2006-01-05	CEN/TC 275/WG 12 **N 0112** **"Food allergens"**

Secretariat of CEN/TC 275/WG 12

Dirk Kostmann

✉ DIN Deutsches Institut für Normung e.V.
D-10772 Berlin
☎ International +49 30 26 01- 20 26
📠 International +49 30 26 01- 4 20 26
💻 dirk.kostmann@din.de

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For action:	For information

Swedish Food Sector Guidelines For:

- **Management and labelling of food products with reference to**

Allergy and Intolerance

English version, August 2005

Contents

Summary

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

The document is based on the list of allergens found in Directive 2003/89/EC of the European Parliament and of the Council of the European Union and provides also an overview of current legislation in the field. A description is given of the prevalence of allergy and food intolerance and how these reactions manifest themselves.

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

The document has been supplemented with checklists for the various specific parts of the food chain, including a list of actions to be taken if, despite all safety measures, a consumer should experience a reaction.

1. Introduction

These guidelines have been developed by the Swedish Food Retailers Federation (*Svensk Dagligvaruhandel*) and the Swedish Food Federation (*Livsmedelsföretagen, **Li***) in cooperation with the National Food Administration (*Livsmedelsverket*) and Swedish Coeliac 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" labelling. The "Food Industry Guide to Allergen Management and Labelling" of the Australian Food and Grocery Council has been used as a basis for these guidelines.

1.1 Scope

The guidelines are intended for persons and businesses that 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 applicable legislation and to provide guidelines for how "may contain" labelling can be made uniform and applied restrictively. The aim is to help consumers with allergies and intolerance in their daily choice of foods.

The term *allergens* refers in this document to allergens and substances that may cause allergy, intolerance and other adverse reactions.

1.2 Current legislation

Current legislation applicable to the food sector can be found on the National Food Administration's website, see www.slv.se.

According to EC Directive 2003/89/EC,[1] the following ingredients and products thereof must always be declared in the ingredient list:

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof,
- Crustaceans and products thereof,
- Eggs and products thereof,
- Fish and products thereof,
- Peanuts and products thereof,
- Soybeans and products thereof,
- Milk and products thereof (including lactose),
- Nuts, i.e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof,
- Celery and products thereof,
- Mustard and products thereof,
- Sesame seeds and products thereof,
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as SO_2.

According to National Food Administration legislation (SLVFS 1996:6 §15), food premises and their equipment and fittings must be kept in good running order and cleaned regularly so that foods handled in the premises are not negatively affected. This cleaning must include

[1]Comment: see National Food Administration legislation on labelling and presentation of foods (LIVSFS 2004:27).

elements motivated from a food hygiene standpoint, to minimize the risks for persons who are allergic or otherwise sensitive to particular ingredients in foods.

According to National Food Administration legislation on supervision of the food sector (SLVFS 1990:10), those who handle food in their profession must *"identify the steps of their work that are critical from a food hygiene standpoint and apply the necessary safety procedures to eliminate potential risks."* This work should be based on HACCP principles (Hazard Analysis and Critical Control Points). The National Food Administration expands on this on page 3 of their sector guideline information (*Information om branschriktlinjer*) as well as in other documentation, see www.slv.se.

Contamination refers in this context to unintentional cross-contact with allergens that may cause adverse reactions.

Fact box: Excerpt from the National Food Administration brochure on self-regulation with respect to food safety and quality (*Egentillsyn ger trygghet och kvalité).*

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 must comply with applicable limits.

HACCP
A Hazard Analysis and Critical Control Points plan is a system for identifying, evaluating and managing hazards that are critical for food safety.
1. Identify hazards that can exist in production (establish flow chart for every product category). Where can the hazards be found in production? Where in the process can these hazards be controlled?
2. Determine critical control points.
3. Set limits for the critical control points.
4. Establish a system for monitoring each critical control point. Examples can include measurement of temperature and time.
5. Determine corrective measures if the critical limits are exceeded.
6. In addition to systematic monitoring, use tests and evaluations to verify (control) that the system is working.
7. Establish documentation procedures.

