Quantitative risk assessment of food products cross-contaminated with allergens

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Background

Allergens in food pose a risk to allergic consumers, particularly if they are present in food without declaration or warning. The current regulatory framework within the European Union mandates the declaration of 14 allergens which are deliberately added as ingredients however, it does not cover the unintentional cross-contamination with allergens or resultant use of advisory labelling. Food manufacturers often use advisory labelling such as "may contain X allergen" to inform allergic consumers of the potential risk of cross-contamination in a food product. Whilst there is some voluntary guidance which includes qualitative advice for industry on how to assess and manage risk from allergenic foods (published by the FSA in 2006 and in 2013 by Food Drink Europe), there is currently no quantitative advice from regulatory bodies on the levels of allergen cross-contamination above which advisory labelling should be used.

Probabilistic modelling is considered to be the most promising approach for use in quantitative risk assessment. It estimates the risk of any allergic reaction following consumption of a food product that contains an allergen due to (unintended) cross-contamination. Several input variables are required to undertake food allergy risk assessments these include: -

- the consumption of the food at an individual meal/eating occasion and
- the concentration of the allergen in the food (i.e. whether the food contains the allergen and in which concentration).

These input variables together determine the exposure to the allergen. Additionally, data on the distribution of minimum eliciting doses (i.e. threshold distribution) is also required. By combining the threshold distribution and the exposure distribution, the probability of an allergic reaction is determined

The Australian Allergen Bureau's Voluntary Incidental Trace Allergen Labelling (VITAL) programme has produced a quantitative guideline based on probabilistic principles. It is hoped that this guideline will support food producers in assessing the impact of allergen cross-contamination in a food manufacturing environment. The guideline has been positively reviewed by the International Life Sciences Institute's (ILSI) European Food Allergy Task Force however; it is yet to be accepted by regulatory bodies such as the European Food Safety Authority (EFSA).

Research Approach

The purpose of this research was to quantitatively assess the public health risks posed by the levels of peanut, hazelnut, milk and wheat cross-contamination detected in UK retail products sampled and tested as part of the FSA funded survey of allergen advisory labelling. This work was done using probabilistic risk assessment techniques. The inputs for the probabilistic risk assessment will be based on UK food consumption data, and the combined food allergic threshold datasets developed by the Contractors. Furthermore, the allergen cross-contamination data will be based on the [FSA's survey of allergen advisory labelling and allergen content of UK retail pre-packed foods](#).

The levels of peanut, hazelnut, milk and wheat cross-contamination in UK retail foods sampled as part of the FSA survey were compared to the action levels proposed by the VITAL programme. This was done by setting a product-specific action level for samples that tested positive.

The results of this project can be used to develop risk based, proportionate action levels. Specifically, the results will help the FSA to:-

- quantitatively assess the public health risks posed by the levels of allergen cross-contamination found to be present in foods sold on the UK retail market (as identified by the FSA survey) to which UK food allergic consumers are currently being exposed.
- give an indication as to whether the proposed levels developed by the VITAL programme are practical in relation to the actual levels of cross-contamination detected in the FSA survey samples. Such information will help the FSA to determine whether the levels UK food allergic consumers would be exposed to if such actions levels were implemented, are comparable to the levels currently being used for allergen control by industry (as identified by the FSA survey) and whether these action levels are likely to be achievable by industry.

Results

The project fed into the FS241038 Survey of allergen labelling and allergen content of processed foods. The snapshot nature of this survey and sampling methodology means that it may not be representative of the entire UK retail market; it is therefore difficult to extrapolate findings to the UK retail market as a whole. The main findings from the FS241038 Survey were:

For food products with and without advisory labelling that didn't have the relative allergens declared as ingredients contained detectable levels of allergenic proteins within the sampled food products; milk was a predominantly identified allergen in 8.2% (39/474) of tested products, followed by gluten 6.1% (33/542), hazelnut 2.9 % (29/988) and peanut 0.21% (2/950). Food products without an allergen declaration or advisory labelling contained gluten and milk in 3.3% (18/542) and 2.1% (10/474) of the tested products, respectively. However, hazelnut and peanut were not identified in tested products where no allergens were declared.

The main findings of this study into the allergen levels found were:

Within this selection of UK products that, the majority that tested positive for an allergen contained a concentration of allergen predicted to cause a reaction in >1% of the allergic population. The concentrations of allergens measured in the majority of products were greater than the VITAL® 2.0 action levels and would trigger a precautionary allergen statement under this system. This was found both for products with or without precautionary allergen labelling (PAL).

Risk assessments carried out on products with PAL and 80% (31/39) of these found to pose a risk to the respective allergic population. The concentration of allergens found in selected products with PAL indicates that allergic consumers could react if they ignore precautionary allergen statements on the labels of the products. Milk, hazelnut and peanut allergic individuals should avoid chocolates with respective PAL due to an elevated risk of allergic reactions, finding

were:

- Dark chocolate contained the highest levels of milk and health risk with reaction predicted in up to 21-52% of stimulated eating occasions.
- Chocolate products were also tested positive for hazelnut and peanut. Both levels predicted to be a significant health risk for allergic consumers.

Risk Assessments were conducted for 12 products which tested positive but had no labelling declaration for the allergen. Key findings of the stimulated eating occasions were:

- Milk in an ice lolly was predicted to pose a risk of reaction in up to 8.7% of allergic individuals.
- Milk in vegetable samosa was predicted to pose a risk of reaction in up to 13%.
- Wheat in ready-made Indian meal was predicted to pose a risk of reaction in up to 17%.

Conclusion

Some food products with no allergen declaration or PAL contained a sufficient undeclared allergen residue to pose a risk to public health. These results highlight the need for the food industries and regulators to adopt a transparent, risk-based approaches for the assessment of the risk associated with potential cross-contact that could occur in the production chain.

Food manufacturers should always assess the potential and impact of allergen cross-contamination and if the risk is found to be real and present, provide appropriate precautionary allergen labelling. Along with this, for risk management, food manufacturers should incorporate analytical methods to detect for the presence of unintended allergens in their products where there is a risk to ensure levels are being kept to a minimum. Where there is no real risk of cross-contamination or unintentional allergen presence then PAL is not required.

Published papers

Remington BC, Baumert JL, Blom WM, Houben GF, Taylor SL, Kruizinga AG. Unintended allergens in precautionary labelled and unlabelled products pose significant risks to UK allergic consumers. Allergy 2015; 70: 813–819