	99	1.0	0.7	↓	6.1
Cashew	245		0.05	+	0.8
Celery	82		0.05	+	1.3
Fish (finfish)	82		1.3	+	12.1
Walnut	74		0.03	+	0.8

↑ Reference Dose increased
✓ Reference Dose unchanged
↓ Reference Dose decreased
\+ New Reference Dose

About portion sizes

Information from the report *Undeclared allergens in food - guide on how to assess the risk of allergic reactions in the population. Swedish Food Agency report series. Uppsala.*

The Swedish Food Agency recommends that the portion size for a risk assessment is the largest amount of food consumed during a meal by 75% of adults or teenagers (see red-coloured columns *p75* in the tables below).

Table 5. Portion sizes (g food/consumption occasion) from two Swedish dietary surveys on adults and adolescents, respectively.

	Adults N=1797, AGE=18-80 YRS, 4-DAY REGISTRATION				Adolescents N=2968, AGE=12-18 YRS, 3-DAY REGISTRATION			
Food	Median gram	p75 gram	p95 gram	% Consumers	Median gram	p75 gram	p95 gram	% Consumers
Chocolate and sweets	35	60	138	48	54	100	275	48
Bread	47	64	96	98	57	76	120	91
Soft bread	57	73	107	95	63	80	128	88
Crisp bread	19	24	39	60	18	28	42	34
”Sweet” bread*	50	76	136	73	60	92	180	47
Meatballs	84	116	210	27	90	128	225	33
Fish fingers	125	150	200	3	100	150	270	5
Sausages	68	100	198	55	70	130	213	38
Black pudding	120	160	240	3	100	150	250	11
Hamburgers	120	180	260	6	125	188	286	17
Pizza	390	600	600	18	310	500	670	25
Pie (main course)	200	200	400	12	200	300	523	4
Noodle wok	280	400	400	2	190	280	560	6
Casserole	200	225	400	30	188	225	450	34
Soup	300	350	500	29	225	300	550	27
Pancakes, waffles, crepes	180	240	420	15	195	260	450	18
Ready-made salad (meal e.g. chicken salad)	250	300	300	3.5	125	240	488	15
Fish gratin	250	350	450	3	150	250	450	6
Lasagne	350	500	500	8.5	350	400	700	14
Pie (dessert)	100	150	200	7.5	83	121	210	3
Pasta	113	175	250	46	113	175	263	56
Rice	140	175	280	29	175	175	315	49
Grains**	113	175	245	7	105	175	246	7
Breakfast cereals/muesli	30	43	90	50	30	45	100	44
Snacks (crisps etc)	30	60	150	20	40	84	200	33
Nuts/seeds	24	54	120	26	22	52	120	11
Mashed potato	203	293	383	21	203	293	406	20
Ketchup	20	40	70	22	25	35	71	34
Juice	200	250	375	42	210	315	520	42

Continuation of Table 5 from Swedish Food Agency Report 13 (2022).

	Adults N=1797, AGE=18-80 YRS, 4-DAY REGISTRATION				Adolescents N=2968, AGE=12-18 YRS, 3-DAY REGISTRATION			
Food	**Median gram**	**p75 gram**	**p95 gram**	**% Consumers**	**Median gram**	**p75 gram**	**p95 gram**	**% Consumers**
Plant-based milk substitute	n.d.				200	250	417	4
Wine	267	350	500	42	n.d.			
Beer	330	500	1300	33	n.d.			
Jam	34	45	80	47	40	58	130	35
Herring	30	45	68	10	20	30	60	0.2
Porridge	225	263	400	31	225	300	413	22
Ice-cream	63	90	150	31	70	104	185	21
Cheese (hårdost)	20	29	50	82	24	40	80	52
Dessert cheese	50	80	225	4	30	60	186	2

The median is presented instead of the average. The average was presented in the 2015 report.

* Sweet bread means buns, cakes, cookies

** In the group grains it was included food grains from wheat (including couscous and bulgur), rye, oat, barley, corn, buckwheat, quinoa and millet.

% Consumers presents the number of participants in the study that consumed the food on at least one occasion during the survey.

n.d. = no data or very little data and is therefore not representative.

The weights for all foods are presented as “ready to eat” i.e. for pasta, rice and grains the weights presented represent the boiled products and not the dry weight.

