The European Labelling Law for Foodstuffs Contains Life-Threatening Exemptions for Food-Allergic Consumers

Timo Buhl\textsuperscript{a} Hubert Kampmann\textsuperscript{b} Jose Martinez\textsuperscript{c} Thomas Fuchs\textsuperscript{a}

Departments of \textsuperscript{a}Dermatology and Venerology, \textsuperscript{b}Legal Medicine and \textsuperscript{c}International and European Law, Georg August University, Göttingen, Germany

Established Facts
- The European labelling law for foodstuffs excludes declarations of the ingredients on individually wrapped foodstuffs with outer packages and products whose largest single surface area falls below 10 cm\textsuperscript{2}.

Novel Insights
- This case report shows the need to discuss the legal situation regarding food labelling in Europe and elsewhere.
- We suggest evaluating the benefits of a mandatory safety warning (symbol) for major allergenic food ingredients on every foodstuff package.

Key Words
Anaphylactic reaction · European directive · Food allergy · Food labelling

Abstract
The prevalence of food allergies still continues to rise in western Europe. As the strict avoidance of food allergens represents a major issue in the management of this disease, information for consumers on food labels about allergenic ingredients is crucial. The European labelling law for foodstuffs excludes declarations of the ingredients on individually wrapped foodstuffs with outer packages and products whose largest single surface area falls below 10 cm\textsuperscript{2}. One potentially avoidable case, with fatal consequences due to this law and the current legal situation, is discussed herein. We suggest evaluating the benefits of a mandatory safety warning (symbol) for major allergenic food ingredients on every foodstuff package, without any exceptions based on the size of the product or the presence of secondary packages.
Introduction

Food allergy can be defined as a reproducible adverse reaction to food or food ingredients that involves the immune system. Most of these reactions are immunoglobulin E (IgE) mediated, and although IgE plays an essential role in the healthy immune system, it displays inappropriate properties in food-allergic people towards everyday food constituents. Until now, no therapeutic regimen has been created that can be offered to individuals suffering from classical IgE-mediated food allergies other than detailed patient education to strictly avoid all problematic foods or food ingredients [1]. In the case of a critical allergic reaction to foodstuffs, emergency management including basic life support and parenteral application of epinephrine, corticosteroids and antihistamines is required. The food-allergic individuals as well as their families and carers are confronted with situations requiring extreme caution during shopping and food ingestion, representing a serious, often lifelong, burden. Additionally, many countries provide insufficient laws for the labelling of ingredients contained in processed foodstuffs [2].

The European Union (EU) established compulsory directives to ensure consistent national food labelling laws in its member states (details in ‘Discussion’) [3]. These laws are updated regularly to ensure that the latest scientific and judicial standards are met. Although the consumer protection in the member states of the EU is relatively strict in comparison to the situation in numerous non-EU countries, some issues remain that need to be urgently addressed. One of the most at-risk groups of food-allergic individuals are children and adolescents dining in unfamiliar surroundings like student cafeterias, birthday parties or group lunches at school [4]. In these situations, food labelling exclusively on the outer packages of products that are additionally wrapped individually is insufficient, as well as the general exemption from labelling of products whose largest single surface area falls below 10 cm².

The following case report, with fatal consequences, raised our awareness of the insufficient legal situation concerning the European laws of food labelling, as well as the necessity for standard prescription of standby medication including self-injectable epinephrine for patients at risk of anaphylaxis.

Case Report

A 14-year-old schoolgirl was diagnosed with a ‘nut’ allergy about 10 years ago by her pediatrician. This food allergy led to the advice given to the parents and the child to completely avoid foods containing nuts (no distinction was made between tree nuts and peanuts). Unfortunately, it cannot be determined today how this diagnosis was established and if more specific allergological tests were performed.

At the age of 12, the girl was seen by a pulmonologist because of intermittent dyspnea. Scratch tests revealed a positive reaction to the dander of her own dog. Details of this testing are not available. Furthermore, high levels of specific IgE against peanuts (>100 kU/l, class 6 CAP FEIA) and soy beans (2.96 kU/l, class 2 CAP FEIA) were detected. Tree nuts were not taken into consideration at this point. The girl was dismissed from the specialist with the diagnosis of bronchial asthma due to a dog allergy and only salbutamol inhalers were prescribed as standby medication.

