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 illinoinensis [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.

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. 852/2004 (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.

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.

According to Article 5 of Regulation (EC) No. 852/2004, 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.

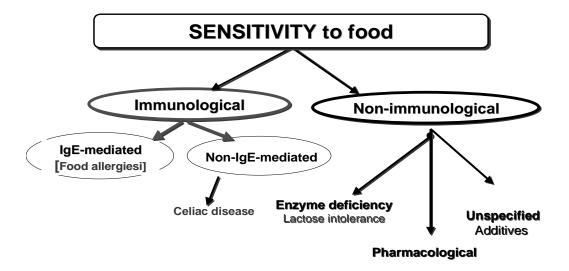
1.3 Consumer expectations

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.

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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*).

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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:

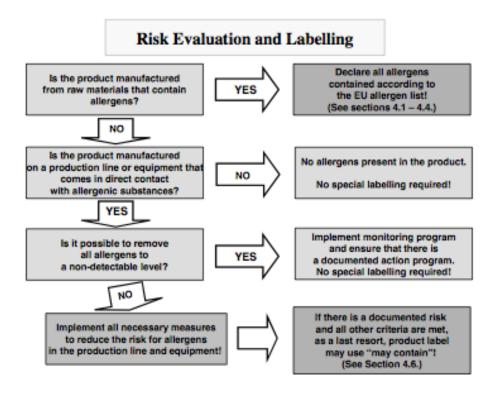
- 1. *Uncontrollable*, i.e. the ability to control the entire process is considered impossible, e.g. where part or parts of production occur in processing equipment that can not accessed for cleaning, or that can not be cleaned with water.
- 2. *Sporadic*, i.e. as identified through:
 - analysis showing 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 additivies 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.
Molluses	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 fraiche, 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 paté, 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
Examples of "nuts" that may need to be considered in addition to the EU list	Apricot kernels, pine nuts.		muesli, cookies, crackers, baked goods, bread, bread crumbs, Asian dishes.
Sesame seeds	Sesame seeds.		Seasoning mixes, breaded coatings, bread, granola and muesli, cookies, crackers, rice
Examples of seeds that may need to be considered in addition to the EU list	Poppy seeds, sunflower seeds, pumpkin seeds.		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)

Appendix 3. Checklists

1. Checklist for:

Product Developers

Purpose: To help product developers improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution

stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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 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 illinoinensis [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 SO_2 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.

If changes involving allergens are made to a product or production process, the following control procedures should be reviewed to ensure that mistakes do not occur.

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.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. Hazard analysis – Risk assessment Is a HACCP-based assessment of allergy risks carried out in the product development work? .	New allergens introduced in a factory without the risk for contamination of other products having been evaluated. New allergens added to products where the consumer does not expect them.			
2. Coordination - Cooperation Do product developers, production staff, purchasers, raw materials suppliers, etc., work together during product development to ensure that allergy risks are considered at every step of the production process – from purchasing and receiving, to handling and storage of raw materials and the finished product?	A risk assessment must always be conducted during trial runs of new products in order to avoid introducing new allergens to the production line and contaminating other products.			
3. Training Do the company's product developers receive ongoing training in allergy issues?	Employees must understand the risks of allergens in order to minimize contamination of the product by allergens.			
4. Documentation of raw materials Are there procedures to ensure that only well-documented raw materials are used?	The supplier has inadequate knowledge about allergies and food intolerance issues, and does not provide complete specifications for raw materials. Note that an allergen can sometimes be present as a sub-component of a raw material, additive, etc., e.g. in the form of a carrier in a seasoning mix or a processing aid.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
5. Raw material specifications Are there raw material specifications for all ingredients in the product as well as other allergy information as required by EU labelling rules?	Carry-over additives, processing aids, etc., stemming from allergenic raw materials.			
6. Raw material suppliers Are there procedures in place to ensure that raw material suppliers are not able to change a recipe without prior approval from the company using the raw material?	The manufacturer does not find out that the supplier has modified a recipe until after the change has been made.			
7. Alternate suppliers Are there procedures in place to ensure that another supplier can not be substituted for a raw material supplier without prior approval?	A new raw material is introduced that involves a change in the ingredient list.			
8. Measures for suspected contamination Are employees encouraged to take immediate action in the case of suspected contamination, incorrect labelling, etc., and are there procedures for how this information should be passed on? Inform appropriate authority if there is reason to believe that a food product that has entered the market may be harmful to human health, and inform of the measures taken.	An employee does not understand the risks and does not know that such cases must be reported immediately.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
9. New allergens When developing products, the addition of new allergens to recipes of existing products should be avoided. If this can not be avoided, are there procedures for recipe changes?	Wrong raw material is used in a product. The risk of this can be reduced, e.g. by changing the product numbers of the raw material, intermediate product or finished product. Rules for GTIN barcodes must be followed.			
10. Consumer information for new allergens If a new allergen is introduced to a recipe of an existing product, are there procedures for how to communicate this to consumers?	When recipes are changed, "new recipe" or similar wording should be stated on the package. When selling unpackaged foods, this information may be provided in other ways, e.g. by posting the information at the sales counter or point of sale.			
11. Contracted manufacturing When a product is made by another company, are there procedures to ensure that the ingredient list is correct and that allergen contamination is minimized?	The contractor has not been informed of the recipient's rules and requirements.			
12. Allergen management systems Are there quality systems in place for the products included, e.g. in an official allergen list, to ensure that the risk of contamination is minimized?	The allergen lists provided do not match the actual production situation.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
13. Procedures for "may contain", "free" labelling	The product developer is not aware of Food Sector Guidelines and			
Are there procedures to ensure that package labelling follows existing regulations, e.g. regarding the use of "may contain" and "free from", etc.?	requirements for using "may contain" on labels. The use of "free from" labelling is also regulated.			

Date:	
Name of person who completed checklist:	
Company name and address:	

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

Handling procedures for product alerts

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's internal	
A.2 Are the procedures used and followed?	procedures should always be followed first.	
	People involved in product alerts are usually those who work with consumer contact, purchasing, and marketing and distribution managers.	
B. Gather information		
B.1 Is the consumer still sick?	If the consumer is sick –	
B.2 Which product did the consumer eat?	suggest that he/she seek medical attention.	
B.3 What else did the consumer eat?	Note the product name, size,	
B.4 Does the consumer have a known allergy or intolerance – to what?	"use by" date, date of purchase, where the product was purchased, batch number and	
B.5 Tell the person you will get back to him/her.	GTIN code. If possible: save the product in question and try to obtain an unopened package from the same batch for testing. (Add your own comments to the checklist!)	
C. Evaluate		
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.	(Add your own comments to the checklist!)	
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the control agency!		

Control Point	Comments	Notes
D. Take action		
D.1 Protect other consumers – Consider whether sales should be stopped!	(Add your own comments to the checklist!)	
D.2 Inform supplier and regulatory agency?		
D.3 Investigate whether the product should be recalled?		
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected consumer.		
D.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		
E.2 Ensure that the responsible product developer is informed of the situation.		

