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"May Contain" Labelling: Adequate Consumer Warning or Unnecessarily Defensive Manufacturer Behaviour?

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Abstract This article answers two questions concerning the liability aspects of the use of "may contain" labelling on food packages, such as "This product may contain traces of nuts." This type of voluntary labelling refers to the unintentional presence of an allergenic foodstuff, the inclusion of which can occur during the production process. Firstly, it is probable that courts consider a food product without a "may contain" warning defective under the Directive, even though this can create unintended consequences. This question is approached in terms of a defect both in design and in warning, since food manufacturers are able to reduce the risk by means of redesigning the production process or by providing a warning. With regard to the second liability question concerning the adequacy of "may contain" warnings, it is not likely that courts will consider the product warning defective in view of the difficulty of providing a better alternative.

Keywords Product liability · "May contain" · Labelling · Cross-contamination · Warnings

Introduction

After eating a chocolate-chip cookie from a vending machine, a 19-year-old girl who suffers from a peanut allergy developed symptoms of anaphylactic shock and was rushed to the emergency room. The list of ingredients on the cookie's package did not include peanuts (Sampson 2002). Evidently, the allergic patient fell victim to a trace amount of hidden peanut. The presence of the hidden allergen may stem from the fact that the production of chocolate-chip cookies occurs on the same line as peanut cookies, and the chocolate-chip cookies were manufactured after the production process of peanut cookies.

This is an illustrative example of how the risk of cross-contamination of allergens can take place in real life. The term "cross-contamination" or "cross-contact" of allergens refers

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to the unintentional presence of an allergenic foodstuff in the final food product (FSA 2006, p. 57). Cross-contamination occurs when different products come into contact with each other: for example, during the production process. It usually concerns only trace amounts of allergens, but even these can have fatal consequences.

In recent years, food manufacturers have increasingly issued warnings such as "This product may contain traces of nuts" or "This product is made on a production line that also handles sesame" on pre-packed food labels. They provide these statements on a voluntary basis to warn consumers against allergens that are or may be unintentionally present in their foodstuffs. It has been suggested that manufacturers provide "may contain" labels to protect themselves against product liability. Product liability under the European Directive requires that the product is defective, which means that the product has failed to meet the safety consumers are entitled to expect. From a manufacturer's point of view, the presence of a "may contain" statement could preclude a successful claim brought against him by an allergic consumer who has suffered injuries as a result of the unintentional presence of an allergen. Interesting in this regard is whether the fear that an allergic victim will succeed in claiming compensation is in accordance with civil safety standards.

In this article, the liability aspects of the use of labelling allergen cross-contamination will be examined. Firstly, the question is whether a food product can be deemed as defective in the event that a warning of the risk of cross-contamination is absent and an allergic consumer has suffereds injuries as a result of the unintentional presence of an allergen. Secondly, in the event a "may contain" warning is present on the food label, the liability question arises as to how manufacturers should warn against the risk of cross-contamination, taking into the account the information needs and information processing abilities of consumers.[1]

The structure of the article is as follows: "A Case of Food Allergen Cross-Contamination" starts with a description of the specific details of the allergen cross-contamination case. The nature and scope of the Directive are discussed in "Product Liability Under the European Directive." Subsequently, the answer to the first question mentioned above is dealt with in "A Design Defect," "A Warning Defect," "Risk Analysis of Courts," and "A Non-standard Product." The second liability question is examined in "The Adequacy of an Allergen Cross-Contamination Warning." The closing paragraph provides a summary of the findings of the article.

A Case of Food Allergen Cross-Contamination

The Food Label

The first step of this exercise consists of exploring the details of the allergen cross-contamination case. The starting point is that the food product contains no statement that points to the risk of cross-contamination. Furthermore, the appearance of the product itself does not indicate the presence of an undeclared allergen. Hence, allergy sufferers cannot conclude from the presentation of the product, mainly its label, that potential danger exists.

Food Safety Regulations

In recent years, the issue of food allergies and cross-contamination has been recognised by the European Commission and the food industry. However, the declaration of the risk of

[1] I do not address the question of whether "may contain" labelling should be the focus of legislative attention or whether a regulatory approach is superior to a tort law approach in dealing with this issue.

allergen cross-contamination on pre-packed food labels is not covered by EU measures. Directive 2003/89/EC only sets out the labelling requirements for allergens that have been intentionally added to foodstuffs as an ingredient.[2] The allergen Directive has been in force since November 2005 and has introduced a list of 12 common allergens that need to be labelled.[3] These are cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame, sulphur dioxide, and sulphites, as well as any product derived from such allergens. Lupine and molluscs and any product thereof have recently been added to the list.[4] According to the first recital, the aim of allergen labelling is to protect the health of allergic consumers and in particular to provide those suffering from food allergies or intolerances with more comprehensive information on the composition of products.

Furthermore, EU provisions stipulating how to deal with the risk of cross-contamination are absent as well. As a result, food manufacturers have different allergen policies and disparate criteria for the use of "may contain" labelling. Although there are no specific provisions on this matter, food safety law does lay down general principles that are applicable to safety hazards such as allergens. According to the General Food Law, a food business operator has the primary legal responsibility to ensure food safety, as he is best placed to devise a secure system for supplying food and ensuring that it is safe.[5] Moreover, article 14 of the General Food Law implies that food manufacturers must take into account special categories of people who may want to consume the product, such as allergic sufferers. If they fail to do so, the food may be deemed unsafe and must not be placed on the market. In addition, European food business operators are obliged to apply Hazard Analysis and Critical Control Point (HACCP) principles to their safety system according to Regulation 852/2004 on the hygiene of foodstuffs.[6] A food safety system based on HACCP focuses on identifying hazards, such as allergens, and establishing the critical control points in the process where food safety hazards could arise. These points must be monitored in order to reduce or to prevent the hazards in an adequate manner. Allergen cross-contamination can be managed by these principles, but manufacturers themselves need to determine the critical points. Most have devised specific guidelines for the handling of allergens through each stage of the product life cycle (Crevel 2002, p. 943). Voluntary guidelines have been drawn up by the industry or regulatory agencies to help food businesses manage and communicate the risk of cross-contamination (FSA 2006). In addition, scientific research provides accessible information to support producers who want to tackle allergen problems.

Knowledge of the Risk of Cross-Contamination

Another important aspect that characterizes the present case is the degree of consumers' knowledge of the risk of cross-contamination. Generally, the risk of cross-contamination

[2] Council Directive 2003/89/EC of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ 2003, L308/15). The general provisions for food labelling are set out in Council Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation, and advertising of foodstuffs (OJ 2000, L 109/29).

[3] Council Directive 2003/89/EC of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ 2003, L308/15).

[4] Commission Directive 2006/142/EC of 22 December 2006 amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients that must under all circumstances appear on the labelling of foodstuffs (OJ 2007, L368/110).

[5] Regulation (EC) 178/2002 (OJ 2002, L31/1), recital 30 and article 17.

[6] Regulation(EC) 852/2004 (OJ 2004, L139/1).

can be viewed as a known threat to food-allergic consumers. Since the risk of cross-contamination can occur even at home during food preparation or cooking, allergic consumers must always be vigilant. Daily tasks such as making a peanut butter sandwich for a non-allergic family member can be hazardous to the peanut-allergic member if the knife used to spread the peanut butter has left a minimum amount of peanut on the cheese sandwich. While allergen cross-contamination is known in the home environment, the production process of the manufacturer is unfamiliar territory. Consumers can only guess at the allergen management. Hence, the risk of allergen cross-contamination with regard to processed food has to be considered as a hidden danger to allergic consumers.

