

# **FINAL REPORT**

## **SURVEY OF ALLERGEN ADVISORY LABELLING AND ALLERGEN CONTENT OF UK RETAIL PRE-PACKED PROCESSED FOODS**

**FS241038 (T07067)**

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READING SCIENTIFIC SERVICES LTD**



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## Final Technical Report

**Project Code FS241038 (T07067)**

**Project title: Survey of allergen advisory labelling and allergen content of UK retail pre-packed processed foods**

### Executive summary

#### Objective

A nationwide 'snap shot' survey reported here has sampled a cross-section of pre-packed processed food products in the UK, both with and without allergen advisory labelling. The survey determined the presence and levels of milk, gluten, peanut and hazelnut in these food products. The survey aimed to provide an improved understanding of the type of allergen advisory labelling used on pre-packed processed foods sold in the UK. It also sought to quantify the levels of allergens present in foods as a result of cross contamination and establish whether the type of advisory labelling used was related to the level of allergen present.

#### Methodology

The survey sampled 508 products with and without advisory labelling (254 of each), in duplicate (1016 samples in total were sampled) across 12 different product categories from July 2012 – March 2013. All products were analysed using validated commercially available immunoassay kits.

#### Results

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 are as follows:

Undeclared allergen cross-contamination in the UK are lower than previously found studies in other countries, notably Ireland and the USA:

The percentage of samples with detectable allergen (both with and without advisory labelling) and where that allergen was not present as an intentional ingredient, were as follows: gluten - 6.1% (33/542); milk - 8.2% (39/474); hazelnut - 2.9% (29/988); peanut - 0.21% (2/950).

The percentage of samples with detectable allergen, where that allergen was not present as an intentional ingredient and which did not carry an advisory label were as follows: gluten 3.3% (18/542); milk - 2.1% (10/474); hazelnut - 0% (0/988); peanut - 0% (0/950).

The percentage of samples in which no allergen was detected but carried an advisory label were as follows: gluten - 19% (97/509); milk - 18% (77/435); hazelnut - 44% (427/959); and peanut - 45% (430/948).

The highest levels of allergen detected were milk proteins in dark chocolate products in the confectionery category (up to 4400 mg/kg were found). However all the products carried an advisory label for milk. A single product, a milk chocolate egg containing milk as an ingredient, contained gluten, hazelnut and peanut, all of which were declared in an advisory label.

In certain product categories (such as cereals and cereal products), the presence of peanut or hazelnut as declared ingredients was low (<5%). Equally, these allergens were not detected as cross contaminants in this category with many products not carrying advisory labelling. Conversely, in the confectionery category, peanut was present in 5% of products as an ingredient, advisory labelling was common and only one product contained peanut as a cross contaminant in duplicate samples.

Peanut was detected in a single sample in the confectionery category. Hazelnut was detected more frequently than peanut as a cross contaminant in three categories; (confectionery, chilled desserts and sweet spreads). Both gluten and milk were detected across a broader range of product categories being found in 6 out of the 12 product categories.

The wording of the advisory label did not reflect the level of cross contamination found (for any of the four allergens across any product category).

A wide variety of different statements were used across the product categories. The most frequently used advisory label was 'may contain traces' (38% (418/1106)). The second most frequently used was 'may contain' (20.6% (228/1106)).

FSA guidance recommends the use of "may contain X" or "not suitable for someone with X allergy". These two statements were found on 20.6% and 7.2% (80/1106) of products, respectively.

## Conclusions

The snapshot nature of the sampling strategy of this survey meant a broad cross section of products could be sampled which would allow significant allergen cross contamination and potential risks to consumers to be identified. However the design prevents firm general conclusions being drawn from the results. The preliminary conclusions drawn are therefore those of RSSL's and will require verification by additional investigations.

Results from the survey suggest that cross contamination for all four allergens (but particularly for hazelnut and peanut) is well controlled. However as this is only a snap shot survey, the results are probably due, in part, to the risk of contamination with peanut and hazelnut as particulates (heterogeneously distributed in the food product) rather than being distributed equally (homogenous distribution), as is more likely with gluten or milk contamination.

Therefore given the sample size, it would have been difficult to detect both peanut and hazelnut as cross contaminants in these products.

Just under half of the samples contained no detectable hazelnut or peanut but carried advisory labelling. Again due to the limitations of the survey, this could have been due to the heterogeneous distribution of the cross contamination. As a result, cross contamination risks remain high, but due to distribution of the contamination the probability of detecting particulate/ heterogeneous contamination in this survey was low.

A greater number of allergens were present as cross contaminants in the confectionery category than in any other, but all the products carried an advisory label. This highlights the challenging nature of cross contact in this category, probably, due, in part, to the dry cleaning system used. It also demonstrates the need for industry to remain vigilant and undertake risk assessments and alert allergic consumers appropriately to the risk of cross contamination.

