

Swedish Food Sector Guidelines For:

Management and labelling of food products
with reference to

Allergy and other Intolerance

English Version, 2015

For exact wording, please read the Swedish version

Summary

The purpose of this document is to support work with food safety, to facilitate compliance with current legislation, and to provide guidelines for how “may contain” labelling can be made uniform and applied restrictively. The aim of these national guidelines is to help consumers with allergies and food intolerances in their daily choice of foods.

These guidelines are based on the allergens and other intolerance-causing ingredients listed by EU. This document provides an overview of current legislation in the field, as well as a description of the prevalence of allergy and intolerance and what allergic reactions can look like.

The document provides concrete advice to all actors in the food production chain and covers all of the steps from raw material to consumption of the final product, as well as training and supervision of personnel. Labelling aspects are examined with respect to the new, more stringent requirements of EU labelling rules. The guidelines presuppose that attention is paid to allergy- and intolerance-causing substances in regular quality work.

The document also has supplementary checklists for each link in the food chain, including a list of actions to be taken if, despite all safety measures, a consumer does experience a reaction.

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1. Introduction

These guidelines have been developed by the Swedish Food Federation (*Livsmedelsföretagen*) and the Swedish Food Retailers Federation (*Svensk Dagligvaruhandel*) in cooperation with the National Food Agency (*Livsmedelsverket*) and Swedish Celiac Society (*Svenska Celiakiförbundet*). The Swedish Asthma and Allergy Association (*Astma- och Allergiförbundet*) has also taken part in the process, but does not accept “may contain traces of” labelling. The guidelines are produced for current Nordic conditions, using the “Food Industry Guide to Allergen Management and Labelling” produced by the Australian Food and Grocery Council as an outline.

1.1 Scope

The guidelines are intended for businesses and people who manufacture, package, distribute, sell, serve or otherwise handle raw materials, ingredients and final food products for the Swedish market.

The purpose of the guidelines is to support food safety work, to facilitate compliance with current legislation and to provide guidelines for how “may contain traces of” labelling can be made uniform and applied restrictively. The aim is to help consumers with allergies and intolerances in their daily choice of foods.

The term *allergens* is used in this document to refer to allergens and other substances that may cause allergic-, intolerance- or other adverse reactions.

1.2 Current legislation

Current legislation applicable to the food sector can be found on the National Food Agency’s website (www.slv.se).

Regulation (EC) No. 178/2002 states the general principles and requirements of food law.

According to EU regulations (EC labelling directive 2000/13/EC, as of 13 December 2014 replaced by Regulation (EU) No. 1169/2011), the following ingredients and products thereof must always be declared and clearly emphasised in the ingredient list:

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats, or their hybridized strains, and products thereof, except:

- a) wheat based glucose syrups including dextrose¹;
- b) wheat based maltodextrins¹;
- c) glucose syrups based on barley;
- d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin.

2. Crustaceans and products thereof.

3. Eggs and products thereof.**4. Fish and products thereof, except:**

- a) fish gelatine used as carrier for vitamin or carotenoid preparations;
- b) fish gelatine or Isinglass used as fining agent in beer and wine.

5. Peanuts and products thereof.**6. Soybeans and products thereof, except:**

- a) fully refined soybean oil and fat¹;
- b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
- c) vegetable oil derived phytosterols and phytosterol esters from soybean sources;
- d) plant stanol ester produced from vegetable oil sterols from soybean sources.

7. Milk and products thereof (including lactose), except:

- a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- b) lactitol.

8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* [Wangenh.] K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin.

9. Celery and products thereof.**10. Mustard and products thereof.****11. Sesame seeds and products thereof.**

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

13. Lupin and products thereof.**14. Molluscs and products thereof.**

¹ And the products thereof in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the authority for the relevant product from which they originated.

Effective 13 December 2014, Swedish National Food Agency regulations (LIVSFS 2014:4 on food labelling including non-prepackaged foods) stipulate that consumers who purchase foods at in-shop deli counters or take-away restaurants shall upon request be provided with information regarding all the ingredients of the food they are buying. For unpackaged foods or foods meant to be consumed on site, the consumer must be able to get information regarding whether the food contains any of the 14 allergens (or products thereof) included on the EU list. In all cases, it must also be clearly indicated, e.g. by way of signage or similar, that information on allergens is available.

According to Regulation (EC) No. 853/2004 (Annex II, chapters I and V) of the European Parliament and EU Council, food premises shall be kept clean and in good working order. The planning, layout, construction, siting and size of premises shall permit adequate maintenance, cleaning and/or disinfection, and be designed such that contamination can be avoided or minimized, and to provide adequate working space to allow for the hygienic performance of all operations.

According to Article 5 of Regulation (EC) No. 853/2004, food business operators shall put in place, implement and maintain a permanent procedure or procedures based on Hazard Analysis and Critical Control Points (HACCP) principles. The National Food Agency expands on this in its information regarding national guidelines (*Information om nationella branschriktlinjer*, available at www.slv.se).

Contamination refers in this context to allergens.

Fact box:

Basic requirements

Establish procedures to create good general hygiene conditions:

- Training in food hygiene.
- Personal hygiene must be good.
- Only water fit for human consumption is to be used.
- Insect and animal pests are to be controlled effectively.
- Cleaning of equipment, premises and transport equipment and facilities must be carried out regularly.
- Temperature of foods and premises to comply with applicable limits.

HACCP

A Hazard Analysis and Critical Control Points plan is a system for identifying, evaluating and controlling hazards that are critical for food safety.