The adolescent consumed individually wrapped cereal bars on 3 consecutive days at school. These individual cereal bars were part of a larger package with the statutory list of ingredients and additional safety advice for food-allergic individuals (ingredients as declared on the outer package: chocolate, peanuts, oat flakes, glucose sirup, hazelnuts, wheat flour, sugar, cornflakes, honey, oil, salt, soy lecithin). However, the individual bars contained no separate list of ingredients – this is consistent with European laws. These bars were not designated for retail separately, so the girl had no opportunity to read the safety advice. She repeatedly suffered from dyspnea after the consumption of the cereal bars, but was apparently not able to make the connection between the cereal bars and the dyspnea. On the third day, after eating another cereal bar at school, dyspnea occurred with a subsequent loss of consciousness. As witnessed by classmates. After a hesitant start to advanced life support, the resuscitation procedures were not successful. Epinephrine was administered intravenously for the first time approximately 25 min after the loss of consciousness. Upon autopsy, the primary cause of death remained unclear, and a nonspecific cerebral oedema and pulmonary oedema were documented. We performed laboratory testing for total and specific IgE antibodies (ImmunoCAP, Phadia, Uppsala, Sweden) with blood samples of the diseased: total IgE 573 kUA/l (normal: 0–150), specific IgE for peanut >100 kU/l (class 6), soy bean 12.2 kU/l (class 3), almond 3.53 kU/l (class 3), hazelnut 2.85 kU/l (class 2), rye flour 1.38 kU/l (class 2) and wheat flour 1.54 kU/l (class 2). Dermatophagoides pteronyssinus and coconut-specific IgE were borderline positive (class 1), timothy, rye, birch and mugwort pollen as well as cat, dog and Cladosporium herbarum revealed no pathological findings (class 0). Tryptase levels (ImmunoCAP) were not elevated.

Discussion

In a study of postmortem findings after fatal anaphylactic reactions, 23 of 56 cases lacked any specific macroscopic pathology suggestive of anaphylaxis [5]. Although increased levels of serum tryptase may be an indicator of systemic anaphylaxis, a negative test result does not exclude this diagnosis. Especially in food-induced anaphylaxis, tryptase levels might be normal (due to the more localized, but just as dangerous, mucosal reaction) in

Exemptions in the European Labelling Law for Foodstuffs

Int Arch Allergy Immunol 2008;146:334–337 335
comparison to venom-induced anaphylaxis, for example [6]. To summarize this case report, the cause of death cannot be fully established. Regarding the history and allergological findings, the repeated exposure to peanuts, and possibly hazelnuts, of an individual with a strong sensitization to these allergens, with a subsequent anaphylactic reaction seems to be most likely the cause of death.

Concerning the treatment of this girl, the opportunities to prescribe self-injectable epinephrine as a first-aid therapy and a quick application of epinephrine upon the arrival of the medical team were missed. It is widely accepted in the medical community that patients who have had anaphylaxis from a food allergy that may be encountered in non-medical settings should carry self-injectable epinephrine for use if anaphylaxis develops and use it promptly if acute anaphylaxis is suspected [7]. The challenge for the consulted specialist is to identify the additional individuals with known allergies who have no recognized history of anaphylaxis or who have a history of only mild symptoms after exposure to a known trigger. These patients might need to be prescribed self-injectable epinephrine for possible life-threatening anaphylaxis in the future. The presence of comorbidities and other factors influences the decision to prescribe such first-aid medication. One of the most important comorbidities in patients with an allergy is asthma, which has been associated with severe and fatal anaphylaxis [8, 9]. The non-prescription of first-aid medication (including self-injectable epinephrine) is an important criticism of the management of the patient in this case report.