On portion sizes, information from the article *Food groups for allergen risk assessment: Combining food consumption data from different countries in Europe*, Sophie Birot, Charlotte B. Madsen, Astrid G. Kruizinga, Amélie Crépet, Tue Christensen, Per B. Brockhoff; Food and Chemical Toxicology 118 (2018) 371-381.

The portion sizes below are based on results from weighted Danish-French-Dutch food consumption data.

Table 13
Food consumption summary statistics per food group (in g) [c].

Name	Country	Mean	SD	P75	P90
Chestnut paste and coconut milk	Combined	63.7	55.3	100.0	116.5
Peanut butter	Combined	27.4	17.5	35.0	45.0
Cheese	Combined	39.8	31.3	48.0	80.0
Milk powder and Cocoa powder	Combined	18.5	14.1	26.4	33.6
Coffee creamer	Combined	4.3	4.2	6.0	8.0
Cream and coffee milk	Combined	22.5	26.1	30.0	40.0
Ice cream	Combined	88.2	47.3	100.0	150.0
Milk and milk products for drinking	Combined	264.5	163.7	317.5	432.0
Milk and milk products consumed with a spoon	Combined	156.9	76.4	200.0	250.0
Peanuts, nuts and dried fruits	Combined	33.3	29.5	40.0	60.0
Potato and other starch based chips (including salty sticks/pretzels))	Combined	43.4	38.2	59.0	79.0
Fried/warm snacks	DK	162.8	103.1	180.0	270.0
Fried/warm snacks	FR	109.0	89.2	140.0	210.0
Fried/warm snacks	NL	77.4	50.5	85.5	140.0
Meal replacements and meat imitates	Combined	105.1	111.6	113.0	250.0
Supplements	Combined	1.7	2.6	2.0	3.0
Pancakes and waffles	DK	151.5	104.6	200.0	300.0
Pancakes and waffles	FR	152.7	102.3	200.0	300.0
Pancakes and waffles	NL	87.1	100.1	100.0	210.0
Soups	Combined	318.9	161.0	400.0	500.0
Small sweets - sweet confectionary unspecified/Combined	Combined	47.9	42.7	60.0	100.0
Small sweets - sweet confectionary specified	Combined	25.5	31.0	28.0	60.0
Sugar	Combined [a]	21.4	12.9	24.0	33.0
Chocolate and chocolate products	Combined	32.1	33.4	40.0	60.0
Sweet confectionary (jam, marmalade)	Combined	33.4	25.0	35.0	60.0
Cereal bars	Combined	31.7	27.1	32.1	50.0
Chewing gum	DK	10.6	7.8	10.0	20.0
Chewing gum	FR	5.9	7.4	6.0	10.0
Chewing gum	NL	2.9	2.5	4.0	5.0
Mashed potato powder	Combined	177.3	84.0	200.0	300.0
Potato product (excl. powder)	Combined	172.2	108.2	225.0	300.0
Vegetable oils and animal fat	Combined	14.8	11.9	20.0	30.0
Butter/halvarine/margarine	Combined	14.3	10.6	20.0	25.0
Sauces used as condiments and dessert sauces	Combined	22.3	20.7	30.0	46.5
Sauces, savory, chutneys and pickles	Combined	57.1	47.7	75.0	105.0
Fish products - mean 35 g such as fish fingers, fish paté	Combined	34.2	29.7	40.0	62.6
Fish products - mean 75 g such as smoked salmon, canned fish in oil	Combined	74.2	49.5	100.0	136.2
Fish products - mean 115 g such as fish cake, fish balls	Combined	115.6	75.0	150.0	190.0
Meat products - mean 65 g such as bacon, salami, paté	Combined [b]	64.5	46.2	75.0	125.0
Meat products -mean 105 g such as meat loaf, sausages	Combined	107.4	63.1	126.3	178.0
Crackers, crisp bread, rusk and toast	Combined	22.9	19.3	28.0	45.0
Bread, bread rolls and bread doughs	Combined	90.9	51.3	120.0	150.0
Herbs and spices mixes, bouillon cubes, yeast extract	Combined [a]	18.1	32.4	20.0	20.0
Spices and salt	Combined	2.9	2.5	3.0	4.0
Alcoholic drinks, alcohol ≤ 15%	Combined	222.1	144.5	282.5	420.0
Alcoholic drinks, alcohol above 15%	Combined	68.9	69.6	83.8	120.0
Beer	Combined	567.1	520.3	660.0	990.0
Syrups	Combined	26.6	30.8	33.8	60.4
Drinks without alcohol (excl. syrup)	Combined	362.3	252.1	483.3	600.0
Cookies (biscuits)	Combined	32.8	27.8	42.0	60.0
Cakes (including pastry)	Combined	144.4	78.0	180.0	250.0
Breakfast products eaten unprocessed (e.g. müsli, oat and maize flakes)	Combined	46.9	28.1	60.0	83.2
Breakfast products, porridge	Combined [a]	168.0	163.2	202.0	257.0
Pasta, rice, couscous and other grains	Combined	155.4	91.2	200.0	270.0
Legumes	Combined	132.2	67.3	175.0	215.0
Fruit and vegetables, processed	Combined	139.1	86.7	190.0	238.0
Eggs	Combined	40.9	29.0	55.0	80.0
Egg based dishes such as omelet	Combined	123.8	69.0	180.0	200.0
Sandwich and pizza	Combined	270.4	209.9	335.0	500.0
Composite dishes such as lasagna, quiche, vegetable casserole	Combined	238.2	155.5	320.0	450.0