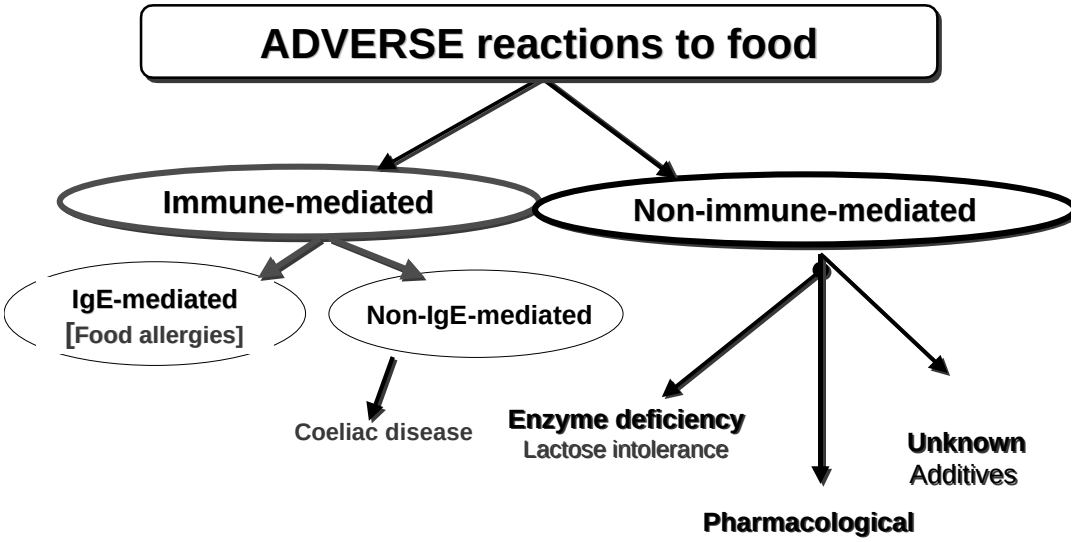
1.3 The consumer's expectations

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 may be involved. IgE--mediated reactions are known as *food allergies*.

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



2.1 Immune-mediated reactions

Reactions mediated by IgE antibodies – Food Allergy

Prevalence. Food allergies affect a small proportion of the population. In some cases, an allergic reaction can be life-threatening or fatal. It is generally estimated that only 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, by the age of 5-7 years. Other allergies, e.g. to fish and peanuts, tend to persist.

The occurrence of allergies is determined by complex interactions of exposure factors and personal susceptibility of the exposed individual. Children born in allergic families 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, figures in the range of 15-20% are reported. A considerable proportion of adults therefore avoid certain foods because of pollen-related food allergies.

Mechanisms. In the case of food allergy, an immunological response involving *IgE antibodies* occurs. This is a two-step process, where an individual must first be exposed to a particular protein in order to develop these antibodies. Once the individual has become sensitized to a particular allergen, he or she may develop symptoms upon re-exposure.

Practically all known food allergens that can cause an immunological reaction are proteins. Allergenic proteins are normally heat resistant and withstand food manufacturing processes and are unaffected by low pH and enzymes in the gastrointestinal tract.

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

The symptoms of an allergic reaction can range from mild to severe, with most individuals suffering only a few of the many possible symptoms, which include:

- respiratory problems (rhinitis, conjunctivitis, asthma, breathing difficulties, swelling of the lips, mouth and throat),
- gastrointestinal problems (nausea, stomach pain, vomiting, diarrhoea),
- skin problems (hives, itching, dermatitis, eczema).

In rare cases, a more severe systemic reaction may occur, leading to a sudden drop in blood pressure, severe constriction of the airways, a generalized shock reaction and multiple organ failure. This is known as *anaphylactic shock* and can lead to death within minutes if not treated. Although only a small number of people with food allergies are at risk of such serious reactions, there are nevertheless many documented cases of death 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 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. However, many other foods can also cause allergies, though reactions to these are less common. Due to many serious reactions to celery, reported in particular from Central and Southern Europe, celery is included among the foods that must always be declared. For examples of other allergens, see Appendix 1.

Non-IgE-mediated reactions

Coeliac disease (gluten intolerance) is an immune-mediated disease that does not involve IgE antibodies. In coeliac disease, a local immunological response to specific cereal proteins (gluten protein or gluten equivalents) occurs in the small intestine. This causes an inflammation and damage to the small intestinal mucosa, which can lead to, among other things, malnutrition. In coeliac disease, products containing wheat, rye, barley and oats[2] must be excluded. The diet can be based on cereals with reduced levels of gluten, such as wheat starch, and naturally gluten-free products like corn, rice, millet or buckwheat. Symptoms may appear immediately after ingestion, but usually take longer to appear. Normalization of an injury to the small intestinal can take up to 6 months. In Sweden, the prevalence of coeliac disease is estimated to be 1%.