<u>Date:</u>	
Name of person who completed product alert checklist:	
Company name and address:	

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

2. Checklist for:

Purchasers for Food Manufacturers

Purpose: To help purchasers for food manufacturers improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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 illinoinensis* [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
- 9. Celery and products thereof.
- 10. Mustard and products thereof.

ethyl alcohol of agricultural origin.

- 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.

If changes involving allergens are made to a product or production process, the following control procedures should be reviewed to ensure that mistakes do not occur.

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.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. General points				
1.1 Are there procedures for choosing suppliers?1.2 Does your company have an internal allergen list?	These points should be included in the internal control program.			
1:3 Do all purchasers receive training in these procedures?				
2. Choice of supplier				
2.1 Is the supplier already approved?2.2 Does the supplier use procedures that guarantee	The supplier is not aware of allergy/intolerance concerns.			
that all allergenic substances are identified and handled correctly?	Pasta with egg and pasta without egg are produced on			
2.3 Has the supplier been informed of and accepted your company's internal allergen list?	the same production line or in the same factory and could be mixed up.			
2.4 Does the supplier have adequate control of its sub-suppliers?	Breaded/battered fish and unbreaded fish are handled on the same production line.			
2.5 Does the supplier declare all ingredients, including carriers and processing aids?	Nuts, peanuts or other allergens are handled in the production line or on the premises with no			
2.6 Are complete product specifications provided?	particular consideration given			
2.7 Does the supplier have good traceability procedures?	to allergen contamination.			
2.8 Is there an approved alternate supplier in case of delivery problems etc.?				
2.9 Are the same procedures used for all suppliers?				
2.10 Are supplier audits carried out?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3. Purchasing procedures				
3.1 Is the supplier familiar with the rules regarding allergens and understand the implications?3.2 Is information provided for all components of all	The supplier lacks an understanding of the serious risks low quantities of allergen can pose.			
ingredients and raw materials from both the supplier and sub-suppliers?	Seasoning mixes used contain milk protein without declaring			
3.3 Are there procedures for how the product should be labelled?	it. The supplier does not state what other products are produced on			
3.4 Are there procedures for how recipe changes or other product changes are communicated and labelled?	the same production line. The supplied product can not be easily identified due to unclear			
3.5 Is the labelling of the supplied products clear and understandable?	or incorrect labelling. Supplier has not informed of recipe changes and labelling			
3.6 Are there internal procedures for handling information on shortcomings noted in the labelling?	does not distinguish old recipes from new. In the case of imports from a			
3.7 Are there procedures for informing suppliers about shortcomings and how improvements can be made?	third country, it is important to check that suppliers are familiar with EU regulations and allergen list.			
3.8 Are the procedures used and followed?				
3.9 Are there procedures for following up suppliers?				

Date:	
Name of person who completed checklis	<u>t:</u>
Company name and address:	

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's internal	(Add your own comments to the checklist!)
A.2 Are the procedures used and followed?	procedures should always be followed first.	
	People involved in product alerts are usually those who work with consumer contact, purchasing, marketing and distribution managers, and shop employees.	
B. Gather information		
B.1 Is the consumer still sick?	If the consumer is sick – suggest that he/she seek	(Add your own comments to the checklist!)
B.2 Which product did the consumer eat?	medical attention.	
B.3 What else did the consumer eat?	Note the product name, size,	
B.4 Does the consumer have a known allergy or intolerance – to what?	"use by" date, date of purchase, store where the product was purchased, batch number and	
B.5 Tell the person you will get back to him/her.	GTIN code. If possible: save the product in question and try to obtain an unopened package from the same batch for testing.	
C. Evaluate		
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.		(Add your own comments to the checklist!)
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the regulatory agency!		

Control Point	Comments	Notes
D. Take action		
D.1 Protect other consumers – Consider whether sales should be stopped!	(Add your own comments to the checklist!)	
D.2 Inform supplier and regulatory agency?		
D.3 Investigate whether the product should be recalled?		
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected consumer.		
D.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		

Date:	
Name of person who completed product alert checklist:	
Company name and address:	

3. Checklist for:

Purchasers for Stores and Retail

Purpose: To help purchasers for stores and retail to improve the safety of food handling.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution

stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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;

- 8. Nuts, namely: almonds (*Amygdalus communis*
- L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis [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.

b) lactitol.

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.

Control Point	Example of Problem	Yes	No	Note current routines and areas for improvement
1. General points				
1.1 Are there procedures for choosing suppliers?	These points should be			
1.2 Does your company have an internal allergen	included in the internal control program!			
list? 1:3 Do all purchasers receive training in these?	At a minimum, the list should include the allergens included in the EU list.			
2. Choice of supplier				
2.1 Is the supplier already approved?				
2.2 Does the supplier have procedures that guarantee	The supplier is not aware of allergy/intolerance issues.			
that all allergenic substances are identified and handled correctly?	Pasta with egg and pasta without egg are produced on			
2.3 Has the supplier been informed of your company's internal allergen list?	the same production line or in the same factory and may get mixed up.			
2.4 Does the supplier have adequate control of its sub-suppliers?	Breaded/battered fish and unbreaded fish are handled on the same production line.			
2.5 Are there product specifications that cover all of the necessary information?	Nuts, peanuts or other allergens are handled in the production line or on the premises with no			
2.6 Does the supplier have good procedures for traceability?	particular consideration given to allergen contamination.			
2.7 Is there an approved alternate supplier in case of delivery problems etc.?	(Add your own examples to the checklist!)			
2.8 Are the procedures used for all suppliers?	Checkiist:)			
2.9 Are supplier audits carried out?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3. Purchasing procedures				
3.1 Is the supplier familiar with the rules regarding allergens and understand the implications?	Seasoning mixes used contain milk protein without declaring it.			
3.2 Is information provided for all components of all ingredients and raw materials from both the supplier and sub-suppliers?	The supplier does not state what other products are produced on the same production line.			
3.3 Are there procedures for how the product should be labelled?	The supplied product can not be easily identified due to unclear or incorrect labelling.			
3.4 Are there procedures for how recipe changes or other product changes are communicated and labelled?	New recipe or recipe changes are not marked so old product may be confused with new.			
3.5 Is the labelling of the supplied products clear and understandable?	In the case of imports from a third country, it is important to check that suppliers are			
3.6 Are there internal procedures for handling information on shortcomings in the labelling?	familiar with the EU allergen list! When importing directly,			
3.7 Are there internal procedures for informing suppliers and requesting improvement when shortcomings occur?	the company itself is responsible, otherwise it is the supplier's responsibility.			
3.8 Are the procedures used and followed?	(Add your own examples to the			
3.9 Are there procedures for following up suppliers?	checklist!)			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
4. Purchasing procedures – In-store packing of foods for the consumer				
 4.1 Are the legal requirements for labelling of substances listed in EU's allergen list being met? 4.2 Is the labelling of delivered products clear and understandable? 4.3 Are there procedures for handling products with missing or improper labels? 	Labels are not affixed properly, text is illegible (small print, poor contrast between text and background). Milk protein used in seasoning mixes without declaring it.			
4.4 Does the store have procedures for communicating shortcomings in the labelling to the supplier?	Check procedures with purchasers for food manufacturers.			
4.5 Are there procedures for informing suppliers and requesting improvement when labelling problems occur?	(Add your own comments to the checklist!)			
4.6 Are there procedures for producing information for labelling of products sold in the store?				
4.7 Are there appropriate work tools and equipment for in-store handling?				
4.8 Does the store have procedures for transferring ingredient lists from supplier packaging to storepacked product?				
4.9 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
5. Existing product with new composition –				
Made from new recipe				
5.1 Are there procedures for suppliers to communicate recipe changes regarding substances on the EU allergen list to the purchaser?	Popsicle with milk protein added is sold in similar packaging as product without milk protein.			
5.2 Does the recipe change involve the addition of any substances on the EU allergen list?	Almonds on baked roll replaced by peanut topping with no clear information or change in			
5.3 Have the store and consumer been informed of the "new recipe" through information on the package, change in design, in-store indication, or similar?	package design.			
5.4 Are there procedures for handling old stock so that the store does not confuse "old" product with "new"?	(Add your own comments to the checklist!)			
5.5 Are the procedures used and followed?				
6. Restaurants and caterers				
6.1 Is food prepared in the store being sold?	See separate checklist for restaurants and catering (Checklist 7)!			
	(Add your own comments to the checklist!)			