The Likelihood of An Allergic Reaction

The next step is to identify the probability that cross-contamination causes an allergic reaction. Several aspects need to be considered (Spanjersberg et al. 2007). Firstly, the likelihood exists that a trace amount of allergen will contaminate a finished product. Secondly, if a product has in fact been contaminated with an allergen, the probability that an allergic reaction will occur depends on whether the person consuming the product is sensitized. Clearly, foodstuffs available in supermarkets have a wide range of buyers, most of whom are not allergic. Statistically viewed, only a portion of the public has been clinically diagnosed with a food allergy.[7] Research estimates that the prevalence of IgE-mediated food allergies in children is up to 8% and, in adults, between 1 and 3%. However, the percentage of people who perceive themselves to be allergic to certain foodstuffs is much higher. This may be related to the fact that most food-adverse reactions are not caused by a food allergy but by food intolerance. Furthermore, it is suggested that the prevalence has increased in the last few years (Asero 2007; De Blok et al. 2007; Miles et al. 2005). Due to the preponderance of diverse and unreliable methods of diagnosing food allergies, clear evidence of their true prevalence is absent. However, this will change. In 2005, the EU-funded research project EuroPrevall embarked upon a series of studies whose ultimate goal is to improve the quality of life for food-allergy sufferers. Establishing objective data on food allergies in children and adults across Europe is one of the project's objectives (Mills et al. 2007).[8] Thus, the probability that allergic sufferers will eat that particular product is also relevant. Thirdly, even though an allergic person has consumed a problematic product, an allergic reaction does not automatically result. The allergenic residue must also be of sufficient quantity to trigger an adverse reaction.

Several studies have examined the presence of undeclared allergens in food products. One study showed that a chocolate bar without a 'may contain peanut' statement or without peanut in the ingredients list is not necessarily a guarantee of a peanut-free chocolate bar. Nearly 31% of chocolate bars from Western Europe and 62% of those from Eastern Europe contained detectable peanut levels (Vadas and Perelman 2003).[9] The results of a Dutch study also confirm that products lacking a declaration of allergen can in fact have traces of allergen in them (Voedsel en Warenautoriteit 2007).[10] Of the products with a precautionary label, 35 of the 77 tested had peanut or casein. Another peanut study showed far less cross-

[7] Food allergy is defined as an adverse reaction to food, mediated by the immune system. Sufferers produce IgE antibodies to one or more allergenic proteins in the food.

[8] For more information on the project: http://www.europrevall.org.

[9] The levels of detectable peanut went up to 245 ppm peanut protein.

[10] Fourteen of the 44 tested products with no declared peanut contained a detectable level of peanut. Twenty-nine of the 64 tested products without casein on the label contained casein.

contamination; of the 179 food packages bearing an advisory statement, such as "may contain" or about shared equipment, only 13 products had detectable levels of peanut. As the levels varied substantially, it is probable that not all amounts would have elicited adverse reactions (Hefle et al. 2007).[11]

The Seriousness of the Injury

Allergic individuals appear to vary widely in their degree of sensitivity to a specific allergen. It is generally agreed that a relationship exists between dose of allergen and severity of injury. Individuals who react to very low doses are those most at risk of a severe reaction (Hourihane and Knulst 2005). Especially with regard to peanuts, very low doses are able to elicit critical symptoms. This means that taking just a mouthful of a food product could be hazardous (Wensing et al. 2002). Within the group of allergic people, the majority are not highly sensitive. As a result, they can be exposed to low levels of an allergen and experience either no reaction at all or a mild one. Common symptoms of food allergy are, for example, itching of the mouth, eyes, and throat, nausea, vomiting, diarrhea, skin rash, and asthma. A severe allergic reaction is anaphylactic shock. It starts off with symptoms such as a swelling of the lips, shortness of breath, rapid fall in blood pressure, and even loss of consciousness. This can be fatal if not treated quickly. The most common causes of anaphylactic shock are peanuts and nuts. Other allergens such as milk have the potential to cause it as well (Bock et al. 2007).

Although it is recognised that exposure to even minute amounts of allergenic food can elicit adverse reactions in people, no hard data exist on the minimum doses of an allergen required to produce an adverse reaction. Such doses are referred to as threshold doses, and they define the lowest observed adverse effect level, an amount of a specific food that would elicit objective symptoms in highly sensitive individuals. The threshold doses differ per allergen. Several studies have reported results with regard to threshold doses for allergens such as peanut, egg, and cow's milk (Bindsley-Jensen et al. 2002; Wensing et al. 2002). These findings are of a preliminary nature, and uncertainty with regard to determining thresholds still exists for various reasons. One is that a variety of different clinical protocols were used to generate data, which makes it difficult to compare the existing data. Another factor is that data on minimal amounts causing highly severe reactions is missing because most physicians exclude the most sensitive individuals from the clinical experiments (EFSA 2004; Taylor et al. 2002). Consensus on a standardized clinical protocol has been developed, on the basis of which an estimation of threshold doses for allergenic foods can be carried out with more certainty. The data on these low-dose challenge trials should become available in the near future (Taylor et al. 2004).

The Use of the Food Product

As follows from above, a food product which is cross-contaminated presents no hazard to a vast majority of the population when it is used as intended. On the other hand, the mere consumption can elicit adverse reactions in allergic individuals. The only treatment available against food allergies is complete avoidance of the allergen, since the risk of cross-contamination can already materialize during normal use.

[11] The products tested were nutrition/meal bars, cereals/cereal bars confectionery products, snack foods, frozen desserts, instant/quick meals, baking ingredients, and bakery products.

The Avoidability of the Risk of Cross-Contamination

Allergen cross-contamination can occur for a number of reasons, all of which are linked to how a manufacturer runs the production process. For example, given that a producer manufactures a variety of products within the same factory, he might choose the option of scheduling several of these to be processed on the same production line. If the allergenic ingredient is powder, then wet cleaning cannot be carried out. It is possible that the removal of the allergen on the basis of a dry cleaning will prove to be ineffective. As a result, the powder can contaminate whatever is being produced afterwards. Even if there is no shared production line, cross-contamination may still occur as a result of shared utensils, rework, air supply, cleaning practices, staff hygiene, manual processes, and shared storage and transport of products with and without allergenic ingredients (FSA 2006; van Ravenhorst 2007, p. 13). Altering the schedule of the production runs, separate and clear storage of allergenic raw materials, physical separation between production lines, and staff training are appropriate measures to reduce and avoid cross-contamination. Adequate recall procedures contribute as well to the prevention of injuries resulting from cross-contamination.

After reading the above, one might feel the answer to how to completely avoid allergen cross-contamination would be simple. A dedicated factory used only to manufacture allergen-free products would solve the problem (FSA 2002a, p. 54). However, giving consideration to the cost and practicability of taking these safety measures, prevention of cross-contamination becomes less feasible. For small food businesses, it may not always be possible to segregate the production environment of foods with allergenic ingredients. The buildings are too small, the equipment is too old, or rearranging the layout of the production area is too expensive. Likewise, a building dedicated production facilities is an enormous financial burden on producers who manufacture a variety of food products.