1. Identify hazards that can exist in production (draw up flow chart for every product category). Where can hazards occur in production? Where in the process can these hazards be controlled?
2. Determine critical control points.
3. Set critical limits for each critical control point.
4. Establish a system for monitoring each critical control point. Examples can include measurement of temperature and time.
5. Establish corrective actions to be taken if the critical limits are exceeded.
6. In addition to systematic monitoring, conduct tests and evaluations to verify (control) that the system is working.
7. Establish documentation procedures.

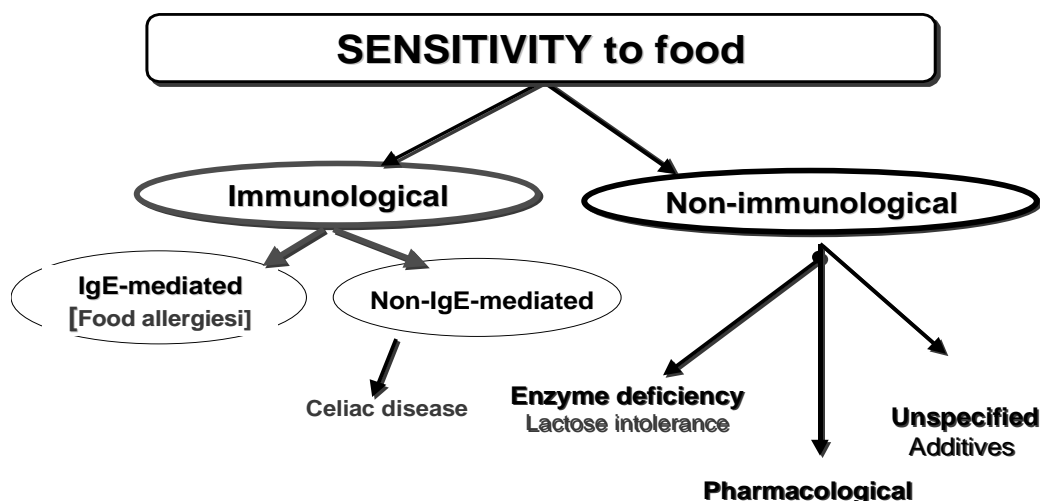
1.3 Consumer expectations

Consumers expect and demand that everyone who handles foods has the knowledge and insight required to supply safe foods of high quality.

2. Adverse Reactions to Food – Allergy and intolerance

Adverse reactions to food include immune-mediated and non-immune-mediated reactions. In the case of an immune-mediated response, IgE antibodies or specific cells are involved. IgE-mediated reactions are known as *food allergies*.

Non-immune-mediated responses include enzyme deficiencies, such as lactose intolerance, pharmacological reactions, and responses arising from as yet unknown mechanisms.



2.1 Immunological reactions

Reactions mediated by IgE antibodies – Allergy

Prevalence. Food allergies affect a small proportion of the population. In some cases, an allergic reaction can be life-threatening or fatal. General estimates suggest that 1-2% of the adult population and 5-8% of children suffer from true food allergies. Many children outgrow their allergies, such as those to milk and eggs. Other allergies, e.g. to fish and peanuts, tend to persist.

The occurrence of allergies is determined by interactions of exposure factors and personal susceptibility of the exposed individual. Children with allergic parents have a greater risk of becoming allergic themselves. Most allergies begin in childhood, but allergy onset can also occur later in life. Many people develop pollen allergies in their teens. In connection with this, allergies to foods such as hazelnuts, almonds, apples and raw carrots often also appear. The actual number of adults with allergies is therefore significantly higher, with figures in the range of 15-20% reported. A considerable number of adults therefore avoid certain foods because of allergies.

Mechanism. In the case of food allergy, an immunological response involving IgE antibodies occurs. An individual must first be exposed to a particular protein in order to develop antibodies against it. Practically all known food allergens are proteins and an individual must first be exposed to a particular protein in order to develop antibodies which may cause symptoms upon re-exposure. Allergenic proteins normally remain unaffected during food manufacturing processes and in the gastrointestinal tract.

Symptoms. Symptoms of an allergic reaction can occur within minutes or appear several hours after ingestion of an offending food. Eczema and other skin reactions can appear days after consumption of the offending food. A small number of people are so sensitive that they may experience a reaction from the mere smell of a food, e.g. fish or peanuts.

The symptoms of an allergic reaction can vary and range from mild to severe. Examples of possible symptoms include:

- respiratory problems (runny nose, tearing, asthma and breathing difficulties, swelling of the lips, mouth and throat),
- gastrointestinal problems (nausea, stomach pain, vomiting, diarrhea),
- skin rashes (hives, itching, eczema).

In rare cases, a more severe reaction may occur, leading to a sudden drop in blood pressure, severe constriction of the airways and a general state of shock (anaphylactic shock) that can lead to death within minutes if not treated immediately. Although only a small number of people with food allergies are at risk of such serious reactions, there are nevertheless several documented cases resulting from accidental ingestion of an offending food.

Offending foods. It is estimated that the majority of all food allergies are to proteins in common foods such as milk, eggs, fish, crustaceans, legumes (e.g. peanuts, soybeans, peas, lupin flour), nuts (e.g. hazelnuts, walnuts, pecans, cashews, pine nuts, pistachios, macadamia nuts, almonds, apricot kernels), seeds (e.g. sesame seeds, sunflower seeds, poppy seeds, mustard seeds) and cereals (wheat, rye, barley, oats), and corn and buckwheat. Many other foods may also cause allergies, though reactions to these are less common. Due to many serious reports of reactions to celery, from Central and Southern Europe in particular, celery is included in the foods that must always be declared. For examples of other allergens, see Appendix 1 of this publication (and in Swedish also the guide *Hjälp i ditt arbete med allergener och andra överkänslighetsframkallande livsmedel*).