[a] The group is combined but the consumption data used are the Danish (see also appendix C for explanation).
[b] The group is combined but the consumption data used are the French (see also appendix C for explanation).
[c] For a description of the foods in the food groups reference is being made to Birot et al., 2017.

Raw material weight - protein amount conversion table

Table from ILSI Europe's document; *Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment within Food Operations*; By Benjamin C. Remington, Joseph Baumert, W. Marty Blom, Luca Bucchini, Neil Buck, René Crevel, Fleur De Mooij, Simon Flanagan, Despoina Angeliki Stavropoulou, Myrthe W. van den Dungen, Marjan van Ravenhorst, Si Wang, Michael Walker; Report commissioned by Food Allergy Task Force June 2022.

7.8. ANNEX for protein content table used in data conversion

Annex Table 2 (special thanks to Allergenen Consultancy)

Allergen	Raw material	Protein content (g per 100g)
Gluten containing cereals	Barley flour	11
	Barley malt syrup	4,8
	Oat meal[1]	13
	Rye flour	16
	Spelt flour	15
	Wheat gluten	77
	Wheat starch[2]	0,3
	Wheat flour	11
	Wheat bran	16
Crustaceans	Shrimps	14
	Crab	18
	Lobster	17
Egg	Whole egg powder	47
	Egg protein powder	81
	Egg yolk powder	34
	Egg (fresh whole)	13
Fish	Anchovy (can)	29
	Herring	18
	Codfish	18
	Saithe[1]	18
	Mackerel	19
	Pangasius	18
	Flatfish	12
	Sardines (can)	24
	Tuna	22
	Salmon	20
Peanut	Peanut bean	26
	Peanut oil	<0,005[4]
Soy	Soy flour	35
	Soy bean (fresh)	13
	Soy bean (dried)[1]	36
	Soy protein isolate	88
	Soy lecithin	<0,3
	Soy sauce[1,*]	3,5

Fresh unprocessed raw materials are listed, unless stated otherwise.
Source USDA National Database for Standard Reference.
Figures are indicative literature values, check with supplier for actual content.

Allergen	Raw material	Protein content (g per 100g)
Milk	Butter[1]	0,7
	Cheese (48+)	24
	Lactose	0,2
	Skimmed milk powder	36
	Milk protein isolate[3]	90
	Milk permeate[3]	3-5
	Whipped cream	3,2
	Whole milk (pasteurized)[1]	3
	Whole milk powder	26
	Whey protein isolate[3]	90
	Whey permeate[3]	2-7
	Whey powder	13
	Skimmed yoghurt[1]	4,1
Nuts	Almond	21
	Hazelnut	15
	Walnut	15
	Cashew nut	18
	Pecan nut	9
	Para nut	14
	Pistachio nut	20
	Macadamia nut	8
Celery	Celery seed (dried)	18
	Celeriac (fresh)	2
	Celery (fresh)	1
	Leaf celery (fresh)	1
	Leaf celery (dried)	11
Mustard	Mustard seed	26
Sesame	Sesame seed	18
Lupine	Lupine flour	40
	Lupine bean (fresh)	36
Molluscs	Calamari (squid rings)	9
	Mussels	15
	Oysters	23
	Snails[1]	16

[1] Source: Nederlands Voedingsstoffenbestand (NEVO).
[2] Source: Starch Europe
[3] Source: American Dairy Product Institute
[4] Source: EFSA-Q-2004-122
[*] The proteins are hydrolysed to smaller fragments, which elicit less often allergic reactions.