Date:	
Name of person who completed checklis	<u>t:</u>
Company name and address:	

Control Point	Comments	Notes
A.1 Are there procedures for handling product alerts? A.2 Are the procedures used and followed?	This is a general guideline and the company's internal procedures should always be followed first.	
	People involved in product alerts are usually those working with consumer contact, purchasers, store managers, site supervisors, and marketing and distribution managers.	
B.1 Is the consumer still sick? B.2 Which product did the consumer eat?	If the consumer is sick – suggest that he/she seek medical attention.	
B.3 What else did the consumer eat?B.4 Does the consumer have a known allergy or intolerance – to what?	Note the product name, size, "use by" date, date of purchase, store where it was purchased, batch number and EAN code.	
B.5 Tell the person you will get back to him/her.	If possible: ensure that the product in question is saved and try to obtain an unopened package from the same batch for testing.	
	(Add your own comments to the checklist!)	
C. Evaluate		
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.	(Add your own comments to the checklist!)	
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the control agency!		

Control Point	Comments	Notes
D. Take action		
D.1 Protect other consumers – Consider whether sales should be stopped!	(Add your own comments to the checklist!)	
D.2 Inform supplier and regulatory agency?		
D.3 Investigate whether the product should be recalled?		
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected consumer.		
D.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		
E.2 Ensure that the purchaser responsible is informed of the situation.		
Date:		
Name of person who completed product alert chec	klist:	
Company name and address:		
Company name and address.		

4. Checklist for people working in:

Food Production

Purpose: To help food producers improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply

safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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 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 illinoinensis [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 SO_2 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.

If changes involving allergens are made to a product or production process, the following control procedures should be reviewed to ensure that mistakes do not occur.

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.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. General points				
1.1 Internal controls/HACCP plans				
Are there HACCP programs that include allergy risks for all parts of the production chain – from receiving and storage of raw materials to finished product?				
1.2 Training	Remember that replacement staff, job rotation workers, maintenance staff, etc.			
Do the people who work in food production receive ongoing training in allergy issues?	must also be trained. Employees must understand the risks of allergens in order to minimize contamination of the product by allergens.			
1.3 Information on recipe changes	It is important that the workers involved			
Are there procedures in place to ensure that those working in production are informed of recipe changes?	attend project meetings and are assigned responsibility.			
1.4 Procedures for recipe changes	HACCP programs may need to be reviewed, changes to product numbers			
Are there procedures for how recipe changes are to be handled in production?	for raw materials, intermediate goods and finished product may be needed, new packaging must be used, etc.			

Control Point	Example of problem	Yes	No_	Note current routines and areas for improvement
1.5 Alternate raw material suppliers				
Are there procedures in place to ensure that a raw material supplier, processing aid, etc., can not be substituted without the prior approval of the responsible persons in the company?	Regulations regarding labelling procedures for proper identification of suppliers. Different codes or other way of marking specific suppliers.			
1.6 Measures for suspected contamination Are employees encouraged to take immediate action in the case of suspected contamination, incorrect labelling, etc., and are there procedures for this? Inform the proper authority if there is reason to believe that a food product that has entered the market may be harmful to human health, and communicate the measures taken.	See also Handling Procedures for Product Alerts", A1–E1, at the end of this checklist! Ensure that workers are aware of the serious risk of even very small quantities of allergen!			
1.7 Internal audits Are regular internal audits conducted to ensure compliance with the general points for control of allergy risks?	Immediate follow-up of corrective actions when shortcomings in allergen management have been detected.			
2. Raw materials: Receiving, storage, weighing				
2.1 Purchasing				
When purchasing and receiving raw materials, is consideration given to the risk of contamination prior to new raw materials entering the premises?	Clearly marked areas for the respective products.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
2.2 Reception of raw materials				
Are there procedures for how raw materials, ingredients and intermediate goods are identified when received to ensure that the right raw materials have been delivered?				
2.3 Labelling				
Are raw materials, intermediate goods and finished product clearly labelled so that there is no risk of mix-ups?				
2.4 Handling				
Are allergenic raw materials, ingredients and intermediate goods kept separate from each other and from other foods in order to minimize the risk of contamination?	This is especially important when handling unpackaged goods. Separate areas for storing and weighing allergenic raw material are needed, separate ventilation exhaust, etc.			
3. Production, premises and equipment				
3.1 Access to instructions Are instructions for how to prevent contamination visible or readily available in				
the production area?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3.2 Design of premises, equipment and work tools Are premises, equipment and work tools designed to facilitate easy cleaning and to minimize the risk of cross-contamination of products and production lines?	This is especially important when handling unpackaged products, e.g. when weighing and mixing dry ingredients.			
3.3 Maintenance schedule Is there a schedule for maintenance of the premises and equipment?	Instructions regarding measures to be taken before maintenance is carried out, as well as cleaning up afterwards.			
3.4 Knowledge on hygiene design Do maintenance personnel have knowledge about hygiene design to minimize the risk of contamination, e.g. through proper design of piping, elbows and bends, pumps, etc.?				
3.5 Hygiene rules for employees Are there hygiene rules for all personnel, covering, e.g., clothing, hand-washing and hand contact with foods?	Keep in mind that hygiene rules also apply to all maintenance staff, contractors and visitors.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3.6 Order of production				
Are there clear procedures for production order and how this is determined?	If products are packaged at a later time, attention must also be paid to allergy risks when establishing the packaging order.			
3.7 Recipes				
Are there procedures to ensure that the right recipe is always used?	Conduct regular controls to ensure that the recipe used on the production line matches the original recipe.			
3.8 Raw materials				
Are there procedures to ensure that the right raw materials are always used?				
3.9 Packaging				
Are there procedures to ensure that the right product is always packed in the right packaging?	In cases where packages have a similar appearance, such as for flavour variants, it is particularly important to ensure that the correct packaging is used. In this context, it is recommended that a checklist be used and signed by the responsible production personnel.			
3.10 Follow-up				
Do factory personnel continuously review possible situations for cross-contamination between products or production lines?	It is important to identify responsibility and authority. These reviews should also be carried out between regularly scheduled internal audits.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3.11 Rework Are there procedures for the use of rework materials (internally recycled product)?	It is important that rework ends up in the right product and does not contaminate other products. Product containing an allergen should only be used in products where that allergen is already present. How and when rework may be used should be documented. Rework must be correctly labelled for proper identification and handling.			
3.12 Traceability of rework Is there a procedure for tracking the rework used to the finished product?	Keep in mind that contamination can also occur after manufacturing, e.g. when handling intermediate goods that have not been packaged for market.			
3.13 Waste management Are there procedures for waste management?	Waste must be labelled and be able to be distinguished from rework.			
3.14 Substandard [kv1] products Are there procedures for handling products that deviate from the standard product?	These procedures are necessary for traceability, blocking of shipments, etc.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
4. Cleaning and controls				
4.1 Cleaning procedures				
Are there documented cleaning procedures to ensure that accidental contamination has not occurred?	Cleaning procedures are needed for the premises, equipment and work tools.			
4.2 Cleaning instructions				
Are there clear instructions for the cleaning required for premises, equipment and work tools?	Sufficient time must be allotted for cleaning. Hidden areas in the equipment must be identified, and equipment may need to be dismantled.			
4.3 Cleaning instructions – Production				
Are there clear instructions for the cleaning required between different products produced on the same production line?	If the products are packed at a later time, attention must also be paid to allergy risks when establishing the cleaning procedures for packing equipment.			
4.4 Post-production controls				
Are there procedures for, when necessary, testing a food after manufacturing to confirm that accidental exposure to allergen has not occurred?	If a suspected allergen is evenly spread throughout the final product, controls can be carried out in the form of analyses. Otherwise, documented visual controls may be used.			
<u>Date:</u>				
Name of person who completed checklist:				
Company name and address:				