Non-IgE-mediated reactions

Celiac disease (gluten intolerance) is an example of an immune-mediated disease that does not involve IgE antibodies. In celiac disease, a local immunological response to specific cereal proteins from wheat, rye, barley, oats¹ occurs in the small intestine. This causes a damage to the small intestinal mucosa, which can lead to, among other things, malnutrition. People with celiac disease must avoid products containing wheat, rye, barley and oats, though one's diet may include cereals where the gluten has been removed, such as wheat starch, and naturally gluten-free products like corn, rice, millet or buckwheat. Symptoms may occur immediately after ingestion, but can also take longer to appear. Healing after intestinal injury can take up to 6 months. In Sweden, the prevalence of celiac disease is estimated to be 1%.

2.2 Non-immunological reactions

Food allergy and celiac disease should not be confused with non-immune-mediated reactions. The latter include lactose intolerance, which is caused by a deficiency of an enzyme needed to digest lactose (the sugar in milk). The main symptoms of lactose intolerance are

¹ The findings of a number of clinical studies suggest, however, that most people with celiac disease are able to eat oats. For more information, see the National Food Agency and Swedish Celiac Society websites (www.slv.se and www.celiaki.se, respectively).

abdominal pain, diarrhea and flatulence. Individual sensitivity to lactose varies, but most lactose-intolerant people are able to tolerate small amounts of lactose. It is estimated that 3-5% of native Swedes are lactose-intolerant. In the non-native Swedish population lactose intolerance is more common. Lactose intolerance should not be confused with milk allergy. Allergy to milk is an immune-mediated response to the proteins in cow's milk and can cause much more severe reactions. In the case of milk allergy, all dairy products and products containing milk protein must be avoided.

A person can experience symptoms similar to an allergic person without the immune system being involved. The sensitivity to certain substances is considered pathologically elevated in one or more of the body's organs. Certain food additives, such as dyes and preservatives, can cause this type of non-immune reaction.

People with asthma can have a sensitivity to sulphites. Sulphites are used as preservatives and antioxidants. Sulphites are volatile and it is mainly when they occur in high concentrations and in acidic foods, where the sulphite is easily released in gaseous form, that they may cause problems. Asthma is a chronic inflammatory condition of the airways and can lead to severe breathing difficulties for the person affected.

3. Allergen Management

Special attention is required to manage potential allergy risks. The recommended method for managing the risks of allergen contamination, incorrect labelling and other handling that may lead to allergens not being declared is establishment of a Hazard Analysis and Critical Control Points (HACCP) program. This includes evaluation of the hazards associated with every step of the entire food production chain, from receiving the raw materials to consumption of the finished product. Each actor must carry out this evaluation for his/her specific segment of the food chain.

The handling instructions for allergens also apply to other ingredients that can cause adverse reactions (see Section 1.2 and Appendix 1).

Accidental exposure

Many foods contain ingredients that are known allergens, but allergens can also appear in foods through unintentional exposure. Awareness of the following points is essential in order to minimize the risks for unintentional contamination:

- A company's ongoing training of employees should always cover education about allergens.
- Allergen risks should be observed at every stage in the process, from the purchasing, receiving, handling and storage of raw materials and finished product, to consumption.
- When developing new products and recipes, every raw material should be carefully identified and evaluated. Use only well-documented raw materials.
- Complete product specifications should be prepared. Note that allergens can sometimes be present as a sub-component of a raw material, additive, etc., e.g. as a carrier in a seasoning mix.
- When developing products, allergens in the recipe should be evaluated.
- When conducting trial runs, the introduction of new allergens onto the production line should be avoided.
- Good procedures should be established for using rework (internally recycled product), e.g. crushings from dried pasta with egg. It is essential that the rework is used in the right product and not in other products, in this case, for example, pasta without egg.
- Premises, equipment and order of handling should be planned to prevent contamination between products, production lines and work tools.
- Good cleaning procedures should be established in order to remove all allergenic substances from the equipment, storage areas and other premises where foods are handled.
- Procedures should be in place to ensure that the right product is packed in the right packaging. The ingredient list on the package should always reflect the actual contents of that product.
- Labelling of raw materials, semi-finished goods and finished product should be such that there is no risk for mix-ups. Keep in mind that contamination can also occur after manufacturing, for example, when handling semi-finished products that have not yet been put in their final packaging.
- When necessary, the food should undergo post-production controls to confirm that no accidental exposure to allergens has occurred.

- When changes are made to a product, production or other handling procedures, all of the above points should be re-examined.

Food manufacturers and food handlers should stay abreast of new information on allergens, e.g. in the form of guidelines and recommendations from sector organizations and authorities. As new knowledge becomes available, it should be evaluated at once based on the circumstances of the handling in question, after which the necessary measures should be taken.

3.1 Training and supervision of personnel

Employees must understand the risks of allergens and the consequences of accidental ingestion. Training employees who handle food constitutes the basis for success. Employees must understand the importance of taking immediate action if contamination is suspected.

Procedures for control and prevention of contamination must be visible or readily available for all employees in premises where food handling occurs.