There is a wide variety of allergen advisory statements being used with only 28% of products following FSA advice in the use of specific phraseology.

### **Limitations of the survey**

The snapshot nature of this survey has meant that it is not representative of the entire UK retail market and as a result, it is difficult to extrapolate these findings to the UK retail market as a whole.

Furthermore, it is important to recognise that advisory labelling for some products and some allergens may be used to indicate the sporadic presence of allergen, especially where contamination may be heterogeneous or particulate in distribution. Thus, it is difficult to extrapolate these findings to the UK retail market as a whole and the levels detected may not be a true representation of the risk of unintentional presence of that allergen.

The choice of allergens, the range of foods analysed and the numbers of samples across this broad range of product categories tested in this survey limits the statistical significance of the data. However, this survey was intended to be a broad snapshot, rather than a definitive analysis but it is the first of its kind in the UK.

The product sampling for the survey was undertaken from July 2012 to March 2013. The EU FICR (1169/2011)<sup>22</sup> was published in October 2011 and as a result food labels have required change and as such this could have promoted a review and revision of advisory labelling over the period of the sampling and beyond.

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## Glossary

**Allergen Advisory Labelling** – Can also be described as precautionary / alibi / defensive labelling to indicate unintentional presence of allergens

**Analyte** – Substance of interest in analytical test

**AOAC** - Association of Analytical Communities

**BRC** – British Retail Consortium

**CIP** – Cleaning in place

**CRM** – Certified Reference Material – A reference material that has had specific qualities assessed and certified to guarantee fitness for purpose

**CV** – Coefficient of variation

**DNA** – Deoxyribonucleic acid

**ELISA** – Enzyme-linked Immunosorbent Assay – Refers to the antibody-antigen based method used for the detection of proteins.

**FAPAS** – Food Analysis Performance Assessment Scheme

**FDF** - Food and Drink Federation

**FICR** - Food Information for Consumers Regulation

**FSA** – Food Standards Agency

**GMP** – Good manufacturing practice

**Heterogeneous** – Non-even distribution/hot spot contamination of analyte

**Homogeneous** – Even distribution of contamination of analyte

**IHRM** – In-house Reference Material

**IQC** – Internal Quality Control

**LIMS** – Laboratory Information Management System

**LOD** – Limit of detection – Referring to the lowest amount of analyte that can be detected by a test

**LOQ** – Limit of quantification – Referring to the lowest amount of analyte that can reliably be quantified by a test

**PCR** – Polymerase chain reaction

**Positive Result** – For the purposes of this survey, a positive result is anything detected above the reporting limit of the test

**Product** – A product is considered a pre-packed food item as purchased. (In this survey 508 separate food products were purchased in duplicate. The duplicate pair comprised 2 separate samples)

**RSSL** – Reading Scientific Services Limited

**Sample** – Each food product was purchased in a duplicate pair of 2 samples which were then treated as individual test samples. (In this survey, 1016 samples were purchased and tested).

**SOP** – Standard Operating Procedure

**Undeclared allergen** – Any allergen detected as a positive and not present in the ingredients list.

**UKAS** – United Kingdom Accreditation Service

**VTL** – Ventress Technical Limited



## 1.0 Introduction

### 1.1 Summary

This is a UK wide 'snap shot' survey which sampled a cross-section of pre-packed processed food products with and without allergen advisory labelling. It analysed products for the presence and level of milk, cereals containing gluten, peanut and hazelnut.

The survey aimed to gain a better understanding of the type of allergen advisory labelling present on pre-packed processed foods sold in the UK. It also aimed to quantify the level of allergens present in the food as a result of cross contamination and establish whether the type of advisory labelling used related to the level of allergen present.

The snapshot nature of this survey meant that the work is not representative of the UK retail market. As a result a limited amount of statistical interpretation or extrapolation to the UK retail market as a whole could be performed on the data. The quantitative levels of four allergens chosen by the FSA (milk, gluten, hazelnut and peanut) were measured. The FSA chose these allergens based on the large number of incidents received between 2008 and 2011 and because of their public health importance (<http://food.gov.uk/science/research/surveillance/guidefsatechsurv>)<sup>8, 9, 10</sup>. This data was then compared to the variety of allergen advisory statements currently being used to establish whether the type of advisory labelling used relates to the level of allergen present. It is important to recognise that advisory labelling for some products and some allergens (heterogeneous or particulate contamination) may be used to indicate the sporadic presence of allergen. This may mean that for a snapshot survey such as this, the levels detected may not be a true representation of the risk of unintentional presence of that allergen.