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's own procedures should always be	
A.2 Are the procedures used and followed?	followed first.	
	People involved in product alerts are usually those who	
	work with consumer contact,	
	purchasing, and marketing and distribution managers.	
B. Gather information		
B.1 Is the consumer still sick?	If the consumer is sick – suggest that he/she seek	
B.2 Which product did the consumer eat?	medical attention.	
B.3 What else did the consumer eat?	Note the product name, size, "use by" date, date of purchase,	
B.4 Does the consumer have a known allergy or intolerance – to what?	store where the product was purchased, batch number and	
B.5 Tell the person you will get back to him/her.	GTIN code. If possible: save the product in	
	question and try to obtain an	
	unopened package from the same batch for testing.	
	(Add your own comments to the	
C. Evaluate	checklist!)	
C.1 Contact your supervisor or person in charge of	(Add your own comments to the	
handling urgent consumer complaints – evaluate together.	checklist!)	
C.2 If necessary, gather more information.		
Contact supplier? Perform analyses? Seek the assistance of the regulatory agency!		

Control Point	Comments	Notes
D. Take action		
D.1 Protect other consumers – Consider whether sales should be stopped!	(Add your own comments to the checklist!)	
D.2 Inform supplier and regulatory agency?		
D.3 Investigate whether the product should be recalled?		
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected consumer.		
D.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		
E.2 Ensure that the production workers responsible are informed of the situation.		
Date:		
Name of person who completed product alert chec	klist:	
Company name and address:		

5. Checklist for people working with:

Consumer Information

stage.

Purpose: To help people working with consumer information to improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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 illinoinensis* [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.

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.

Control Point	Example of problem	Yes	No_	Note current routines and areas for improvement
1. Training	-			
Do the people who work with consumer information receive ongoing training in allergy issues?				
2. Guidelines Are there guidelines for how your customer care department or similar informs consumers about the company's products?	A database on allergy information can, for example, be established as a basis for responding to consumer queries. It is essential that this information be kept up to date.			
3. Statistics				
Are statistics kept on incoming questions about allergens, and are there procedures for following up these questions?				
4. Procedures regarding product information Are there procedures in place to ensure that those working with consumer information are informed of product contents, recipe changes, or similar?	Recipe changes are made without informing customer care department, salespersons, etc. Websites and other online information are not up to date or can be misunderstood.			

Control Point	Example of problem	Yes	No_	Note current routines and areas for improvement
5. Procedures for immediate measures Are there procedures in place for those working with consumer contact to take action in the case of suspected contamination or incorrect labelling?	It is important to assess the risk of contamination, and use this as a starting point when responding to consumer queries.			
6. Emergency plan				
Does the company have an emergency plan that gives clear instructions on what should be done in the case of suspected allergic reactions?				
7. Updating procedures Are there procedures to ensure the information on allergen lists and other product information is correct and up to date?	Recipe changes are made without informing the customer care department, salespersons, etc. Websites and other online information are not up to date or can be misunderstood.			
8. Sector agreement – Product fact sheets Is the sector agreement regarding product fact sheets from Li being followed?	(This point only applies if allergen lists			
Date:				
Name of person who completed checklist:				
Company name and address:				

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's internal procedures should always be	
A.2 Are the procedures used and followed?	followed first.	
	People involved in product alerts are usually those who	
	work with consumer contact,	
	purchasing, and marketing and distribution managers.	
B. Gather information		
B.1 Is the consumer still sick?	If the consumer is sick – suggest that he/she seek	
B.2 Which product did the consumer eat?	medical attention.	
B.3 What else did the consumer eat?	Note the product name, size, "use by" date, date of purchase,	
B.4 Does the consumer have a known allergy or intolerance – to what?	store where the product was purchased, batch number and	
B.5 Tell the person you will get back to him/her.	EAN code. If possible: save the product in	
	question and try to obtain an	
	unopened package from the same batch for testing.	
	(Add your own comments to the	
C. Evaluate	checklist!)	
	(Add your own comments to the	
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.	checklist!)	
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the		
assistance of the control agency!		

Control Point	Comments	Notes
D. Take action		
D.1 Protect other consumers – Consider whether sales should be stopped!		
D.2 Inform supplier and control agency if there is reason to believe that a food product that has entered the market may be harmful to human health, and communicate the measures taken.		
D.3 Investigate whether the product should be recalled?		
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected consumer.		
D.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		
E.2 Ensure that the person who received the complaint is informed of the situation.		

<u>Date:</u>	
Name of person who completed product alert checklist:	
Company name and address:	

6. Checklist for people working in:

Stores and Retail

Purpose: To help people in stores and retail to improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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;

- 8. Nuts, namely: almonds (*Amygdalus communis*
- L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis [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 SO_2 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.

b) lactitol.