A less rigorous approach to avoid harm resulting from cross-contamination is to allow small levels of allergenic contamination that would probably not harm the vast majority of allergic consumers (Crevel et al. 2007, p. 692). Currently, the food industry maintains a zero tolerance level for allergens, since there is little accurate information on the threshold doses for common allergens. Without a consensus on what the exact threshold doses are, it is difficult for manufacturers to manage the risk of cross-contamination (Taylor et al. 2002, p. 25). When threshold levels are established, the food industry and regulatory agencies will be able to create an acceptable level of safety for the vast majority of allergic consumers. If a level can be identified that does not elicit an adverse reaction in the group tested, then statistically, it is highly probable that 90% of the allergic consumers will not react to this dose of the particular allergen. It must be noted that on the basis of this approach, not all allergic consumers would be protected (Taylor et al. 2004, p. 694).

Hence, avoidability of harm refers not only to the theoretical side in terms of whether it is possible to actually prevent cross-contamination but also to the practical side of product safety. The financial ability of a manufacturer to bear the cost of a safer version of the product also determines to what extent a manufacturer will minimise the risk of cross-contamination.

Product Liability under the European Directive

Liability Without Fault

Following the discussion of the circumstances of the present case, it now boils down to the actual examination of the nature of the Directive and the ensuing liability questions.

Directive 85/374/EEC on liability for defective products (hereafter "the Directive") came into effect in 1985 and led to the introduction of a new concept of liability in the Member States of the European Community.[12] The Directive constitutes an internal market measure designed to harmonize within its scope a liability system without fault on the part of the producer. Hence, proof of negligent conduct on the part of the producer is not required. The Directive's guiding principle is that a producer is liable for damage caused by a defect in his product. What constitutes a defect or, in other words, what product can be considered defective is of crucial importance for determining liability. Article 6 states that a product is defective when it does not provide the safety that a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected to be put, and the time when the product was put into circulation.

This test of consumer expectations gives rise to two potential obstacles in determining defectiveness in the allergen case. Firstly, a civil court will instantly wonder what level of safety consumers are entitled to expect of food products. Are consumers entitled to expect that all food products from the supermarket are 100% allergen free if the allergen is not declared in the ingredients list? Or can customers with allergies be expected to view each single food product as a possible threat to their lives, even if there is no warning? Secondly, another problem arising from the application of the consumer expectation test is whether the Directive protects the safety interests of food-allergic consumers, in particular since the test of defectiveness depends on the safety expectations of the public in general.

A Special Category of Consumers

One potential hurdle to overcome is the application of the consumer expectation test to a particular group of people in society. Article 6 of the Directive stipulates that the defectiveness of the product should be determined with reference to the lack of safety that the public at large is entitled to expect. This is an objective test. It is not the safety expectations of the injured claimant in a particular case that are decisive but those of persons in general. Thus, it seems that the test refers to the concept of the safety expectations of the normal, average consumer (Howells 1993, p.12). This may be problematic in the present case given that the average consumer does not have a food allergy. Furthermore, it is plausible that the safety expectations of food allergic sufferers depart from those who are not allergic.

There are good grounds to believe that the safety interests of this special group of people need to be protected. Although allergic consumers are in the minority, they do form part of the general public. Available statistics point to a significant number of people allergic to food in Europe. Moreover, the issue should not just be substantiated quantitatively.[13] The severity of the injury caused by an adverse reaction should carry weight too, especially for those people who are highly sensitized and whose injury from ingesting even a small amount of allergen is severe or fatal. It seems likely that in view of the commonness of food allergies among consumers and the potential severe reactions, the general public would expect those persons to be protected, at least to some extent. Furthermore, public food

[12] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (OJ 1985, L 210/29).

[13] Several American courts have addressed a similar problem by adopting a substantial number test in cases of allergic reactions. According to comment k of the Third Restatement of Torts, it is important that the allergic reaction of the claimant is not unique. The more severe it is, the more justified is the conclusion that the number of persons at risk need not be large to be considered substantial (Owen 2005, p. 596).

safety regulations indicate the need to protect the allergic consumer. Over the last few years, adverse reactions to foods have become recognized as a public health problem. New legal developments in food safety, such as the requirement to label the common allergens, indicate the importance of this group. Article 14 (2) of the General Food Law provides that food is deemed to be unsafe if it is considered injurious to health or unfit for human consumption.[14] To determine this, consideration must be given to the particular health sensitivities of a specific category of consumers, where the food is intended for that category.[15] It seems to follow from this paragraph that food manufacturers are obliged to take into account the interests of consumers who may experience allergic reactions to their products, as they are foreseeable product users.[16]

The Concept of Defectiveness

The Consumer Expectation Test and its Flaws

The next important step in determining whether a product is defective consists of assessing the level of safety that allergic consumers are entitled to expect from foodstuffs that have no allergen labelling. Unfortunately, the execution of the consumer expectation test contains weaknesses, as many commentators have already pointed out (Clark 1989, p. 29; Howells 1993, p. 11; Henderson and Twerski 1999; Stapleton 1994, p. 234). Instead of providing the answer to the question of when is a product defective, its application raises the subsequent question of how much safety is the general public entitled to expect of a product. Especially with regard to complex technological products, the test provides scant guidance, as consumers have difficulty assessing the safety level of such products. Failing to provide absolute safety is not the criterion for assessing product defectiveness (Whittaker 2005, p. 485). Similarly, a product is not defective simply because the use of it involves risks and one of those risks materializes and causes harm to a consumer. However, the area between absolute safety and no safety is grey. Just such a difficulty arises in the case at hand as well. Does a food product carrying a risk of allergen cross-contamination provide the safety that people are entitled to expect or will these safety expectations be met only if an adequate warning is present? Or could it even be argued that a food product would only be regarded safe if the risk of cross-contamination were fully eliminated? Furthermore, the Directive states that all circumstances must be taken into account to assess whether there is a defect, but it has left open how to determine what circumstances are of relevance as well as in what way the relevant circumstances ought to be balanced against each other. As a result, the outcome of a judgement can be unpredictable, a consequence which can undermine the goal of European harmonization of product liability.

A Distinction Between Product Defects

A common way to tackle the problem of establishing the defectiveness of a product is by exploring what type of deficiency the case at hand covers. Although the Directive does not distinguish between three types of product defects, doing so provides a useful tool that is

[14] Regulation (EC) no. 178/2002 (OJ 2002, L31/1).

[15] Paragraph 4c of article 14.

[16] Also within the definition of a safe product under article 2b of the General Product Safety Directive 2001/95/EC (OJ 2002, L11/4), specific categories of consumers at risk must be taken into account.

used in the European literature and in case law as well. In American product liability law, three product defects have been formulated: design, manufacturing, and warning.[17] Manufacturing defects exist when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. Design defects occur when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, and failure to use the alternative design renders the product not reasonably safe. Warnings or instructions for use are defective when the foreseeable risks of harm posed by the product could have been reduced or avoided by reasonable instructions or warnings, and their omission renders the product not reasonably safe.

What is the defect in this case? As follows from the description of the allergen cross-contamination case, a food manufacturer has two precautions at his disposal to reduce and even avoid the risk. Firstly, one could contend that there is a defect in design, as the possibility of cross-contamination is a fundamental and recurring problem in the production process. The products all carry the risk of cross-contamination as a result of the way in which the food manufacturer has designed the production process. The risk of cross-contamination can be managed by a producer. Hence, a producer's decisions can be treated as a potential design defect. It must be noted that it is also possible to treat it as a manufacturing defect because the food product has been contaminated with an allergenic ingredient during the production process. Indeed, in practice, the theoretical distinction between manufacturing and design defects is not always clear. In the end, however, it may be best to look upon this issue as one of a design rather than of a manufacturing defect because theoretically a producer has the power to choose the alternative of avoiding the risk completely and choosing the level of safety. Secondly, it is likely that the number of accidents resulting from the risk of cross-contamination will decrease if a product warning is given by a producer. In other words, the defectiveness of a food product without a "may contain" statement may depend on its design or be a result of the absence of warning.