[2] The findings of a number of clinical studies suggest, however, that oats can be consumed by most people with coeliac disease. See the National Food Administration and Swedish Coeliac Society websites, www.slv.se and www.celiaki.se, respectively.

2.2 Non-immune reaction

Food allergy and coeliac disease should not be confused with non-immune-mediated reactions. The latter include lactose intolerance, which is caused by a deficiency of lactase, an enzyme needed to digest lactose (the sugar in milk). Major symptoms of lactose intolerance are stomach pain, diarrhoea and flatulence. Individual sensitivity to lactose varies, but most lactose intolerant people are able to ingest small amounts of lactose. It is estimated that 3-5% of native Swedes are lactose intolerant. In the non-native Swedish population, as well as in other parts of the world, lactose intolerance is more common. Lactose intolerance should not be confused with milk allergy. Allergy to milk is an IgE immune-mediated response to the proteins in cow's milk and can cause severe reactions, even anaphylaxis. Lactose intolerance does not provoke such severe reactions. In the case of milk allergy, all dairy products and products containing milk protein must be avoided.

A non-allergic person can experience symptoms similar to an allergic person without the immune system being involved. An individual's sensitivity to certain substances is considered pathologically elevated if a reaction occurs 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 in food products. As sulphites are volatile, their use in high concentrations and particularly in acidic foods, where the sulphite is easily released in gaseous form, may cause problems. Asthma is a chronic inflammatory condition of the airways and can lead to serious breathing difficulties for the person affected.

3. Allergen Management

Special attention is required to control potential allergy risks. The recommended method for controlling the risk of allergen contamination is through establishing a HACCP program. This includes evaluation of the hazards associated with every step of the entire chain, from receiving raw materials to consumption of the finished product. This evaluation must be done by each actor for their part of the food chain.

Allergen handling instructions also apply to other ingredients that can cause sensitivity 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:

- The company's continuous training of employees should always cover education about allergens.
- Allergen risks should be observed in every part of the chain, from 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 on 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, for example, in this case pasta *without* egg.
- Premises, equipment and order of handling should be planned to prevenet 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, in handling of 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 be encouraged to take immediate action if contamination is suspected.

Procedures for control and prevention of contamination must be visible or readily available for all employees in the work area.

The procedures should contain information about:

- Good hygiene, for example, rules regarding clothing, hand-washing and hand contact with foods.
- Cleaning of premises, equipment and tools.
- Handling of rework materials, for example, the conditions under which such product may be used.
- Waste management, for example, how waste should be labelled and kept separate from rework.
- Situations where potential cross-contamination can occur between products, production lines or equipment, and the employee's responsibility for preventing this.
- Production order and handling, as well as how this order 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 looked at 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 intolerance. 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 for 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 – Product specifications

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 contamination risks.

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

Allergenic raw materials, ingredients, semi-finished products, etc., should be identified upon receipt and, if possible, kept separate from each 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 alternative 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 different 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 documents 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 those used for products that contain allergenic substances and 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 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 for handling and production

There should be control procedures 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 different 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 performed. 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 cleaning equipment and documented procedures are needed. 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 required in order to assess the cleaning results. Note that one negative test result is never a guarantee that the equipment is thoroughly cleaned.

To control that the equipment has been properly cleaned, analyses can be conducted to test for the presence of allergens. Normally, the presence of such allergens is determined using immunological techniques, for example, ELISA[3], based on specific antibodies. The 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 can be detected, however, it is proof of inadequate cleaning.

A list of manufacturers who produce allergen test kits can be found on the National Food Administration website, www.slv.se.

[3] Enzyme Linked Immuno Sorbent Assay

3.7 Packaging and post-production controls

Production planning includes the order in which different products are manufactured and packaged. Special attention must be paid when the production of bulk volumes takes place at one location and the packaging of the finished product at another. In such cases, the order of packaging must be designed to reduce the risk of contamination by allergens and to include 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 must be used immediately. It is also essential to ensure that the product is packed in the appropriate packaging. When choosing packaging of the same or similar appearance, such as different 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 when individual ingredient changes have been made 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 so that they can not contaminate other products.

3.8 In-store handling

As 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.

