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Precautionary Allergy Labelling: NO MORE TRACES!

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Dietary avoidance of allergens is crucial in the management of food allergy. Food allergic individuals (and those who prepare their food) rely on the disclosure of allergens as ingredients. Under the EU Food Information for Consumers (EC Regulation No. 1169/2011), food producers are required to disclose the presence of any of 14 allergens as ingredients, whether pre-packed or not (e.g. from restaurants and other catering outlets).

However, legislation does not extend to the possibility of food allergens present from cross-contamination or cross-contact in the supply chain or due to shared production facilities. In consequence, many food producers use precautionary allergen labelling (PAL) to alert consumers to the possible unintended presence of allergens (1). The figures speak for themselves. Up to half of pre-packed foods sold in supermarkets in the UK, USA, and Australia have a “may contain” or precautionary allergen label (PAL) (2-4). The use of PAL is voluntary and unregulated; this results in different practices by individual manufacturers and food outlets, with a plethora of labelling formats

which both consumers and the healthcare professionals advising them find to be vague, confusing and inconsistent (1,5,6).

In this issue of *Allergy*, Marchisotto et al report the results of a patient survey on attitudes to PAL conducted across 16 countries (7). Almost 10,000 consumers completed the survey, and while 58% of respondents were resident in the USA, the authors attempted to control for this in their analysis.

The majority of consumers reported that they would be more likely to purchase products labelled “may contain ‘traces’ of...” compared to those products labelled “may contain allergen X”. There was significant country-to-country variation: overall, 25% would purchase “traces” while 16% would purchase an item with a “may contain X” label. However, in some countries (most notably Australia, France, Germany, New Zealand and Netherlands), well over 50% of consumers would purchase products labelled “traces” – double that for PAL where the wording was more explicit e.g. “may contain X”. Even more would purchase an item where the PAL indicated “manufactured in a facility that also processes X”. These data are not novel, having been previously reported in prior surveys conducted in the UK (8) and Australia (9). Consumers associate less explicit, more “wordy” PAL as implying a lower risk. However, this is not supported by the available evidence: food products with phrases such as “manufactured in a facility that also processes X” often have the same or even a higher rate of unintended allergen presence compared to products with more explicit phraseology (e.g. “may contain...”) (10). Thus, PAL may – paradoxically – lead to increased risk-taking, with fewer allergic consumers avoiding products with less explicit PAL phrases.

Concerningly, the results of the survey by Marchisotto et al indicate a significant inconsistency. Consumers were also asked if they would purchase a product that actually contains the allergen, even if the company could guarantee (presumably on the basis of testing and with the support of national regulation) that no reaction would occur (whether this is a realistic scenario, given the limitations in allergen detection and inconsistent distribution (“particulate contamination”) of allergen within most food products, is debatable). Nonetheless, far more consumers would purchase a food item with a PAL (where there is an unclear risk of reaction) than an item where the allergen is present but not in sufficient quantities to cause a reaction. One could argue that this might be due to a lack of trust over labelling – however, apparently more consumers ‘trust’ a PAL which has no regulatory basis, than an ingredient label which does.

The survey has a number of limitations which are discussed by the authors. These include the fact that respondents were in contact with patient support groups which tend attract allergic consumers with higher levels of education and who perceive their (or their child’s) allergy to be more severe. Indeed, in this survey, this perception might have been reinforced by the survey itself; the authors defined a severe allergic reaction as including symptoms which might include tongue/ facial angioedema, something generally considered to be symptomatic of a non-severe reaction by most accepted working definitions (11).

However, this incongruity – where consumers apparently ‘trust’ PAL more than a declaration of risk dependent on actual allergen presence – must be taken seriously by all stakeholders (including the healthcare sector, government regulators and food industry) who are currently working towards improving the scientific basis of PAL. There is increasing interest in a VITAL-type system, where food producers conduct a risk assessment to help guide the need for PAL (12). However, a fundamental principle of VITAL and similar schemes is that no food can be guaranteed to be 100% safe (13). While

this has been acknowledged by many stakeholders, one has to wonder whether a typical allergic individual (or a person preparing their food) would consider this to be acceptable. Allergic consumers need to have trust in the information provided to them, yet clearly this is not currently the case. Trust is based on factors beyond the information on the label (14).

To improve the current situation, any allergen information (including PAL) on packaging must be clear, legible and easy to find. If PAL must be used, then providing this information under a flap, in tiny text, in poor colour contrast or on a shiny surface is unhelpful (3). The introduction of a consistent format for PAL within different languages is essential – important given that food production is becoming increasingly global (15). Such a view was shared by 89% of Australasian and UK healthcare professionals in a recent survey (16), and some food manufacturers are beginning to embrace this too. A case may be made for using a “may contain X” format, purely because with fewer words, the text may be more legible.

In particular, the concept of “traces” needs to be abandoned. PAL with the format “may contain traces” is the most common phrase used in Australia (4) and the UK (17), and also the PAL phrase more likely to be ignored by consumers (7-9). A “trace” is defined as “a very small quantity, especially one too small to be accurately measured”. Whilst the word “trace” has been used in an analytical context for many decades (indicating a barely observable and unquantifiable presence), the amounts of allergen which can cause allergic reactions in at least 1% of the allergic population do not meet these criteria (18) as depicted in Figure 1, and are therefore more than a trace!

The concept of “traces” in PAL is counter-productive: either allergic consumers consider themselves to be less allergic (or better, react to a higher threshold than that in a “trace”) and so ignore PAL, or consider themselves to be so allergic that “even a trace” could cause a potentially life-threatening allergic reaction. The reality is that fatal allergic reactions occur following exposure to significant quantities of allergen exposure, and not “traces” (19). Both extremes are unhelpful, reducing self-efficacy and confidence in managing an appropriate level of dietary avoidance (6). The potential for allergen cross-contamination is not uniform across a food production line; where allergen risk management fails, this may result in significant levels of unintended allergen presence. Consumers may perceive their own food allergy as more mild if they have previously tolerated “traces”, resulting in an allergy-equivalent of Russian roulette, where consumers continue to consume the product as a result of unintended risky behaviour.

“Traces” has, in effect, become a code word to imply erratic occasional presence, but the term fails to indicate the possibility of significant amounts e.g. gross contamination by pieces of nut or whole seeds in otherwise homogeneous foods. This is particularly an issue for non-prepacked foods sold from catering outlets such as restaurants, delicatessens and take-aways: these now fall under the remit of the new EU Regulations in terms of actual allergens as ingredients, but an unintended consequence has been the proliferation of PAL on these food items too, something which is again outside the remit of the legislation. The risk of allergen contamination in catered foods is particularly concerning: most fatal food-allergic reactions occur through exposure to foods supplied by catering outlets, and not to pre-packed foods (19).

The concept of “traces” is a misrepresentation; the term is unhelpful, and counter-productive to safe and appropriate allergen risk management. The survey by Marchisotto et al indicates there is a long way to go. Scrapping “traces” would be a good start.

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FIGURE LEGEND

Figure 1: Not a “trace”: Visual representation of the ED05 and ED01 (the eliciting dose needed to trigger an allergic reaction for 5% and 1% of the allergic population, respectively) for five common allergens. Data from (18).

