Allergens in Law;
Imperfections in the current European legislation, related to the safety
and preferences of food allergic consumers

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Autor: Marie-José Hendriks
Registration number: 831118-324-010
Supervision: Bernd van der Meulen & Lynn Frewer
Course: LAW-80436 (Thesis Law and Governance)
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Author: Marie-José Hendriks
Reg. No. 831118-324-010
MSc-program: Food Safety
Course LAW-80436 (Thesis Law and Governance)
Supervisors: Bernd van der Meulen
Law and Governance Group
Wageningen University and Research centre
Lynn Frewer
Consumer Behaviour Group
Wageningen University and Research centre
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Abstract

Food allergy is an immunological reaction to a food product, which results in symptoms when the individual is exposed to a particular food. The symptoms vary from mild (swelling or itching feeling in the mouth area or gastrointestinal problems) to life threatening (anaphylactic shock). Approximately 2% of adults and 8% of children suffer from food allergy. The only proven treatment for food allergy is elimination of the problematic ingredient from the diet, in which adequate product labelling is the major source of information. The objective of this thesis is to review European legislation concerning allergens and their labelling, related to consumer protection and food allergic consumers preferences.

European food labelling legislation requires pre-packaged food products to be labelled with a list of ingredients, and if necessary an additional reference to allergens. However, some food products and ingredients are excluded from these labelling requirements. Furthermore, European legislation has failed to enforce food business operators to adequately accomplish the food hygiene measures. Hence unwanted allergens may potentially be present in the end product. To warn allergic consumers about the possible presence of these allergen traces, food producers increasingly use precautionary labelling. European legislation also lacks in concrete demands concerning the readability of the product labels.

It is recommended that legislation requires all food products to label the list of ingredients, representing all ingredients/constituents present in the end product. At all times consumers should be warned, by the means of allergen labelling, if a food product includes allergenic ingredients. The production process should be controlled in such a way that the absence of allergens can be guaranteed, hence precautionary labelling can be eliminated. Legislation should include concrete measures to improve the readability of product labels. The information provision should be uniform among European Member States. Threshold levels and symbol labelling should be
introduced and the tasks of authorities and controlling food business operators should be revised in order to reduce the presence of unsafe foods on the market.
## List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission</td>
</tr>
<tr>
<td>DBPCFC</td>
<td>Double-blind placebo-controlled food challenges</td>
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<tr>
<td>EAACI</td>
<td>European Academy of Allergy and Clinical Immunology</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>EFSA</td>
<td>European Food Safety Authority</td>
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<tr>
<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
</tr>
<tr>
<td>GFSI</td>
<td>Global Food Safety Initiative</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<tr>
<td>HRQoL</td>
<td>Health-Related Quality of Life</td>
</tr>
<tr>
<td>IGD</td>
<td>Food &amp; Grocery Information, Insight &amp; Best Practice</td>
</tr>
<tr>
<td>IgE</td>
<td>Immunoglobulin E</td>
</tr>
<tr>
<td>ILSI</td>
<td>International Life Sciences Institute</td>
</tr>
<tr>
<td>NACMCF</td>
<td>National Advisory Committee on Microbiological Criteria for Foods</td>
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<tr>
<td>OAS</td>
<td>Oral allergy syndrome</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
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<tr>
<td>tTG</td>
<td>tissue transglutaminase</td>
</tr>
<tr>
<td>TEEC</td>
<td>The European Evaluation Consortium</td>
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<tr>
<td>VWA</td>
<td>Voedsel en Waren Authoriteit</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Acknowledgements

I gratefully acknowledge Bernd van der Meulen and Lynn Frewer for their advice, supervision and contribution. Their involvement triggered me to think in directions I would not have invented myself.

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# Table of contents

1. Introduction ................................................................................................................................. 1
   1.1. Objective ............................................................................................................................... 2
   1.2. Research questions ................................................................................................................. 2
   1.3. Methodology .......................................................................................................................... 3
   1.4. Thesis framework .................................................................................................................... 4

2. Medical aspects of a food allergy ................................................................................................. 5
   2.1. Physiological aspects .............................................................................................................. 5
   2.2. Epidemiological data .............................................................................................................. 8

3. The Quality of life ......................................................................................................................... 10
   3.1. The Quality of life .................................................................................................................. 10
      3.1.1. Parents of allergic infants ............................................................................................... 11
      3.1.2. Children ........................................................................................................................ 11
      3.1.3. Adolescents ..................................................................................................................... 12

4. European Legislation concerning allergens and their labelling .................................................. 14
   4.1. Basis of European food law .................................................................................................... 14
   4.2. Labelling requirements ........................................................................................................... 15
      4.2.1. The fundamental labelling requirement ........................................................................... 16
      4.2.2. Ingredient labelling ........................................................................................................ 18
      4.2.3. Allergen labelling ............................................................................................................ 20
   4.3. Gluten labelling ..................................................................................................................... 25

5. European law related to hazard management .............................................................................. 28
   5.1. Hygiene on food products ...................................................................................................... 28
   5.2. Traceability ............................................................................................................................ 31
   5.3. Shortcomings .......................................................................................................................... 32

6. Consumer perception .................................................................................................................... 33
   6.1. Problems concerning labelling experienced by allergic consumers ....................................... 33
      6.1.1. The readability and content of the present information .................................................... 33
      6.1.2. Precautionary labelling .................................................................................................. 34
6.2. Desires from allergic consumers

7. Allergen and ingredient labelling of the future

7.1. Context of proposal COM(2008)40 on ‘the provision of food information to consumers’

8. Possible improvements in European legislation

8.1. Exceptions in legislation verified

8.1.1. Absence of mandatory labelling

8.1.2. Food products excepted from ingredient declaration

8.1.3. Exception allergen labelling

8.2. Hygiene and tracking and tracing

8.2.1. Exceptions on food hygiene requirements

8.2.2. Improve enforcement food hygiene regulation

8.2.3. Precautionary labelling

8.3. Wishes and demands of food allergic consumers

8.3.1. The content of the food labels

8.3.2. Lay out and readability

9. Discussion

10. Conclusion and recommendations

References
1. Introduction

This thesis assignment is part of an EU-funded multidisciplinary integrated project “EuroPrevall”. The overall aim of this project is to improve the quality of life of consumers suffering from food allergy (www.europrevall.org). This document reviews the current European legislation concerning allergens and their labelling, in particularly in relation to optimising consumer protection and meeting the needs of food allergic consumers.

Several directives and regulations are related or relevant for allergens in food products and their labelling, including the General Food Law (Regulation 178/2002/EC, labelling Directive 2000/13/EC and the food hygiene Regulation 852/2004/EC. The European Commission has submitted proposal COM(2008)40 to replace Directive 2000/13/EC as soon as it enters into force.

The prevalence of a food allergy is more common in children than in adults. Approximately 2% of adults and 8% of children suffer from food allergy which is proven by a double-blind placebo-controlled food challenge (DBPCFC) (Niestijl Jansen et al. 1994; Rona et al. 2007; Sampson 1999; Young et al. 1994; Zuidmeer et al. 2008). The human diet contains a broad variety of food products. However, a relatively small number of food products elicit the majority of the adverse reactions. In young children milk, eggs, peanuts, soy, fish and wheat account for approximately 90% of the hypersensitive reactions (Sampson 1999), of which milk is the major source (Taylor and Hefle 2001b). In adolescents peanuts, fish, shellfish and tree nuts account for approximately 85% of the reactions (Sampson 1999).

The symptoms can include conjunctivitis and watering eyes, hives, flushed skin or rash, tingling or itchy sensation in the mouth face and/or tongue, lip swelling, vomiting and/or diarrhoea, coughing, wheezing, dizziness, light-headedness,
swelling of the throat and vocal cords, difficulty breathing, loss of consciousness and in severe cases a deathly anaphylactic shock (EFSA 2004).

To date, once diagnosed with food allergies, the only proven therapy remains elimination of the offending allergen (Sampson 2004). Effective communication about the presence of (potentially) allergic ingredients is hereby essential (Voordouw et al. 2009). A prominent type of information provision is product labelling, which should present the complete composition of a food product (EC 2003). Hence, information present on the product label should allow allergic consumers to eliminate the problematic ingredients. However, despite labelling, food allergic consumers are still suffering from food allergic reactions, and even death, after the consumption of pre-packaged food products.

1.1. Objective

The main objectives of this research are to assess the capability of European legislation related to guarantee interests and safety of food allergic consumers, and to suggest recommendations to better meet the needs and expectations of food allergic consumers.

1.2. Research questions

To accomplish the objectives the following questions have to be answered.

1) What are the medical aspects of a food allergy?
2) What is the influence of a food allergy on the quality of life?
3) Which regulations, directives or other legislative documents relate to allergens and the labelling there off?
   a. What are the requirements?
4) Are the interests of food allergic consumers adequately guaranteed in European legislation with regard to labelling?
   a. Are all products and ingredients included?
   b. Are all parts of the production chain covered?
   c. If products, ingredients or parts of the production chain are derogated, does this represent a hazard for food allergy individuals?
5) How do food allergic consumers experience product labelling in practice?
   a. What is the consumers’ perception of the presentation?
   b. What is the consumers’ perception of the context?
   c. What are consumers’ preferences?
6) Which alterations are possible in European legislation?
   a. To optimise food allergic consumer protection?
   b. To meet the needs of food allergic consumers?
7) Are there other ways than product labelling, to provide product information?

1.3. Methodology

In order to identify how European legislation deals with food allergies, a systematic literature review and document search was applied. More specific information was asked from relevant stakeholders by email. During an event, organised by the Dutch food allergy association, informal conversations were held with food allergic consumers, parents of food allergic children, producers of allergen “free” food products, members of the Dutch food allergy association and scientists in order to obtain a good impression of ‘life with food allergies’.

During the thesis I tried to visit a production plant, to develop a more concrete picture of the problems and investigate management strategies to control allergens. The quality departments, from the approached manufacturing plants, rejected the proposed visit.
1.4. Thesis framework

Chapter 2 will introduce the topic with the physiological aspects and epidemiological data of food allergies. This will be followed by chapter 3 including information concerning the influence of having a food allergy on the quality of life. Chapter 4 and 5 describe the strategies by which current European legislation protects food allergic consumers. In chapter 6 will be analysed how this legislative framework is perceived by food allergic consumers. The European Union already has already submitted a new proposal covering labelling practice. Chapter 7 will discuss these prospective labelling requirements. In chapter 8 possible improvements in legislation will be discussed. These chapters will be followed by the discussion in chapter 9 and the final chapter 10 will present the conclusion and recommendations.
2. Medical aspects of a food allergy

The greatest part of the European population eats three meals a day and in addition between each meal a snack. Consequently it is not surprising that food is so often associated with adverse reactions. “What is food for one, is to others biting poison” is written down by Lucretius (99 b.Chr.-55 b.Chr.). This is more or less what a food allergy is about. Although definitive surveys are lacking, it looks like the prevalence of food allergy is increasing over the years and receives a more prominent place in our society. To what extend food allergies have impact on society will be discussed in this chapter in the form of physiological aspects and epidemiological data and is relevant to prioritise legislative measures.

2.1. Physiological aspects

The European Academy of Allergy and Clinical Immunology (EAACI) defines food sensitivity as ‘causing objectively reproducible symptoms or signs, initiated by exposure to a defined stimulus at a dose tolerated by normal subjects’. In other words food sensitivity causes symptoms that return when the sensitive individual is exposed to a particular food in a certain dose whereas normal individuals would tolerate it.

On basis of the pathogenesis, food sensitivity can be classified in two groups including 1) allergic reactions e.g. peanut allergy and 2) non-allergic reactions e.g. lactose intolerance. A food allergy is initiated by immunologic mechanisms, which are absent by a food intolerance. The allergic reaction is initiated by a reaction between protein in the food and immunoglobulin (IgE) antibodies from food allergic individual (Jackson 2003; Stapel, Asero et al. 2008).

Physiological pathway

IgE antibodies recognise a specific food protein present in one or more food products. The combination of ‘antibodies - food proteins’ cross links to IgE receptors
on circulating basophils (type of white blood cell) and tissue mast cells which are present throughout the body, e.g. the skin, gastrointestinal tract and respiratory tract. This cross link results in a release of inflammatory mediators, like histamine and synthesis of additional factors like chemotactic factors and cytokines. These inflammatory mediators are responsible for the symptoms (see figure 1) (Jackson 2003; Sicherer et al. 2003a; Sampson, Maloney et al. 2008; Scott and Sicherer 2009)

Figure 1.
Physiological pathway food allergy (source: stichting voedselallergie)

Threshold level
A threshold level is the minimal dose of an allergen able to elicit objective symptoms in food sensitive individuals. The threshold level depends on several factors e.g., health status of the individual (like asthma induces severe reactions), food matrix, exercise, alcohol, medication (Hourihane and Knulst 2005) and the individual’s ethnicity. The amount of allergen necessary to provoke an allergic reaction also varies per allergen and might be very small, up to micrograms, as measured for peanut (Bindslev-Jensen et al. 2002; EFSA 2004).

In 2004 the European Food Safety Authority (EFSA) concluded that the information available was insufficient to set concrete threshold levels for allergens (EFSA 2004).
**Symptoms**

The symptoms of an IgE-mediated food allergic reaction usually occur within minutes to one hour following ingestion of the causal food (Sampson et al. 2008). The symptoms can include conjunctivitis and watering eyes; hives; flushed skin or rash; tingling or itchy sensation in the mouth, face and/or tongue; lip swelling; gastrointestinal problems; coughing; wheezing; dizziness and light-headedness; swelling of the throat and vocal cords; difficulty breathing; loss of consciousness and in severe cases potentially fatal anaphylactic shock (EFSA 2004).