To assess whether a product is defective in design or as a result of the absence of an adequate warning, the circumstances of the case must be balanced against each other according to article 6 of the Directive. The Directive leaves it to the discretion of the court to decide what circumstances are of significance in a particular case. Article 6 does, however, offer some guidance by specifying three circumstances. These include the presentation of the product, the reasonably expected use of the product, and the time when the product was put into circulation. However, those factors alone will not help a judge to make a sound judicial analysis of the product's defectiveness. Circumstances such as the likelihood that a danger emerges, the degree of harm arising from that, and the knowledge and the obviousness of the danger are of importance, too. Of interest is whether the Directive permits the use of the avoidability of the harm by the manufacturer as a relevant factor. This factor represents the yardstick of fault-based product liability. Whereas strict liability focuses on the safety of the product, fault liability assesses the negligent behaviour of the manufacturer. The vital question is whether this risk created by the food manufacturer is reasonable in view of the level of care taken. Hence, it applies a risk-utility test to determine defectiveness. In assessing consumer safety expectations, many courts apply fault elements to the defectiveness standard, such as taking into account the avoidability of the harm and the cost and practicability of a safer product. Indeed, courts and scholars have recognized that the assessment of liability under both theories proceeds rather identically with regard to design and warning cases (Lord Griffiths et al. 1988; Miller and Goldberg

[17] Restatement (Third) of Torts: Product Liability § 2a,b,c.

2004, p. 354; Stapleton 1994, p. 236; Whittaker 2005, p. 488). Whether a product is defective due to an unsafe design is related to whether a producer has taken sufficient precautions to reduce or to avoid the harm associated with the design. Similarly, the question of whether the absence of a warning renders the product defective or if there is a duty to warn under fault liability is considered on the basis of similar circumstances.[18]

A Distinction Between Standard and Non-standard Products

By contrast, other scholars have argued that the liability system of the Directive does impose liability without fault (Deards and Twigg-Flesner 2001; Taschner 2005).[19] Especially Justice Burton holds the view that the avoidability of the harm and what a manufacturer could and should have done differently are not of relevance, as they do not correspond to the purpose of the Directive, which is to provide a liability system without fault. Taking such factors of reasonableness into consideration would mean reintroducing fault-based liability by way of the back door. He introduces an approach to defectiveness based on a distinction between standard and non-standard products. In view of the fact that his way of thinking has grabbed the judicial headlines, it is interesting to examine if and how liability can be established in the present case. Burton J's approach to defectiveness will be discussed after the sections that deal with the liability question regarding a design defect and/or warning defect.

A Design Defect

The American Restatement of Torts provides a helpful definition to explore whether there is a design defect in the case at hand. According to this definition, a design defect occurs when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, and failure to use the alternative design renders the product not reasonably safe.[20]

In applying this tool, a civil court must first determine what precautions the particular manufacturer has taken to reduce the risk of cross-contamination. An acceptable level of food safety can be achieved on the basis of the implementation of a safety management system that is required under EU food safety law. The responsibility to apply the HACCP principles properly to allergens rests with the food producers. As mentioned above, EU regulations offer little guidance, as those obligations are described in general terms. Best practice guidelines about allergen risk management are available but are provided voluntarily.

Normally, EU food safety law can provide a clear starting point for a civil court to decide what level of safety is at least required, as regulations and standards usually set a minimum level of safety. Although the Directive only provides a defence of regulatory compliance in cases of detailed provisions, it seems that fulfilling all the applicable food

[18] The new American Restatement has also accepted the view that warning and design defects need to be defined in terms of reasonable safety (Owen 2005, p. 332). As for manufacturing defects, it is generally agreed that strict liability is well suited. Since the product has failed to meet the manufacturer's own standard, it will no doubt be considered to have failed to meet consumer expectations (Stoppa 1992, p. 211; Van Dam 2006, p. 377). For example, the German case of the exploded water bottle: BGH 9 May 1995, NJW 1995, 2162.

[19] Justice Burton in A. & Others v National Blood Authority [2001] 3 ALL ER 289, para 63.

[20] Restatement (Third) of Torts: Product Liability § 2b.

safety law requirements is a relevant indication of non-defectiveness. Conversely, non-compliance indicates that a product has failed to meet the required level of safety.[21] It is uncertain whether this reasoning is valid in respect of voluntary guidelines (Fairgrieve and Howells 2007, p. 972; Miller and Goldberg 2004, p. 380).[22] Guidelines usually serve as a means of assisting businesses. Consequently, the decision is left to the manufacturer to choose this approach or another guideline. It is more conceivable that a product is rendered defective if food safety management taking account of the potential hazard of allergens is absent. In all cases in which a producer has in fact implemented a HACCP-based food safety system, defectiveness will turn upon whether the producer has created an appropriate level of safety. Since there are no mandatory requirements with regard to the extent to which the risk of cross-contamination needs to be avoided, it is for the court to determine, with the benefit of hindsight, what level of safety should have been achieved according to civil safety standards.

Defectiveness does not depend merely on the existence of a safer alternative of the product or on whether a manufacturer could have produced a safer product (Stapleton 1994, p. 259). The financial costs associated with the production of a safer alternative, as well as the practicability of the alternative design, form part of the burden of the costs of precautions. Defectiveness is established if the manufacturer has failed to implement the safer design, for which the safety benefits are outweighed by its costs (Owen 1996).[23]

An alternative design available to manufacturers is a food product for which the potential presence of the risk of allergen cross-contamination has been avoided. The only way to ensure such a safety level would be to adopt an allergen-free production environment: for example, the creation of a closed area with a production line that handles only allergen-free products. In circumstances where the risk of cross-contamination can prove fatal to an allergic consumer, full segregation would be the only solution (FSA 2002a, p. 54). Cleaning the production lines will not suffice. Such an alternative would be costly to implement and, for many businesses, also less practicable in view of the number of products processed in the factory. It would probably entail food businesses having to close down because they are not financially capable of fully eliminating the risk of cross-contamination. As a result, products would disappear from the market, and the vast majority of the public would no longer be able to buy and enjoy them. Furthermore, segregation is currently the only reliable solution, as there is a lack of scientific evidence concerning the minimum amounts of allergens needed to trigger adverse reactions in sensitive individuals. As long as there is no definite consensus on the threshold doses, it is difficult for food businesses to manage the risk in an acceptable way. Nevertheless, science offers means for risk assessment (Spanjersberg et al. 2007).

Requiring manufacturers to implement this alternative of complete avoidance of cross-contamination means in essence that allergic consumers are entitled to expect absolute safety. Thus, allergic consumers would be entitled to expect that food products that have no "may contain" statement or other allergen-related information on the label are indeed 100% free of allergens. Based on this assumption, a food manufacturer is liable for the sole reason

[21] For example, the judgment of the Dusseldorf District Court of 30 November 2005, 10 O 144/04, NJW-RR 2006. See Lenze (2006), p. 20.

