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Observations: This allergies hysteria is just nuts (*BMJ* 2008;337:a2880)

Advisory food labels: consumers with allergies need more than "traces" of information

Vague warnings of possible allergen contamination of food are often unhelpful and may contribute to unintentional exposure. **Paul Turner**, **Andrew Kemp**, and **Dianne Campbell** call for a standardised approach

Immunoglobulin E mediated food allergy is increasing, affecting up to 2% of adults and 8% of children in the United Kingdom.[1] The mainstay of management remains avoiding the implicated allergen, which requires accurate labelling on packaged foods. A bewildering array of warning labels can be found on food products (opposite), leaving consumers confused and anxious. Leading consumer associations and health professionals have raised concerns over widespread use of such advisory labels. Are these products safe to eat for someone who is at risk of a life threatening anaphylactic reaction? What does the consumer understand by such warnings, and are they useful in preventing food reactions?

Consumers' perspective

Advisory labels are helpful if they provide reliable information on the allergen content. However, manufacturers widely use them as a "safety net" to convey an unspecified risk of possible contamination. An audit by the UK Anaphylaxis Campaign found that 69% of cereals and 56% of confectionery items were labelled as containing traces of nuts, despite none listing peanut or tree nuts as an ingredient.[2]

Allergen labelling causes considerable anxiety to people with allergies and their carers.[2-4] The format of labels varies considerably, and it is not uncommon for consumers to miss allergy warnings.[2] The use of different expressions on advisory statements is confusing[2 5] and may contribute to the increasing trend for consumers to ignore them altogether.[6 7] A UK based survey found that 60% of parents of children with nut allergies avoided products labelled "may contain traces," but only 40% did so when the statement was more vague—for example, "made in a factory that uses nuts."[8] Similar findings have been reported elsewhere,[9] suggesting that the more ambiguous the warning, the less likely consumers are to heed the content. However, there is no correlation between the wording and the risk of cross-contamination.[7 10 11] Thus, widespread use of poorly defined advisory labelling might paradoxically lead to increased risk taking.

Table 1 | Prevalence of allergen cross-contamination in prepacked food (assessed as detectable amounts of allergen not declared as an ingredient

Study and allergen	% (No) of foods with advisory warning	% (No) of foods with no advisory warning
US (2007)[7]:		
Peanut	7 (13/179)	Not assessed
Europe (2010)[10]:		
Peanut	33 (109/333)	25 (52/211)
Hazelnut	60 (175/291)	31 (64/209)
US (2010)[14]:		
Peanut	4 (5/112)	0 (0/120)
Egg	2 (1/57)	3 (3/117)
Cows' milk	10 (6/59)	3 (4/134)
US (2010)[11]:		
Cows' milk	42 (34/81)	Not assessed

Do ambiguous labels contribute to the occurrence of allergic reactions? Published case series suggest that many food allergy reactions (including most deaths) happen outside the home after exposure to non-prepacked foods such as those sold in catering establishments, which are currently exempt from allergen labelling legislation.[12] However, few well controlled studies have investigated this. A Canadian study found that labelling remains an important factor in unintentional exposure, with 47% of 651 allergic people attributing their reaction to a labelling related issue.[4] In 29% of cases, the reaction was due to not reading the label correctly, while 8.3% were attributed to ignoring a precautionary statement.

Manufacturers' perspective

Under European directive 2006/142/EC, it is a legal requirement to list any of 14 allergens or ingredients (cereals containing gluten (wheat, rye, barley, oats, spelt, kamut), crustaceans, egg, fish, peanuts, milk, tree nuts, soy, sesame, celery, mustard, lupin, molluscs, and sulphur dioxide or sulphites) present in prepacked foods. Advisory statements, in contrast to ingredient listing, are voluntary, a fact not widely appreciated.[1 12]

Legislation does not extend to the problem of unintentional cross-contamination during production. Nevertheless, manufacturers may be held liable for cross-contamination under both UK criminal and civil law on the basis that a product unintentionally contaminated with an allergen may be considered defective.[1] Whether the presence of an advisory warning lessens the legal risk is unclear. The UK Food Standards Authority has produced a comprehensive guide to best practice that recommends a non-quantitative approach to determining whether there is a possibility of cross-contamination and, if so, providing an advisory warning. Although uniform wording of advisory warnings is recommended, the guidelines are voluntary and have done little to reduce the prevalence and variety of advisory labels currently used.[13]

Unintentional cross-contamination is an important problem during food manufacture. Table 1 summarises the results of studies assessing the prevalence of undeclared allergens in prepacked foods since the introduction of more stringent legislation in Europe and the US that mandated full ingredient listing for common allergens, even when present in small quantities. Most foods with an advisory warning do not contain detectable allergen when the allergen is not in the ingredients. For many items, the prevalence of contamination and, where present, the amount of allergen detected are similar, irrespective of the presence or absence of a warning label.[10]