The procedures should contain information about:

- Good hygiene, including rules regarding clothing, hand-washing and hand contact with foods.
- Cleaning of premises, equipment and tools.
- Handling of rework materials, e.g. the conditions under which this type of product may be used.
- Waste management, including how waste should be labelled and kept separate from rework.
- Situations where potential cross-contamination can occur between products, production lines or equipment, e.g. how this can happen and each employee's responsibility for preventing this.
- Scheduling of production and handling, as well as how it is decided.
- Labelling of raw materials, semi-finished goods and finished products.

Internal compliance with instructions and procedures for control of allergen risks should be ensured regularly by trained internal auditors.

3.2 Product development and new recipes

The starting point for all food production is ensuring that complete product specifications are available.

In product development, the ingredients and manufacturing procedures should be reviewed from an allergy perspective. The people responsible for development of products and recipes must have sound knowledge of the risks for people with allergies and other intolerances. Allergenic ingredients should only be used if they are necessary for the product.

Avoid the introduction of new allergens into well-known products and different package sizes.

It is essential that the people in charge of production are given ample advance notice when new ingredients are to be used. Appropriate preventive product safety measures can then be taken, such as reviewing documentation, recipe collections and labelling procedures at all stages of the process. Plan the production order and inform all employees of the upcoming changes.

See also Section 4.9, *Recipe changes*.

3.3 Raw materials and ingredients

Products can be contaminated with allergens via improper handling of raw materials by the supplier. Raw material suppliers should have sufficient expertise, use HACCP, and fulfil allergen control procedures according to these guidelines.

When purchasing and receiving raw materials, the manufacturer should consider the risk of contamination prior to the goods entering the premises. Information should be requested from raw material suppliers to identify raw materials and products that may be allergenic. This documentation is required since some ingredients are easy to identify as potentially allergenic, while others are not as obvious. Manufacturers and purchasers can also carry out supplier audits in order to identify possible risks of contamination, incorrect labelling or other handling that can lead to allergens not being declared.

When it comes to allergens and other risks, reliable contacts and good relations between raw material suppliers and manufacturers promotes good product safety.

Allergenic raw materials, ingredients, semi-finished product, etc., should be identified upon receipt and, if possible, kept separate from one other and from other foods. This is especially important when handling unpackaged foods and ingredients. Clear labelling reduces the risk for mix-ups and contamination.

At times there may be a need for securing access to several ingredients that can be substituted in a product, e.g. alternative seasonings and raising agents with carriers. In some cases, a particular ingredient may need to be purchased from other suppliers. The manufacturer should identify which ingredients and which suppliers can be accepted. Alternative ingredients should be handled in exactly the same way as standard ingredients and the required product specifications and documentation should be requested to ensure that no allergenic raw materials are used accidentally.

3.4 Premises and equipment

Premises should be designed to facilitate allergen control. It is preferable to have separate equipment and work tools to clearly distinguish between tools used for products that contain allergenic substances and those for products that do not. Manufacturers with multiple production units should consider separating products or production steps to reduce or prevent contamination.

3.5 Manufacturing

In order to minimize the risk of unintentional allergens and contamination, HACCP principles and good manufacturing practices should be used.

When planning production, attention should be paid to how one can best minimize the risk for contamination between different raw materials and products. The process should be designed to minimize the amount of equipment exposed to allergenic substances. The manufacturer should identify where in the work area, equipment and tools contamination risks exist. A monitoring system must be in place to prevent contamination. When handling products with allergenic substances, separate work tools and equipment are preferable. If the same equipment must be used, where possible, product containing allergenic substances should be produced last.

Effective cleaning procedures are of particular importance when allergens are present. This can often require the disassembling of equipment for manual cleaning. Controls must be carried out after cleaning to confirm that no allergens remain.

3.5.1 Rework – internally recycled product

There should be procedures for the handling of rework in production. Allergen-containing rework should only be used in product where that allergen is already present. How and when rework may be used should be documented.

Rework materials must be correctly labelled to ensure correct identification and handling. There must be a procedure for tracking the rework materials used through to the finished product.

3.5.2 Labelling during handling and production

There should be control procedures in place to ensure proper labelling of raw materials, semi-finished goods and products. When choosing packing materials of the same or similar appearance, e.g. for flavour variants, it is especially important to ensure that the correct packaging is used. In this context, a checklist to be signed by the person responsible is recommended.

3.5.3 Design of equipment and production line

When choosing equipment, one should assess the ease with which the equipment's outer surfaces and internal parts can be cleaned. To facilitate cleaning and reduce the risk of contamination, production lines that cross or are too close to one another, should be avoided.

3.6 Cleaning

Documented cleaning procedures are essential to ensure that effective and proper cleaning is achieved. Adequate time must be allocated for cleaning. Hidden areas of the equipment must be identified and dismantling of equipment may therefore be necessary. Failure to clean properly can lead to a build-up of raw material- or product residue inside the equipment.

In order to guarantee effective cleaning, proper equipment and documented procedures are required. A visual inspection should always be conducted. In some cases, sampling of the production line for analysis, e.g. through documented cleaning tests, may be necessary in order to assess the cleaning results. Note that a negative test result is never a guarantee that the equipment is thoroughly cleaned.

To check that the equipment has been cleaned properly, analyses can be conducted to test for the presence of allergens. The presence of allergens is normally determined by immunological techniques based on specific antibodies, such as ELISA.³ This analysis should be performed by personnel trained in the technique.

Detection limits for different allergens vary. Note that a test result of “not detected” is never a guarantee that it is completely allergen-free, but it is an indication of good cleaning routines. If allergens are detected, however, it is proof of inadequate cleaning.