[22] For example, the judgment of the English Court of Appeal in Tesco Stores Ltd v Pollard [2006] EWCA Civ 393. See Webber (2006), p. 21. The Court of Appeal held that violation of the voluntary standard did not lead to a conclusion that the product is defective.

[23] Such an approach resembles the one of Judge Learned Hand in the famous case United States v Carroll Towing Co (1947) 159 F. (2d) 169, 173.

that an allergic consumer has suffered injuries, as it turned out that the product did contain an allergen. All allergic consumers would be protected under the scope of the Directive, irrespective of their sensitivity and the severity of the reaction. As noted above, the Directive does not impose a system of absolute liability.[24] Consequently, an absolute level of safety, and hence full segregation, is not reasonable because the financial costs and impracticality of eliminating the risk of cross-contamination outweigh the safety benefits achieved.

A reasonable alternative, for example, could be to minimize shared equipment and to schedule the manufacture of an allergen-free product before the production of foodstuffs containing allergenic ingredients. Such an adjustment is mentioned in the voluntary guidelines. As a result, the probability that the risk of cross-contamination occurs will have been reduced. If a producer fails to take such steps, the safety benefits resulting from the alteration would probably necessitate incurring the costs of the alternative design. Although this new production process design probably does not protect the most sensitive allergic consumers, it will protect the majority from experiencing severe reactions. However, this cannot be concluded with certainty. To determine the acceptable level of safety, reliable data on the threshold levels and on the prevalence of food allergy are important. An approach to create an acceptable level of safety would be to determine an upper limit of the amount of an undeclared allergen that is allowed to be present in a food product. However, these upper limits are only meaningful if on the basis of reliable scientific information it can be concluded that they sufficiently protect the majority of allergic consumers. As explained earlier, a consensus on firm threshold doses has not yet been reached (Crevel et al. 2008, p. 599). In the absence of such data food businesses are being plagued by uncertainty as to whether they have assessed the risk adequately. It may be possible—certainly given the EuroPrevall project—that in the near future, a further consensus will be reached with regard to the threshold doses for the most common allergens. This could influence liability, as article 6 stipulates that the state of science at the time the product is put into circulation is decisive. Especially with regard to food products with an expiry date, manufacturers must keep abreast of the latest technical and scientific developments.

In the event that a judge decides that the food product without a "may contain" statement is defective, escaping liability by invoking the development risks defence of Article 7(e) of the Directive will, in all probability, be unsuccessful.[25] The risk of cross-contamination is known to manufacturers, and complete avoidance is possible as described above. Alleging that the costs of providing a safer alternative design of the production process are too high is not a convincing argument in this respect. Furthermore, even if it is not possible to discover the existence of contamination of a specific food product on the basis of the scientific and technological knowledge at the time when he put the food product into circulation, in the end, complete avoidance by full segregation is still optional.

A Warning Defect

A Failure to Warn Case

Due to uncertainties with regard to the prevalence of allergens and the threshold doses, a warning statement could be a good safety measure. But does the Directive require

[24] Blood products are an exception to this rule.

[25] See the judgment of the European Court of Justice C-300/95, ECR 1997, p. I-2649 (Commission v UK).

manufacturers to alert the public, particularly allergic consumers, of this risk of cross-contamination in view of its small likelihood?

Within the meaning of a consumer expectation standard, the presentation of the product seems to be of great significance. Referring to this circumstance as a determinant of safety expectations is not without reason. Indeed, the way in which a manufacturer presents a product can strongly influence a consumer's perception of its safety. It is recognized that this factor should be broadly interpreted, suggesting that warnings, instructions for use, advertising, and other information that may influence consumer safety can contribute to the adoption of defectiveness (Howells 1993, p. 37; Miller and Goldberg 2004, p. 371). Safety expectations can be lowered by the presence of product warnings that imply that the product's use involves risks. Furthermore, it might create a false sense of safety when important safety information is missing or misleading. It could follow from this that every risk, irrespective of its size, must be communicated to consumers, as this enables them to adjust their safety expectations. Given that there is a hidden danger and that public knowledge thereof is lacking, one might judge in favour of the allergic consumer and establish defectiveness based on the conclusion that the absence of information on this danger renders the product unsafe. Hence, this also constitutes a flaw in the consumer expectation test. Such a strict application should not be considered appropriate, as other factors need to be considered as well. Those that need to be balanced in the process of determining defectiveness are in essence identical, as in a failure to warn case under liability in negligence (Stoppa 1992, p. 221).[26] In fault liability, it is generally agreed that the greater the likelihood of damage, and the more practicable the measures to guard against it, the more comprehensive is the warning that will be required (Miller and Goldberg 2004, p. 583). The relevant factors must be weighed in order to assess whether the benefits of providing a "may contain" warning are outweighed by its costs.

The Benefits of the Warning

Several factors point to the desirability of providing information about cross-contamination on the label. Firstly, it cannot be concluded from the presentation of the food product that there is a risk of cross-contamination attached to its use, as there is no allergen information on the package. Secondly, a consumer has no knowledge of the potential presence of allergens in the processed product. It should be noted that it is possible that the safety expectations regarding one food product will be different for another. It is not strange to expect that, in the absence of a "may contain" label, there are no sesame seeds or nuts in chewing gum.[27] It may be easier to imagine that a currant bun might be infected with a trace of nut.[28] Nevertheless, in both cases, consumers do not have a clear view of what goes on in the food business. They lack accurate information concerning the diversity of products being made in the factory, the manufacturing conditions, the cleaning procedures, and so on. Furthermore, although consumers are currently being confronted with products that carry advisory statements, they are still not able to assess the risk of cross-contamination of products that have no advisory labelling. Thirdly, allergic consumers

[26] See, e.g., Lenze (2003), pp. 44–45 for a discussion of a judgment of the Austrian Supreme Court, where the approach of the Court towards a warning defect hardly differed from the traditional concept of reasonableness.

[27] A package of Stimorol Fusion gum, bought in The Netherlands, carries the statement that it may contain traces of sesame and nuts.

[28] A bag of currant buns from the Dutch supermarket Albert Heijn contains the statement that the product is made in a factory that also handles nuts.

benefit from this warning statement since they are liable to suffer physical harm as a result of normal use. Allergic consumers can sustain severe adverse reactions, even fatal injuries, from minute amounts of an allergen. A bite of something can prove fatal if the person is not treated quickly and properly. The only remedy for food allergies is avoidance, and clear labelling is a positive step. Moreover, the warning can be an effective means to reduce the risk, as it allows consumers to easily avoid a potential adverse reaction. From a manufacturer's viewpoint, putting a warning statement on a food label can compensate for the inability to adequately assess the risk of cross-contamination. Its use might also reduce the cost of recall measures that would have had to be taken in the absence of a "may contain" statement.

The Costs of the Warning

Cross-contamination can cause serious injuries. However, the group of allergic consumers who experience severe reactions from trace amounts of an allergen appears to be smaller than the majority of allergic consumers. In addition, the probability that a product becomes contaminated in the factory is small. Nevertheless, as explained above, this probability also depends on what steps a manufacturer has taken to reduce the likelihood.

Furthermore, not only are expenses involved in the design of a "may contain" warning, but an obvious consequence of providing such information could be a decrease in profit, as allergic consumers would probably stop buying the product (Viscusi 1990, p. 602).

Additional Costs of the Warning

In addition to the costs described above, other potential disadvantages are associated with the presence of a "may contain" statement. These costs are based more on a general level.