Cross-contamination can be greatly reduced with specialised cleaning, but this may not be commercially feasible.[15] Contamination of dark chocolate with milk is a particular problem, with one study reporting over 75% of brands (not

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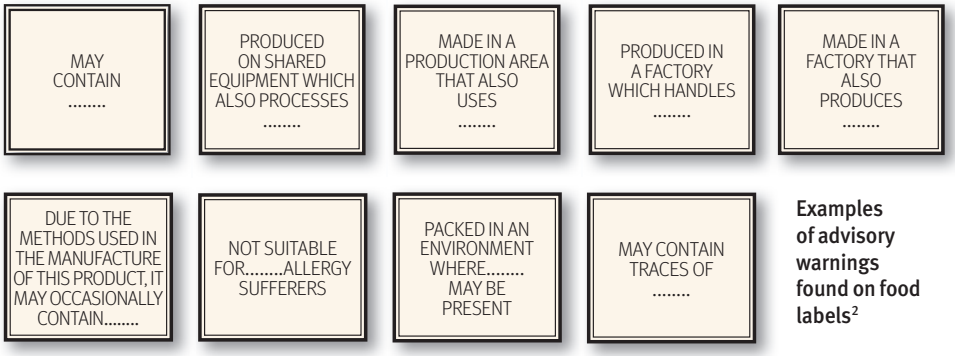

Examples of advisory warnings found on food labels[2]

listing cows' milk as an ingredient) containing cows' milk protein on analysis.[11] One UK producer began to list milk powder in the ingredients of its dark chocolate despite this not being used as a raw ingredient,[16] although it has now stopped this, suggesting a change in policy. There are also anecdotal reports of some producers intentionally adding small amounts of allergen to foods where cross-contamination may be a risk, so that they can list the allergen as an ingredient and thus avoid the need to address the issue altogether (Food Standards Agency, personal communication).

Alternatives to the status quo

Attempts to standardise the content of advisory labels using voluntary guidance have not been successful. Almost two thirds of enforcement officers and food manufacturers think that the current voluntary UK guidance should become compulsory.[1]

The listing of all potential allergens as an ingredient when cross-contamination is likely might reduce ambiguity but would further restrict consumer choice. The best solution would be to quantify the hazard—that is, whether the degree of contamination is sufficient to trigger an allergic reaction—and communicate this clearly to the consumer. However, obtaining robust data on allergen thresholds has proved difficult. The minimum eliciting dose varies widely between individuals, and there will always be a few highly sensitised individuals who react to minute amounts of allergen. Furthermore, the threshold can vary by several orders of magnitude within the same person, depending on various factors. These include:

Processing and denaturation of the allergen—Many people who are allergic to egg or milk tolerate the allergen in products that have been baked at high temperature for long periods such as cakes or biscuits.[17] The processing probably changes the structure of the allergen, making it less allergenic.

Derived ingredients—Immunoglobulin E mediated food allergy reactions are caused by proteins, and thus products such as wheat derived glucose syrup (a carbohydrate) do not require allergen disclosure under current legislation. However, legislation regarding disclosure of derived ingredients is inconsistent. Soy derived lecithin (a lipid) and refined soy oil generally contain similar (low) amounts of soy protein, and most people with soy allergy can tolerate these ingredients.[18] Regulatory authorities require products made with soy lecithin to be labelled as containing soy, but not those containing refined soy oil.[1]

Food matrix—Chemical and physical interactions between allergenic proteins and other proteins, fats, and carbohydrates within the molecular structure of the food (known as the food matrix) alter the ability of an allergen to induce an allergic response. The mechanism for such interactions is complex and poorly understood.[17]

Individual factors—The levels of allergen required to trigger an allergic response in a person can vary significantly from day to day. This variation is probably the result of viral illnesses and the status of the lower airways in patients with asthma.[19]

Thus, a true safe threshold for any one food and person is impossible to determine. However, the aim of quantitative risk assessment is to reduce the risk of harm from cross-contamination to a level considered tolerable, rather than to eliminate the risk altogether.[13] Researchers have therefore developed the concept of the lowest observed adverse effect level (LOAEL), a threshold below which most people will not react. Only a few studies have been published assessing LOAELs for the more common food allergens by double blind, placebo controlled food challenges.[19] One concern is that highly allergic people may have been excluded from these studies. The Food Standards Agency stated in 2007 that "there is a lack of scientific and clinical evidence on which to base firm conclusions regarding the minimum amounts of some allergens needed to trigger adverse reactions in sensitive individuals."[1] Nonetheless, for many common food allergens, there is a high degree of agreement between published LOAELs. Further data are expected from high quality double-blind placebo-controlled studies, particularly the Euro-PREVALL collaboration, in the next 12 months.[13 19]