Anaphylaxis is a serious allergic reaction which can result in death (Sampson et al. 2006). In adults, peanuts and tree nuts are mainly responsible for anaphylactic reactions (Pumphrey 2000; Banks 2003). Close to 40% of the fatal cases are caused by the presence of peanut or tree nut in desserts (candy and bakery products) prepared away from home (Bock et al. 2007). For children, cow’s milk is the main cause of food allergy and, in addition, responsible for the majority of the anaphylactic shocks (Macdougall et al. 2002; Simons et al. 2005). However, fatal anaphylactic reactions have been reported as a consequence of consuming a wide variety of foods including soybeans, sesame and other seeds, egg, milk, seafood, spices, celery and fruits (Jackson 2003).

The most common locations for food allergic reactions are restaurants or bars followed by take-away restaurants and at home or the home of friends (Pumphrey 2000; Bock et al. 2007). The observation that most anaphylactic shocks occur outside home is partly explained by the protective effect of ingredient declarations on food labels (Taylor and Hefle 2001a).
Oral allergy syndrome

Oral allergy syndrome (OAS) is the most common food allergy (Ortolani and Pastorello 2006) and principally caused by plant derived proteins. It involves (most commonly) less severe reactions like oral itching and lip swelling (Asero et al. 2007). Many proteins provoking OAS are not heat resistant, hence only raw variants are able to elicit symptoms (Jackson 2003).

Celiac disease

Celiac disease is an autoimmune disorder expressed in genetically susceptible individuals. It involves, as for food allergies, an abnormal immunological response triggered by dietary gluten. However, in Celiac disease the enzyme tissue transglutaminase (tTG), recognises normal body tissue as a target. It progressively leads to flattening of the small intestinal mucosa resulting in malabsorption (Setty et al. 2008); (Dieterich et al. 1997). Wheat, rye, barley, oats, spelt, kamut or their hybridised strains contain gluten hence toxic for patients with celiac disease and should be avoided in the diet.

2.2. Epidemiological data

Prevalence

Approximately 2% of adults and 8% of children suffer from food allergy (Niestijl Jansen et al. 1994; Young et al. 1994; Sampson 1999; Rona et al. 2007). Self-report surveys show a higher prevalence up to 35% (Rona et al. 2007). The prevalence of a food allergy in adults is lower compared to children, because 80% of food allergic children outgrow their allergy (Sampson et al. 1989; Jackson 2003). Nevertheless, the greatest number of fatalities occur in adolescents and young adults (Bock et al. 2007). There is a great differentiation between the allergenicity of ingredients. Table 1 gives an overview of the prevalence per food product based on a double-blind placebo-controlled food challenge (DBPCFC).
Table 1.  
*Prevalence of food allergies per food product*

<table>
<thead>
<tr>
<th>Food product</th>
<th>Prevalence</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cow’s milk</td>
<td>0% to 3%</td>
<td>(Rona et al. 2007)</td>
</tr>
<tr>
<td>Egg</td>
<td>0% to 1.7%</td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>1.5% to 1.6%</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>Near to 0%</td>
<td></td>
</tr>
<tr>
<td>Fruits</td>
<td>1.22%</td>
<td>(Zuidmeer et al. 2008)</td>
</tr>
<tr>
<td>Vegetables</td>
<td>0.89%</td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td>0.40% to 2.08%</td>
<td></td>
</tr>
<tr>
<td>Tree nuts</td>
<td>0.52% (children)</td>
<td></td>
</tr>
<tr>
<td>Soy</td>
<td>0.34% (children)</td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td>0.43% (children)</td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>0.0% to 0.4% (children)</td>
<td>(Rona et al. 2007)</td>
</tr>
</tbody>
</table>

Food allergy sufferers experience, IgE mediated, symptoms that return when the sensitive individual is exposed to a particular food in a certain dose whereas “normal” individuals would tolerate it. Food allergy is more common under children than in adults. Food allergic individuals have to be extremely careful about what they eat because exposure to the hazardous ingredient can cause serious symptoms and even death.
3. The Quality of life

Besides the adverse physiological reactions to foods, food allergies also determine the quality of life of individuals suffering from it. Which factors influence the quality of life will be presented and discussed in this chapter. Food allergies sufferers are represented in all age groups of the population and thus form variable group with probably their own determinants towards the quality of life.

3.1. The Quality of life

The influence of food allergies on the individual’s functioning in daily life can be measured with support of the Quality of Life (QoL). WHO defines QoL as “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (WHO 1997). In other words, QoL reflects the way an individual actually perceives his wellbeing. The QoL narrowed to a specific disease, in this case food allergy, and the related impairments is called the Health-Related Quality of Life (HRQoL) (Meltzer 2001). Allergic individuals in all age groups report the continuous need for alertness of what they are eating, restricted dietary choice and recipe changes in products as the main factors reducing the QoL (Miles et al. 2006b; Flokstra-de Blok et al. 2008). In addition, physical complaints, limitations in daily life and the attitude of society or authorities are mentioned (Marklund et al. 2007). Other factors, like care taking, physical activity and responsibility of the diet may vary between different groups of allergic consumers. For this reason the different age groups will be discussed individually.
3.1.1. Parents of allergic infants

The prevalence of food allergies is highest amongst young children (Niestijl Jansen et al. 1994; Young et al. 1994; Sampson 1999; Rona et al. 2007). Taking care of an infant suffering from food allergies is, according to 88% of the parents, more demanding than taking care of a healthy child (Arvola et al. 2000).

Breast feeding mothers have to eliminate the ingredient(s), for which the child is allergic, in their diet (Marklundt et al. 2007). 87% of the mothers followed such an elimination diet. However in the majority cases, the infants’ symptoms continued irrespective (Arvola et al. 2000). This could be caused by unfeasibility to adequately eliminate the ingredient responsible for the adverse reaction.

Parents of food allergic children perceive a lower level of general health, experience more parental distress and worry, and report more limitations during normal family activities in comparison to parents with children not suffering from a food allergy (Sicherer et al. 2001; Avery et al. 2003). This negative influence of the QoL of parents from food allergic children occurs irrespectively the severity of the symptoms. So experience parents of children suffering from mild symptoms, like problems related to the gastro-intestinal tract, more emotional concerns compared to parents having a child without these symptoms (Marklund et al. 2006).

The family cohesion was significantly greater in families with a food allergic member (Sicherer et al. 2001).

3.1.2. Children

Children suffering from a food allergy have a lower physical condition as a consequence of their food allergy compared to children without a food allergy. They also report feeling restricted in the extent to which they are able to be involved in physical activities (Avery et al. 2003). Another consequence of the food allergy is a lower psychosocial condition in comparison to their friends without this allergy. These reductions are dependent on gender, whereas boys had a significant lower
score for physical functioning and general health status in comparison to girls. The mental health of boys was better compared to girls (Marklund et al. 2006).

As soon as food allergic children are able to talk, and aware of their dietary restriction, they feel unconformable when people do not understand their diet (Avery et al. 2003).

The reductions of above mentioned HRQoL’s occurred regardless whether the child experienced allergic reactions or not. Hence, the HRQoL reduction is probably caused by stress associated with the preventative measures in order to avoid the allergen, rather than the symptoms induced by the actual allergen intake (Sicherer et al. 2001; Marklund et al. 2006).

3.1.3. Adolescents

Compared to other age categories, adolescents tend to be higher risk takers. They may eat products containing allergens and not always carry the self-injectable epinephrine pen which is needed for emergency treatment of allergic reactions (Greenhawt et al. 2009); (Sampson et al. 2006). 54% of the food allergic adolescents admitted eating foods of which they knew it contains potentially allergens. These adolescents were willing to take this risk since they were “hanging out” with friends (23%) or all their friends were eating the food in question (18%) (Sampson et al. 2006). Other reason that could play a role in the high prevalence of allergic reactions is this group are the incorrect perception of immortality (Akeson et al. 2007); (Flokstra-de Blok et al. 2008), teasing by peers (Sampson et al. 2006), experiencing an allergic shock as ‘no great issue’, peer pressure, social embarrassment and inconvenience (Akeson et al. 2007).

Friends and family may not be adequately informed about the food allergy with regard to the symptoms or treatment. Adolescents might not share this information because they already feel ‘different’ when they compare themselves to the rest of the group (Sampson et al. 2006; Bock et al. 2007). Food-hypersensitive adolescents and
adults experience negative emotional reactions (like frustration, embarrassment, anger and sadness) but also experience having a food-hypersensitivity as "no big deal" (Marklund et al. 2007). The experience of anaphylaxis does not interact with the HRQoL in adolescents or adults (Flokstra-de Blok et al. 2008).

Each group of allergic consumers has particular needs and concerns. Nevertheless, product labelling should be effective for all consumers, including for parents confronted with the diagnosis of food allergy in their child, the children themselves, risk-taking adolescents and adults suffering from a food allergy.

| Quality of life reflects the way individuals actually perceive their wellbeing. Allergic individuals in all age groups report the continuous need for alertness of what they are eating, restricted dietary choice and recipe changes in products as the main factors reducing the QoL. A reduction of health related quality of life occurs, regardless of individual experience of allergic reactions. The reduction of the HRQoL life seems mostly caused by stress associated with measures to avoid allergen consumption and anxiety about accidentally consumption of the food allergen. Besides similarities between the different age groups does each group also have their particular needs and concerns. Food labelling is the primary source of information concerning the content of a food product and should be useful for each individual suffering from a food allergy. The question arises whether European legislation is able to ensure that all consumers are provided with the information they need? |
4. European Legislation concerning allergens and their labelling

European legislation mainly consists of regulations, which are directly applicable to all Member States, and of directives which require transposition and implementation into national legislations. Legislative documents relevant to the issue of ‘allergens in food products and food allergen labelling’ will be further verified in order to assess how food allergy sufferers are currently protected by European legislation.

4.1. Basis of European food law

Regulation 178/2002/EC, the General Food Law, forms the basis of European food legislation. It lies down the general principles and requirements of food law; procedures in matters of food safety; and establishes the European Food Safety Authority (EFSA). Regulation 178/2002/EC requires food law to protect consumers’ interests and to assure that consumers are able to make an informed product choice. This Regulation clearly prohibits unsafe foods to be placed on the market. “Unsafe” is defined as injurious to health or unfit for human consumption. In addition is mentioned that food products should be safe for health sensitivities of a specific category of consumers as well. Safety is also associated with the information provided. This information should not mislead consumers. This may imply that food products containing allergenic ingredients, which are not indicated on the product label, are unsafe for a specific category of consumers.

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1 Treaty on the Functioning of the European Union Article 249
3 Regulation 178/2002/EC Article 8
4 Regulation 178/2002/EC Article 14(1)
5 Regulation 178/2002/EC Article 14(2)a; b
6 Regulation 178/2002/EC Article 14(4)c
7 Regulation 178/2002/EC Article 14(3)b
8 Regulation 178/2002/EC Article 16
(consumers with a food allergy) and consequently should not be placed on the market.

4.2. Labelling requirements

Food labelling is established in 1979, in Directive 79/112/EC and stipulates demands on food labelling. In 2000, the original Directive 79/112/EC, and its amendments were consolidated into a single horizontal (applicable to all foods) directive, namely 2000/13/EC\(^9\). This Directive is up till now leading. The principle objectives are:

1) to inform and protect consumers;
2) to ensure functioning of the internal market within the Community; and
3) to enable consumers to make an informed choice in full knowledge of facts.

This Directive has been adjusted eight times, in chronological order by Directive 2001/101/EC; 2003/89/EC; 2005/26/EC; 2006/107/EC; 2006/142/EC and 2007/68/EC and Regulation 1332/2008/EC and 596/2009/EC. With regard to allergens, Directive 2003/89/EC\(^10\); 2006/142/EC\(^11\) and 2007/68/EC\(^12\) are particularly relevant. These amendments include respectively, the establishment of mandatory allergen labelling (including a list of mandatory allergens and their requirements concerning labelling); the addition of two allergens to the list of mandatory allergens; and a revision of food products excluded from the list of allergens.

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Directive 2000/13/EC lays down common labelling requirements applicable to products delivered to the ultimate consumer and to restaurants, hospitals, canteens and similar mass caterers\textsuperscript{13}.

Directive 2000/13/EC demands certain information to be present on each pre-packaged food product. Here to will be referred as the fundamental labelling requirements. The same Directive also contains specific information concerning the list of ingredients and demands related to allergen labelling. These three parts of food product labelling will be extended discussed since they influence the presence of essential information for food allergic consumers.

4.2.1. The fundamental labelling requirement

The mandatory information (see table 2) must be present on the label of pre-packaged food products\textsuperscript{14} and should be easy to understand by consumers\textsuperscript{15}. The mandatory information includes the list of ingredients\textsuperscript{16}. Allergens belong to the group of ingredients\textsuperscript{17}. This means that food products excluded from the fundamental labelling requirements, neither present the list of ingredients or the allergens.