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.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. General points				
1.1 Are there procedures for handling allergens?	These points must be included in the internal control			
1.2 Does the store have an internal allergen list?	program!			
1.3 Do all employees who handle unpackaged food products receive training?				
2. Sweets, "natural sweets", nuts - unpackaged				
2.1 Are sweets, nuts or products that contain allergens included in the EU allergen list sold in bulk?	High-risk products include chocolate with nuts, chocolate- coated hazelnuts, yoghurt- coated fruit, sesame seed			
2.2 Are the products placed in such a manner as to reduce the risk for contamination of (or exposure to) other foods?	candies. (Add other allergen-containing goods sold in your store to the checklist!)			
2.3. Is information about product ingredients available?	checklist:)			
2.4 Are there procedures for ongoing control and updating of ingredient lists?				
2.5 Are appropriate tools (scoops, tongs) provided to take these products?				
2.6 Are separate tools provided for different allergenic foods?				
2.7.Are there filling and cleaning procedures to reduce the risk of contamination?				
2.8 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3. In-store bakery				
3.1 Are breads and other goods baked in the store sold?	High-risk products include country bread with soy flour, French rolls with sesame seeds,			
3.2 Do these products contain allergens? If so, which one(s)?	peanut butter cookies, cream pastries, decorative peanut toppings.			
3.3 Are the products placed in such a manner as to reduce the risk of exposure to (or contamination of) other foods?	(Add other allergen-containing goods sold in your store to the checklist!)			
3.4 Is information about product ingredients available?				
3.5 Are there procedures for ongoing control and updating of ingredient lists?				
3.6 Are appropriate tools (tongs) provided to take these products?				
3.7 Are separate tools provided for different allergenic foods?				
3.8 Are there filling and cleaning procedures to reduce the risk of contamination?				
3.9 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
4. Marinated delicacies – unpackaged				
4.1 Are marinated delicacies that contain allergens included in the EU list sold in bulk?	High-risk products include feta cheese and olive mixtures, anchovy-stuffed olives, satay-			
4.2 Are the products placed in such a way as to minimize the risk of exposure to other foods?	based marinades (peanuts). Keep in mind that marinade			
4.3 Is information about product ingredients available?	drippings can contaminate other products.			
4.4 Are there procedures for ongoing control and updating of ingredient lists?	(Add other allergen-containing goods sold in your store to the checklist!)			
4.5 Are appropriate tools (spoons, tongs) provided to take these products?				
4.6 Are separate tools provided for different allergenic foods?				
4.7 Are there filling and cleaning procedures to reduce the risk of contamination?				
4.8 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
5. Restaurants and caterers				
5.1 Are ready-to-eat foods sold in serving size portions?				
5.2 See separate checklist for restaurant workers (Checklist 7)!				
6. Meat counter – in-store packing				
 6.1 Are products that contain the substances on the EU allergen list handled and packed in the store? 6.2 Are products placed in such a manner as to reduce the risk for contamination of other foods? 6.3 Is information about product ingredients available? 6.4 Are there procedures for ongoing control and updating of ingredient lists? 6.5 Are appropriate tools used? 	High-risk products include sausages, refrigerated ready-to-eat foods, salad mixtures, liver paté. (Add other allergen-containing goods sold in your store to the checklist!)			
6.6 Are separate tools used for different allergenic foods?				
6.7 Are there filling and cleaning procedures to reduce the risk of contamination?				
6.8 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
7. Cheese counter – in-store packing				
 7.1 Are products that contain the substances included in the EU allergen list handled and packed in the store? 7.2 Are the products placed in such a manner as to reduce the risk for contamination of other foods? 7.3 Is information about product ingredients available? 7.4 Are there procedures for ongoing control and updating of ingredient lists? 7.5 Are appropriate tools used? 7.6 Are separate tools used for different allergenic foods? 	High-risk products include cheeses that contain nuts. (Add other allergen-containing goods sold in your store to the checklist!)			
7.7 Are there filling and cleaning procedures to reduce the risk of contamination?7.8 Are the procedures used and followed?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
8. Fish counter – in-store packing				
8.1 Are products that contain the substances included in the EU allergen list handled and packed in the store?	High-risk products include fish- and shellfish patés, seafood/egg salad, breaded/battered herring.			
8.2 Are products placed in such a manner as to reduce the risk for contamination of other foods?	Keep in mind that drippings and splashes can contaminate other products.			
8.3 Is information about product ingredients available?	(Add other allergen-containing goods sold in your store to the checklist!)			
8.4 Are there procedures for ongoing control and updating of ingredient lists?	checklisi:)			
8.5 Are appropriate tools used?				
8.6 Are separate tools used for different allergenic foods?				
8.7 Are there filling and cleaning procedures to reduce the risk of contamination?				
8.8 Are the procedures used and followed?				

9. Unpackaged foods of other types than those listed above 9.1 Are products that contain the substances included High-risk products include	Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
9.1 Are products that contain the substances included High-risk products include					
in the EU allergen list handled, packed, or sold in bulk in the store? 9.2 Are products placed in such a manner as to reduce the risk for contamination of other foods? 9.3 Is information about product ingredients available? 9.4 Are there procedures for ongoing control updating of ingredient lists? 9.5 Are appropriate tools used for different allergenic foods? 9.7 Are there filling and cleaning procedures to reduce the risk of contamination? 9.8 Are the procedures used and followed?	 9.1 Are products that contain the substances included in the EU allergen list handled, packed, or sold in bulk in the store? 9.2 Are products placed in such a manner as to reduce the risk for contamination of other foods? 9.3 Is information about product ingredients available? 9.4 Are there procedures for ongoing control updating of ingredient lists? 9.5 Are appropriate tools used? 9.6 Are separate tools used for different allergenic foods? 9.7 Are there filling and cleaning procedures to reduce the risk of contamination? 	frozen shrimp, pickled cucumbers, marinated chicken grilled in the store, beer sausages and salad bars. (Add other allergen-containing goods sold in your store to the			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
10. Purchasing procedures – supplier-packed				
foods				
 10.1 Choice of supplier and product – see separate checklist for purchasers (Checklist 2). 10.2 Is the labelling of delivered products clear and easy to understand? 10.3 Are there procedures for handling products with missing- or improper labelling, or that have no 	Examples of improper labelling: Labels are not affixed properly, text is difficult to read (small print, poor contrast between text and background). (Add your own examples to the			
Swedish text?	checklist!)			
10.4 Are there procedures for informing the supplier and person responsible for purchasing when there are shortcomings in the labelling? 10.5 Are the procedures used and followed?				
11. Procedures for providing information to the				
consumer – non-prepackaged foods				
11.1 Are there routines for how your store provides information on food products packaged at the request of the consumer or pre-packaged for direct sales? (All information must be available to be provided verbally or in writing. Allergens must always be declared.)	These points must be included in your internal control program!			
11.2 Are there routines for how your store provides				
information about non-prepackaged products				
sold, e.g. self-serve bulk foods or foods served in				
a restaurant or from a kiosk or deli. (Allergens				
must always be declared. Information regarding a				
food's contents must be able to be provided at the request of the consumer.)				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
 12. Existing product with new composition – made from new recipe 12.1 Is there a procedure for communicating recipe changes to the people working with production and labelling? 12.2 Does the change in recipe involve the addition of any of the allergens listed in the table given in this checklist? 12.3 Is the "new recipe" brought to the attention of consumers, e.g. through information on the package, a change in design, or in-store indication? 12.4 Are there procedures for handling old stock so that consumers do not confuse "old" product with "new"? 12.5 Are the procedures used and followed? 	Examples of changes: Popsicle containing milk protein is sold in packaging similar to product without milk protein. Almonds on baked roll replaced by peanut topping without clear information or change in package design. (Add your own examples to the checklist!)			Note current routines and areas for improvement
Date:				
Name of person who completed checklist:				
Company name and address:				