Allergenic protein conversion table - total amount of protein in the allergenic foodstuff

Table from ILSI Europe's document; *Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment within Food Operations*, section 5.2.2.1 (see also Table 2 in Swedish Food Agency report 13 in the next section) (ILSI Europe 2022; Livsmedelsverket 2022).

The result is stated as one of the proteins of the allergenic product. To obtain the total protein content from the allergenic source, the ratio sub protein: total protein is needed.

Commonly used sub proteins for allergen analysis and their ratios to total protein:

Sub protein	Allergen source	Ratio	Conversion factor to total protein from allergenic source
ß-lactoglobulin	Milk	10:100	x 10 (= 100/10)
Casein	Milk	80:100	x 1,25 (= 100/80)
Gliadin	Gluten	50:100	x 2 (= 100/50)
Tropomyosin	Crustaceans	Varies by species (Eurofins)	
Lysozyme	Egg	Do not convert to total egg, use other egg test when total egg result is needed. Use this method only when lysozyme is used in its pure form (wine, cheese)	

On analytical methods and measurement uncertainty

Laboratories performing the analyses shall be accredited for the relevant analytical method according to ISO/IEC 17025. For each measurement result an expanded measurement uncertainty (*U* with 95 % confidence) shall be provided.

Below are examples of limits of quantification (LOQ) and expanded measurement uncertainties for methods used at the Swedish Food Agency (measurement uncertainty values marked in red).

Table from report; *Undeclared allergens in food - guide on how to assess the risk of allergic reactions in the population*. Sjögren Bolin Y, Warensjö Lemming E. 2022. L 2022 nr 13: Swedish Food Agency report series. Uppsala

Table 2. Analytes for which the Swedish Food Agency is accredited and performance of the methods used at the agency

Analyte	Type of analysis	LOQ	Measurement uncertainty[a]	Special consideration	Conversion factor to whole protein*
Casein	ELISA	≥0.5 mg/kg ≥2.5 mg/kg Depending on matrix	60 %	Caseins are heat-stable and thus suitable for analyses of milk protein but if whey fractions have been used casein analysis should not be performed.	1.2 (caseins constitute 80% of the milk proteins)
Egg (whole egg powder)	ELISA	≥0.5 mg whole egg powder/kg	45 %	Lysozyme is not detected.	0.45-0.49
Hazelnut	ELISA	≥2.5 mg/kg	55 %		0.16 (proteins constitute 16% of hazelnut flour)
Soy protein	ELISA	≥2.5 mg/kg	30 %		
Gluten	ELISA	≥ 5 mg/kg	30 %	Fermented foods should be analyzed with a competitive ELISA	1.2 (gluten constitutes 80% of the wheat proteins)
Walnut	ELISA	≥2.4 mg/kg	60 %		0.14 (proteins constitute 14% of walnuts)
Fish (raw cod)	ELISA	≥5 mg/kg	40 %	Less sensitive to some fish species e.g. salmon and anchovies. Heating and processing can also affect quantification.	0.18 (raw cod contains 18 % protein)

[a])Laboratories usually update measurement uncertainties annually. It is the measurement uncertainty of the methods at the Swedish Food Agency, calculated for 2022, that is described in the table. * General conversions factors have been collected from the article by (Holzhauser et al., 2020) for most food allergens. For walnut and fish (cod) data on protein content has been collected from the Swedish food database (Livsmedelsverket, 2021a). For egg protein a range is presented depending on figures presented by (Holzhauser et al., 2020) and the ELISA test kit manufacture R-biopharm (https://food.r-biopharm.com/). Gluten constitute approximately 80% of the total wheat proteins but differences between 70 to 90 % has been described (EFSA Panel on Dietetic Products and Allergies, 2014, Biesiekierski, 2017). Casein constitute 80 % of the total milk proteins (EFSA Panel on Dietetic Products and Allergies, 2014).