Table 2. Labelling requirements according to Directive 2000/13/EC Article 3

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product name</td>
<td>Under which the product is sold</td>
</tr>
<tr>
<td>List of ingredients</td>
<td></td>
</tr>
<tr>
<td>The quantity of certain ingredients or categories of ingredients</td>
<td>In the case of pre-packaged food products</td>
</tr>
</tbody>
</table>

\textsuperscript{13} Directive 2000/13/EC Article 1(1; 2)  
\textsuperscript{14} Directive 2000/13/EC Article 13(1)a  
\textsuperscript{15} Directive 2000/13/EC Article 13(2)  
\textsuperscript{16} Directive 2000/13/EC Article 3  
\textsuperscript{17} Directive 2000/13/EC Article 6(3)a and Annex IIIa as amended in Directive 2003/89/EC
<table>
<thead>
<tr>
<th>The date of minimum durability</th>
<th>In the case of food products which from the microbiological point of view, are highly perishable, the ‘use by’ date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special storage conditions or conditions of use</td>
<td></td>
</tr>
<tr>
<td>The (business) name and address of the manufacturer, packager or seller</td>
<td></td>
</tr>
<tr>
<td>Place of origin or provenance</td>
<td>Where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the food product</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>When it would be impossible to make appropriate use of the food product in the absence of such instructions</td>
</tr>
<tr>
<td>The actual alcoholic strength by volume</td>
<td>Beverages containing more than 1.2 % by volume of alcohol</td>
</tr>
</tbody>
</table>

Two groups of food products are excluded from the fundamental labelling requirement, hence can be sold in absence of the information mentioned in table 2.

The group of food products belonging to this exclusion:

- Non pre-packed food products - for which individual Member States shall adopt detailed rules\(^\text{18}\). Non pre-packaged foods include, for example, food provided in restaurants and other catering establishments, and fresh food counters in supermarkets.
- Products existing of smaller food items, packaged as single items in a bigger outer packages (e.g., muesli bars) – the list of ingredients and allergen labelling only have to be present on the outer box.

\(^{18}\) Directive 2000/13/EC Article 14
4.2.2. **Ingredient labelling**

The definition of an ingredient is “*any substance, including additives and enzymes, used in the manufacture or preparation of a food product and still present in the finished product, even if in altered form*”\(^{19}\). All ingredients present in a food product shall appear on the product label, in descending order of weight. This list of ingredients shall appear preceded by a heading containing the word ‘ingredients’\(^{20}\). However, some food products have an exception on ingredient labelling and some ingredients do not have to be mentioned in the list of ingredients.

Food products not obliged to label the list of ingredients:

- Beverages containing more than 1.2% of alcohol\(^ {21}\).
- Food products packaged in glass bottles intended for reuse which are indelibly marked and which therefore bear no label/ ring or collar\(^ {22}\).
- Food products of which the packaging or container has a largest surface being less than 10cm\(^2\)\(^ {23}\).
- Cheese, butter, fermented milk and fermented cream - in case the composition is according to legislation\(^ {24}\).
- Products composed of a single ingredient (including fermented vinegar) where the trade name is identical with the ingredient or can be clearly identified\(^ {25,26}\).

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\(^{19}\) Directive 2000/13/EC Article 6(4)a as amended by Regulation 1332/2008/EC  
\(^{20}\) Directive 2000/13/EC Article 6(5)  
\(^{21}\) Directive 2000/13/EC Article 6(3)  
\(^{22}\) Directive 2000/13/EC Article 13(4)  
\(^{23}\) Directive 2000/13/EC Article 13(4)  
\(^{24}\) Directive 2000/13/EC Article 6(2)b  
\(^{25}\) Directive 2000/13/EC Article 6(2)c  
\(^{26}\) Directive 2000/13/EC Article 6(2)a
Ingredients and constituents not mentioned in the list of ingredients:

- Group names (see table 3) – ingredients belonging to a group may be labelled by the group name instead of the specific ingredients name27.
- Constituents not considered as ingredients - constituents which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions; additives and enzymes (when present in one or more ingredients and serving no technological function in the end product); processing aids; substances used in quantities strictly necessary as solvent or media for additives, enzymes and flavourings 28.
- Compound ingredients constituting less than 2% of the end product and defined in community legislation29.
- Mixes of herbs and spices constituting less than 2% of the end product30.

Table 3.

<table>
<thead>
<tr>
<th>Definition</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refined oils (except olive oil)</td>
<td>‘Oil’</td>
</tr>
<tr>
<td></td>
<td>Either the adjective ‘vegetable’ or ‘animal’ and their origin</td>
</tr>
<tr>
<td></td>
<td>The adjective ‘hydrogenated’ must be accompanied by the indication of a hydrogenated oil</td>
</tr>
<tr>
<td>Refined fats</td>
<td>‘Fat’</td>
</tr>
<tr>
<td></td>
<td>Either the adjective ‘vegetable’ or ‘animal’ and their origin</td>
</tr>
<tr>
<td></td>
<td>The adjective ‘hydrogenated’ must be accompanied by the indication of a hydrogenated fat</td>
</tr>
<tr>
<td>Mixtures of flour obtained from two or</td>
<td>‘Flour’, followed by a list of the</td>
</tr>
</tbody>
</table>

28 Directive 2000/13/EC Article 6(4)c i, ii, iii as amended by Regulation 1332/2008/EC
29 Directive 2000/13/EC Article 6(8)a
30 Directive 2000/13/EC Article 6(8)b
<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>More cereal species</td>
<td>Cereals from which it has been obtained, in descending order by weight</td>
</tr>
<tr>
<td>Starches (or modified by physical means or by enzymes)</td>
<td>‘Starch’</td>
</tr>
<tr>
<td>All species of fish where the fish constitutes an ingredient of another food product and provided that the name and presentation of such food product does not refer to a specific species of fish</td>
<td>‘Fish’</td>
</tr>
<tr>
<td>All types of cheese or mixture of cheeses</td>
<td>‘Cheese’</td>
</tr>
<tr>
<td>All spices not exceeding 2% by weight of the food product</td>
<td>‘Spice(s)’ or ‘mixed spices’</td>
</tr>
<tr>
<td>All herbs or parts of herbs not exceeding 2% by weight of the food product</td>
<td>‘Herb(s)’ or ‘mixed herbs’</td>
</tr>
<tr>
<td>All types of gum preparations used in the manufacture of gum base for chewing gum</td>
<td>‘Gum base’</td>
</tr>
<tr>
<td>All types of crumbed baked cereal products</td>
<td>‘Crumbs’ or ‘rusks’</td>
</tr>
<tr>
<td>All types of sucrose</td>
<td>‘Sugar’</td>
</tr>
<tr>
<td>Anhydrous dextrose or dextrose monohydrate</td>
<td>‘Dextrose’</td>
</tr>
<tr>
<td>Glucose syrup and anhydrous glucose syrup</td>
<td>‘Glucose syrup’</td>
</tr>
<tr>
<td>All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof</td>
<td>‘Milk proteins’</td>
</tr>
<tr>
<td>Press, expeller or refined cocoa butter</td>
<td>‘Cocoa butter’</td>
</tr>
</tbody>
</table>

### 4.2.3. Allergen labelling

The safety of food products depends on the information present on the food label\(^{31}\). To this end ingredients, and especially the ones likely to cause adverse reactions in susceptible individuals, should be indicated on the product label. Table 4 represents an overview of ingredients which must, under all circumstances, appear on the

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\(^{31}\) Regulation 178/2002/EC Article 14(d)
product label because they are known to provoke the majority of the food allergic reactions. The last column of table 4 represents the food products which are excepted from the allergen labelling\textsuperscript{32}. These fourteen ingredients will be referred to as ‘allergens’ in this document. The basis of which the European commission determined these fourteen ingredients as allergens and the manner of labelling these allergens will be further addressed.

Table 4.

\textit{Allergens mandatory to label according to Directive 2003/89/EC and Directive 2006/142/EC and the exceptions according to Directive 2007/68/EC.}

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Additional information</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten</td>
<td>Wheat, rye, barley, oats, spelt, kamut or their hybridised strains (*)</td>
<td>Wheat based glucose syrups including dextrose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wheat-based maltodextrins</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Glucose syrups based on barley</td>
</tr>
<tr>
<td>Crustaceans (*)</td>
<td></td>
<td>Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.</td>
</tr>
<tr>
<td>Eggs (*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish (*)</td>
<td>Fish gelatine used as carrier for vitamin or carotenoid preparations</td>
<td>Fish gelatine or Isinglass used as fining agent in beer and wine.</td>
</tr>
<tr>
<td>Peanuts(*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soybeans(*)</td>
<td>Fully refined soybean oil and fat</td>
<td>Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>tocopherol acetate</td>
<td>natural D-Alpha tocopherol succinate from soybean sources</td>
</tr>
<tr>
<td>Vegetable oils</td>
<td>derived phytosterols and phytosterol esters from soybean sources</td>
</tr>
<tr>
<td>Plant stanol ester</td>
<td>produced from vegetable oil sterols from soybean sources</td>
</tr>
<tr>
<td>Milk(*)</td>
<td>Including lactose</td>
</tr>
<tr>
<td></td>
<td>Whey used in distillates for spirits</td>
</tr>
<tr>
<td></td>
<td>Lactitol</td>
</tr>
<tr>
<td>Nuts</td>
<td>I.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia and Queensland nut(*)</td>
</tr>
<tr>
<td></td>
<td>Nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages</td>
</tr>
<tr>
<td>Celery(*)</td>
<td></td>
</tr>
<tr>
<td>Mustard(*)</td>
<td></td>
</tr>
<tr>
<td>Sesame seeds(*)</td>
<td></td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>At concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO2</td>
</tr>
<tr>
<td>and sulphites</td>
<td></td>
</tr>
<tr>
<td>Lupin (*)</td>
<td></td>
</tr>
<tr>
<td>Molluscs(*)</td>
<td></td>
</tr>
</tbody>
</table>

(*) and products thereof

**Realisation of the major allergens**

In 1985 the Codex Alimentarius Commission (CAC) created the General Standard for the labelling of pre-packaged foods. The revision of 1991 revealed a list of eight types of foods causing the majority of hypersensitivity reactions worldwide. The foods included in this list have been based on a risk assessment and include cereals containing gluten, crustacean, eggs, fish, peanuts and soybeans, milk, tree nuts and sulphite (CAC 1991). The European Union added five ingredients to this list because
the European population tends to be highly allergic to them. These are celery, mustard, sesame, lupin and molluscs (EFSA 2004). This results in the list described in table 4.

In 2004, 2005, 2006 EFSA evaluated the list of allergenic foods in response to a request from the European Commission. EFSA, concluded that the allergens, selected by the EC, are the most common food allergens in Europe generally resistant to food processing (EFSA 2004; EFSA 2005; EFSA 2006e).

Allergen labelling

Allergens and their derivates have to be indicated on the product label, with a clear reference to the name under which the allergen is known (the names mentioned in legislation), even if the ingredients are present in an altered form\(^{33}\). The indication shall include the word ‘contains’ followed by the name of the ingredient(s) of concern\(^{34}\). To this manner of labelling will be referred as allergen labelling.

Previously mentioned were the food products and ingredients/constituents excluded from ingredient labelling. However, allergen labelling disposes some of these exceptions including’:

- Ingredients derived from an allergenic source present in a compound ingredient (including a mix of herbs and spices) or belonging to a group name.
- Ingredients derived from an allergenic source and present in beverages containing more than 1.2% of alcohol.
- Constituents not considered as ingredients - are considered as ingredients when originating from an allergenic source\(^{35}\).


\(^{34}\) Directive 2000/13/EC Article 6(3)a as amended by Directive 2003/89/EC

\(^{35}\) Directive 2000/13/EC Article 6(10) as amended by Directive 2003/89/EC
Directive 2000/13/EC excludes two groups of food products from allergen labelling and even more ingredients do not have to refer to their origin even though they are derived from an allergenic source.

Food products excluded from allergen labelling:

- Cheese, butter, fermented milk and fermented cream - in cases the composition is according legislation. These trade names are considered to refer clearly to milk. Further allergen labelling is not considered necessary (EC 2003).
- Single ingredient products (including vinegar) where the trade name is identical with the name of the ingredient, or clearly identifies the nature of the ingredient\(^\text{36}\).

Ingredients excluded from allergen labelling:

- Food products where a precise reference to the allergen of concern is made in the list of ingredients or in the name of the product\(^\text{37}\).
- Ingredients originating from an allergenic source, however proven not to cause adverse reactions, and mentioned in Annex IIIa \(^\text{38}\).
- Food products packaged in glass bottles intended for reuse which are indelibly marked and which therefore bear no label/ ring or collar \(^\text{39}\).
- Food products with a packaging or containers having a largest surface being less than 10cm\(^2\) \(^\text{40}\).

\(^{36}\) Directive 2000/13/EC Article 6(2)a; c


\(^{38}\) Directive 2000/13/EC Article 6(11) and Annex IIIa as amended by Directive 2003/89/EC

\(^{39}\) Directive 2000/13/EC Article 13(4)

\(^{40}\) Directive 2000/13/EC Article 13(4)
4.3. Gluten labelling

Currently, the maximum level of gluten in a gluten “free” product is set at 200mg/kg by the CAC. New scientific evidence resulted in a tightening of the limits, which are laid down in Regulation 41/2009/EC41. The acceptable levels will reduce to 100mg/kg and 20mg/kg for respectively ‘very low gluten’ and ‘gluten-free’. The Regulation will apply to all food products with the exception of baby foods42.