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

Handling procedures for product alerts

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's interal	
A.2 Are the procedures used and followed?	procedures should always be followed first.	
	People involved in product alerts are usually those who work with consumer contact, purchasers, store managers, site supervisors, marketing and distribution managers.	
B. Gather information		
B.1 What are the consumer's symptoms?	If the consumer is sick –	
Is the consumer still sick?	suggest that he/she seek medical attention.	
B.2 Which product did the consumer eat?	Note the product name, size,	
B.3 What else did the consumer eat?	"use by" date, date of purchase, store where the product was	
B.4 Does the consumer have a known allergy or intolerance – to what?	purchased, batch number and EAN code. If possible: save the product in	
B.5 Tell the person you will get back to him/her.	question and try to obtain an unopened package from the same batch for testing. (Add your own comments to the	
	checklist!)	
C. Evaluate		
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.	Add your own comments!	
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the regulatory agency!		

Control Point	Comments	Notes			
D. Take action					
D.1 Protect other consumers – Consider whether sales should be stopped!	(Add your own comments to the checklist!)				
D.2 Inform supplier and regulatory agency?					
D.3 Investigate whether the product should be recalled?					
D.4 Investigate, in cooperation with authorities, whether a press statement should be issued?					
D.5 Inform the affected consumer.					
D.6 Request an investigation and follow-up by supplier if it is established that the error is earlier in the production chain.					
E. Follow up – Improve					
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!					
D .					
Date:					
Name of person who completed product alert checklist:					

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

Company name and address:

7. Checklist for people working in:

Restaurants and catering

Purpose: To improve the safety of food handling and comply with current legislation.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

To read and understand the food sector guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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;

- 8. Nuts, namely: almonds (*Amygdalus communis*
- L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis [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.

b) lactitol.

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.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. Purchasing				
1.1 Are there procedures for choosing suppliers?	These points should be			
1.2 Does your company have its own allergen list?	included in the internal control program!			
1:3 Do all purchasers receive training on these	At a minimum, the list should			
procedures?	include the substances on the EU allergen list.			
2. Choice of supplier				
2.1 Is the supplier already approved and does it	The supplier is not aware of allergy/intolerance issues.			
follow the requirements you have laid out in your	Pasta with egg and pasta			
internal control program?	without egg are produced in			
2.2 Does the supplier have procedures that guarantee	same factory and may get			
that all allergenic substances are identified and	mixed up.			
handled correctly?	Breaded/battered fish and			
2.3 Does the supplier have adequate control of its	unbreaded fish are handled on the same production line			
sub-suppliers?	Nuts, peanuts or other allergens			
2.4 Are the procedures used for all suppliers?	are handled in the production line or on the premises with no			
	particular consideration given			
	to allergen contamination.			
	(Add your own examples to the checklist!)			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
3. Purchasing procedures				
3.1 Is the supplier aware of the regulations for allergens and labelling/information and have procedures to ensure these regulations are followed?3.2 Is information provided for all components of all	Herb- and seasoning mixes used contain milk protein without declaring it. The delivered product can not be easily identified due to unclear or incorrect labelling.			
ingredients and raw materials from both the supplier and sub-suppliers?	New recipe is not identified and old product is mixed with new.			
3.3 Are there procedures for how recipe changes or other product changes are communicated and labelled?				
3.4 Are there procedures for informing suppliers about shortcomings in the labelling and requesting improvement?	(Add your own examples to the checklist!)			
3.5 Is the risk of contamination considered before new raw materials are taken into the premises?				
3.6 Are the procedures used and followed?				
3.7 Are there procedures for following up suppliers?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
4. Procedures and training				
4.1 Internal controls/HACCP plans				
Are there internal controls/HACCP programs that include allergy risks for all parts of food preparation – from receiving, handling and storage of raw materials to finished food dishes?				
4.2 Training Have the people preparing the foods received training in allergy issues?	Training must include replacement staff, job rotation workers, maintenance staff, etc. All employees must understand the risks of allergens in order to minimize contamination of the product by allergens and be able to meet the needs and wishes of the consumer. E.g. servers must know what gluten is.			
4.3 Information on recipe changes				
Are there procedures in place to ensure that those who prepare and serve food are informed of recipe changes?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
4.4 Procedures for recipe changes				
Are there procedures for how altered recipes are to be handled?				
4.5 Measures for suspected contamination	See also Handling Procedures for Product Alerts, A1–E1, at			
Are employees encouraged to take immediate action in the case of suspected contamination, incorrect labelling, mistakes in menus and other consumer information, and are there procedures in place for this?	the end of this checklist!			
4.6 Emergency plan	See also Handling Procedures			
Does the company have an emergency plan that gives clear instructions on what should be done in the case of a suspected allergic reaction to a meal?	for Product Alerts, A1–E1, at the end of this checklist!			
4.7 Internal audits				
Are regular internal audits conducted to ensure compliance with the general points for control of allergy risks?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
5. Raw materials: Receiving, storage, weighing				
5.1 Receiving raw materials				
Are there procedures for how raw materials, ingredients and intermediate goods are identified when received in order to ensure that the right raw material has been delivered?				
5.2 Labelling				
Are raw materials and intermediate goods clearly labelled to avoid the risk of mix-ups?				
5.3 Handling				
Are allergenic raw materials, ingredients and intermediate goods kept separate from each other and from other foods to minimize the risk of contamination?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
6. Preparation, premises and equipment				
6.1 Preparation of foods for special diets and foods for people with allergies.Is there a special area and specially labelled utensils for preparation of such foods?	If several foods for special diets are prepared in the same area, is there a risk of crosscontamination? When preparing foods and heating foods in a microwave oven, specially designated protective lids should be used for each special food dish.			
6.2 Recipes Are there procedures to ensure that the right recipe is always used/followed?	If no recipe is used, it is critical that there are procedures to control the content of food products, especially the 14 regulated allergens included in the EU list.			
6.3 Raw materials				
Are there procedures to ensure that the right raw materials are always used? Are there procedures to ensure that ingredient lists are always carefully reviewed?				
6.4 Labelling				
Are there procedures to ensure that packaged food dishes are always labelled correctly?	Label the container – labelling the lid can lead to mix-ups.			
6.5 Follow-up				
Do the personnel continuously review possible situations for cross-contamination between meals or between work counters, and cooking- and food preparation vessels and utensils?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
7. Distribution and serving				
7.1 Serving Do servers know that they must be able to inform dining guests of whether the food served contains any of the 14 allergens included in the EU list?	Open handling of several different food dishes can lead to a risk of contamination. Plated dishes for allergic guests can be confused with meals for other guests.			
	In the case of self-serve buffets, it is especially important that food dishes be clearly marked or that personnel are easily accessible to provide this information. Extra emphasis of the risks of contamination with buffet service may be necessary.			
7.2				
Is there a clear division of responsibility to ensure that the guest and kitchen staff receive the right information?	Mistakes and mix-ups can easily occur on the way to and from the kitchen. Communication between the person(s) preparing the food and the person(s) eating it must be clear and without fault.			
7.3				
Are there procedures in place to ensure that the right food is served to the right guest?				
7.4 Utensils				
Are there separate utensils for each food dish?				