3.7 Packaging and post-production controls

Production planning includes the order in which different products are packaged. Special attention must be paid when the production of bulk volumes occurs at one location and the packaging of the finished product at another. In such cases, the order of packaging must be designed to minimize the risk allergen contamination and to maximize good cleaning routines.

When preparing package labels, it is necessary to ensure that the text reflects the actual recipe ingredients. If a recipe change occurs and a new allergen is added, new packaging materials or a new label must be used immediately. It is also essential to ensure that the product is packed in the correct packaging with the correct label. When choosing packaging of the same or similar appearance, such as for flavour variants, it is especially important to ensure that the right packaging is used.

Only one list of ingredients is permitted, and this must be complete and clear. Affixing an additional label or sticker with individual ingredients is not acceptable.

Unpackaged finished product containing allergens should be kept separate from products that do not contain allergens. Finished products containing allergens should be securely packaged to eliminate the risk of cross-product contamination.

3.8 In-store handling

When products containing allergens are handled in the store completely or in part without packaging, for example, at service counters manned by shop personnel, handling should follow these guidelines as well as the food sector's self-inspection guidelines for HACCP-based food hygiene for retail handlers (*Säker mat i din butik*).

³ Enzyme Linked ImmunoSorbent Assay

Self-serve areas where consumers themselves handle unpackaged food products can never be completely safe from an allergy standpoint, but the risk of contamination should nevertheless be reduced to a minimum.

4. Labelling

4.1 Allergenic ingredients that must be labelled

See list of allergens given in Section 1.2.

The list will be updated as necessary. See also Appendix 1, the guide *Hjälp i ditt arbete med allergener och andra överkänslighetsframkallande livsmedel*, and the labelling handbook for prepackaged foods (*Märkning av färdigförpackade livsmedel*) from the Swedish Food Federation (available at www.li.se).

4.2 Scope of labelling

The allergens referred to in Section 4.1 must always be declared and clearly emphasised in the list of ingredients when they are included as:

- ingredients, i.e. raw materials or additives, including flavourings and enzymes,
- ingredients in a compound ingredient, including additives and enzymes that serve no function in the finished product,
- processing aids, i.e. substances used in the manufacturing process that may unintentionally remain in the finished product,
- carriers, e.g. for additives, seasoning mixes and flavouring substances.

All items in the ingredient list should be declared in descending order by weight, and the list should begin with a heading that includes the word “ingredients” (Swedish: *ingredienser*).

Ingredient lists must be given on foods packaged for the consumer. For other packaged foods, e.g. certain industrial raw materials, sufficient information must be provided in order that food producers can in turn label their products correctly.

Note that all ingredients in rework are also ingredients in the finished product and must be stated in the list of ingredients.

4.3 Complexity of labelling

Documentation enables manufacturers to know which raw materials the ingredients they use originate from. The comprehensive labelling requirements described in Section 4.2 require manufacturers to be responsible for identifying all ingredients, components in compound ingredients, additives and processing aids used in their products.

Additives, seasoning mixes, processing aids and vitamins are often mixed with carriers or solvents that may contain one of the allergens that must be declared, such as wheat starch or lactose.

All components of a compound ingredient must be stated. Exceptions may only be made if the compound ingredient is recognized in EU legislation and makes up less than 2% of the finished product. In this case, it is sufficient to state the name of the compound ingredient followed by additives and possible allergens (see Regulation (EU) No. 1169/2011). For example, chocolate may contain hazelnuts, an allergen that must always be declared. Note that this means that, despite exceptions, allergens must always be declared and emphasised.

Suppliers of compound ingredients, additives, processing aids, etc., are responsible for providing their customers with information about any of the allergens referred to in Section 4.1 present in their products. (See also Appendix 1).

There may be ingredients manufactured from allergens listed in 4.1 in which the allergen is no longer present. Such exceptions are also listed in Section 4.1.

Food producers and food handlers should stay apprised of new information on allergens as it becomes available.

4.4 How to declare allergens

Regulation (EU) No. 1169/2011 states that allergens must be indicated in the ingredients list “with a clear reference to the name of the ingredient or product” listed in Section 1.2. The name of the allergen must be emphasized in a typeset that clearly distinguishes it from the other ingredients listed, for example, in a different font, style or background colour. In cases where several ingredients come from the same allergen, this shall be clearly stated and emphasized for each ingredient in question.

It is the allergen itself that shall be emphasized with the use, for example, of bold type: **wheat flour**. Another option is to use bold for the entire ingredient: **wheat flour**. If, for technical reasons, the use of bold type in the label is not possible, upper case lettering may be used (**WHEAT flour** or **WHEAT FLOUR**), or some other clear method of marking that the allergen is present. In the case of electronic labelling of products for distance selling, problems may arise with the use of bold fonts in labelling as all recipients may not be able to view this emphasis. In such cases, upper case lettering or some other way of clearly distinguishing the allergen in the labelling should be used.

This means that starch produced from wheat must be declared as **wheat starch**, and lecithin produced from soy as **emulsifier: soy lecithin** or **emulsifier E322 (from soy)**.

When an allergen is present in another ingredient (see Section 4.3), this can be stated as “chocolate (contains **hazelnuts**)”.

Example:**Vanilla ice-cream cone with strawberry jam and bits of chocolate**

Ingredients: Skim **milk**, strawberry jam 30% [strawberries, sugar, water, dextrose, stabilizer (E440), acid (E330)], waffle cone [**wheat** flour, water, sugar, sunflower oil, salt, emulsifier (**soy** lecithin)], sugar, canola oil, chocolate coating [sunflower oil, sugar, cocoa powder, emulsifier (**soy** lecithin)], glucose syrup, chocolate 1.5% [with ground **hazelnuts** and emulsifier (**soy** lecithin)], emulsifier (E471, **soy** lecithin), stabilizer (E407), flavouring (contains **lactose**).