Vital information

Australia and New Zealand have already started to use LOAEL data to improve labelling. In 2007, the food manufacturing industry, with the input of consumer groups and regulatory authorities, developed a standardised risk assessment tool called voluntary incidental trace allergen labelling (VITAL).[20] This allows manufacturers to assess potential cross-contamination quantitatively and determine the need for advisory warnings. Threshold levels were based on published LOAEL data with a 10-fold safety factor (this derives from toxicology, where a 10-fold uncertainty factor is typically applied to account for intraspecies variation within a population, although this has not been validated for allergic responses). When the amount of allergen present is above the threshold level (but not at sufficient amounts to be listed as an ingredient), manufacturers use an advisory statement with the format "may be present." No advisory warning is recommended if levels are lower than this cut-off. Although some very sensitive people might react to levels of allergen below the cut-off, these people are in general more likely to avoid potentially problematic foods. The scheme means that advisory warnings are used only when warranted and that the warnings are standardised, so providing clear and simple information to consumers.

Table 2 | Proportion of foods labelled with an advisory warning that contain any detectable allergen or levels above VITAL thresholds[20] when allergen is not declared as an ingredient

	% (No) of confectionery items		% (No) of other foods	
Study and allergen	Any allergen	>VITAL	Any allergen	>VITAL
US (2007)[7]:				
Peanut	11 (13/115)	8 (9/115)	0 (0/64)	0 (0/64)
Europe (2010)[10]:				
Peanut	33 (109/333)	23 (78/333)	Not assessed	
Hazelnut	60 (175/291)	52 (152/291	Not assessed	
US (2010)[14]:				
Peanut	6 (5/86)	1 (1/86)	0 (0/26)	0 (0/26)
Egg	5 (1/21)	0 (0/21)	0 (0/36)	0 (0/36)
Cows' milk	19 (6/32)	13 (4/32)	7 (2/27)	0 (0/27)
US (2010)[11]:				
Cows' milk	43 (19/44)	34 (15/44)	41 (15/37)	22 (8/37)

VITAL=voluntary incidental trace allergen labelling.

NB: Differences in prevalence between studies is thought to be due to differences in the type and variety of foods assessed.

Studies from Europe and the US assessing cross-contamination have found that most foods with advisory warnings for allergens not listed as an ingredient do not contain allergen levels above VITAL thresholds (table 2). Cross-contamination is more common in confectionery. Nevertheless, in one European study, only 23% of 333 items labelled "may contain traces of peanut" had sufficient protein to cause a reaction.[10] The other 255 items were safe for the vast majority of people with peanut allergy.[10] In another study, 57 items were labelled "may contain egg," but only one actually did so, in an amount less than the VITAL threshold.[14] Thus adoption of the VITAL scheme in Europe would mean that most products with advisory labels would no longer require them.

Although the VITAL scheme is voluntary in Australia, there has been considerable interest from manufacturers, perhaps because of pressure from major food retailers for producers to participate in the scheme. Efforts are currently under way to introduce a similar scheme in Europe (www.EU-VITAL.org), although this is unlikely to be implemented soon. In the UK, the Food and Drink Federation (which represents over one third of UK food and drink producers) has embraced the VITAL concept and recently stated: "We firmly believe that industry risk management practices are sufficiently capable to deliver this vision to the highest standards."[13]

Food labels need to convey as accurate information as possible; over-stringent measures reduce food choice, increase anxiety, and affect quality of life. With the exception of confectionery, most foods with advisory labels for allergens undeclared in the ingredients do not contain sufficient amounts to trigger an allergic reaction (table 2). We believe that there are adequate data for the introduction of a VITAL-type system now without compromising consumer safety. The current situation does not benefit producers, consumers, or health practitioners, who have to provide safe and accurate advice to patients with food allergies.

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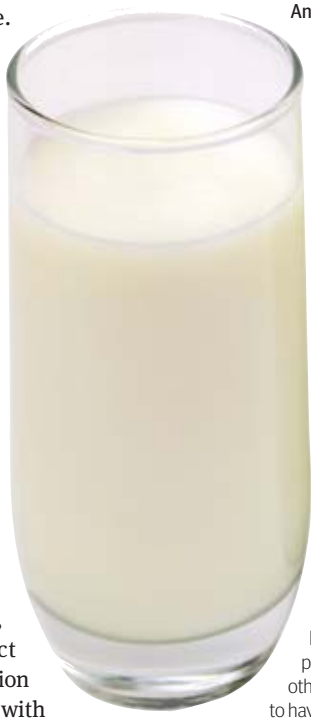

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