Self-serve areas where the consumer him/herself handles 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

According to EC Directive 2003/89/EC,[4] the following allergenic ingredients must always be stated in the list of ingredients:

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof,
- Crustaceans and products thereof,
- Eggs and products thereof,
- Fish and products thereof,
- Peanuts and products thereof,
- Soybeans and products thereof,
- Milk and products thereof (including lactose),
- Nuts, i.e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof,
- Celery and products thereof,
- Mustard and products thereof,
- Sesame seeds and products thereof,
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as SO_2.

The list will be revised as necessary. See also Appendix 1 and the ***Li*** labelling handbook, see www.li.se.

4.2 Extent of labelling

The allergens listed in Section 4.1 must always be declared in the list of ingredients when they are included as:

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

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

Ingredient lists must be given on foods packaged for the consumer. For other packaged foods, e.g. certain industrial raw materials, an exception may be granted where the ingredient list can be provided in a separate document. See LIVSFS 2004:27 on labelling and presentation of foods (www.slv.se, subheading *Swedish Food Legislation*).

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

[4] Comment: see LIVSFS 2004:27.

4.3 Complexity of labelling

Via documentation, manufacturers know from which raw materials the ingredients they use originate. The comprehensive labelling requirements given 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 EC Directive 2003/89/EC.
For example, chocolate may contain hazelnuts, an allergen that always must be declared.

Suppliers of compound ingredients, additives, processing aids, etc., are responsible for providing their customers with information on any allergens listed 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. The European Commission will continuously decide on which ingredients can be excluded from the list, see Appendix 2.

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

4.4 How to declare allergens

EC Directive 2003/89/EC states that allergens should be indicated "with a clear reference to the name of this ingredient." 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: Skimmed milk, strawberry jam 30% [strawberries, sugar, water, dextrose, stabilizer (E440), citric acid (E330)], waffle cone [wheat flour, water, sugar, vegetable shortening, salt, emulsifier (soy lecithin)], sugar, vegetable shortening, chocolate coating [vegetable shortening, 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 "Free from" labelling

In order to include statements such as "gluten free" or "milk free" in their labelling, products must meet the provisions for foods for particular nutritional uses (SLVFS 2000:14) and be registered with the National Food Administration, according to §12 of noted legislation. The statement must however be relevant, e.g. margarine can not be labelled "gluten free".

Among the requirements for using "… free" labelling is that production take place under specially controlled conditions. The supervisory authority shall have conducted an evaluation of the company's ability to ensure "… free" production and issued a statement to this effect.

There are, for example, currently products registered that use the labelling *milk free, soy free, egg free, gluten free,* or alternatively *naturally gluten free, lactose free* and *lactose reduced.* One may also register products that are free of allergens other than those listed above.

On registering products with the National Food Administration, see www.slv.se.

4.6 When can "may contain" labelling be used?

Labelling that emphasizes a risk of contamination may never be used as an excuse for poor controls and hygiene management. If procedures are not established or not applied, wording such as "may contain traces of peanuts" is not helpful for the consumer. It can instead lead to the consumer taking a risk and eating the product, or avoiding a product that could be safely eaten by that consumer. Using wording to this effect can also create problems for the manufacturer, as it can be interpreted 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 each allergen in a specific production line is:

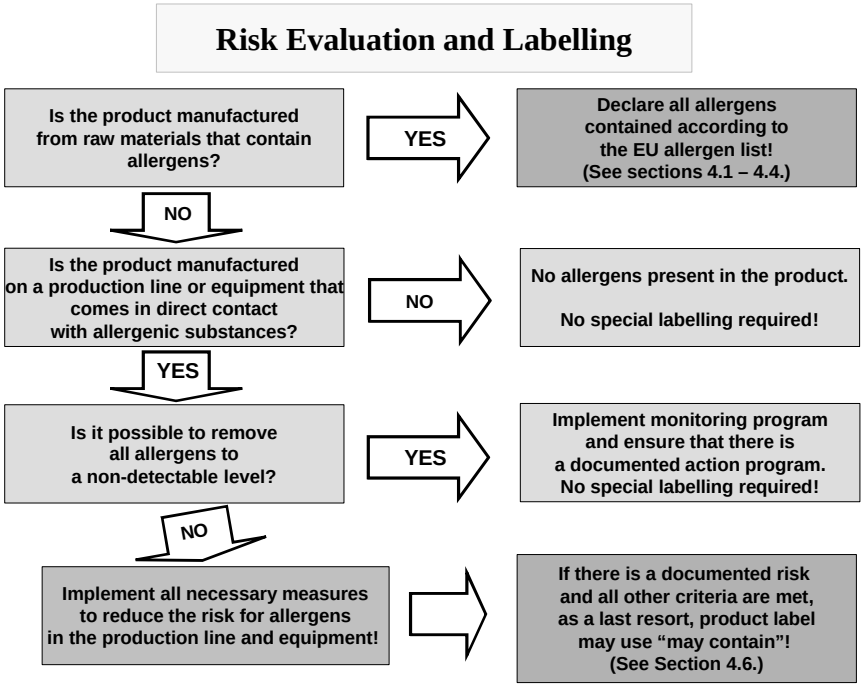
1. Uncontrollable, i.e. the ability to ensure the entire process is considered impossible, e.g. due to manufacturing in part occuring in systems that can not be cleaned with water.
2. Sporadic, e.g. if the allergen is detected sporadically after product changes.
3. Documented through cleaning controls, test results, or substantiated consumer reaction.

