Precautionary Allergen Labelling: a case study in a ready-meal sector small and medium enterprise (SME).

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Introduction

Food allergy prevalence has been documented to affect as much as 10% of the global population[1]. With the United Kingdom being believed to have the highest milk allergy prevalence in Europe[2]. From a food business operator's perspective, this poses a great challenge due to a number of factors such as legislative, clinical, technological and consumer-behaviour related. Legislation-wise[3], food business operators are mandated to disclose and communicate to the consumer any intentionally added allergens.

Unintentional presence of trace amounts of allergens, due to cross-contamination, are at the manufacturer's voluntary discretion to be disclosed by the use of a 'precautionary allergen label', with the remark that this is done only following a risk assessment. In EU, there are no regulations to date mandating the levels of allergens that warrant the use of such label, and additionally, there are no guidelines manufacturers can follow to determine a realistic risk.

Without reliable eliciting dose data [4], food business operators do not have the scientific basis to rely their decisions on[5]. This leads to an inconsistent use of precautionary labels across the industry, making them a less effective tool for risk communication to the consumers[6].

Additionally, technological hurdles such as the lack of precise and practical analytical methodologies[7], contribute further to the allergic consumer's behaviour of ignoring precautionary label's statements[8–11]. With the prospective of an increase in the prevalence of food allergies[12], the magnitude of the issue becomes even greater.

Potential milk contamination risks have been identified during a cleaning validation in a ready-meal sector SME in Wales and this study aims to review the cleaning validation data to determine if precautionary allergen labelling is required.

Purpose

The aim of this study was to review cleaning validation data from a ready-meal manufacturer to determine if precautionary allergen labelling is required.

Methods

Company documentation including cleaning validation reports and product ingredient lists were reviewed to determine potential risk of milk contamination.

Performance documentation available from cleaning validation exercises conducted at the business (*n*=2) were reviewed to identify potential risk of milk contamination. Documentation included; external laboratory results (*n*=25), environmental samples (*n*=218) from different locations (*n*=89) and end-products (*n*=6).

Descriptive analysis were conducted using a Microsoft Excel spreadsheet created by collating the data from the available documents.

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Results and Discussion

Case study – Cleaning validation in a Welsh food manufacturing SME

The manufacturer produces over 100 food products, using only one production site belonging to the processed foods, ready-to-eat (RTE) or ready to heat category, under a 'retailer own brand' for some of the UK's leading retail chains, as well under their own label for retail and food service sector.

Milk is the most handled allergen on the site, being an intentionally added ingredient in over 50% of the products. During a cleaning validation exercise, several samples have been taken from visually clean equipment following a standard cleaning operation. The cleaning operation followed the production of the manufacturer's highest risk product in regards to milk allergens, representative for a worst-case scenario.

The sampling method and location choice has been made based on a risk assessment with considerations regarding the amount of allergens that are handled on the site on a daily basis and knowledge from previous cleaning validations. A visual inspection for equipment damage, such as cracks or scratches that could harbour traces of milk residue, have been carried out, with no reported issues. The manufacturer has to take a decision on the course of action, based on the resultant information.

Outcome of the cleaning validation

The manufacturer decided to send a selection of representative samples (*n*=25) to a UKAS accredited laboratory to validate the rapid test methods results. The results, based on a more sensitive method (ELISA) reported positive results (*n*=3) on two pieces of equipment, namely cooling trays and a depositor head. Finished products (*n*=6) made following the cleaning operation have also been sent to a UKAS accredited laboratory to assess the presence of milk allergens. A summary of the results is presented in Table 1. The decision process of the food manufacturer, including results from the cleaning validation are presented below in Figure 1.

Table 1 - Environmental 1-4 represent positive results from the environmental sampling (n=218). Product 1-3 represent finished product positive results (n=3). *AccuClean swabs have not been used for finished product testing.