A difference in presentation requirements is made for food products specially for people intolerant to gluten and for regular food products43. Products produced for people intolerant to gluten bear the term ‘very low gluten’ or ‘gluten-free’ depending on the level of gluten present. The regular food products may be labelled as ‘gluten-free’ if the gluten content does not exceed 20 mg/kg. The term ‘very low gluten’ cannot be used. This regulation will enter into force January 2012.

The fundamental labelling requirements include the labelling of all information as mentioned in Directive 2000/13/EC. Also included in these requirements are the list of ingredients and allergen labelling.

The list of ingredients contains all ingredients present in food product in descending order of weight. This list of ingredients shall appear preceded by a heading containing the word ‘ingredients’.

Allergens and their derivates have to be indicated on the product label, with a clear reference to the name under which the allergen is known. The indication shall include the word ‘contains’ followed by the name of the ingredient(s) of concern.

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42 Regulation 41/2009/EC Article 1; 3
43 Regulation 41/2009/EC Article 3(2; 4)
Figure 2 on the next page represents an overview of the requirements and compatible exceptions of the current European labelling legislation. Under the heading ‘requirements’ are mentioned the fundamental labelling requirements, ingredient labelling and the labelling of the allergens. The exceptions on these requirements are mentioned under the heading exceptions.
Figure 2.
5. European law related to hazard management

Besides the product labelling, contributes the production process to a great extend on the safety of food products. Regulation 852/2004/EC on food hygiene enforces the production of safe foods in Europe and demands food business operators to control the production process, which includes allergen management. With a good working traceability program food business operators and authorities have the possibility to withdraw or recall unsafe products, e.g. food products containing allergens which are not mentioned on the product label (EC 2007).

In 2008, 6% of the recalls in Europe were due to undeclared presence of allergens in food products (EC 2009) and there are still food products on the market which contain unlabelled allergens. Do food business operators and competent authorities accept the appearance of unsafe products and thus handle infringe legislation or does Regulation 852/2004/EC leave space to produce unsafe food products?

5.1. Hygiene on food products

Regulation 852/2004/EC lays down general rules for food business operators regarding the hygiene of food products. Outside the ambit of this Regulation is direct supply or local retail of primary products to the final consumer, when sold in small quantities.

Food business operators are responsible for food safety throughout the whole food chain, from primary production until foods reach the final consumer. Food safety

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44 Regulation 852/2004/EC consideration (3)
46 Regulation 852/2004/EC Article 2c
should be reinforced by Hazard Analysis and Critical Control Points (HACCP) principles together with the application of good hygiene practice.\textsuperscript{47}

**HACCP**

The application of HACCP principles is not yet feasible for primary production farms\textsuperscript{48} and are not obliged to work according to these principals. However in order to assure product safety HACCP will be replaced by different hygiene provisions.\textsuperscript{49}

The definition of HACCP is not mentioned in European legislation, so the definition of the Codex Alimentarius will be used. HACCP is a tool to identify, evaluate, and control hazards which are significant for food safety. A hazard is defined a "biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect."\textsuperscript{50} Allergens are a hazard (Jenner et al. 2005) and should be included in the HACCP system. Details concerning the implementation of HACCP principles are given in table 5.\textsuperscript{51} Inadequate application of HACCP principles does result in the presence of unwanted constituents, including allergens.

Food business operators need to provide the competent authority with evidence of their compliance with the hygiene provisions.\textsuperscript{52} Based on this information the competent authority determines if the production process meets the hygiene requirements\textsuperscript{53} to assure safe food products.

\textsuperscript{47} Regulation 852/2004/EC Article 1a; b; d and Article 5(1)
\textsuperscript{48} Regulation 852/2004/EC consideration (11)
\textsuperscript{49} Regulation 852/2004/EC Article 4(1; 2)
\textsuperscript{50} Regulation 178/202/EC Article 3(14)
\textsuperscript{51} Regulation 852/2004/EC Article 5(2)
\textsuperscript{52} Regulation 852/2004/EC Article 5(4)a
\textsuperscript{53} Regulation 852/2004/EC Article 6(3)
Table 5.
*Principles of the HACCP system (Article 5(2) Regulation 2004/852/EC)*

<table>
<thead>
<tr>
<th>PRINCIPLE 1</th>
<th>Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRINCIPLE 2</td>
<td>Identifying the critical control points at the step(s) at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels</td>
</tr>
<tr>
<td>PRINCIPLE 3</td>
<td>Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards</td>
</tr>
<tr>
<td>PRINCIPLE 4</td>
<td>Establishing and implementing effective monitoring procedures at critical control points</td>
</tr>
<tr>
<td>PRINCIPLE 5</td>
<td>Establish corrective actions when monitoring indicates that a critical control point is not under control</td>
</tr>
<tr>
<td>PRINCIPLE 6</td>
<td>Establish procedures, which shall be carried out regularly, to verify that the measures outlined in the principles 1 to 5 are working effectively</td>
</tr>
<tr>
<td>PRINCIPLE 7</td>
<td>Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in principle 1 to 6. When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes</td>
</tr>
</tbody>
</table>

**Good Practice**

Member States are encouraged to create voluntary national guidelines of Good Practice. The Commission develops a registration system for these guidelines, in order to make consultation in all member states possible\(^{54}\). These guidelines can be used on a voluntary basis by food business operators\(^{55}\). Despite implementation of food hygiene measures, unsafe products might be produced and placed on the market. Traceability is needed to respond on this.

\(^{54}\) Regulation 852/2004/EC Article 8(4)

\(^{55}\) Regulation 852/2004/EC Article 7
5.2. Traceability

Traceability provides mechanisms to respond to potential risks that can arise in food products. An adequate traceability system supports food business operators and/or competent authorities to identify the source of the present hazard and to accomplish targeted withdrawals of the hazardous food products (EC 2007).

The requirements for traceability are laid down in the General Food Law\textsuperscript{56}. This Regulation defines traceability as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution”\textsuperscript{57}.

Food business operators must have systems in place to identify their suppliers and customers\textsuperscript{58}. This enables competent authorities to track any food through all stages of production, processing and distribution. Food business operators should control all stages of production, processing and distribution, and should ensure that the foods produced satisfy the requirements of food law\textsuperscript{59}. This shall be enforced and monitored by the Member States\textsuperscript{60}. If a food business operator considers, or has reason to believe, that a food does not comply with the food safety requirements, a withdrawal procedure from the market shall immediately be initiated. If the initial food business operator has lost immediate control over the food, the competent authorities should be informed\textsuperscript{61}. Food business operators must inform the competent authority about the actions already taken to prevent the risk, and food business operators must collaborate with the competent authorities\textsuperscript{62}.

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\textsuperscript{57} Regulation 178/2002/EC Article 3(15)

\textsuperscript{58} Regulation 178/2002/EC Article 18(1; 2; 3)

\textsuperscript{59} Regulation 178/2002/EC Article 17(1)

\textsuperscript{60} Regulation 178/2002/EC Article 17(2)

\textsuperscript{61} Regulation 178/2002/EC Article 19(1)

\textsuperscript{62} Regulation 178/2002/EC Article 19(3; 4)
5.3. Shortcomings

Undeclared allergens in foodstuffs have been found to provoke food allergic reactions (Añíbarro et al. 2007). The most common source of undeclared allergens is cross contamination (Kurt et al. 1997; Huggett and Hischenhuber 1998; Añíbarro et al. 2007). Cross contamination represents the presence of allergens in food products, due to shortcomings in the food hygiene measurements. Here for can be questioned if the production process is according legislation and whether Member States and competent authorities adequately control the work of food producers.

Regulation 852/2004/EC lays down general rules for food business operators regarding the hygiene of food products. Food business operators should implement the HACCP principles in order to guarantee food safety. The implementation of the food hygiene requirements by food business operators will be controlled by the competent authority.

Traceability enables food business operators and competent authorities to identify the source of the present hazard and accomplish targeted withdrawals of the hazardous food products.

However, even the combination of these two safety measures is unable to prevent unsafe food products to enter the market and are food allergic confronted with allergens in food products, for which they were not warned on the product label.
6. Consumer perception

Product labels are the primary source of information provision to consumers. Food allergic individuals use this information to avoid the consumption of offending allergens. 99% of allergic consumers indicate to read the product label ‘always’ or ‘often’ during shopping. Similarly, 94% of consumers read the food label again before using the product (Elinor et al. 2005). The product label, however, does not satisfy the expectations and needs of food allergic consumers, which is identifiable in the number of food allergic reactions. 16% of the food allergic reactions, due to the intake of pre-packed foods, is caused by consumer misunderstanding of the labelled terminology (Elinor et al. 2005). In this chapter will be determined to what extend European legislation approaches consumer preferences.

6.1. Problems concerning labelling experienced by allergic consumers

Effective and adequate communication about ingredients in food products is essential if food allergic consumers are to eliminate problematic ingredients from their diets. As well the readability as the content of the information are perceived as factors reducing the effectiveness of communication by food allergic consumers. Experienced as annoying are the use of precautionary labelling and the undeclared presence of allergens in food products.

6.1.1. The readability and content of the present information

Consumers experience difficulties reading the label due small font sizes, poor colour contrast and shiny packaging materials (Gowland 2001; Hengel 2006; Voordouw et al. 2009). Some products are labelled in a different language than the native language of the country in which the product is sold (Voordouw et al. 2009).
A further problem relates to consumer comprehension of the meaning of labels. The information present on the label is perceived as contrary, incomplete or insufficient specific and overwhelming (Gowland 2001; Hengel 2006; Voordouw et al. 2009). The different terminologies for additives and E-numbers were perceived as problematic (TEEC 2003; Voordouw et al. 2009). 24% of the reported allergic reactions from eggs was caused by lysozyme, an egg protein, and when used during cheese processing and in wine as preservative declared as E1105 (Yman 2004). Allergic consumers identified discrepancies between information on the label, e.g., the general description of the food product showed different information compared to the analytical and chemical description of the product. Likewise, product label show an image of a peanut which is not present in the list of ingredients. In addition, do confusion by consumers arise due to the use of jargon used on product labels (Voordouw et al. 2009).

6.1.2. Precautionary labelling

Precautionary labelling is a voluntary declaration on food labels which informs consumers about the potential presence of an allergen in a food product. 75% of the consumers declared to never purchase products bearing precautionary labelling (Hefle et al. 2007). However, disagreement exists on whether the use of precautionary labelling is satisfactory, since it does not necessarily indicate cross-contamination but it used more widely (TEEC 2003). Peanut protein, has been detected in significant levels per serving size (>1mg of peanut or > 0.25mg of peanut protein) in 6.5% of the total food products bearing advisory statements (Hefle et al. 2007). Thus the remaining 93.5% from the food products containing the warning are unnecessary eliminated in the, already restricted, diet of food allergic consumers. Here for it is not surprising that food allergic consumers report the use of this “allergen trace labelling” as a significant obstacle preventing them from leading a normal life (Mills et al. 2004).
Precautionary labelling is often found in a separate location to the list of ingredients and was reported by consumers as ‘not standing out on the package’ and ‘being difficult to identify’ (UK Food Standards Agency 2002; Hengel 2006). This might be the reason for consumers experiencing difficulties in locating the warning (Voordouw et al. 2009).

“Hidden” allergens

In contrast with precautionary labelling, which is too frequently used on the product label to protect allergic consumers, are food allergic consumers also confronted with allergens unrecognisable or not declared on the product label (Voordouw et al. 2009). These constitutes are called “hidden” allergens. 22% of food allergic reactions are due to these hidden allergens (Añíbarro et al. 2007).

6.2. Desires from allergic consumers

Food allergic consumers prefer, in addition to the textual allergen information, symbols on the package which indicate whether or not an allergen is present in the product (Cornelisse-Vermaat et al. 2008; Voordouw et al. 2009). When allergens are mentioned in the list of ingredients, they preferred a standard font through which these ingredients are easy identifiable. Mentioned examples are bold letters or written in a standardised colour. Another option mentioned by food allergic consumers is a special allergen “framed box”, present regardless allergens are mentioned in a different place on the food label (Voordouw et al. 2009).

An universal approach to (allergen) labelling would be preferred by many food allergic consumers (UK Food Standards Agency 2002; Cornelisse-Vermaat et al. 2008). This approach is also supported by other stakeholders, including professionals with an interest in food processing, food retailers, caterers, researchers in research institutes and laboratories and regulators with an interest in food allergy (Cornelisse-Vermaat et al. 2008).
Food allergic consumers would like to be informed when the recipe of a food product changes (Voordouw et al. 2009).

Product labels are the primary source of information provision to consumers, however is it capable of satisfying the expectations of food allergic consumers at all times? In General can be concluded that food allergic consumers are not satisfied about the current labelling practice. This is caused by food allergic consumers experiencing the presentation as unclear and the information present on the label as contrary, incomplete or insufficient specific and overwhelming. Precautionary labelling is used extendedly and does lack of a specified place on the product label. Food allergic consumers experience allergic reactions from ingredients not mentioned on the product label.

An universal approach to (allergen) labelling would be preferred by many food allergic consumers, this can be in the form of symbols a standardised font or a special allergen “framed box”. Food allergic consumers would like to be informed when the recipe of a food product changes.
7. Allergen and ingredient labelling of the future

Legislation is regularly updated to ensure the latest scientific and judicial standards are met. In this regard, proposal COM(2008)40\(^{63}\) has been submitted, combining Directive 2000/13/EC on the labelling, presentation and advertising of food products and Council Directive 90/496/EEC on nutrition labelling for food products\(^ {64}\). In addition, the proposal simplifies the structure of the food labelling legislation. Directive 2000/13/EC and its amendments will be abolished when proposal COM(2008)40 enters into force\(^ {65}\).

