Determination of milk allergen contamination in a ready-meal sector small and medium enterprise (SME): a case study.

Aline Turila1, Ellen Williams2 and Elizabeth C. Redmond2
1Cardiff School of Sport and Health Sciences, Cardiff Metropolitan University, Cardiff, United Kingdom.
2ZERO2FIVE Food Industry Centre Food and Drink Research Unit, Cardiff Metropolitan University, Cardiff, United Kingdom.
*Corresponding author: aturila@cardiffmet.ac.uk

Introduction

Food allergy prevalence has been documented to affect as much as 10% of the global population1. With the United Kingdom being believed to have the highest milk allergy prevalence in Europe2 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, food business operators are mandated to disclose and communicate with 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, food business operators do not have the scientific basis to rely on their decisions on3. This leads to an inconsistent use of precautionary labels across the industry, making them a less effective tool for risk communication to the consumer4.

Additionally, technological hurdles such as the lack of precise and practical analytical methods5,6, combined with further to the allergic consumer’s behaviour of ignoring precautionary label's statements7-9, with the prospective of an increase in the prevalence of food allergies10, 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.

Methods

Company documentation including cleaning validation reports and product inspection reports 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=88) and end-products (n=6).

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

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 sectors. 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.

The manufacturer decided to send a selection of representative samples (n=25) to a UKAS accredited laboratory to validate the rapid test method used6.6.14, based on a more sensitive method (ELISA) reported positive results (n=5) on two pieces of equipment, namely, cooling trays and a depositor head. Finished products (n=40) 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=4).

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Result & Discussion

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

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