Example of the performance of analytical methods from Eurofins Food & Feed Sweden (2022-11-02). Note that the measurement uncertainty for the method used by the analysing laboratory should always be used when calculating the decision limit.

eurofins

ELISA	Specificity	Quantification limit	Uncertainty	Code
Casein / in meetproducts	Casein	0,2 mg/kg / 1 mg/kg	+/- 50%	LW29E / LW29F
Betalaktoglobulin	Betalaktoglobulin	0,1 mg/kg	+/- 50%	LW0PD
Egg	Egg protein	0,5 mg/kg	+/- 50%	LW0PF
Gluten	Gliadin	3 mg/kg / 7 mg/kg	+/- 40%	LW23Q / LW23R
Crustacean (Tropomyosin)	Tropomyosin	0,05 mg/kg	+/- 50%	LW17X
Sesame	Sesame protein	2 mg/kg	+/- 50%	LW1JG
Soja protein	Soja protein / Trypsininhibitor	2,5 mg/kg	+/- 50%	LW0PE
Mustard protein	Mustard protein	2,5 mg/kg	+/- 50%	LW18G
Lupin	Lupin protein	2 mg/kg	+/- 60%	JKLUP
Almond	Almond protein	2,5 mg/kg	+/- 50%	LW0WS
Peanut	Peanut protein	2,5 mg/kg	+/- 50%	LW186
Hazelnut protein	Hazelnut protein	0,5 mg/kg	+/- 50%	LW0WT
Pecan nut protein	Pecan nut protein	2 mg/kg	+/- 60%	JKEPE
Walnut	Walnut protein	2 mg/kg	+/- 65%	JKEWA
Cashewnut	Cashewnut protein	2 mg/kg	+/- 70%	JKECA
Macadamianut	Macadamianuts protein	1 mg/kg	+/- 50%	JKEMA
Brazilnut	Brazilnut protein	1 mg/kg	+/- 60%	ID1CX
Coconut	Coconut protein	2 mg/kg	+/- 60%	JKECC
PCR	**Specificity**	**Detection limit**		**Code**
Pea	Pea specifikt DNA	20 DNA copies*	-	JJ00D
Soja	Soja specifikt DNA	20 DNA copies*	-	JKPSY
Celery	Celery specifikt DNA	20 DNA copies*	-	JJ600
Mustard	Mustard specifikt DNA	20 DNA copies*	-	JKPMU
Sesame	Sesame specifikt DNA	20 DNA copies*	-	JKPSE
Fish	Fish specifikt DNA	20 DNA copies*	-	JJB0R
Peanut	Peanut specifikt DNA	20 DNA copies*	-	JKPPN
Almond	Almond specifikt DNA	20 DNA copies*	-	JKPAL
Hazelnut	Hazelnut specifikt DNA	20 DNA copies*	-	JKPHA
Walnut/Pecan nut	Walnut/Pecan nut specifikt DNA	20 DNA copies*	-	JKPWP
Cashewnut	Cashewnöt specifikt DNA	20 DNA copies*	-	JKPCA
Pistachio nut	Pistachio nut specifikt DNA	20 DNA copies*	-	JKPPI
Oat	Oat specifikt DNA	20 DNA copies*	-	JKPAV
Wheat	Wheat specifikt DNA	20 DNA copies*	-	JKPWH
Lupine	Lupine specifikt DNA	20 DNA copies*	-	JJ08L
Sample prep. DNA extraction				J6000
		*equal to 10-50 mg/kg		
LC-MS/MS				
Multiscreening 7 Allergens	Almond, Hazelnut, Peanut, Walnut,	Qualitative		PJKMS
	Casein, Soja and Egg			
Lactose free		0,01-0,04 g/100g	+/- 35%	LP025
		>0,04 g/100g	+/- 25%	
Sample prep. Sugar extraction				LPP01
Sulfit SO2		10 mg/kg	+/- 25%	LP04X

On the shape and cleanability of allergens.

The form and solubility of allergens and whether they are homogeneously distributed in the food or particulate affect how and when the use of PAL can be justified.

Some allergens can adhere very strongly to the substrate. Whether water cleaning is possible or only dry cleaning (e.g. in muesli production) also has a major impact.