In this chapter the context of the proposal will be discussed, with emphasis on whether it solves the current gaps in European legislation, and if it meets the preferences of allergic consumers.

7.1. Context of proposal COM(2008)40 on ‘the provision of food information to consumers’

This Regulation covers any food intended for the final consumer or mass caterers\(^ {66}\). Mass caterers refers to places where, in the course of a business, food is prepared for delivery to the final consumer e.g., restaurants, canteens, schools and other businesses\(^ {67}\). The primary aim for requiring mandatory food information is to enable consumers to make choices that suit their individual dietary needs\(^ {68}\).

The major changes related to labelling will be the requirement of a minimum font size of 3mm for the mandatory information\(^ {69}\); non pre-packaged foods should be


\(^{65}\) proposal COM(2008)40 Article 52

\(^{66}\) proposal COM(2008)40 Article 6

\(^{67}\) proposal COM(2008)40 Article 2(2)b

\(^{68}\) proposal COM(2008)40 consideration (17)

\(^{69}\) proposal COM(2008)40 Article 14(1)
accompanied by allergen information\textsuperscript{70}; and ingredients present in food product packages with their largest surface no greater than 10cm\textsuperscript{2} should be made accessible to the consumer, although not necessary printed on the product label itself\textsuperscript{71}.

**Mandatory requirements**

The complete list of mandatory labelling requirements includes the list of ingredients and the labelling of the major fourteen allergens\textsuperscript{72}. The information must be printed on the food package, or on a label attached on it\textsuperscript{73} and shall be accurate, clear and easy to understand for the consumer\textsuperscript{74}. The information must be printed on the package in a minimum font size of 3mm, and there should be a significant contrast between the print and background\textsuperscript{75}. The ingredient and allergen labelling should be easy visible, clearly legible and indelible\textsuperscript{76}. The information should be present in a language easy understood\textsuperscript{77}. Food business operators are responsible to ensure compliance with the requirements relevant to their activities\textsuperscript{78}. Individually packaged food products within a bigger box must label the list of ingredients and additional allergen labelling exclusively on the outer package.

**Ingredient labelling**

‘Ingredients’ is defined as “*any substance, including food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ingredients*”\textsuperscript{79}. Added in the current definition are the individual

\textsuperscript{70} proposal COM(2008)40 Article 41(2)
\textsuperscript{71} proposal COM(2008)40 Article 17(1; 2)
\textsuperscript{72} proposal COM(2008)40 Article 9 b; c
\textsuperscript{73} proposal COM(2008)40 Article 13(2)
\textsuperscript{74} proposal COM(2008)40 Article 7(2)
\textsuperscript{75} proposal COM(2008)40 Article 14(1)
\textsuperscript{76} proposal COM(2008)40 Article 14(6)
\textsuperscript{77} proposal COM(2008)40 Article 16(1)
\textsuperscript{78} proposal COM(2008)40 Article 8(1)
\textsuperscript{79} proposal COM(2008)40 Article 2(2)f
ingredients contributing to compound ingredients. The requirements for the indication of ingredients remain similar to the demands under Directive 2000/13/EC\textsuperscript{80}.

Just as for the current legislative situation, there are food products excluded from ingredient declaration, namely:

- Food products packaged in glass bottles intended for reuse which are indelibly marked and which therefore bear no label/ ring or collar\textsuperscript{81}.
- Cheese; butter; fermented milk and fermented cream (if composition is according legislation)\textsuperscript{82}.
- Products containing of a single ingredient (including fermented vinegars) where the trade name is identical with the ingredient or can be clearly identified\textsuperscript{83,84}.

The ingredients/ constituents present in food products which do not have to be mentioned in the list of ingredient:

- Some constituents are not considered as ingredients - ingredients temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions; food additives and enzymes having no technological function in the finished product and present in the end product due to ingredients containing these food additives and enzymes; processing aids; and solvents or media for nutritional substances, food additives, flavouring or processing aids, which are still present in the finished product\textsuperscript{85}.

\textsuperscript{80} proposal COM(2008)40 Article 19
\textsuperscript{81} proposal COM(2008)40 Article 17(1)
\textsuperscript{82} proposal COM(2008)40 Article 20d
\textsuperscript{83} proposal COM(2008)40 Article 20f
\textsuperscript{84} proposal COM(2008)40 Article 20c
\textsuperscript{85} proposal COM(2008)40 Article 21a; b; c; d
• Group names\textsuperscript{86} – are mentioned in the list of ingredients, however they might be labelled under their group name instead of their specific name.
• Compound ingredients constitute less than 2% of the end product and defined in community legislation \textsuperscript{87}.
• Mixture of only herbs and spices constitution less than 2% of the end product\textsuperscript{88}.

\textit{Allergen labelling}

Just like to Directive 2000/13/EC, proposal COM(2008)40 includes an annex listing ingredients causing the majority of the food allergies\textsuperscript{89}. The fourteen allergens remain the same and should, when present in a food product, be mentioned on the product label. Exceptions are made for ingredients derived from an allergenic source, however unable to cause a food allergic reaction. These exceptions are reduced in comparison to Directive 2000/13/EC (see table 6).

Table 6.
\textit{Allergens mandatory to label according to proposal COM(2008)40}

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten (namely wheat, rye, barley, oats, spelt, kamut or their hybridised strains)</td>
<td>Wheat based glucose syrups including dextrose</td>
</tr>
<tr>
<td></td>
<td>Wheat based maltodextrins (***))</td>
</tr>
<tr>
<td></td>
<td>Glucose syrups based on barley</td>
</tr>
<tr>
<td></td>
<td>Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1.2 % by volume of alcohol</td>
</tr>
<tr>
<td>Crustaceans(*)</td>
<td></td>
</tr>
<tr>
<td>Eggs(*)</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{86} proposal COM(2008)40 Annex VI part B
\textsuperscript{87} proposal COM(2008)40 Annex VI part E
\textsuperscript{88} proposal COM(2008)40 Annex VI part E
\textsuperscript{89} proposal COM(2008)40 Annex II
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish(*)</td>
<td>Fish gelatine used as carrier for vitamin or carotenoid preparations</td>
</tr>
<tr>
<td></td>
<td>Fish gelatine or Isinglass used as fining agent in beer and wine.</td>
</tr>
<tr>
<td>Peanuts(*)</td>
<td></td>
</tr>
<tr>
<td>Soybeans(*)</td>
<td>Fully refined soybean oil and fat(*)</td>
</tr>
<tr>
<td></td>
<td>Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources</td>
</tr>
<tr>
<td></td>
<td>Vegetable oils derived phytosterols and phytosterol esters from soybean</td>
</tr>
<tr>
<td>Milk (including lactose) (*)</td>
<td>Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1.2 % by volume of alcohol</td>
</tr>
<tr>
<td></td>
<td>Lactitol</td>
</tr>
<tr>
<td>Nuts (almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts) (*)</td>
<td>Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1.2 % by volume of alcohol</td>
</tr>
<tr>
<td>Celery(*)</td>
<td></td>
</tr>
<tr>
<td>Mustard(*)</td>
<td></td>
</tr>
<tr>
<td>Sesame(*)</td>
<td></td>
</tr>
<tr>
<td>Sulphur dioxide and sulphites(**)</td>
<td></td>
</tr>
<tr>
<td>Lupin(*)</td>
<td></td>
</tr>
<tr>
<td>Molluscs(*)</td>
<td></td>
</tr>
</tbody>
</table>

(*) and products thereof
(**) at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO2
(***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.)
Derogations on allergen labelling:

- Ingredients which cannot induce food allergic reactions and are excepted in proposal COM(2008)40.  
- Food products where the name of the food clearly refers to the ingredient of concern or when the specific name is mentioned in the list of ingredients. 
- Cheese, butter, fermented milk and fermented cream - the Commission and EU Member States still perceive these names to refer clearly to “milk” and here for no reference to milk is mandatory.

Non pre-packaged food products

Proposal COM (2008)40 requires, contrary to the current legislative situation, that non pre-packaged food products should be accompanied by information concerning the allergen of the food product in order to provide the final consumer with it. This information will be communicated to each food business operator receiving the food, so ultimately the information can be provided to the final consumer. Member States are able to introduce detailed rules concerning mandatory information on non pre-packaged food.

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90 proposal COM(2008)40 Article 22(1) 
91 proposal COM(2008)40 Article 22a; b 
92 proposal COM(2008)40 Article 41(2) 
93 proposal COM(2008)40 Article 8(5; 6) 
94 proposal COM(2008)40 Article 41(1)
Proposal COM(2008)40 includes some changes, in comparison to the current labelling legislation, of which food allergic consumers profit. This changes include a minimum font size of 3mm for the mandatory information, non pre-packaged foods should be accompanied by allergen information and ingredients present in food product packages with their largest surface no greater than 10cm² should be made accessible to the consumer, although not necessary printed on the product label itself.

Figure 3 is an overview in which the labelling requirements and their exceptions according to proposal COM(2008)40 are mentioned in comparison to Directive 2000/13/EC and its amendings. The figure is similar to the figure used previously to image the allergen labelling of the current European legislation. Under the heading ‘requirements’ are the fundamental labelling requirements, ingredient labelling and the labelling of the allergens mentioned. The exceptions on these requirements are mentioned under the heading ‘exceptions’. In addition the demands, eliminated in COM 2008(40), are striped through.
Figure 3.
Labelling requirements and their exceptions according to proposal COM(2008)40 ‘the provision of food information to consumers’ in comparison to Directive 2000/13/EC.
8. Possible improvements in European legislation

Current European legislation related to allergens and their labelling has been discussed, together with the way food allergic consumers perceive the application of these requirements in practice. The main gaps, from prospective of the food allergic consumer, in legislation are (1) food products or ingredients excluded from the list of ingredients and/or from allergen labelling, (2) the readability of the essential information, and (3) the use of precautionary labelling. Proposal COM(2008)40 already improves the current situation by reducing the number of exceptions for ingredient and allergen labelling and requiring a minimum font size of 3mm for mandatory information. However, there are still possibilities to further optimize product labelling in order to reach adequate communication between the food business operator and the final consumer.

8.1. Exceptions in legislation verified

Any ingredient containing protein is potentially a causative factor in IgE-mediated food allergic reactions. Possible protein containing constituents, intentionally added to food products or raw materials used in the production process should be included in the list of ingredients, and food products should be accompanied by such a list of ingredients.

Exceptions, as suggested in proposal COM(2008)40, will be verified on hazardous and, when required, possible solutions will be discussed. First will be discussed the food products packaged in such a way, for which neither ingredient nor allergen labelling are required. This will be followed by food products which are excluded from ingredient labelling and finalising with the food products excepted from allergen labelling.
8.1.1. Absence of mandatory labelling

Food products packaged separately and sold as part of a bigger container, are the only remaining food category excluded from the fundamental labelling requirement. Here the way of packaging responsible for exception and is it applicable regardless the kind of food product present in the package. Products packaged this way are only required to list ingredients and allergens information on the outer box. As a consequence identification of the composition is impossible if the outer box is not nearby. Food allergic consumers do not report this as problematic. Nevertheless cases have been reported in which single packaged food products are the probable cause of death due to the presence of allergenic ingredients (Buhla et al. 2008).

It would be desirable for each single packaged product to label the list of ingredients and allergen information. However the size of the label might be a limitation. European legislation should at least require the labelling of food allergens on each single wrapped item.

8.1.2 Food products excepted from ingredient declaration

One of the main objectives of food law is ‘to give consumers the ability to make an informed choice’. This objective is not realised when the list of ingredients is not present on the product label. In particular, individuals allergic to ingredients outside the scope of the major fourteen allergens are inadequately informed, since the list of ingredients is relevant to determine product safety. Consumers allergic for one or more of the fourteen major allergens don not receive sufficient information either. Exclusively allergen labelling provides no information on the level of allergen present. Hence consumers are unable to determine if the level of allergen present is high enough to trigger an adverse reaction. For example, if the allergen labelling on a food product declares ‘peanut’, this might be refined peanut oil (minimal amount of protein present) or whole peanuts. Although the list of ingredients does not provide the exact composition, the descending order, in which the ingredients are mentioned
in the list of ingredients, give at least an impression on the amount of allergen present.

European legislation permits certain food products and ingredients to escape from ingredient labelling, even though this is important information for food allergic consumers. Potential improvements will be discussed per approved exception by legislation.

*Compound ingredients and mixes of herbs and spices*

Compound ingredients are composed themselves of two or more ingredients (including mixes of herbs and spices). The ingredients, of which the compound ingredients exist, do not have to be specified on the product label when the compound ingredients is defined in community legislation and does not exceed 2% by weight of the end product. Directives present in community legislation are present for coffee and chicory extracts (1999/4/EC); cocoa and chocolate products (2000/36/EC); honey (2001/110/EC); certain sugars (2001/111/EC); fruit juices and similar products (2001/112/EC); fruit jams, jellies and marmalades and sweetened chestnut purée (2001/113/EC); partly or wholly dehydrated preserved milk (2001/114/EC).

Research data show that these unlabelled ingredients, of a compound ingredient, are a cause of food allergic reactions (Añíbarro et al. 2007). Beside, these unlabelled ingredients are a source of adverse reaction, food producers know the composition of the compound ingredient used in the production process\(^5\) and/or the composition is recorded in legislation. It is unreasonable those food producers do not share their full knowledge with consumers, and that consumers have to consult legislation in order to determine the complete composition of food product.