4.5 Use of “free from” labelling

In order to use statements such as “gluten-free” or “lactose-free” in the labelling of foods, the food products must meet the requirements for foods for particular nutritional uses (SLVFS 2000:14) and be registered with the National Food Agency according to §12 of the noted legislation (see the National Food Agency website, www.livsmedelsverket.se).

Statements regarding gluten are also regulated according to Regulation (EC) No. 41/2009.

When the new Regulation (EU) No. 609/2013 takes effect in July 2016, the rules for labelling of “gluten-free” foods will instead be added to Regulation (EU) No. 1169/2011.

The National Food Agency only confirms receipt of registration of a product and does not evaluate products. The Agency shall then send the registration confirmation to the appropriate inspection authority for control.

The necessary handling and supervision procedures shall be included in companies’ self-monitoring systems in order to ensure that foods for special nutritional uses meet the legal requirements. Significant factors in a quality system like this is a well thought-out hazard analysis and procedures for training in hygiene and allergy issues, as well as labelling procedures.

Current products registered use labelling such as *milk-free*, *soy-free*, *egg-free*, *gluten-free* or *naturally gluten-free*, *lactose-free* and *low lactose*. It is important, however, that any “free from” claims are relevant. For example, margarine can not be labelled *gluten-free*.

4.6 When can “may contain traces of” be used?

Labelling that states a risk of contamination may never be used as an excuse for substandard controls and hygiene management. If procedures are not established or not applied, wording such as “may contain traces of peanuts” is of no help to the consumer. It can instead lead to the consumer taking a risk and eating the product, or avoiding a product that may be safely eaten by that consumer. The use of wording to this effect can also create problems for the manufacturer, as consumers may assume that the product is free from all other allergens.

“May contain” labelling should only be used as a last resort when the risk for contamination by an allergen in a specific production line is:

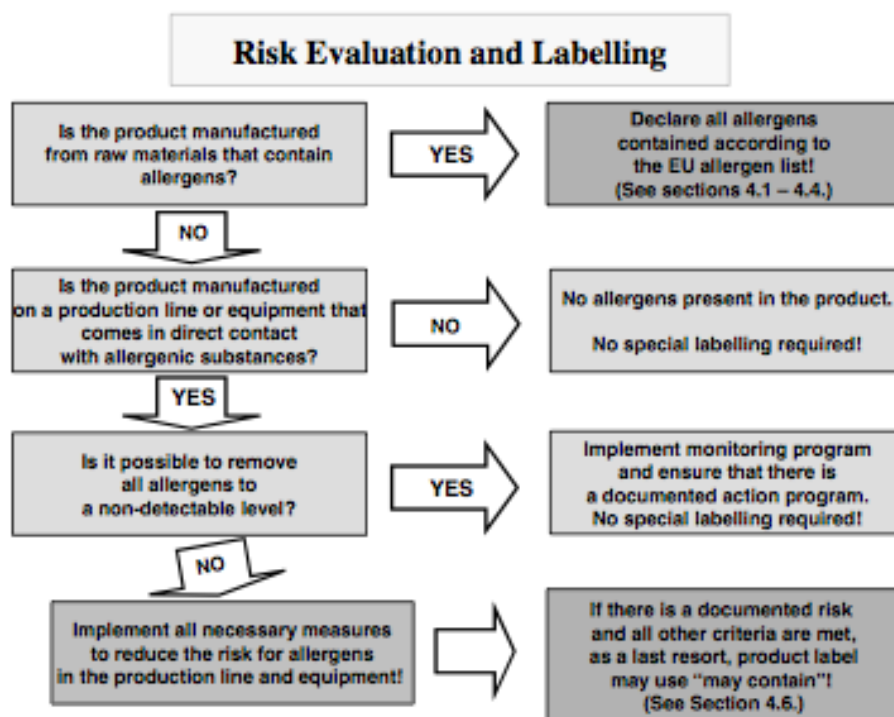
1. *Uncontrollable*, i.e. the ability to control the entire process is considered impossible, e.g. where part or parts of production occur in processing equipment that can not accessed for cleaning, or that can not be cleaned with water.
2. *Sporadic*, i.e. as identified through:
 - analysis showing the allergen to be homogeneously distributed in a product or in the form of visible bits or pieces in the processing equipment after cleaning
 - cleaning controls
 - substantiated consumer reaction

“May contain traces of” is permitted in the labelling only when both of these conditions are met!

Labelling should be designed for each specific allergen and group names should be avoided. For example, “may contain traces of nuts” may not be used. Each specific variety of nut should be declared.

The National Food Agency states that cleaning must meet certain standards. If there nevertheless remains a risk of allergen residue in the product, in accordance with the points above, “may contain traces of” may be used. The inspection authority will follow up to ensure that adequate measures have been taken to justify this labelling.

The following flowchart shows the decision points in determining how a product’s label should be designed. A decision to use “may contain” on the label should always be based on a documented risk assessment performed according to HACCP principles. A separate assessment should be made for each individual allergen because there may be products that contain one allergen but that may be contaminated by other allergens, such as a milk chocolate that contains traces of hazelnuts.



4.7 Alternative ingredients

According to Regulation (EU) 1169/2011, ingredients that are of similar type or mutually substitutable, and that constitute less than 2% of the finished product, may under certain circumstances be declared in the form of “contains ... and/or ...”, e.g. if the composition has not been altered. However, this does not apply to additives or the allergens listed in Section 1.2. (See also Appendix 1.)