Cleaning must therefore be adapted to allergens and equipment. A good hygienic design of the equipment helps. Production planning also has a major impact. The summary below is based on information in the document "Help in your work with allergens and other hypersensitivity-inducing foods, the Swedish Food Federation and the Swedish Retailers Federation" from November 2021.

- Liquid foods - easier to clean, often more evenly distributed allergens.
  Examples: milk, liquid egg, soya oil, celery and kiwi juice.
- Liquid from particulate foods - as above.
  Examples: liquid from fish, seafood, fruits like kiwi.
- Powders - sometimes water soluble, more or less uniformly distributed, may be statically charged.
  Examples: milk and egg powder (egg static), wheat and lupine flour, fish and insect meal.
- Pasta - sometimes "sticky", oily, more difficult to clean, more or less evenly distributed.
  Examples: seafood paste, peanut butter, apricot kernel paste, mustard, tahini.
- Particle form or pieces - unevenly distributed, contamination difficult to prevent.
  Examples: various nuts, peas, sesame and poppy seeds (poppy static).

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Annex 3 - Guidance for evaluation of the risk assessment on labelling "may contain traces of allergen X"

KRAV

1. Producers of Own Brand products Swedish Food Retailers Federation members must maintain a certification against a food safety standard recognised by GFSI.

If yes - go ahead

If no - warning labelling (PAL) not accepted

(see comment on IP certification)

2. The producer's food safety system must, among other things, be based on effective implementation of the requirements of any industry guidelines/recognised guides on handling allergens and other hypersensitive foods accepted by Swedish Food Retailers Federation.

If yes - go ahead

If no - warning labelling (PAL) not accepted

DECISION CRITERIA	COMMENTS
See https://mygfsi.com/	Producers of products and brands other than Swedish Food Retailers Federation members' own brands should have the same kind of certification. Suppliers (agents) should but be certified according to BRCGS or IFS standards. The farming chain is recommended to be Global-GAP certified. In case of "no" or if companies only have an IP food certification *accepted by the retail company*, a deeper evaluation of the PAL risk assessment needs to be done.
Food industry and retailers and guidelines for Allergy and other hypersensitivities: Food handling and labelling (2015). Guidance on Food Allergen Management for Food Manu facturers, FoodDrink Europe (2022). Food Industry Guide to Aller gen Management and Label ling, Allergen Bureau (2021). Components of an Effective Allergen Control Plan, A framework for food process sors, Food Allergy Research & Resource Program (2008). (see more examples on page 8)	One or more of the documents may have been used. Producers and suppliers should primarily use the Swedish national guidelines approved under Article 7 of EC Regulation 852/2004). Other national or international guidelines for allergen management that are equivalent in scope to those above may be accepted, provided that Swedish Food Retailers Federation members and owners of private label products have been informed and approved.

3. Any warning labelling (PAL) needs to be clear and consistent.

If yes - go ahead

If no - warning labelling (PAL) not accepted

4. Warning labelling (PAL) may be indicated only for the allergens, and gluten, listed in the EU regulation.

If yes - go ahead

If no - warning labelling (PAL) not accepted

5 A and B. Risk assessment for PAL needs to be based on reference doses, portion size and appropriate sampling plans and analytical methods.