Hence, the name of compound ingredients should immediately be followed by the contributing ingredients. Mentioning the exact amounts of the individual ingredients

\(^5\) Directive 2000/13/EC Article 13(1)b
is not necessary. When the contributing ingredients are already used in the end product, the ingredients can be aggregated and mentioned once in the list of ingredients. Examples of these types of labelling are given in the text box below (text box 1). It is an imaginary list of ingredients for cake, in which ‘chocolate’ is the compound ingredient. Example 1 refers to the labelling of compound ingredients followed by its ingredients and in example 2 are the ingredients of the compound ingredient and the ingredients of the cake aggregated.

Textbox 1

<table>
<thead>
<tr>
<th>Example 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cake with chocolate</td>
</tr>
<tr>
<td>Ingredients: wheat (35.5%), sugar (35.5%), butter (27.1%), chocolate (butter, sugar, cacao) (1.9%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Example 2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cake with chocolate</td>
</tr>
<tr>
<td>Ingredients: sugar (36.1%), wheat (35.5%), butter (27.7%), cacao (0.7%)</td>
</tr>
</tbody>
</table>

The percentages in the example, representing the contribution of the ingredients, are exclusively used to clarify the separation of the ingredients and are not mandatory to mention.

**Glass bottles**

Glass bottles intended for reuse, which are indelibly marked, and therefore bear no label/ ring or collar, were in the past commonly used as packaging material for dairy products, like milk or yoghurt. In Europe is this manner of packaging is not commonly used anymore. Food products packaged in glass bottles may be re-introduced into the European market to improve sustainability. Hence, legislation should demand the presence of ingredients on glass bottles intended for reuse. As soon as proposal COM(2008)40 enters into force, allergens present in the food product packaged in glass bottles should be labelled. Here for is suggested that this
information might as well be expanded by the list of ingredients. This information can be presented on an adhesive label (like beer bottles).

Packages with a smaller surface than 10cm²
The ingredients of food products should, on request, be provided to the consumer if the product is present in a packaged with a biggest surface smaller than 10cm². Since ingredient labelling might be impossible due to lack of space on the product label, this manner of information provision is a good alternative. To prevent consumers forget the information, the list of ingredients should be printed and offered to the consumer. The printed information should include a reference to the food product. A self adhesive label which can be (immediately) adhered to the product would be a good option. The manner of information provision should be demanded in legislation.

Beverages containing more than 1.2% of alcohol
It is strange that soft drinks have to be ingredient labelled, and as soon as the beverage contains more than 1.2% of alcohol this is not necessary anymore. The explanation for this exception is discussible, probably the alcoholic beverage industry plays a key role here. This, very poor explainable, exception in legislation should be eliminated.

Products containing of a single ingredient
Food products, including fermented vinegar, derived from a single ingredient are excluded from ingredient labelling because the origin of single products can be defined in the descriptive name of the food product (Article 5(b) Directive 2000/13/EC). Here for is ingredient labelling simply redundant. When vinegar is used as an ingredient within a food product, the origin is non derivable on the label (except when derived from an allergenic source, because of the mandatory allergen labelling). Origin labelling for white vinegar it is not essential in
the context of protection food allergic consumers, since the product does not contain any protein. Hence it is unable to cause allergic reactions. This is in contrast to malt vinegars, in which the crucial step needed to eliminate proteins, namely distillation, is missing from the production process (Marcason 2004).

Further research is needed regarding the amount of malt vinegar used in the food production chain; the sources from which vinegar can be derived; and the amount of protein present in malt vinegar.

**Not acknowledged ingredients**

Additives and enzymes without a function in the end product; processing aids; temporarily separated constituents which are later reintroduced, but not in excess of their original proportion; solvents or media strictly used for additives or enzymes or flavourings; and substances which are not food additives but used in the same way and with the same purpose as processing aids are, even though intentionally added to food product, not considered ingredients and thus are exempted from ingredient labelling. Note that if these constituents are derived from an allergic source they are considered as ingredients and are labelled.

The exclusion of these constituents in the definition of food ingredients seems illogical, given the regulatory emphasis on “consumers being able to make informed choices in relation to the foods they consume”.

Producers should define the presence of these constituents on the product label, in order to provide consumers with complete information concerning the composition of a food product, and this should be required in legislation. This requirement does not have to apply to temporarily separated constituents which are later reintroduced, when the present ingredients remains equal.

**Cheese, butter, fermented milk and fermented cream**

Cheese, butter, fermented milk and fermented cream do not have to specify the ingredients present on the product label, in case the composition is according
legislation. The consequence of this exception is that milk, lactic products, enzymes, micro-organism and salt are unlabelled present in dairy products and this is contradictive with European legislation since milk, enzymes and salt are covered by definition of ingredients\textsuperscript{96}. The use of lactic acid products in the production process can be considered as processing aids, labelling not required, or as ingredients, labelling required (Feord 2002). This depends on the confirmation of a European Member State.

No acceptable reason has been communicated to explain why these products are excluded from the ingredients labelling requirement. In the interest of the ability of consumers to make informed choices this exception should be abolished.

\textit{Group names}

“Group names” are general terms which are used to represent several ingredients. Food producers can use the group name instead of the specific ingredient name. The labelling of group names does not pose a direct hazard to food allergic consumers. However its use does reduce product choice due to consumer uncertainty regarding the presence of allergens and ingredients.

The group names specifically mentioned in European legislation are, oil, fat, flour (followed by the list of cereals from which the flour is obtained), starch, fish, cheese, spices, herbs, gum base, crumbs and rusks (from now on referred to as breadcrumbs), sugar, dextrose, glucose syrup, milk proteins, cacao butter, wine and meat (followed by the animal species from which it is derived). From a food allergy point of view, only group names containing protein are of interest. These are wine, cheese, fish, milk proteins, breadcrumbs, herbs and spices.

A separation of group labelling into the actual ingredients is preferred when the separate ingredients in a group do not cross react among each other. Cross-reactivity means that antibodies originally produced against a specific protein also respond to

\textsuperscript{96} Directive 2000/13/EC Article 6(4)a as amended by Regulation 1332/2008/EC
additional proteins. Table 7 contains information concerning possible cross reactions among different ingredients belonging to the group labels.

Table 7,  
*Necessity for separation of the group names containing protein*

<table>
<thead>
<tr>
<th>Group name</th>
<th>Cross-reaction</th>
<th>Source</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wine</td>
<td>No, the composition of wine can vary to a great extent, due to the possible added ingredients.</td>
<td>(Article 1(10); 46(3) and Annex IV Regulation 1493/1999/EC(^{97}))</td>
<td></td>
</tr>
<tr>
<td>Cheese</td>
<td>Milk of different mammalian species do not always cross react among each other</td>
<td>(Restani, Beretta et al. 2002)</td>
<td>European legislation and the Codex Alimentarius fail in defining milk, here for is assumed that ‘milk’ includes milk derived from different mammalian species such as cows, buffaloes, goats and sheep</td>
</tr>
<tr>
<td>Fish</td>
<td>The most proteins cross react between the different fish species. Nevertheless, fish specific allergens exist as well.</td>
<td>(Hansen et al. 1997; Pascual et al. 1992; Ferreira et al. 2004).</td>
<td></td>
</tr>
<tr>
<td>Milk proteins</td>
<td>The majority of the cow’s milk allergic children reacts on a selection of proteins</td>
<td>(Sharma et al. 2001)</td>
<td>Milk allergy is most common is children</td>
</tr>
<tr>
<td>Breadcrumbs</td>
<td>Cross-reaction between different cereals is sporadic</td>
<td>(Ferreira et al. 2004).</td>
<td></td>
</tr>
<tr>
<td>Herbs and</td>
<td>Cross reactivity between</td>
<td>(Schöll and</td>
<td>Processing can</td>
</tr>
</tbody>
</table>

spices | the different herbs and species is known. Nevertheless, exist ingredient specific allergens as well. | Jensen-Jarolim 2004) | influence the allergenicity of a herb of spice

Literature is unanimous concerning the cross contamination and each group name contains proteins that are specific for an individual ingredient. This means that the group names should be extended with more specific information. The ingredients present in wine should be mentioned after the group name, wine. The same measure should be used for breadcrumbs, and herbs and spices. There should be referred to the type of mammalian milk of which the cheese is produced. The different milk proteins and fish species should be included in the list of ingredients. This does not apply to the allergen labelling of fish and milk, which can remain aggregated as ‘fish’ or ‘milk’.

*Non pre-packaged food products*

Most food allergic reactions occur after ingestion of non pre-packaged food products. The labelling of these hazardous non pre-packaged food products is outside the ambit of current food labelling legislation. When proposal COM(2008)40 enters into force allergen information provision will be required, potentially improving consumers protection.

Allergen provision on menu cards in catering outlets could facilitate food allergic consumers making an informed choice. This information needs to be linked to some form of guarantee, such as formal recognition of compliance, for example, verification by the competent authorities or a certification system. This is particularly relevant because currently restaurants do not control allergens (Ahuja and Sicherer 2007). This recommendation also applies to other establishments providing food products.

Non pre-packaged foods which are not immediately consumed (products from fresh food counters in supermarkets, bakeries or butchers) should be accompanied by a
printed version of the allergen information, enabling consumers to re-consult the information at the time of consumption. The requirement to provide allergen information is introduced, could this be extended with the list of ingredients.

8.1.3. Exception allergen labelling

There are three groups of food products excluded from allergen labelling. These are ingredients derived from a source commonly involved in IgE-mediated food allergies which do not cause an allergic reaction, some dairy products (cheese, butter, fermented milk and fermented cream) and products where the packages refer clearly to the allergen of concern present besides the actual allergen labelling.

*Ingredients derived from allergenic sources*

Some ingredients, although derived from allergenic source, do not provoke allergic reaction and are for this reason excluded from allergen labelling. There is ample scientific evidence to support these derogations (see table 8).

**Table 8.**

*Ingredients originating from an allergenic source, however unable to cause allergic reactions according to proposal COM(2008)40*

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Exceptions</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten</td>
<td>Glucose syrups based on wheat or barley (including dextrose) and maltodextrins</td>
<td>(EFSA 2007b; Kaukinen et al. 2008; Kupper 2005; EFSA 2007g; EFSA 2007h)</td>
</tr>
<tr>
<td></td>
<td>Distillates or ethyl alcohol used for spirit drinks and other beverages originating</td>
<td>(Taylor and Hefle 2001a; Campbell 1982; EFSA 2007f; Kupper 2005)</td>
</tr>
<tr>
<td>Fish</td>
<td>Fish gelatine used as carrier for vitamin or carotenoid preparations</td>
<td>(EFSA 2007a)</td>
</tr>
<tr>
<td></td>
<td>Fish gelatine used as fining agents in beer and wine</td>
<td>(EFSA 2006d; Kirschner et al. 2009)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soybean</td>
<td>Fully refined soybean oil and fat</td>
<td>(EFSA 2007c; Ramazzotti et al. 2008)</td>
</tr>
<tr>
<td></td>
<td>Phytosterols and phytosterol, natural mixed tocopherols (E306), natural D-</td>
<td>(EFSA 2006a; EFSA 2006c)</td>
</tr>
<tr>
<td></td>
<td>alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha</td>
<td></td>
</tr>
<tr>
<td></td>
<td>tocopherol succinate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plant stanol ester</td>
<td>No scientific document found declaring that this ingredient is “free” of soy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>protein. Nevertheless, it can be concluded that proteins are logically</td>
</tr>
<tr>
<td></td>
<td></td>
<td>absent if extracted from an allergen free source, like refined soya oil.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Attention should be paid when plant stanol esters are derived from a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>source containing proteins.</td>
</tr>
<tr>
<td></td>
<td>Nuts</td>
<td>(EFSA 2006b)</td>
</tr>
<tr>
<td></td>
<td>Distillates or ethyl alcohol of agricultural origin for spirit drinks and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>other beverages containing more than 1.2% by volume of alcohol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Milk</td>
<td>(EFSA 2007d; EFSA 2007e)</td>
</tr>
<tr>
<td></td>
<td>Lactitol and whey used for making distillates or ethyl alcohol of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>agricultural origin for spirit drinks and other alcoholic beverages</td>
<td></td>
</tr>
</tbody>
</table>

A potential problem is that excluded ingredients are not completely purified. E.g., refined oil is not defined in legislation, nor by the Codex Alimentarius. The final level of protein content depends on the quality and efficiency of the purification steps in the processing of the oil. Guidelines should be established containing procedures to achieve the “absence” of proteins.

*Cheese, butter, fermented milk and fermented cream*

Cheese, butter, fermented milk and fermented cream can be sold on the market without a reference to the allergenic source “milk” (if the composition is according legislation), even though the main ingredient in these products is milk. The
assumption is made that consumers recognise these commercial product names as derivates of milk.

There are several ways in which this exception can be confusing to consumers. Fromage frais and mascarpone are obliged to label allergens, however their composition only differs slightly from the composition laid down in legislation to be considered for derogation of allergen labelling. Here the question arises ‘does it cause confusion that some dairy products are not allergen labelled?’ And what about consumers on holidays in a country with a different native language, ‘do they know the commercial terms used for cheese, butter, fermented milk and fermented cream in the languages of the other Member States of the EU?’.