4.8 Clear labelling on the package

The list of ingredients must be given adequate space on the package.

Regulation (EU) No. 1169/2011 states that the information on labels must be “easy to understand” as well as “easily visible, clearly legible and indelible.” A clear and understandable ingredient list is of particular importance for people with food intolerances. The font type, size of print and contrast between the text and background colours is of great significance with respect to legibility.

Simple, linear fonts and contrasting colours for print and background colour are appropriate. Narrow or wide fonts should be avoided. Empty space around the print improves legibility. If coloured print or background are used, the highest possible contrast should be sought. Keep in mind that the colour combinations of red and green, and blue and orange/red, are poor contrasts.

The font size used should be such that the height of lower case ‘x’ measures at least 1.2 mm. For smaller packages, where the largest surface area is less than 80 cm², lower case ‘x’ must be at least 0.9 mm.

4.9 Recipe changes

When making a recipe change or substituting one ingredient for another, the consumer should be clearly informed of the change in product content, especially if a new allergen has been introduced or a substitution has occurred. One way of doing this is to write “new recipe” on the front of the package.

If peanut flakes are used in place of almond flakes, for example, the product packaging should clearly state that a change in ingredients has been made. Otherwise, there is a risk that someone who tolerates almonds, but not peanuts, may eat the product out of habit and suffer severe allergic shock. Making the change in the ingredient list alone is not sufficient. Consumers come to rely on products they are able to eat and do not read the ingredient list every time they buy a certain product.

4.10 Other information – Product fact sheets

Manufacturers who produce allergen lists must recognize their responsibility to ensure that these lists are correct and that risk assessments are carried out. There must be quality systems in place to minimize the risk of contamination in these products. When preparing product fact sheets, it is of major importance that they state the ingredients a product does contain and not what the product “does not contain”. See also the Li labelling handbook (available at www.li.se).

Appendix 1: Examples of foods and ingredients that may contain allergens

Examples of food and food ingredients that may contain allergens are given below. In addition to the allergens listed in Section 1.2 of the Food Sector Guidelines (hereafter “Guidelines”), a number of additional allergens are included here. It is up to the individual company to evaluate, based on its regular product safety efforts, which of these additional allergens may need to be considered.

The paragraph regarding *Offending foods* on page 7 of the Guidelines states:

It is estimated that the majority of all food allergies are to proteins in common foods such as milk, eggs, fish, crustaceans, legumes (e.g. peanuts, soybeans, peas, lupin flour and seeds), nuts (e.g. hazelnuts, walnuts, pecans, cashews, pine nuts, pistachios, macadamia nuts, almonds, apricot kernels), seeds (e.g. sesame seeds, sunflower seeds, poppy seeds, mustard seeds) and cereals (wheat, rye, barley, oats), and corn and buckwheat. Many other foods may also cause allergies, though reactions to these are less common. Due to many serious reports of reactions to celery, from Central and Southern Europe in particular, celery is included in the foods that must always be declared.

For examples of other allergens, see the table below. The table is an appendix to the Guidelines and should not be considered a complete list. Other information may need to be obtained. See also the latest versions of National Food Agency allergy information brochures and the National Food Agency website (www.slv.se).

The examples of products given in the table show that extreme care must always be taken to ensure the origins of substances such as proteins and carriers in flavourings, bouillon powder, colours and dyes, seasoning mixes, marinades, hydrolyzed protein and similar ingredients.

Keep in mind, however, that even if an ingredient is not included in the EU list of allergens that must always be declared, the basic rule is that **all** ingredients used in the manufacturing of food must be stated in the list of ingredients (see section 4.2 of the Guidelines, Regulation (EU) No. 1169/2011, National Food Agency regulations and guides, Li labelling handbook, etc.).

The noted rules and regulations impose special requirements on how the food ingredients in the table below should be declared.

Allergens according to EU list	Specification	Examples of products	Examples of foods and food ingredients that may contain these
Cereals containing gluten	Wheat, rye, barley, oats, spelt, kamut, and hybridized strains thereof.	Fibre, bran, sprouts, gluten, semolina, malt, oat gruel. HVP (hydrolyzed vegetable protein), wheat syrup, starch/modified starch, glucose syrup, malt extract (malt syrup), maltodextrin.	Sourdough, bread crumbs, pasta, couscous, bouillon powder, potato products (treated with wheat flour), wort, seasoning mixes, roasted onion, soy sauce, confectionery (e.g. licorice).
Examples of cereals that may need to be considered in addition to the EU list	Corn, buckwheat.	Cereal mixes, muesli, cereal flakes	Corn flakes
Crustaceans	Shrimp, crab, lobster, crayfish.		Imitation crab made from fish, soups, bouillon, concentrated stock, flavourings, sandwich fillings, salads, shellfish salads and stews.
Molluscs	Snails, mussels, oysters, squid and octopus.		Shellfish stews, soups and salads.
Fish	Fish (all species).	Fish preparations. Fish gelatine, fishmeal, fish protein.	Cured, smoked, pickled and canned fish, fish roe, fish bouillon, caviar, fish cakes, anchovy-stuffed olives, marinades, steak sauces, sauces, seasoned pasta (e.g. chili pasta), liver paté, imitation crab made from fish.
Eggs		Whole eggs, egg yolks, egg whites. Egg albumin, lysozyme (E1105, preservative), lecithin (E322, emulsifier). Lecithin is produced mainly from soybeans and not from eggs.	Pasta, noodles, liver paté, meringue, aioli, mayonnaise, bread crumbs, batter coatings, potato flakes (treated with egg white), meatballs, cheese (with lysozyme), imitation crab made from fish.
Milk, including lactose		Cream, butter, buttermilk, skim milk, cultured and sour (fermented) milk products, e.g. acidophilus, curd milk, kefir, yoghurt, crème fraîche, whey cheeses. Butter oil, whey, whey powder, milk protein, casein, caseinate, lactoglobulin, lactalbumin. Milk sugar is the same as lactose.	All types of cheese, including hard cheese, dessert cheese, processed cheese, fresh soft cheese, cottage cheese, quark, enzyme-modified cheese, margarine cheese, garlic powder. Chocolate, meringue, nougat, bread crumbs, coconut milk, sausage, seasoning mixes (e.g. for crisps), margarine.