Another fundamental issue contributing to the fatal outcome concerns the labelling of the cereal bars: the European Directive 2000/13/EC [10] and its amendments, Directive 2001/101/EC, 2002/67/EC, 2003/89/EC and 2006/142/EC, apply to prepackaged foodstuffs to be delivered to the final consumer or to restaurants, hospitals, canteens and other similar mass caterers in the European Union. All EU member states are obliged to transpose European directives to national law according to the EC treaty (article 249) [11].

The Directive 2000/13/EC demands that consumer information on prepackaged foodstuffs shall appear on the packaging or on a label attached thereto (article 13, paragraph 1a) allowing, for example, the non-declaration of the ingredients of an individually wrapped cereal or chocolate bar within additional outer packaging. In principle, this directive excludes the labelling of products whose largest single surface area falls below 10 cm² (article 13, paragraph 4), leading again to the non-declaration of foodstuffs of smaller sizes. The deadline for the transposition of Directive 2000/13/EC to national law ended on 15th March, 2003 for the United Kingdom, France, Germany, Italy, Luxembourg, The Netherlands, Denmark, Ireland, Belgium, Greece, Portugal, Spain, Austria, Finland and Sweden. All EU-member states that did not introduce the directive can be confronted with an infringement procedure by the European Commission. The newly associated member states of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia were bound by contract to introduce the relevant directive no later than 2007 [12]. The above-mentioned labelling exemptions of Directive 2000/13/EC are consistent with the Codex General Standard for the Labelling of Prepackaged Foods (article 6 and 8.1.3) [13]. This standard 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 in accordance with the general principles of the Codex Alimentarius.

### Conclusion

Firstly, the non-declaration of individually wrapped foodstuffs with outer packages and the general exclusion of the labelling of products whose largest single surface area falls below 10 cm² are legally allowed in the EU and

---

**Table 1. Major allergenic foods listed in annex IIIa of Directive 2000/13/EC, last amended by Directive 2006/142/EC [10]**

<table>
<thead>
<tr>
<th>Category</th>
<th>Foods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten</td>
<td>wheat, rye, barley, oats, spelt, Kamut or their hybridized strains</td>
</tr>
<tr>
<td>Crustaceans</td>
<td></td>
</tr>
<tr>
<td>Eggs</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td></td>
</tr>
<tr>
<td>Peanuts</td>
<td></td>
</tr>
<tr>
<td>Soy beans</td>
<td></td>
</tr>
<tr>
<td>Milk (including lactose)</td>
<td></td>
</tr>
<tr>
<td>Nuts</td>
<td>almonds, hazelnuts, walnuts, cashews, pecans, brazils, pistachios, macadamias and Queensland nuts</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 and sulphites at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO2</td>
<td></td>
</tr>
<tr>
<td>Lupin</td>
<td></td>
</tr>
<tr>
<td>Molluscs</td>
<td></td>
</tr>
</tbody>
</table>

Foods produced from these are also considered allergenic.
elsewhere. In particular, children and adolescents in unfamiliar surroundings do not always have access to the outer packages of foodstuffs containing the important list of ingredients. Secondly, small-sized foodstuffs may represent a life-threatening danger to food-allergic individuals. Consequently, we encourage the medical and judicial communities to address these issues. One solution could be a mandatory safety warning of major allergenic food ingredients, as defined by Directive 2000/13/EC (table 1), on every foodstuff package, without any exceptions based on the size of the product or the presence of secondary packages. Due to space limitations on small packages and the number of European languages, this safety warning could be a unique European symbol to warn and inform food-allergic individuals. Before bringing such an symbol into general use, studies should be performed to evaluate consumers’ perceptions of these symbols, ensuring that food-allergic people interpret them correctly as danger signals. Our proposal of a mandatory symbol does not include labelling for possible cross-contamination with the allergen at some point during the manufacturing process or transport of the foodstuff (so-called ‘may contain’ labels) [2] – excessive usage of food allergen warning labels restricts not only consumer choice, but also devalues the impact of such warnings.

Acknowledgement

We thank Prof. H. de Haen, former Assistant Director-General and head of the Economic and Social Department of the FAO, for a careful review of the manuscript and helpful contributions.

References