This ridiculous exception should be removed and all dairy products should, like all ingredients originating from an allergenic source and containing significant amounts of protein, be allergen labelled. In addition, Directive 2000/13/EC and proposal COM(2008)40 demand a precise reference to the name of the allergenic ingredient. ‘Precise’ is not further defined. However it seems clear that there is a significant difference between the demanded reference in legislation namely ‘milk’ and the product names ‘cheese’, ‘butter’, ‘yoghurt’, ‘fermented cream’. In order to maximize consumer understanding and interpretation of the product label and to encourage identical allergen labelling between different food products, these dairy products labels should refer to milk.

*Food products already containing a clear reference to the allergen of concern*

Single ingredient products, where the product name is identical to the only present ingredient, or where the origin is clearly identifiable, are excluded from allergen labelling. Equally, food products, composing of more than one ingredients, where a precise reference to the allergen of concern is made in the list of ingredients or in the name of the product are exempted from allergen labelling.
With regard to single ingredient products, confusion may in particular arise when different terminologies are used for the product name and the legally demanded allergen reference. For example, the package of ‘wheat flour’ does not have to be labelled with ‘contains gluten’. The accepted replacement for the mandatory allergen labelling in the list of ingredients or in the product name, has as consequence insomuch as the information can be found in three different places, namely the product name, the list of ingredients or/and in the actual allergen labelling.

Food products, including single ingredients food products, that already “clearly” refer to allergens in the product name or in the list of ingredients, should implement additional allergen labelling, where is aimed at the presentation of the allergens after the heading ‘contains’. This will encourage identical allergen labelling and simplify allergen recognition.

8.2. Hygiene and tracking and tracing

Regulation 2004/852/EC offers principles and procedures for food business operators and the competent authorities regarding good food hygiene during the production process. Implementation of these food hygiene standards is the responsibility of food business operators. Regulation 2004/852/EC is excluded for small quantities of primary products sold to the final consumer (or to a local retail establishment) by the food business operator who produced the products. Implementation of the HACCP principles is not achievable for primary production, and these production farms are for this reason excluded to produce according to the HACCP-principles. Beside these exceptions mentioned above is legislation concerning food hygiene and tracking and tracing in theory indisputable because, no sectors of the food chain can deny this Regulation and the requirements should lead to the desirable effect of safe foods. However, in practice there are shortcomings. Consumers still experience allergic reactions from foods containing undeclared or incorrectly labelled allergens, and
8.2.1. Exceptions on food hygiene requirements

Primary products sold to the final consumer or local retail establishments are outside the ambit of Regulation 2004/852/EC and primary production farms in general are not obliged to work according to the HACCP-principles. However, in order to guarantee consumers health, all primary products are covered by national legislation.

8.2.2. Improve enforcement food hygiene regulation

To warn food allergic consumers about possible allergen traces present in food products, food producers use precautionary labelling. However, this warning is increasingly used, hence not only protects food allergic consumers, it also unnecessarily restricts their product choices. Food producers should control of the production process to ensure absence of allergens in food products and adequately inform consumers.

22% of the allergic reactions, provoked by the intake of pre-packaged food, attributed to undeclared ingredients present in food products (Añíbarro et al. 2007). Incorrectly labelled allergens or allergens present in food products, but not mentioned on the product label belong to “hidden” allergens. 5.7% of the pre-packages food products contain “hidden” allergens (egg, gluten, milk, peanut and soya).

The most common cause of hidden allergen is cross-contamination (Kurt et al. 1997; Huggett and Hischenhuber 1998; Añíbarro et al. 2007). Rework, compound ingredients, additives and single ingredients are mentioned as problematic as well (VWA 2007). In addition, some allergens are labelled under a different name as their mandatory nomenclature e.g. among products that were purchased in Belgium and
the Netherlands, different terms for peanut were found, such as “aardnoot” (groundnut) and “arachide” (Hengel 2006).

There are several sources on the basis of cross contamination, like many manufacturing plants which were constructed before mandatory allergen labelling was introduced in 2003 and, despite the best efforts of food business operators to eliminate cross-contact, these manufacturing plants can not grant the elimination of cross contamination (Mills et al. 2004; Hengel 2006). However, lack of knowledge has also been identified as a source of cross contamination (Van Ravenhorst 2008). In addition, the emphasis on food hygiene currently focuses on microbiology and not on food allergens. So do the guidelines with regard to the general principles of good food hygiene published by the Codex Alimentarius (CAC/RCP 2003).

Currently it seems that cross contamination of allergens is not regarded as a result of poor food hygiene by either food businesses nor by food safety inspectors. Food business operators should take more measures to eliminate the unintended addition of allergens to food products. Furthermore the role and efficiency of the competent authorities should be verified. Competent authorities should control the production process management accomplished by food business operators. However, if despite this second control allergens are still able to enter a food product can be concluded that the performance of food business operators as well as competent authorities is inadequate.

Training of food handlers is one of the most effective tools used to improve food hygiene (Kurt et al. 1997). Food producers should be informed of the potential severe and even fatal consequences of contamination with allergens, and should be guided in using the HACCP system to control allergens, e.g. working according to appropriate scheduling of manufacturing operations, effective cleaning between operations and controlling the production process.
Currently, legislation demands supervision and instructions, training can be accomplished on voluntary basis\(^99\). Legislation should enforce mandatory training as a requirement for workers employed as food handlers. Training may also be useful for inspectors and auditors, contributing to more effective control. The authorities should, during the course of auditing, stress the compliance of allergen control, and provide food business operators with relevant feedback. Cross contamination can also occur in earlier stages of the production chain. Here for, a good working relation with trading partners should result in more accurate information about the allergen content of raw materials and the allergen control practices, regarding sanitation, storage, processing and packaging of the supplier (A. C. Huggett 1998; Taylor and Hefle 2001b; Miles, Crevel et al. 2006b).

### 8.2.3. Precautionary labelling

Precautionary warning should only be used when appropriate, thus not to replace good hygiene practice and be understandable to consumers and especially food allergic consumers. Currently, precautionary labelling is applied on a voluntary basis, thus Directive 2000/13/EC does not define any requirements. This will remain the same in the future since precautionary labelling is outside the ambit of proposal COM(2008)40 as well.

A diversity of statements is used such as ‘may contain traces of X’ and ‘produced in a factory also processing X’. However the intention is the same. Also the warning can be found at different locations on the product label, which may be problematic in terms of effective information delivery. One particular warning should be used and this warning should appear in the same “field of vision” as the list of ingredients and allergen labelling (for example, at the bottom of the ingredients list).

\(^{99}\) Regulation 2004/852/EC chapter XII
Food producers apply precautionary labelling more widely than necessary (Taylor and Hefle 2001a; TEEC 2003; Hefle et al. 2007). This results in a burden for food allergic consumers because it restricts the food choice unnecessarily (Voordouw et al. 2009). Food allergic consumers have indicated to prefer a negative or positive allergen indicator instead of precautionary labelling. However, this would lead to practical problems for the food industry, since there is no legal definition or requirement for allergen “free” yet. Replacements for precautionary labelling may arise as soon as threshold levels are established for the different allergens. In principle, is the presence of an allergen not elevating the threshold level, incapable of causing adverse reactions and labelling is unnecessary. When threshold levels and detection limits reach the same level, could these replace precautionary labelling. The regulatory limit will be based on a “community” threshold level, covering the great majority of the population (Crevel et al. 2008). This manner of labelling is already accepted for gluten\(^{100}\) and for sulphur dioxide and sulphites\(^{101}\). Another aspect of the allergen detection is a “sampling plan”. A sound international sampling plan, is needed to obtain a certain degree of confidence that allergens are “absent” (FDA 2006). Legislation should demand the maximum allergen residue level in the food and/or during the production process and a sampling plan per food product or group of food products. Table 9 offers a draft of food safety criteria regarding food allergens.

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\(^{100}\) Regulation 41/2009/EC

\(^{101}\) Directive 2000/13/EC Annex IIIa as amended by 2003/89/EC
A drawback of this recommendation is that individuals with an exceptionally low threshold are not protected. They may require different approaches, e.g. specialized food manufacturers (Miles et al. 2006b).

### 8.3. Wishes and demands of food allergic consumers

Food allergy sufferers revealed to experience problems with regard to the presentation and the content of the food labels, in particular with regard to layout, readability, inaccurate labelling, language and discrepancies on the product label.

#### 8.3.1. The content of the food labels

The language, in which a product label represents information, should be easily understood by consumers. Further determination is set in national legislation and will be the native language(s) of a Member State.

Food allergic consumers find discrepancies on product labels. That mislabelled products are on the market shall no body deny. However, the perceived discrepancies may be a consequence of consumers misinterpreting the product label. 16% from all adverse allergic reactions by the intake of pre-packed foods are due to misunderstanding of the labelled terms (Simons et al. 2005).
Absence of the native language and discrepancies on the product label probably originate from non-compliance with legislation. The health endangering problems experienced by food allergic consumers can be attributed to food business operators as well as competent authorities failing in protecting food allergic consumers. Since legislation already covers the remaining complaints, altering legislation seems inadequate. Also here, training seems of food handlers the most effective tool to improve the awareness concerning labelling errors, like the use of a different language as the national language or discrepancies on the product label (Kurt et al. 1997). Controls should ensure compliance with regulations of processing and labelling. Competent authorities could consider a certification and accreditation system in which the standard includes good labelling practice. Although it is outside the scope of legislation, consumer education may help interpretation of product labels.

8.3.2. Lay out and readability

Effective and clear product labelling is essential for food allergic consumers, in order to eliminate problematic ingredients in their diets, however consumers experience difficulties reading the label due to small font sizes, poor colour contrast and shiny packaging materials. The lay out and readability can be interpreted in different ways as the demands are currently described in Directive 2000/13/EC. Proposal COM(2008)40 demands ingredient labelling and allergen information to be printed in a minimum font size of 3mm. It remains unclear in which way the 3mm is measured (horizontal or vertical and which letter is used for the standard). Nevertheless, this will already make concessions to better readability. Table 10 shows the influence of font size and font on the readability. Font size 9 and 10 are easier to read than font size 8. There is also a great difference between the readability of the different fonts. A positive list with fonts having approval for the use of mandatory information could become an additional requirement. With regard
to contrast, a mandatory background and printing colour or a minimum percentage of contrast can be required. However, before these requirements are included in legislation, research needs to determine which contrast and font are optimal and the possibilities for implementation in legislation, e.g. economical feasibility.

Table 10. 
Influence on readability of font size and font

<table>
<thead>
<tr>
<th>Font size</th>
<th>Font size 10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Font size 9</td>
</tr>
<tr>
<td></td>
<td>Font size 8</td>
</tr>
<tr>
<td>Font</td>
<td>Ingredients: wheat (gluten)</td>
</tr>
<tr>
<td>(all examples written in font size 10)</td>
<td>Ingredients: wheat (gluten)</td>
</tr>
<tr>
<td></td>
<td>Ingredients: wheat (gluten)</td>
</tr>
</tbody>
</table>

The European Union could offer one standard guideline concerning good labelling practice. Competent authorities or Member States can also contribute to improving readability by offering an “approving presentation service” to which food producers can send their printed package for authorization (or suggestion for improvement) of consumer friendly packaging practice.

8.4. Preferences of food allergic consumes

Food allergic consumers would like to be informed when the composition of a food product has changed. The use of symbols and/or a standardised layout to present allergen information would simplify identification of allergens. Possibilities regarding these preferences will be considered below.

At present, food business operators do not have to inform consumers when the composition of food products has changed. In new formulas the allergen content can remain unaltered, new allergens can be introduced or a reduction of allergens can occur. The unannounced introduction of an allergen in the end product, poses a hazard for food allergic consumers because they assume that the product is safe since that particular product was safe in the past, hence the product label is not read repeatedly. Thus, communication via labelling might also address changes in the
ingredient composition, in particular when the recipe change is related to a change in the allergen composition. For example, this could be identified on the front of the package with a claim or symbol. Possibilities for claims are “new formulation”, “recipe change” or “improved composition”. The announcement has to be displayed for certain period of time to ensure it will reach consumers. On this topic is more research needed.

Allergic consumers prefer symbolic labelling, in addition to textual allergen information, representing the presence or absence of allergens (Cornelisse-Vermaat, et al. 2007; Voordouw et al. 2009). Symbolic labelling can overcome linguistic problems and fewer space is needed on the label in comparison to multi-lingual labelling (EC 2006) and the shopping time may be reduced. Symbolic labelling covering all fourteen allergens, may confuse consumers (EC 2006; Halliday 2009). Symbolic labelling of the fourteen mandatory allergens can be replaced by the allergens that have the greatest impact on society. The list could for example include peanuts and tree nuts, since these allergens are most often implicated in severe food-induced anaphylactic reactions in adults (Pumphrey 2000; Banks 2003) and cow’s milk, since this is the main cause of food allergy and anaphylactic shocks in children (Simons et al. 2005; Macdougall 2002). Regardless of the type of symbolic labelling applied, legislation should address the symbol format, it’s location on the package and the application, e.g. should the symbols only be used for ingredients or as well for cross contamination.

Another option to simplify the recognition of allergens is to apply a mandatory “summary” of the allergens. The allergen information should be printed near the list of ingredient, ideally immediately below or above. An internationally recognised heading, symbol or sign can be used. Legislation should specify the lay-out, place and information in an explicit way. Current labelling legislation and proposal COM(2008)40 already demand this manner of labelling. However, exceptions are made for food products where the product name clearly refers to the allergen, or when the specific allergen term is used in the list of ingredients.
Allergenic ingredients can easily attract attention if presented in a specific font. This font should be significantly different from the other ingredients present in the list of ingredients. Examples which can be used are bold or a specific colour.