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
8. Cleaning and controls				
8.1 Post-preparation controls Are there procedures for when post-preparation controls of food dishes should be carried out to confirm that accidental exposure to allergen has not occurred?	Cleaning routines must exist for the premises, equipment and utensils. Sufficient time must be set aside for cleaning. Hidden areas in the equipment must be identified, and equipment may therefore need to be dismantled. If the products are packed at a later time, attention must also be paid to allergy risks when establishing the cleaning routines for packing equipment.			
Date:				
Name of person who completed checklist:				

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

Company name and address:

Handling procedures for product alerts

Control Point	Comments	Notes
A. General points		
A.1 Are there procedures for handling product alerts?	The company's own procedures should always be	
A.2 Are the procedures used and followed?	followed first.	
	People involved in alerts are often those who handle	
	consumer contact, purchasing, and marketing and distribution	
	managers.	
B. Gather information		
B.1 Is the guest still sick?	If the guest is sick – suggest that he/she seek medical	
B.2 Which food(s) did the guest eat?	attention.	
B.3 What else did the guest eat?	Note the product name, size, "use by" date, date of purchase,	
B.4 Does the guest have a known allergy or intolerance – to what?	store where the product was purchased, batch number and	
B.5 Tell the person you will get back to him/her.	EAN code. Note the name and telephone	
	number of the guest.	
	(Add your own comments to the checklist!)	
C. Evaluate		
C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together.	Save as much of the remaining food that was served to the guest as possible to enable testing.	
C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the control agency!	(Add your own comments to the checklist!)	

Control Point	Comments	Notes
D. Take action		
D.1 Protect other guests – Consider whether sales should be stopped!	(Add your own comments to the checklist!)	
D.2 Inform supplier and control agency?		
O.3 Investigate whether the food dish should be recalled?		
O.4 Investigate, in cooperation with authorities, whether a press statement should be issued?		
D.5 Inform the affected guest.		
O.6 Request an investigation and follow-up by supplier.		
E. Follow up – Improve		
E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved!		
E.2 Ensure that the person who prepared the food dish is informed of the situation.		

Name of person who completed product alert checklist:

Company name and address:

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

8. Checklist for those working with:

Food Inspection and Control

Purpose: To help to improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution

stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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;

- 8. Nuts, namely: almonds (*Amygdalus communis*
- L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis [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.

b) lactitol.

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.

Control Point	Example of problem	Yes	No	Notes – Evaluation results
1. Hazard analysis1.1 Has the risk of allergy and intolerance been addressed in the hazard analysis?1.2 Critical control points (CCP)	Only one type of substance, i.e. nuts, is considered; the company uses "may contain" labelling with no thorough analysis or without having taken the necessary measures; allergens and intolerance-causing substances on the EU list are not discussed at all. Critical limits, procedures for corrective actions, verification procedures. Have appropriate preventive measures			
2. Supplier assessment	been taken in handling, storage and labelling? Critical review of the supplier's claims.			
2.1 Are there established procedures?2.2 Are they appropriate for the purpose?2.3 Are they followed?2.4 Are they updated as needed?	Proper certificates/product specifications. Is the supplier's information assessed to be accurate?			
3. Training and supervision of employees?3.1 Are there established procedures?3.2 Are they appropriate for the purpose?3.3 Are they followed?3.4 Are they updated as needed?	Is the problem of allergens and food intolerances addressed in the training content? Training of different personnel groups, including also product developers, purchasers, sales staff, dishwashers and cleaning staff, and temporary workers.			

Example of problem	Yes	No	Notes –	Evaluation results
Clear labelling.				
New recipe contains allergens – clearly				
packaging.				
Carriers for herb/spice mixes.				
Compound ingredients, e.g. roasted				
Separate storage of opened packages and food carts.				
Included in the product flowchart.				
Clear labelling to distinguish				
containers for waste.				
	Clear labelling. New recipe contains allergens – clearly marked by changes to the consumer packaging. Carriers for herb/spice mixes. Compound ingredients, e.g. roasted bread crumbs and mixes. Separate storage of opened packages and food carts. Included in the product flowchart. Clear labelling to distinguish rework/recycled food containers and	Clear labelling. New recipe contains allergens – clearly marked by changes to the consumer packaging. Carriers for herb/spice mixes. Compound ingredients, e.g. roasted bread crumbs and mixes. Separate storage of opened packages and food carts. Included in the product flowchart. Clear labelling to distinguish rework/recycled food containers and	Clear labelling. New recipe contains allergens – clearly marked by changes to the consumer packaging. Carriers for herb/spice mixes. Compound ingredients, e.g. roasted bread crumbs and mixes. Separate storage of opened packages and food carts. Included in the product flowchart. Clear labelling to distinguish rework/recycled food containers and	Clear labelling. New recipe contains allergens – clearly marked by changes to the consumer packaging. Carriers for herb/spice mixes. Compound ingredients, e.g. roasted bread crumbs and mixes. Separate storage of opened packages and food carts. Included in the product flowchart. Clear labelling to distinguish rework/recycled food containers and

Control Point	Example of problem	Yes	No	Notes –	Evaluation results
7. Labelling of raw materials during production and handling	Intermediate goods stored before further processing (e.g. in open food tubs/carts) are properly labelled.				
7.1 Are there established procedures?					
7.2 Are they appropriate for the purpose?					
7.3 Are they followed?					
7.4 Are they updated as needed?					
8. Cleaning	Production planning.				
8.1 Are there established procedures?	Cleaning with respect to allergens.				
8.2 Are they appropriate for the purpose?	Documented post-cleaning control.				
8.3 Are they followed?	Has someone been assigned				
8.4 Are they updated as needed?	responsibility for the control?				
9. Labelling	Clear labelling with large enough print				
9.1 Are there established procedures?	and contrast. Are there procedures in place for providing ingredient				
9.2 Are they appropriate for the purpose?	information for food products at all stages before final packaging?				
9.3 Are they followed?	Allergens in the recipe's raw materials				
9.4 Are they updated as needed?	included in the ingredient list.				
	New recipes, new raw materials, labelling controls.				
				<u> </u>	

Control Point	Example of problem	Yes	No	Notes – Evaluation results
10. Finished product and post-production controls	Analyses of sufficient precision and sensitivity.			
10.1 Are there established procedures?	Representative sampling.			
10.2 Are they appropriate for the purpose?				
10.3 Are they followed?				
10.4 Are they updated as needed?				
11. Is "free from" used on product label?	How should product safety work be conducted to meet the requirements of			
11.1 Are there established procedures?	"free from" labelling?			
11.2 Are they appropriate for the purpose?	Due duest an electroned with the Metional			
11.3 Are they followed?	Product registered with the National Food Agency.			
11.4 Are they updated as needed?				
12. Is "may contain" used on product label?	How should product safety work be conducted to meet the required standards and still permit the use of			
12.1 Are there established procedures?	"may contain" labelling?			
12.2 Are they appropriate for the purpose?				
12.3 Are they followed?				
12.4 Are they updated as needed?				