Only when all of these conditions are met can "may contain" be used in the labelling!

Labelling should be designed for each specific allergen and group names should be avoided. For example, "may contain traces of nuts" should not be used, but each specific variety of nut should be stated.

The National Food Administration states that cleaning must meet certain standards. However, if there still remains a risk of allergen residue in the product, according to the points above, "may contain" labelling may be applied. Such labelling should be done in consensus with the supervisory authority who also follow up that adequate measures have been taken to justify this labelling.

The following flow chart shows the decision steps in assessing how a product's label should be designed. A decision to use "may contain traces of" in the labelling should always be based on a documented risk assessment, performed according to HACCP principles.



4.7 Alternative ingredients

According to EC Directive 2003/89/EC, ingredients that are of a similar type or mutually substitutable and 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 otherwise not been altered. However, this does not apply to additivies or the allergens listed in Section 4.1, see also Appendix 1.

4.8 Clear labelling on the package

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

Labelling information must be *"easy to understand, clearly visible, legible and permanent"* according to (LIVSFS 2004:27). A clear and easily understandable ingredient list is of particular importance for people with food intolerance. The font type, print size and contrast between text and background is of great importance with respect to legibility.

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

The size of print required for good legibility depends on the font type and contrast. A font size of at least 1.1 mm for lower case "o" is recommended. Some exceptions, such as in the case of small packages may be acceptable, with a minimum font size of about 0.9 mm used for lower case "o", but this requires a font type and contrast that will ensure good legibility.

4.9 Recipe changes

When making a recipe change or substituting one ingredient for another, the consumer should be clearly informed about the change in product content, especially if a new allergen

is introduced or a substitution has occurred. This can be done, for example, by writing “new recipe” on the front of the package.

If, for example, peanut flakes are used in place of almond flakes, the product’s packaging should clearly state that a change in ingredients has been made. Otherwise, there is a risk that a person who tolerates almonds, but not peanuts, may eat the product out of habit and suffer severe allergic shock (anaphylaxis). Making the change in the ingredient list is not enough, however, because consumers get used to relying on products they are able to eat and do not read every ingredient list every time they buy a product.

4.10 Other information – Product fact sheets

Manufacturers that provide 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, www.li.se.

Appendix 1. Examples of foods and ingredients that can contain allergens.

Examples of food and food ingredients that can contain allergens are given below. In addition to the allergens addressed in Section 1.2 of the food sector guidelines for *Management and Labelling of Food Products with reference to Allergy and Intolerance* (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 table below serves as an appendix to the Guidelines and is not considered a complete list. Other information may need to be obtained. See also the latest versions of National Food Administration information brochures 1-11 on allergy and the National Food Administration 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 added ingredients.

Keep in mind, however, that even if an ingredient is not on the EU allergen list of food ingredients that must always be declared, the basic rule is that **all** ingredients used in the manufacturing must be stated in the list of ingredients (see Section 4.2 of the Guidelines, National Food Administration regulations and guides, ***Li'***s labelling handbook, etc.).