Analytical method [sensitivity] / Sample type	AccuClean [10 µg sample]	ELISA [0.25 ppm]	Reveal 3-D Total Milk Protein [5-10 ppm]
Environmental 1	Green - Pass	970 ng/ml	Negative
Environmental 2	Green - Pass	>1000 ng/ml	Negative
Environmental 3	Green - Pass	>1000 ng/ml	Negative
Environmental 4	Green - Pass	210 ng/ml	Negative
Product 1	Not applicable	2.5 ppm	Negative
Product 2	Not applicable	2.5 ppm	Negative
Product 3	Not applicable	3.8 ppm	Negative

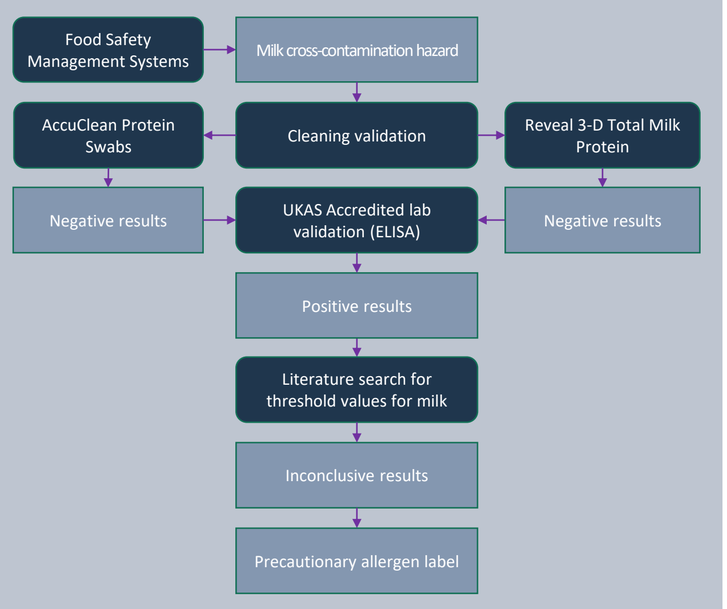

Figure 1 – Decision process taken by manufacturer to decide on the action to be taken based on the outcome of the cleaning validation results. Round boxes represent a tool or process, rectangular boxes represent the outcome.

Positive results (n=3) have been reported for non-dairy containing finished products with levels between 2.5 – 3.8 ppm. With higher levels for the first product on the line. The rapid test samples (*n*=218) for selected locations (*n*=89), based on nonspecific total protein assay (AccuClean Protein Swabs, Neogen) and a lateral flow device (Reveal 3-D Total Milk Protein, Neogen), reported negative results. The sensitivity of these two assays is relatively low, at 10 µg per 50 cm^2 sample and 5-10 ppm per sample, respectively, while only ELISA can detect below 5 ppm.

Additionally, during the cleaning validation, visual inspections for damage on equipment, such as cracks or scratches that could harbour traces of milk residue, have been carried out, with no reported issues.

Has the manufacturer made the right decision based on the outcome?

The cleaning validation resulted in the detection of levels of milk protein in the finished product that are under the detection limit of the commonly used rapid test methods.

In this situation, the food manufacturer may opt to use precautionary allergen labelling. Although the low levels of the allergen found in the finished product (2.5 – 3.8 ppm) poses a risk to a very small percentage of consumers[4], in the unfortunate event of product-related injury to consumer's health, the food manufacturer would not be considered liable as it demonstrated due diligence to inform the consumer of the possible risks. Conversely, if the risk is considered to be unlikely, the use of precautionary allergen labelling could be considered to be misleading, even if there are currently no agreed quantitative criteria. Both scenarios could potentially affect the food manufacturer by loss of business as products containing a precautionary allergen label can be seen as less desirable, as they restrict sensitive individuals' dietary choices even further. The equipment items related to this issue are shared by all the products produced, increasing the likelihood of cross-contamination drastically.

In order to mitigate the above risks, the food manufacturer could use an allergen risk management tool such as VITAL[13], which provides information for the necessity of a precautionary label, based on the scientific review of literature on allergen thresholds. The tool can be used to provide rationale for the inclusion of a precautionary allergen label, which can be useful to all involved stakeholders.

Conclusions

- Milk proteins were detected in the lower 1-5 ppm range in the finished product only by using more sensitive testing methods (ELISA). This is of concern, as even such low levels can provoke reactions in hypersensitive individuals4, potentially requiring the inclusion of precautionary allergen labelling to inform consumers of the product's allergen status, thus ensuring a reduction in liability risk for the food manufacturer.
- The lower levels in the environment could indicate contamination from food handlers during the manufacturing process, which could be mitigated using bespoke cleaning optimisation interventions based on behavioural change. Further investigations are required to detect the source of contamination in order to provide mitigations associated with cleaning optimisation, reducing the likelihood of precautionary allergen labelling being required and used.
- Until better data regarding allergen thresholds together with improvements in the analytical methods for allergen detection become accessible, food manufacturers need to thoroughly consider the need for precautionary allergen labelling for their products in order to communicate real risks to the sensitive consumers, while not burdening their choice of foods.

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