Control Point	Example of problem	Yes	No	Notes – Evaluation results	
13. Premises and equipment13.1 Are there established procedures?13.2 Are they appropriate for the purpose?13.3 Are they followed?13.4 Are they updated as needed?	Maintenance. Ventilation. Tidiness and order in storerooms and temporary storage areas.				
14. Handling procedures for product alerts14.1 Are there established procedures?14.2 Are they appropriate for the purpose?14.3. Are they followed?14.4 Are they updated as needed?	The company's internal procedures should always be followed first. People involved in alerts are often those working with consumer contact, purchasing, and marketing and distribution managers. Corrective measures. Access to decision-makers. Traceability.				
15. Consumer complaints 15.1 Are there established procedures? 15.2 Are they appropriate for the purpose? 15.3. Are they followed? 15.4 Are they updated as needed?	Carefully review incoming complaints. Corrective measures for products and raw materials.				
Date: Name of person who completed checklist: Name of object of supervision:					

9. Checklist for:

Consumers

Purpose: To improve the safety of food handling with respect to food allergies and intolerances.

To minimize the risk for mistakes.

To draw attention to the consumer's own responsibility.

Requirements: Consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

- 1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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.

L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* [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

8. Nuts, namely: almonds (*Amygdalus communis*

- 9. Celery and products thereof.
- 10. Mustard and products thereof.

ethyl alcohol of agricultural origin.

- 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.

As a consumer, you can help to improve food safety, for example, by using this checklist.

People with severe allergies must be cautious with all foods made from multiple ingredients because the risk that a food may contain traces of ingredients from other manufacturing processes can never be ruled out completely. People with severe allergies must always carry with them any medications prescribed by their physician or health care provider to counteract severe allergic reactions.

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.

Control Point	Example of problem	Yes	No	Notes – Evaluation results
1. Do you know enough about your or your family member's food intolerances? Do you contact your physician or health care provider when you have questions about allergies or intolerances? Have you read information from recognized sources (e.g. the 1177 helpline or website, National Food Agency website, Swedish Asthma and Allergy Association, Swedish Celiac Society)?	In the case of suspected allergy or other intolerance, always contact your physician or health care provider. Attempting to diagnose yourself carries the risk that you may have a serious allergy or intolerance that is not diagnosed, that you will not receive the help needed (e.g. dietary advice), and/or that you may be avoiding a particular food unnecessarily. Note that peanuts are not a nut but a legume. Allergy to peanuts and soy may be combined with allergy to other legumes as well.			
2. Insight regarding the level of sensitivity, reactions and consequences is essential. Different people have different levels of sensitivity. Based on previous reactions and information you have received from your health care provider, how would you rate your sensitivity or that of your family member? Do you know how to administer medication should it be necessary?[kv1]	Examples of levels of sensitivity: Someone who is lactose-intolerant may experience symptoms that pass, while someone allergic to milk protein can become very ill. Lactose-intolerant individuals should therefore limit their intake of dairy products, while people with a milk allergy must avoid all milk and dairy products. Peanuts and other nuts as well as other foods such as milk and wheat can cause severe allergic reactions. For some people, however, these foods may cause less severe symptoms. Pollen allergy can lead to allergies to foods as well (e.g. apples, hazelnuts), but most people experience relatively mild symptoms.			

Control Point	Example of problem	Yes	No	Notes – Evaluation results
3. Do you communicate clearly when	Examples of clear communication:			
requesting or giving information?	I am allergic to milk protein. Does this			
Do you ask for ingredient lists for	dish contain any form of cow's milk or			
unpackaged foods and food dishes?	cheese? I can not eat food prepared on			
1	surfaces, in pots, or with other utensils			
	used to prepare foods containing milk or			
	milk products unless they have been washed in between. I have a very severe			
	allergic reaction to any foods that contain			
	milk or dairy.			
	•			
	I have celiac disease, which is often also called gluten intolerance. I can not eat			
	any foods that contain wheat, rye or			
	barley.			
	Keep in mind that:			
	Statements like "I am gluten" are not			
	correct or clear communication.			
	Restaurants must be able to tell you if a			
	food dish contains any of the 14 most			
	common allergens (see above). They do			
	not have to provide it in writing but the			
	information must be available to you upon request.			
	Restaurants that offer dishes "free" from			
	certain foods must have special			
	procedures to accommodate guests with			
	severe allergies. Most restaurants do not			
	have these procedures in place but many			
	people with allergies and intolerances			
	can eat their food anyway. It is therefore			
	better to word your questions as noted			
	above rather than simply asking: "Is this			
	`			
	dish milk-free?" (See also Control Point 7, below.)			

Control Point	Example of problem	Yes	No	Notes – Evaluation results
4. Do you always read the ingredient lists?	If your answer to this is "No", you are exposing yourself to serious risks!!			
	Examples of misunderstandings:			
	Changes in a food's content are often not marked in any way other than changes to the information in the ingredient list.			
	Hard-to-read print can make it impossible to get information about what a product contains – demand clear, legible text!			
5. Do you always demand ingredient lists on food packages?	You should! If you lack information due to unclear labelling, let the staff in the stores where you shop know. You may also contact the local food inspection office in your municipality. New EU labelling regulations state that the allergens listed in the table on pages 1 and 2 must always be declared and emphasized.			

Control Point	Example of problem	Yes	No	Notes – Evaluation results
6. Are you aware that buffet tables and food production pose a risk of contamination, i.e. where a food may have come in contact with a substance that it is not supposed to contain?	Examples of risks: Self-serve buffets and bulk sweets etc. present a high risk of cross- contamination via spills and splashes and the shared use of utensils for more than one item. A food may be produced on a production line that is difficult to clean properly, e.g. in the chocolate industry. Dark chocolate is therefore often contaminated with milk. Raw materials are contaminated at some			
	point in the handling process, e.g. during harvest, transport, storage or packaging. Cross-contamination of oats with wheat, rye and barley is therefore common.			
	Only a food for particular nutritional purposes (known as PARNUT foods), i.e. clearly marked as being "free" from a particular ingredient on the label, is guaranteed to be completely free from that particular allergen.			
	See Control Point 9.			

Control Point	Example of problem	Yes	No	Notes – Evaluation results
7. Are there foods that are safe for me to eat?	One's own level of sensitivity and the information available about a product should form the basis for an assessment of potential risks and risk-taking. PARNUT foods (see Point 6) require extra quality-assurance practices in accordance with special regulations, and production and sales of PARNUT foods must be registered with the National Food Agency. Only a PARNUT food that states it is "free" from a particular ingredient on the label is guaranteed to be completely free from that particular allergen. Note that in the case of severe		No	Notes – Evaluation results
	intolerance/allergy, the only alternatives are PARNUT foods and foods prepared from pure, uncontaminated raw materials.			

<u>Date:</u>	
Name of person who completed checklist:	