If yes - go ahead

If no - warning labelling (PAL) not accepted

5 C. Risk assessment for PAL according to VITAL is accepted if:

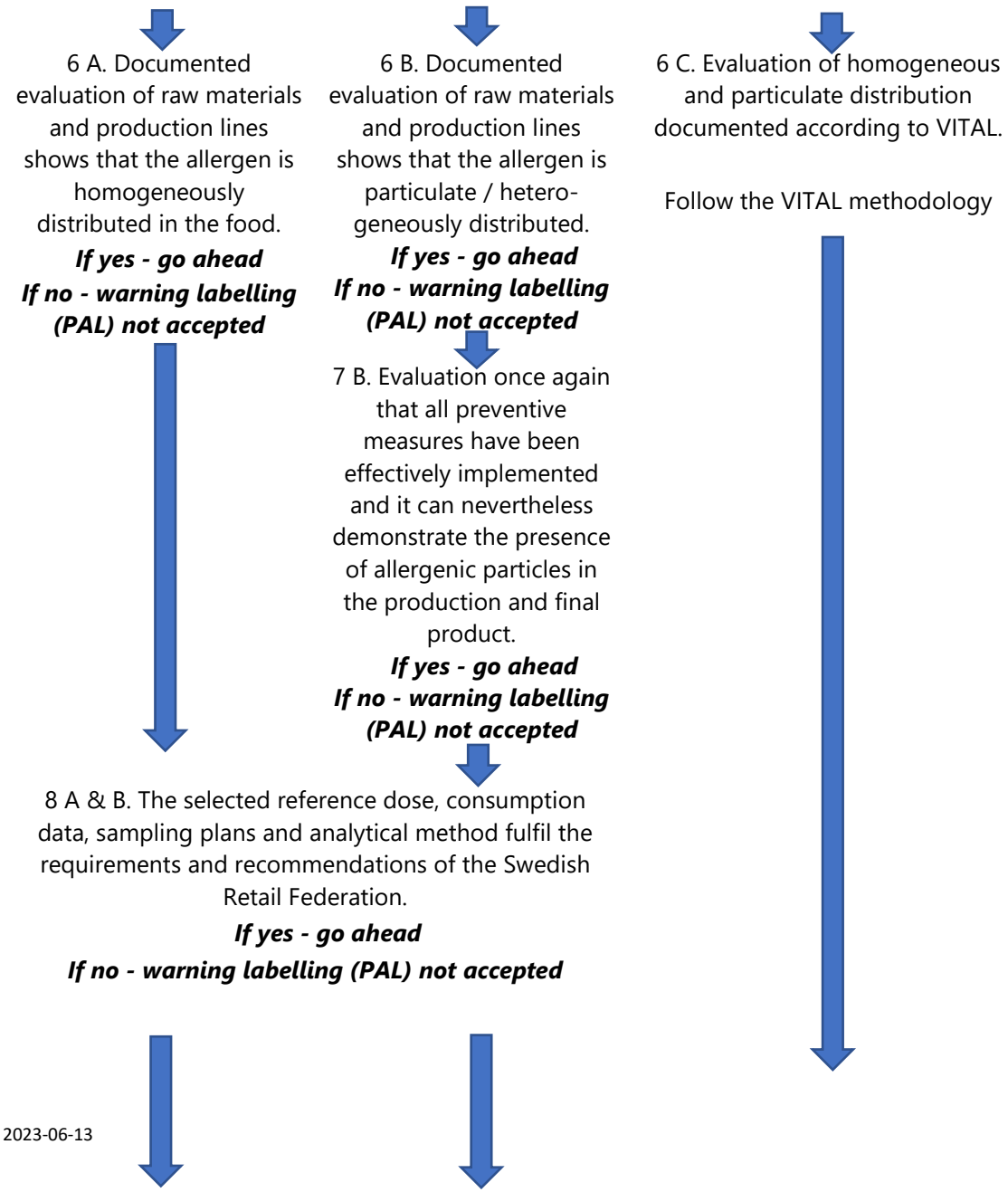
i. Portion size/consumption data (reference amount) is based on 75 or preferably 90/95 % levels.

ii. Theoretical data confirmed with sampling and analysis results.