Table 10 represents the three discussed possibilities on allergen labelling namely symbolic labelling, a mandatory allergen “summary” and the use of a specific font.

Table 10.  
*Examples of allergen labelling*

<table>
<thead>
<tr>
<th>Symbol labelling</th>
<th>Allergen block</th>
<th>Specific font labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredients: wheat flour, egg, chicken, pasteurised cow’s milk, salt, water, butter, modified corn starch, garlic, soybean oil, peanut.</td>
<td>Ingredients: wheat flour, egg, chicken, pasteurised cow’s milk, salt, water, butter, modified corn starch, garlic, soybean oil, peanut.</td>
<td>Ingredients: <strong>wheat flour</strong>, <strong>egg</strong>, chicken, <strong>pasteurised cow’s milk</strong>, salt, water, butter, modified corn starch, garlic, <strong>soybean oil</strong>, <strong>peanut</strong>.</td>
</tr>
<tr>
<td><img src="image1" alt="Wheat" />, <img src="image2" alt="Egg" />, <img src="image3" alt="Chicken" />, <img src="image4" alt="Pasteurised Cow's Milk" />, <img src="image5" alt="Salt" />, <img src="image6" alt="Water" />, <img src="image7" alt="Butter" />, <img src="image8" alt="Modified Corn Starch" />, <img src="image9" alt="Garlic" />, <img src="image10" alt="Soybean Oil" />, <img src="image11" alt="Peanut" /></td>
<td>Allergen information: gluten, egg, milk, soy</td>
<td></td>
</tr>
</tbody>
</table>

The objective is to improve the recognition of allergens, which can be achieved by different ways. Symbolic labelling; an allergen summary; or a special font for allergens are represent labelling strategy which create the potential for fast recognition of the allergens present in foods. The manner of labelling chosen is less important than the uniformity of its implementation.

However, increased information provision may be problematic given the limitations of label space available. Other approaches to information delivery, information and communication technologies (ICT), might offer a solution. However, at the time of writing, consumer requirements for information provision still focus on the food label itself (Cornelisse-Vermaat et al. 2008).
All potentially protein containing constituents, intentionally added to food products or the raw materials used in the production process of food products, should be included in the list of ingredients. In addition all ingredients derived from an allergenic source should refer clearly to their allergenic origin. These rules should apply to all food products and ingredients and the potential hazardous exceptions should be eliminated.

Precautionary labelling should only be used when cross contamination is unavoidable by the HACCP-principles. In order to eliminate precautionary labelling food business operators should control their production process including allergen management. European legislation should explicitly define precautionary labelling including its presentation and meaning. Further research is needed to establish threshold levels which can be used to declare whether a food product is allergen free. Training of food handlers, inspectors and auditors will reduce cross contamination and will also have a positive effect on the number of incorrectly labelled food products.

Legislation should specify the demands concerning the labelling demands to improve the label readability. It would be helpful if food allergic consumers could quickly identify recipe changes on the product label. Further research is essential to explore different options in this regard.

Improved recognition of allergens can be achieved by different ways like symbolic labelling, an allergen summary or a special font. The manner of labelling chosen is less important than the uniformity of its implementation.
9. Discussion

The main objectives of this research were to assess the effectiveness of European legislation regarding health protection of food allergic consumers, and to suggest recommendations to better meet the needs and expectations of food allergic consumers. The requirements of legislative documents related to the allergens and the labelling thereof have been assessed. These requirements are compared to the interest and wishes of food allergic consumers and there are potential changes possible to improve consumer protection and to meet the wished of this susceptible group of consumers.

The continuous need for alertness regarding food consumption, in order to avoid ingestion of allergenic ingredients and restricted dietary choices are mentioned as impacting the quality of life significantly (Flokstra-de Blok et al. 2008). The reduction of the health related quality of life is mostly caused by stress associated with measures to avoid allergen consumption and anxiety about accidentally consuming the food allergen (Marklund et al. 2006; Sicherer et al. 2001; Blok et al, 2009).

The labelling requirements included in Directive 2000/13/EC and proposal COM(2008)40 are, principally, consistent with the Codex General Standard for the Labelling of Prepackaged Foods (CAC 1991), which has been submitted to all member nations and associate members of the Food and Agriculture Organization (FAO) of the United Nations and WHO for acceptance (CAC 2001). This includes more than 90% of the countries worldwide. The word principally is used because there are also some differences. The CAC only considers eight ingredients as major allergens and compound ingredients are already allowed to label by the name of the compound ingredient when constituting less than 5%, where European legislation includes fourteen allergens and compound ingredients are allowed to label by the name of the compound ingredients when present in less than 2%. 
Directive 2000/13/EC and its amending directives have a direct influence on the labelling of allergens and ingredients. These directives require all ingredients to be mentioned in the list of ingredients and all product labels should contain such a list of ingredients. However, some ingredients are excluded from ingredient labelling and some food products are not obliged to label the list of ingredients due to their way of packaging or for what they are. Ingredients derived from an allergenic source should refer to their origin. However, the same Directive which approves exceptions on ingredient labelling, also excludes a selection of ingredients and food products from allergen labelling. When the product composition of a food product is not completely detectable or, even worse, not mentioned at all, how are food allergic consumers able to determine if a product is safe for them to consume? These derogations on ingredient and allergen labelling should be eliminated when the presence of such ingredients can cause allergic reactions.

Indirectly related to allergens and their labelling is food hygiene and production process control. Food business operators often use precautionary labelling to protect food allergic consumers from allergen traces, present in a food product due to the consequences of an uncontrolled production process. The extended use of precautionary labelling results unnecessarily in a restriction of foods included in food allergic individuals diets. In the most optimal situation, the production process should be controlled in such a way that the absence of allergens can be guaranteed and precautionary labelling can be eliminated. Until this mode of control is achieved precautionary labelling should only be used when elimination of cross contamination cannot be achieved through application of HACCP principles.

Food allergic consumers experience difficulties reading the product labels, caused by poor labelling practice. Currently, European legislation holds no specific requirements for the presentation of product information, like the list of ingredients, allergen labelling and precautionary labelling. Legislation should require concrete measures to improve the readability of product labels. Proposal COM(2008) 40 will demand a minimum font size of 3mm as soon as it enters into force. This is already a
start towards readability of all product labels. Besides font size, spacing, font colour and contrast influence the readability of labels significantly (IGD 2003). Legislation might consider demanding standard labelling requirements in which font size, spacing and font can be specified. More research is needed to determine if more requirements in legislation are possible. Competent authorities could offer compliance assistance, or maybe even an “approval” service to which food producers can send their printed package for authorization.

Table 11 summarizes the implications for possible improvements in European legislation.

Table 11. 
Implications for European Legislation

<table>
<thead>
<tr>
<th>Ingredient labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compound ingredients constituting less than 2% of the end product should include information about the ingredients present.</td>
</tr>
<tr>
<td>All food products packaged in glass bottles intended for reuse should be provided with the list of ingredients.</td>
</tr>
<tr>
<td>Food products packaged in containers with their largest surface being less than 10cm² should be provided with the list of ingredients, e.g. by use of an adhesive label.</td>
</tr>
<tr>
<td>It should be mandatory to label beverages containing more than 1.2% of alcohol with a list of ingredients.</td>
</tr>
<tr>
<td>Single ingredient products where the trade name identifies the present ingredient (including vinegar) can remain derogated.</td>
</tr>
<tr>
<td>Constituents not considered as ingredients should be included in the list of ingredients. This requirement does not apply to temporarily separated constituents which are later reintroduced, when the composition remains equal.</td>
</tr>
<tr>
<td>“Group” labelling is too unspecific and legislation should require more precision regarding the ingredients.</td>
</tr>
<tr>
<td>Non pre-packaged food products should be accompanied by a printed list of ingredients (unless the product is for immediate consumption, for which verbal information provision is sufficient).</td>
</tr>
<tr>
<td>Cheese, butter, fermented milk and fermented cream should be labelled with the list of ingredients.</td>
</tr>
</tbody>
</table>
| Products packaged separately, and sold as a part of a bigger container might (if space on the product label allows it) label the list of ingredients on each
<table>
<thead>
<tr>
<th><strong>individual prepackage food product.</strong></th>
</tr>
</thead>
</table>

**Allergen labelling**

Ingredients derived from an allergic source and proven not to cause allergic reactions can remain derogated (only applicable for ingredients declared by European legislation).

Single ingredient products where the trade name identifies the ingredient (including vinegar) should label origin when derived from an allergic source.

Food products where a precise reference to the allergen of concern is made in the list of ingredients or in the product name.

Cheese, butter, fermented milk and fermented cream should refer to the allergen milk.

Products packaged separately, and sold as a part of a bigger container should label the allergens on each individual prepackaged food product.

Food products where a precise reference to the allergen of concern is made in the list of ingredients or in the product name.

Non pre-packed food products should be provided with adequate information concerning the ingredients and allergens present. Training of food handlers is needed to guarantee reliable information.

**Food hygiene**

Primary products sold to final consumers or local retail establishments can remain derogated from the food hygiene Regulation.

Training is currently on a voluntary basis. Legislation should change this into an obligation.

Allergen contamination should be eliminated due to improved implementation of allergens in the HACCP principles, appropriate manufacturing process, and building good working relation with trading partners.

Control should be evaluated. Training auditors and competent authorities should result in a more effective control of allergens in the food production chain.

**Precautionary labelling**

European legislation should specify the presentation and meaning of precautionary labelling.

Threshold levels, when established, could replace precautionary labelling.

**Presentation**

“Hidden” allergens, absence of the native language and discrepancies on the product label should be prevented. A standardized accreditation and certification system with regard to control of labelling practice should be introduced.

Legislation should specify font size, font and contrast to label the list of ingredients and related allergens.

Authorities or Member States could offer an ‘approval service’ or a standard guideline presenting good labelling practice.

Consumers could be warned when a recipe change has consequences for the allergen composition.
Implementation of symbol labelling, allergen summary or a standardized font to simplify identification of allergens.

ICT should be taken into account as matter of information provision of the future.

<table>
<thead>
<tr>
<th>Implementation of symbol labelling, allergen summary or a standardized font to simplify identification of allergens.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICT should be taken into account as matter of information provision of the future.</td>
</tr>
</tbody>
</table>

There are several possibilities for improvement possible in European legislation, hence priorities should be set. Uniform labelling among different food products in different European Member States is among the most important and is supported by other stakeholders. In the first place this will improve consumers’ recognition of the allergen content, and in the second place it will reduce the confusion and misunderstanding of the product label. The most practical and uncomplicated approach is to eliminate the derogation of allergen labelling for food products of which the name clearly refers to the allergen concerned or when the name of the allergen is clearly mentioned in the list of ingredients. In addition it should be assured that the allergen labelling refers to the allergen of concern, using the term included in European legislation. Even though in some cases, this might result in redundant allergen labelling, e.g. peanut butter which is allergen labelled with ‘peanut’.

Another major issue relates to the presence of allergen traces in food products. It is clear that the unwanted introduction of constituents in a food product is a consequence of inadequate control of the production process. Food allergens should receive a more prominent place in the prospective application of food hygiene. As discussed in chapter 8.2, food business operators and additional control systems (certification) should prevent the unintended addition of allergenic substances. Transposing the routine and requirements from certification might, and most likely,

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103 proposal 2008(40)EC Article 22a
104 Directive 2000/13/EC Article 6(2)c
105 proposal 2008(40)EC Article 22b
107 proposal COM(2008)40 Annex II
take a long time. In contrast to private initiatives, which adapt to the current issues relative easily. An example of a private initiative is the Global Food Safety Initiative (GFSI). Their Guidance Document sets out the key requirements for food safety management schemes and gives guidance for compliance. In their current guidance document are allergens and cross contamination specifically mentioned (GFSI 2007).

Developments in information and communication technology (ICT) should be taken into account as a potential information provider in the future. The barcode of products can bear the needed information. Consumers can, by scanning the barcode, demand for information that meets their individual needs and can potentially overcome space limitation on the product label. Food allergic consumers still prefer to communicate via labelling, however improvements in ICT approaches and greater familiarity with ICT should facilitate the introduction of these novel information providing method (Cornelisse-Vermaat et al. 2008). Implementation in legislation should be considered. The main two objectives of food law are, to protect the interests of consumers and to provide a basis for consumers to make informed choices in relation to the foods they consume. Consumer safety is dependent on the information provided to the consumer, including information on the label. It is unsure if this also refers to ICT.
10. Conclusion and recommendations

It can be concluded that improvements in European legislation are possible in order to meet the needs and expectations of food allergic consumers, improve consumer protection, and to facilitate the basis of consumer informed choice.

Specific food products are excluded from ingredient labelling, and some ingredients do not have to be included on the list of ingredients. Similar exceptions are made for allergen labelling. These derogations should be eliminated when the presence of such ingredients can cause allergic reactions. The information provision should be uniform across European Member States at least, or even internationally and European legislation could be more specific about readability requirements.

In some cases, further research is required before legislation can be enacted, e.g. regarding the establishment of threshold levels, improving readability, announcement recipe change, symbol labelling and the implementation of ICT as source of information.

It can be concluded that improvements in European legislation are possible regarding the context and presentation of ingredients and allergen labelling in order to meet the needs and expectations of food allergic consumers, improve consumer protection, and to facilitate making an informed choice.
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