A widespread use of precautionary statements about the risk of cross-contamination can lead to adverse effects for allergic consumers. To begin with, an extensive use of "may contain" labelling leads to a restricted food choice, which in turn could eventually give rise to an unhealthy diet. This continuous attention to avoiding foodstuffs to which consumers are or may be allergic has a negative impact on the quality of life (De Blok et al. 2007, p. 734). In addition, too many "may contain" labels can result in a devaluation of the label itself. Research indicates that there is a group of allergic consumers who disregard these labels. An American survey revealed that consumers with food allergies increasingly ignore advisory statements and consume these potentially dangerous food products. Consumers paid less heed to the warning labels in 2006 than they did in 2003 (Hefle et al. 2007. p. 172). A study undertaken by the British Food Standards Agency likewise reports that some allergic consumers regularly ignore these statements on food packages, thus putting themselves at potential risk (FSA 2002b). Adolescents and young adults in particular exhibit risk-taking behaviour (Miles et al. 2006, p. 796; Sampson et al. 2006). It could also be that such a proliferation of warnings contributes to a warning overload (Geistfeld, 1996, p. 351; Noah 1994, p. 381). Too many "may contain" warnings in the world may result in consumers paying less attention to them (Wogalter and Vigilante 2006, p. 258).

Conclusion

Since the facts of each case are unique, it is difficult to answer unequivocally the question of when is a "may contain" warning needed to make a food product reasonably safe. It might be that in the aftermath of an incident, a civil court decides that the absence of a

"may contain" warning renders the food product defective, given that the harm done to the consumer was severe. It is most likely that only such a claim would be taken to court as opposed to a claim of a consumer who suffered mild reactions. If the harm is serious or fatal, courts usually require considerable precautionary measures, even if the risk itself does not immediately indicate the need to warn. Courts often view the costs of printing a warning as minimal, as a result of which the scales will almost always tip in favour of warning (Owen 2005, p. 568; Rheingold and Feinglass 1996, p. 362).

A difficulty in this respect is that product liability law does not provide courts with a proper answer to the question of when can a relatively small risk be considered sufficiently large to warn about. In fact, the Directive implies the opposite by emphasizing the presentation of the product. As a result, manufacturers might be encouraged to enumerate all the dangers associated with the use or foreseeable misuse of the product, irrespective of the size of the risk (Clark 1989, p. 100; Howells 1993, p. 38). If many manufacturers allow themselves to be carried away in this manner, the use of "may contain" labelling may even result in adverse side effects such as an unnecessary restriction of the food consumption of allergic consumers, as well as a dilution of the content of a "may contain" warning and of product warnings in general (Noah 1994, p. 374). However, courts cannot easily determine and apply such costs to the balancing process. Consequently, they will probably not be treated as additional costs, and the increased safety benefits will outweigh the costs of providing a warning (Geistfeld 1996, p. 335).

It may well be that civil courts also attach value to the existing scientific uncertainty with regard to the actual risk of cross-contamination. Considering the circumstance that the precautionary principle is imbedded in the General Food Law, a court could be convinced that a warning is needed to render the product reasonably safe. Nevertheless, this can be reviewed when firm evidence on threshold doses has been established.

Risk Analysis of Courts

From the above, it follows that claimants will probably allege warning defectiveness, and it appears that courts will render the food product defective as a result of the absence of a "may contain" warning. However, a judge must be careful not to deliver this ruling too eagerly. Even though each case is decided on its merits, the ruling that a food product without a "may contain warning" is defective can give out a misleading signal to manufacturers. Manufacturers might interpret such a decision in such a way that they need to provide a warning as well, in spite of the fact that, on the basis of their circumstances, a warning is legally unnecessary or notwithstanding that there are more effective safety measures available. It promotes an abundance of "may contain" warnings and limits the food choice of allergic consumers. How unfortunate it may be for the individual claimant, denying liability cannot be ruled out.

A court's guiding principle should be to prevent the misuse of "may contain" warnings. "May contain" labels should be used only on the basis of a responsible risk assessment and not in case of very small risks or as a means to cover up a design defect. Where possible, a court should rule in such a way as to create the incentive for manufacturers not to settle for a "may contain" label but to seek for other feasible options to reduce the risk of cross-contamination. Therefore, it is essential that courts evaluate the allergen risk assessment and management system of the defendant. How did the manufacturer assess the probability of cross-contamination? Did the manufacturer do proper tests to find out whether and to what extent the products are contaminated? Did the defendant receive complaints from

customers? Did he take measures into account that could reduce the risk, such as making changes in the production process, the recipe, working procedures and so on? If necessary, an independent expert in the field of allergen risk assessment can be appointed in order to make the balancing process of courts more robust. Such a thorough examination will enable courts to conclude on a case to case basis that, having regard to the trivial risk, consumers were not entitled to expect a warning or that in view of the real risk, consumers were entitled to expect a warning.

The importance of a good risk assessment is reflected in food safety law.[29] Under the HACCP approach, cross-contamination needs to be identified and controlled. When monitoring indicates that the hazard is not under control, corrective action is necessary. There are models on the basis of which this risk can be assessed, for example the probabilistic model (Spanjersberg et al. 2007).

A Non-standard Product

Although in my opinion, it would seem that courts decide this complex liability case on the basis of the use of risk-utility factors within the consumer expectation test, the innovative approach of Burton J. in the English Hepatitis C case also deserves attention.[30] It may well be that this approach will gain more prominence in the near future. In his attempt to create an approach towards defectiveness that serves the purpose of the Directive and differs from fault-based liability, factors of reasonableness are set aside. The test of defectiveness is framed on the basis of a classification of standard and non-standard products. Standard products are products that perform as the manufacturer contends. Non-standard products are different from the standard product because they are deficient or inferior in terms of safety: they have a harmful characteristic that caused the damage.[31] Having characterized a product as non-standard, the next step is whether the public at large accepts the non-standard nature of the product, by taking into account the relevant circumstances. Whether it would have been possible, practicable or costly to avoid the defect is not relevant to consumers' expectations. However, a risk-utility balancing can be applied in the limited circumstance of whether with full information and proper knowledge the public does and ought to accept the risk.[32]

The judge treated the infected blood products as non-standard products because the products contained the harmful characteristic (the virus). He argued that consumers do not have to have knowledge of this risk. As a result, the judge concluded that the blood products infected with hepatitis C were defective since the public at large was entitled to expect that the blood transfused to them would be free from infection.[33] In fact, he imposes

[29] Article 6 of the General Food Law stipulates that food law shall be based on risk analysis. Also in respect of non-food products, thorough risk assessment procedures have drawn the attention of the European Commission. See for example, the Commission's draft revised Risk Assessment Guidelines, which are specifically designed for risk assessors from the Member State market surveillance authorities who are dealing with non-food consumer products within the framework of the General Product Safety Directive 2001/95/EC.

[30] A. & Others v National Blood Authority [2001] 3 ALL ER 289.

[31] Para. 36 and 67.

[32] Para. 68.