If yes - go ahead

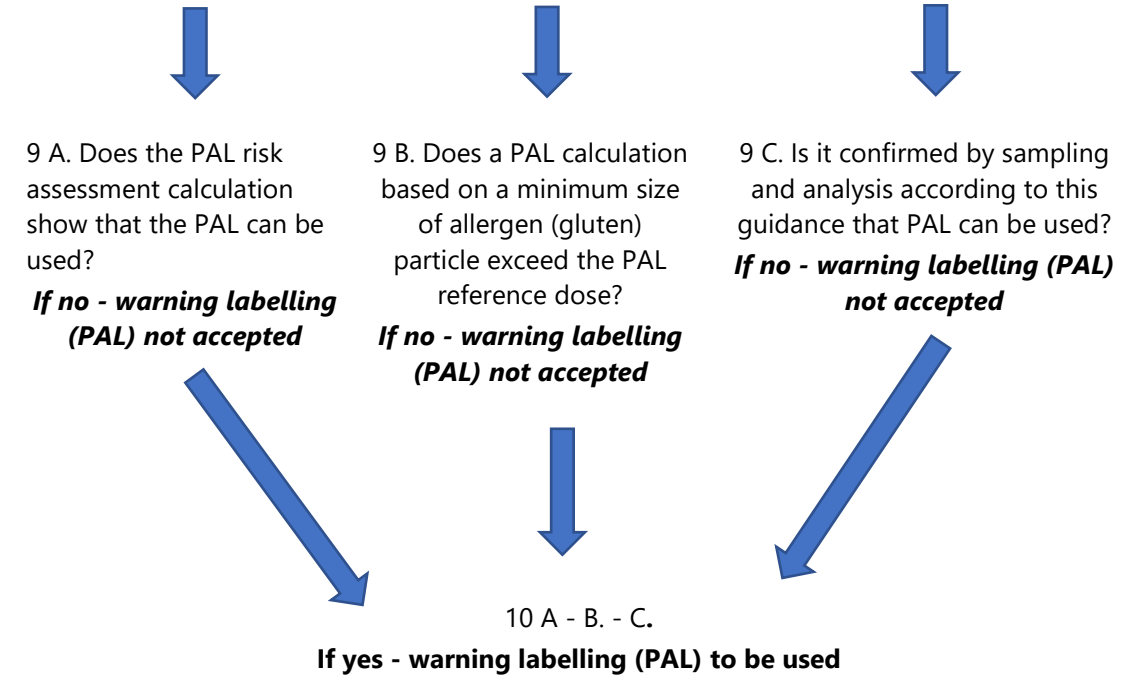
If no -PAL is not accepted

DECISION CRITERIA	COMMENTS
May only be formulated as "May contain traces of x" or "May contain x" (x= a name given allergen, or gluten according to EU information Regulation 1169/2011).	Swedish Food Retailers Federation recommends that the Swedish industry guideline and the Swedish and Nordic authorities' formulation "May contain traces of" be used.
Annex to the EU Information regulation 1169/2011	PAL may not be applied for lactose and sulphite (mentioned in 1169/2011). PAL must not be used on life means labelled with "Free from x" SvDH accepts the use of PAL on products labelled as "vegan". The EU Novel Foods Regulation 2017/2470 sets out specific requirements for the labelling of rapeseed protein, some authorised insect raw materials, etc. for allergic persons.
5A & B. See *Guidance on requirements and recommendations for the use of precautionary allergen labelling (PAL) for food products.* 5 C. See references Birot et.al. 2018, FAO/WHO 20 August 2021, FAO/WHO 4 April 2022; ILSI 2022, Livsmedelsverket 2022 and documentation published on www.allergenbureau.net.	Swedish Food Retailers Federation primarily follows the advice set out in the Swedish Food Agency's Report 13 - 2022 *Undeclared allergens in food - guide on how to assess the risk of allergic reactions in the population*, Version 2 (Livsmedelsverket 2022).



DECISION CRITERIA	COMMENTS
	The evaluation needs to be based on knowledge of the shape of allergens (including gluten) and the possibility of cleaning using a validated allergen cleaning. See also *Help in your work with allergens and other hypersensitive foods*, Swedish Food Federation & Swedish Food Retailers Federation Nov. 2021" (in Swedish).
The selection of raw materials, hygienic design of equipment and production management updated where possible after 7B (also part of the VITAL methodology). See www.allergenbureau.net	It is important to be able to demonstrate continuous improvement by, for example, providing equipment with improved hygienic design, new cleaning methods, etc.
Reference dose at ED01 - ED05 level. Portion size (reference quantities) based on 75% (*p75*). Sampling carried out according to SvDH recommendation or by other statistically based method. Analytical results from a laboratory accredited for the method used. Laboratory measurement uncertainty for method and matrix known.	About sampling and analyses - see above in the document " Swedish Food Retailers Federation, Menigo and Martin Servera's requirements and recommendations for the use of PAL (PAL - Precautionary Allergen Labelling) for food products".

Swedish Food Retailers Federation, Menigo and Martin Servera's requirements and recommendations for the use of PAL.



DECISION CRITERIA	COMMENTS
According to the method documented in the producer's or supplier's risk assessment report.	If analytical data are not available or if the retailer wants to verify the supplier's results and safety data, five samples per life batch should be taken and sent to a laboratory accredited for the method in question.
The results of the PAL assessment shall be documented in a report from the producer/supplier of the EVM product.	NOTE: The retailer's value ring using this guide needs to be documented. Documentation should be archived with traceability to the producer/vendor's PAL assessment report.