Allergens according to EU list	Specification	Examples of products	Examples of foods and food ingredients that may contain these
Peanuts		Peanut oil, peanut flour.	Peanut butter, satay seasoning, bouillons, sauces, pastry fillings, peanut flakes as a substitute for almond flakes in baked goods, sprinkles, confectionery, chocolate, marinades.
Soybeans		Soybeans, sprouts, soy flour, soy protein, soy concentrate, soy isolates, soy texturates, lecithin (E322), HVP (hydrolyzed vegetable protein).	Tofu, fermented products such as soy sauce, mushroom soy, tempeh, miso, imitation crab made from fish, bouillons, sauces, roasted onion, margarine, bread crumbs, chocolate, 'bars', sausages, ground meat products, kebab, seasoning mixes, marinades, flavourings, bread, bread mixes, baked goods, pasta, snack foods.
Lupin		Lupin seeds and flour	Bread, bread mixes, baked goods, chocolate bits, 'bars', pasta, snack foods, cakes, ground meat products.
Examples of legumes that may need to be considered in addition to the EU list	Peas, beans, chickpeas, lentils, licorice, fenugreek.	Pea fibre, pea protein, pea starch, locust bean gum/carob bean seed gum (E410), guar gum (E412), tragacanth (E413), acacia/gum arabic (E414), tara gum (E417).	Bread, bread mixes, cakes, baked goods, chocolate bits, 'bars', pasta, snack foods, ground meat products, liver pâté, ice-cream, licorice, curry (may contain fenugreek and other spices).
Nuts	Almond, hazelnut, walnut, cashew, pecan, Brazil nut, pistachio, macadamia nut/Queensland nut.		Nut paste, nougat, marzipan, almond paste, 'baking' paste. Chocolate, confectionery, pesto, granola and muesli, cookies, crackers, baked goods, bread, bread crumbs, Asian dishes.
Examples of "nuts" that may need to be considered in addition to the EU list	Apricot kernels, pine nuts.		
Sesame seeds	Sesame seeds.		
Examples of seeds that may need to be considered in addition to the EU list	Poppy seeds, sunflower seeds, pumpkin seeds.		Seasoning mixes, breaded coatings, bread, granola and muesli, cookies, crackers, rice cakes, snack foods, dressings, bread crumbs, Asian sauces, tomato sauce, sushi.

Allergens according to EU list	Specification	Examples of products	Examples of foods and food ingredients that may contain these
Celery	Celery root, celery stalks (all parts of the plant)	Celery, celery root, celery seeds.	Seasoning mixes.
Mustard	Mustard seeds (white, yellow, brown/oriental, black).	Mustard seeds (white, yellow, brown/oriental, black).	Mustard, mayonnaise, lox sauce, dressings, seasoning mixes, coated/breaded ham, pickled herring, pickled cucumbers.
Sulphur dioxide and sulphites at concentrations over 10 mg/kg or 10 mg/litre, expressed as SO ₂			Wine, vinegar, vinegar-based pickling mixtures, potato products, dried fruit, canned crab.
Examples of other substances that may need to be considered			
Preservatives	Benzoic acid (E210), benzoic acid salts (E211-213), and benzoic acid esters (E214-E219).		Occur naturally in several wild berries (e.g. lingonberry, cloudberry). May be used in most canned foods.
Colours and dyes	Carmine, carminic acid (E120), annatto extract (E160b), azo dyes (E102, E110, E122-124, E128-129, E151, E154-155, E180).		According to EU regulations these may be used in most foods that may be coloured. This does not apply to azo dyes, however, which may only be used in certain foods. According to the Guidelines, azo dyes should be avoided on the Swedish market (see also www.li.se).
Fruits and berries	Pineapple, apricot, banana, kiwi, cherries, mango, melon, nectarine, papaya, peach, plum, pear, apple.	Flavourings.	
Seasonings	Paprika, cayenne, chili pepper, piri piri (of the capsicum family), pink peppercorns, anise, dill, fennel, coriander, caraway, cumin, lovage, parsley, nutmeg, peppermint, horseradish, cinnamon, garlic, vanilla.		Chili powder (seasoning mix), onion powder, garlic powder.

Appendix 2. Food sector guideline committee members

Swedish Asthma and Allergy Association	www.astmaoallergiforbundet.se
Swedish Food Federation	www.livsmedelsforetagen.se
National Food Agency	www.slv.se
Swedish Celiac Society	www.celiaki.se
SDVH (Swedish Food Retailers Federation)	www.svdh.se
Anders Nilsson, Chair: SWETIC (Swedish Association for Testing, Inspection and Certification)	www.swetic.org

Appendix 3. Checklists