[33] A similar decision was made by the Amsterdam District Court 3 February 1999, NJ 1999, 621. The District Court held that the general public is entitled to expect that blood products are 100% HIV-free, particularly since blood products are vitally important and there is no alternative available, as well as the fact that the risk of infection is estimated at one in a million and not of general knowledge.

a form of absolute product liability. This could also be the outcome in the present case in the event that a judge regards a food product that contains a trace amount of allergen as a non-standard product. If consumers do not have to have knowledge of the risk of cross-contamination, then they are entitled to expect that food products are 100% allergen-free, without taking into account the enormous costs of avoiding the risk or the unresolved scientific questions. Such a judgement would certainly break with the current approach of using risk-utility factors to determine consumer expectations. While under the latter approach, a court might sympathize with the defendant and not require full segregation of the production process of products without an allergenic ingredient, Burton J's approach might require just that.

A more suitable distinction is to view the absence of a may-contain warning as the harmful characteristic. Then, the focus will be on the question of whether consumers ought to accept the risk of cross-contamination. Warning the public of the risk of cross-contamination would make the risk known and, as a result, probably acceptable to society as well. The Directive emphasizes the relevance of product information. In addition, providing accurate information to consumers is also high on the consumer policy agenda of the European Commission, as it empowers consumers to make informed choices.[34] On the other hand, it remains unclear if and how Burton J. would consider the potential unintended consequences of providing risk information, such as consumers' information processing abilities in general, the restriction of the food choice of allergic consumers, and the evidence that people increasingly ignore these statements. Would such factors make the risk unacceptable? It is expected that the answer will be in the negative, too, under Burton's method. The benefits of the information including its value under European consumer law will probably outweigh the costs.

The Adequacy of an Allergen Cross-Contamination Warning

An Informed Choice Warning

The liability question is also interesting in cases where products have in fact been provided with a warning that indicates the possible inadvertent presence of an allergen. It is generally agreed that a product can be considered defective under the Directive as a result of the presence of an inadequate warning. However, neither the text of the Directive nor a decision of the European Court of Justice clarifies what governs an adequate product warning. Nevertheless, fault liability with regard to the duty to warn adequately can offer some guidelines. It is suggested that the adequacy depends on whether the warning allows a consumer to adequately identify, assess, and consequently avoid or reduce the risk (Hodges 1993, pp. 108, 109; Miller and Goldberg 2004, p. 463). To achieve this, not only the content of a warning but also its form must be designed in such a way that it allows consumers to avoid the risk. In this case, it is important that the warning with regard to the risk of cross-contamination is sufficiently prominent for allergic users to notice on the label, that it is legible, and that consumers understand the risk accurately in order to use the product safely.

[34] Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee. EU Consumer Policy Strategy 2007–2013 (COM(2007) 99 final).

Warnings against the risk of cross-contamination differ from ones you will find in the instructions for use of household appliances. Instead of explaining how to use the product safely, they are such that they instruct allergic consumers not to use the product. The third American Restatement sets forth a definition of informed choice warnings that can be applied to the case at hand. Informed choice warnings are those that allow the consumer to avoid the particular risk by making an informed choice decision not to purchase or to use the product at all.[35] This new comment states that a warning may be needed not only to reduce the risk of harm but also to inform consumers of non-obvious and not generally known risks that unavoidably inhere in using or consuming the product (Henderson and Twerski 2000, pp. 15, 16). It follows that allergic consumers want this information so that they can decide on the basis of a risk assessment whether to purchase and hence consume the product. Although, ultimately, a "may contain" warning serves the goal of accident reduction, it can be said that here the emphasis is mainly placed on providing accurate information about the risk of cross-contamination to potential buyers who are allergic.

Form of the Warning

Naturally the form of a warning (i.e., its design) must be conspicuous and legible. Factors that attract the attention of consumers are the positioning of the warning on the product label, the size of the text, and the colours used. Its legibility largely depends on whether the wording is easy to read as the result of a large letter size together with the contrast of the wording against the background of the label.

The European labelling legislation on foodstuffs and allergens stipulates that the information must be easy to understand and in a conspicuous place.[36] The regulations do not set any specific requirements on how the information should be presented. Manufacturers thus have the freedom to determine the location of the warning and the font size of the wording as well as other design factors. Most space on the label is usually set aside for marketing information. As a result and due to limited space, only a small area is left for information about the ingredients and the allergens. Even in cases were the package is larger, it still takes time to find the information.

Several studies indicate that food labels do not meet the needs of allergic consumers. The results of British consumer research show that allergic consumers are dissatisfied with the presentation of food labels, as the allergen risk information is often hard to find and difficult to read. For example, it reported the finding that only 2.6% of the food packaging was dedicated to ingredient information and an average of 0.53% to allergen information (FSA 2002a, p. 13). Other recent European studies also highlighted the problems of allergic consumers with regard to the readability and visibility of the food label. Many comments were made about the large amount of information on a package, the small font size of the information, the poor colour contrast of the label, and the shiny packing material, all of which made reading difficult (Cornelisse-Vermaat et al. 2007; Van Hengel 2007). In addition, consumers complained about the absence of a standard approach for the labelling of cross-contamination warnings (FSA 2002b, p. 42).

The British guidance document on allergen risk management and communication advises manufacturers on how to provide allergen cross-contamination information to consumers (FSA 2006, p. 27). It recommends putting the "may contain" warning close to the ingredients list. Nevertheless, it must be clear to the consumer that there is a distinction

[35] Restatement (Third) Torts: Product Liability Section 2 (c), comment i.

[36] Article 13(2) of Directive 2000/13/EC.

between mandatory information on the intended ingredients and information on potential ingredients as a result of cross-contamination. This information can be listed in boxes or panels. Moreover, allergic consumers preferred the allergen information to be placed above the ingredients list, if possible with a symbol to make the warning more prominent (Cornelisse-Vermaat et al. 2007, p. 117; FSA 2002b, p. 65). More labelling guidelines, set up by scientific experts, for example, are readily accessible by food manufacturers. Nevertheless, it is doubtful whether the labelling requirements are implemented properly in practice. It is possible that food manufacturers are not willing to spend more money and effort on the design of an adequate food label that takes into account the information needs of consumers. This can change. A new proposal for a regulation with regard to food information to consumers lays down several labelling requirements to improve the legibility of mandatory food information, for example a minimum print size.[37] Even though these obligations pertain to mandatory and not voluntary label information, such as the risk of cross-contamination, a judge can use these as a guiding principle when assessing the label's legibility.

Content of the Warning

As regards the content of a warning, comprehension is an important indication of adequacy. The meaning of the warning message must be understandable to consumers, and it must allow them to assess whether the risk will affect them (Howells 2005a,b, p. 161). Hence, if a consumer cannot accurately appreciate the risk on the basis of the information given, it will be difficult to make an informed decision to buy and consume the product.

Factors that may influence the comprehension of a warning are the language in which the risk is described and the explicitness of the information. A study reported that allergic consumers have difficulty with unfamiliar terms or scientific jargon used to describe allergens (Cornelisse-Vermaat et al. 2007, p. 117; Joshi et al. 2002, p. 1020). For example, the word "milk protein" is preferable to the term "whey powder" or "casein" (Crevel 2002, p. 943). Additionally, the use of the word "nuts" in a "may contain" statement can be unclear to consumers, as it does not state which particular type of nut is involved. It may not always be the case that several sorts of nuts and peanuts are used in a factory. Given that it is known that some people are only allergic to specific tree nuts like hazelnut, walnut, or almond, such labelling is confusing (FSA 2006, p. 29).