National Food Administration regulations regarding labelling and presentation of foods (LIVSFS 2004:27) imposes particular 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.	Sour dough, bread crumbs, pasta, cous cous, bouillon powder, potato products (treated with wheat flour), wort, seasoning mixes, corn flakes, roasted onion, soy sauce, confectionery (e.g. liquorice).
Crustaceans	Shrimp, crab, lobster, crayfish.		Imitation crab made from fish, soups, bouillon, concentrated stock, flavourings, sandwich fillings, salads, shellfish salads and stews.
Examples of molluscs that may need to be considered in addition to the EU list	Mussels, oysters, squid and octopus.		
Fish	Fish (all species).	Fish preparations. Fish gelatin, fish meal, fish protein.	Cured, smoked, pickled and canned fish, fish roe, fish bouillon, caviar, fish balls, 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 egg.	Pasta, noodles, liver paté, meringue, aioli, mayonnaise, bread crumbs, bread coating, 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, such as hard cheese, dessert cheese, processed cheese, fresh soft cheeses, 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, sausages, ground meat products, kebab, seasoning mixes, marinades, flavourings.
Examples of legumes that may need to be considered in addition to the EU list	Peas, beans, chickpeas, lentils, lupine, liquorice, fenugreek.	Pea fibre, pea protein, pea starch, lupin flour, locust bean gum/carob bean gum (E410), guar gum (E412), tragacanth (E413), acacia/gum arabic (E414), tara gum (E417).	Bread, cakes, ground meat products, liver paté, ice-cream, liquorice, curry (may contain fenugreek and other spices).
Nuts	Almond, hazelnut, walnut, cashew, pecan, Brazil nut, pistachio, macadamia nut/Queensland nut.		Nut paste, nougat, marzipan, almond paste, 'baking' paste. Chocolate, confectionery, pesto, granola and muesli, cookies, crackers, baked goods, bread, bread crumbs, Asian dishes.
Examples of "nuts" that may need to be considered in addition to the EU list	Apricot kernels, pine nuts.		
Sesame seeds	Sesame seeds.		Seasoning mixes, bread coatings, bread, granola and muesli, cookies, crackers, rice cakes, snack foods, dressings, bread crumbs, oriental sauces, tomato sauce, sushi.
Examples of seeds that may need to be considered in addition to the EU list	Poppy seeds, sunflower seeds, pumpkin seeds.		

Allergens according to EU list	Specification	Examples of products	Examples of foods and food ingredients that may contain these
Celery	Celery root, celery leaves (all parts of the plant).	Celery root, celery leaves, celery seeds.	Seasoning mixes.
Mustard	Mustard seeds (white, yellow, black).	Mustard seeds (white, yellow, black).	Mustard, mayonnaise, mustard sauces, dressings, seasoning mixes, 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 a number of wild berries (e.g. lingonberry, cloudberry). May be used in most foods that can be canned (see LIVSFS 2003:20).
Colours and dyes	Carmine, carminic acid (E120), annatto extract (E160b), azo dyes (E102, E110, E122-124, E128-129, E151, E154-155, E180).		According to EC regulations these may be used in most foods that may be coloured (see Swedish regulations LIVSFS 2003:20). 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. Excerpt from Commission Directive 2005/26/EC.

ANNEX

List of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	— Wheat based glucose syrups including dextrose (1) — Wheat based maltodextrins (1) — Glucose syrups based on barley — Cereals used in distillates for spirits
Eggs	— Lysozym (produced from egg) used in wine — Albumin (produced from egg) used as fining agent in wine and cider
Fish	— Fish gelatine used as carrier for vitamins and flavours — Fish gelatine or Isinglass used as fining agent in beer, cider and wine
Soybean	— Fully refined soybean oil and fat (1) — Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources — Vegetable oils derived phytosterols and phytosterol esters from soybean sources — Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk	— Whey used in distillates for spirits — Lactitol — Milk (casein) products used as fining agents in cider and wines
Nuts	— Nuts used in distillates for spirits — Nuts (almonds, walnuts) used (as flavour) in spirits
Celery	— Celery leaf and seed oil — Celery seed oleoresin
Mustard	— Mustard oil — Mustard seed oil — Mustard seed oleoresin

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

Appendix 3. Food sector guideline committee members.

Marianne Jarl	Swedish Asthma and Allergy Association	www.astmaoallergiforbundet.se
Helena Svensson	Axfood Sverige AB	www.axfood.se
Anders Nilsson	Coop Norden Sverige AB	www.coop.se
Madelene Brogren	ICA Sverige AB	www.ica.se
Boel Östlund	***Li*** (Swedish Food Federation)	www.li.se
Ulrika Ehrhardt	***Li*** (Swedish Food Federation)	www.li.se
Ulla Fäger	National Food Administration	www.slv.se
Ingrid Malmheden Yman	National Food Administration	www.slv.se
Anders Lindström	Swedish Coeliac Society	www.celiaki.se
Helene Arrenfeldt	Swedish Food Retailers Federation	www.dagligvaror.se