With respect to explicitness, the risk of cross-contamination may be misunderstood because of the vague phrasing of the warning. It appears that allergic consumers are uncertain as to what "may contain" statements mean for a person with an allergy (FSA 2002b, p. 5; Van Hengel 2007, p. 99). Indeed, the real risk of cross-contamination cannot be concluded easily from the information provided. Is the probability that contamination took place remote? And does it tell a consumer anything about the amount of the undesired allergen present in the food product? Furthermore, various forms of labels are in circulation to warn allergic consumers of cross-contamination. Not only statements such as "this product may contain allergen X" or "this product may contain traces of allergen X" exist but also "produced in a factory that also handles allergen X" or "made in a production area that also uses allergen X" (FSA 2002a, p. 59). This variety of explanations can be confusing to allergic consumers in the sense that it is unclear to what extent they pose different levels of risks. An American survey demonstrated that the format of a statement

[37] Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers (COM(2008) 40 final).

can influence consumers' risk perception: 75% of the respondents said that they would not purchase a product with a "may contain" statement. This is in contrast to 64% of the respondents who reported not purchasing products with statements such as "manufactured in a facility that also processes or uses allergen X" (Hefle et al. 2007, p. 174).

Changes to the content of cross-contamination warnings have been suggested by allergic consumers. Some preferred the inclusion of more meaningful information to enable them to make their own informed choice with confidence, such as the inclusion of the probability of contamination. Others wanted clear negative statements, such as "not suitable for nut allergy sufferers" or positive statements, such as "the product is nut free" (FSA 2002b, pp. 67–70). One idea could be to apply a grading system using phrases such as "not suitable for individuals highly sensitive to allergen X."

Hence, a disadvantage of a cross-contamination warning is that the statement does not specify the risk. The only way to avoid it would be to stay clear of the particular food product with a "may contain" statement. As a consequence, it may be questioned whether the allergic consumer is actually capable of an informed choice.

Conclusion

In view of the above, it follows that several points for improvement are applicable to food labels in general. Neither the form nor the content of "may contain" labels satisfy the information needs of the majority of allergic consumers. Even so, the question remains as to whether the informed choice warning is considered defective under the Directive. Paragraph 2 of article 6 stipulates that a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation. Equally, this assumes that the Directive does not require a product warning to be designed in the best way possible (Howells 2005a,b, p. 146).[38]

It is possible that a court is displeased with the way in which the "may contain" statement is presented. However, it must be noted that the small magnitude of the risk does not support the expression "the bigger the better." Furthermore, consumers have indicated that they want more detailed information about cross-contamination. A grading system to express the risk's diversity could enhance consumers' risk perception. Nevertheless, a food manufacturer has few available alternatives, since risk assessment is hindered by scientific uncertainty. Thus, it appears that a "may contain" warning would not be deemed inadequate under the Directive, despite the information needs of allergic consumers.[39]

Perhaps, the approach of Burton J. allows a judge to establish product defectiveness more easily because of the view that warnings should not be used to waive or limit liability.[40] Article 12 of the Directive implies such a notion by stating that limitations or exclusions of liability are prohibited (Howells 2005a,b, p. 146). For the rest, it remains ambivalent how one must consider the adequacy of product warnings under this approach. To determine whether the product accompanied with a warning imposes an acceptable level of risk, use of negligence factors is permitted by Burton J. This reintroduces risk-utility factors

[38] This is reflected in the English case Worsley v Tambrands Ltd., High Court [2000] PIQR P95. The judge decided that the warning of toxic shock syndrome on a tampon box was sufficient even though the warning could have been improved by design alterations.

[39] The studies on consumers' information needs indicate the actual expectations of consumers, which may be too high. It must be borne in mind that the consumer expectation test addresses the legitimate safety expectations.

[40] A. & Others v National Blood Authority [2001] 3 ALL ER 289, para. 65.

into the consumer expectation test as shown earlier. Consequently, both methods may lead to a similar conclusion. Yet, imposing liability due to the use of the may contain warning as a waiver would seem more in line with the spirit of a liability system without fault.

Summary

The liability aspects of the use of the labelling of allergen cross-contamination were discussed in the previous sections. This type of precautionary labelling is provided on a voluntary basis. The EU labelling requirements only apply to foodstuffs that intentionally contain allergenic ingredients. The prevalence of food allergies in the general population has been roughly estimated to be around 3% in adults and up to 8% in children. Thus, it appears that a food allergy can affect the lives of a considerable number of people in Europe, with effects ranging from very mild to potentially fatal. From this, it follows logically that their safety interests have been acknowledged in European food law.

Two central questions have been answered. Firstly, it is discussed whether a food product can be deemed as defective under the Directive in the event that a warning of the risk of cross-contamination is absent and an allergic consumer has suffered injuries as a result of the unintentional presence of an allergen. This liability question is approached within the scope of a defect in design and a warning defect, since food manufacturers are able to reduce the risk of cross-contamination by means of redesigning the production process or by providing a warning statement. Thus, risk-utility factors have been taken into account to assess whether the product failed to meet consumers' expectations. With regard to the existence of a design defect, there are safer alternatives available for manufacturers to reduce the risk. One would be the creation of an allergen-free environment with production lines that are only used to produce products that have no allergenic ingredients. However, this implies an absolute level of safety, the costs of which will outweigh the benefits. Pursuant to Burton J's approach to defectiveness, it may well be that requiring full segregation is the only correct decision. What relative level of safety must be achieved in the production process is uncertain, as there is a lack of scientific evidence concerning the minimum amounts of allergens needed to trigger adverse reactions in sensitive individuals. Consequently, it is difficult for the industry and the government to draw firm conclusions. Only after such thresholds can be determined if it is possible for food businesses to adjust their allergen management to these levels and thus create an acceptable level of food safety for the vast majority. Nevertheless, this uncertainty does not mean that it is permissible for producers to sit still and await further developments. There are tools available to help producers cope with these problems, and safety measures such as cleaning procedures or changes in the production lines can reduce the risk.

As for this scientific uncertainty, producers and courts may currently consider a warning to be an adequate safety measure even in cases where the risk is small. It is certainly possible that a judge considers a food product defective where the risk of cross-contamination has not been declared on the food label. The essential key elements for a judge would probably consist of the circumstance that there is a hidden danger and that it can cause severe injuries. Providing allergic consumers with information about the risk will enable them to appreciate the risk and consequently behave accordingly. In addition, courts probably assess the costs of making a product warning low. However, this may be the wrong solution in view of the potential unintended effects of the use of such warnings. "May contain" labels do not only restrict the food choices of allergic consumers but can also lead to warning ineffectiveness when many food manufacturers provide them

extensively and when consumers start to disregard them. Therefore, judges ought to be cautious in establishing a warning defect. It is suggested that courts should take on the mantle of a risk assessor and ascertain whether the risk assessment carried out by the defendant is appropriate. Design defectiveness due to failure in implementing feasible changes in the production process is preferred to the ruling that a warning renders the product reasonably safe. In addition, a court should not be unaware of the possibility to deny liability in case of a very small risk, albeit the unfortunate victim.

The second liability question concerned the adequacy of "may contain" warnings. Consumer studies showed that these fail to meet the information needs and information processing abilities of consumers. Often they do not present the information in a visible and legible manner. Furthermore, the statement can be considered vague and not appropriate for consumers to assess the risk accurately. Small improvements of the label can be devised. However, scientific uncertainty surrounding food allergies hinders a detailed prescription of the risk on the food label. Notwithstanding the shortcomings of "may contain" statements in general, courts will be reluctant to accept liability on the basis of an inadequate warning, since it is difficult to provide an improved alternative.

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