Sampling of foods was based on those categories of foodstuffs which present either the greatest risk of allergen cross contact or where there was a widespread use of advisory labelling<sup>3, 5, 6, and 24</sup>. Within each product category, comparable samples were purchased in pairs; one that carried an advisory statement and one that did not for any given allergen. Comparable products were those considered to be from the same product type (e.g. breakfast cereal) and to be as similar as possible as the original product sampled but they did not necessarily have to have exactly the same ingredients. Sampling was managed by Ventress Technical Limited (VTL). Samples were chosen from a range of small and large retailers, as well as independent stores, from across the UK, but with a focus on Greater London and East Anglia.

Sample selection within each product category was guided by RSSL's extensive experience of product analysis and practical food manufacturing experience, to help identify the greatest risks of cross contact. All information from samples were collected and assessed to determine the analytical testing required for each sample. This information was used to establish the levels of allergens detected with the different allergen advisory labelling statements used.

Analysis of the samples was undertaken using commercially available ELISA kits appropriate for the detection of the allergens included in the study, and all of

which are covered by RSSL's flexible scope of accreditation from UKAS. ELISA was selected because it is currently the method of choice for allergen detection by industry and regulatory bodies. Certain ELISA kits are more suited to particular product matrices; therefore the most appropriate assays for each allergen were selected. The importance of matrix validation is critical. This project made use of RSSL's sample matrix databases to assess whether a sample required validation for any of the four allergens with each specific ELISA kit. This ensured that results were robust and the risk of false positives or negatives was minimised. The reporting of results was done on a weekly basis in accordance with the FSA survey protocol (<http://food.gov.uk/science/research/surveillance/guidefsatechsurv>) and in the absence of allergen thresholds, any results above the reporting limit will be deemed an adverse result and was reported to the Agency for review and risk assessment.

## **1.2 Scientific basis of the project**

The current regulatory framework within the European Union mandates the declaration of allergens as constituent ingredients in pre-packed foods. This legislation does not cover the accidental cross-contamination with allergens or the resultant use of advisory labelling. The FSA introduced 'best practice' guidance on managing food allergens in 2006 <sup>1</sup> to assist the food industry in the use of advisory labelling. Due to the lack of standardisation in allergen risk assessment methodology and the resultant allergen management practices, the application of advisory labelling is currently inconsistent <sup>1</sup>. Although best practice guidance was developed by the FSA and supported by industry <sup>1</sup> there are currently large variations in the way that advisory labelling is presented to consumers. These variations have led some allergic consumers to believe that different types of advisory statements constitute different levels of risk (i.e. made in a factory that also handles allergen X, versus made on a line that also handles allergen X) <sup>2</sup>. This survey was confined to gain a better understanding of the type of allergen advisory present on pre-packed processed foods sold in the UK and to compare the different advisory statements to the levels of allergens detected or not detected in a broad range of pre-packed foods.

Previous surveys of advisory labelling conducted in the US, Europe and UK have shown that certain categories of food tend to carry a greater number and variety of advisory warnings for allergens <sup>3-12</sup>. This has usually been related to the number of allergens used in a particular category, a lack of dedicated manufacturing facilities or issues associated with cleaning, as has been evidenced in the chocolate industry with cross contamination between milk and dark chocolate <sup>11</sup>. There is also a perception by allergic consumers <sup>2, 17</sup> that some manufacturers/retailers use advisory labelling inappropriately. Without a detailed investigation, it is impossible to verify if the use of or lack of advisory statements is determined by thorough allergen risk assessments by food manufacturers.

This study aimed to gain a better understanding of quantitative levels of allergen cross contamination. The principal aim of this study was to help inform the FSA's understanding of allergen advisory labelling and allergen content of pre-packed foods sold in the UK. No other survey of its kind has been conducted in

the UK before. The results of the snap shot survey aimed to give an indication of the level of contamination to which allergic consumers are being exposed, taking into account the sporadic contamination, especially of particulates. It was envisaged that the data generated by this survey would inform the work on the development of allergen management thresholds (action levels) similar to those used in Australia and New Zealand (VITAL 2.0 <sup>12</sup>). These action levels could be used to inform decisions about allergen management, guide quantitative risk assessments and enable the appropriate use of allergen advisory statements. These action levels could help food businesses make evidence based decisions on the use of factual statements on whether or not a food is suitable for consumption by a food allergic individual. An additional benefit should be greater consistency in the use and wording of allergen advisory labelling.

## 1.3 Objectives

The main objectives of the survey are:

- i) to investigate the frequency and level of allergen cross-contamination in a sample of pre-packed processed food products, with and without advisory labelling for the following four food allergens; milk, gluten, peanut and hazelnut.
- ii) to compare the level of food allergens in a sample of pre-packed processed food products with and without advisory labelling for milk, gluten, peanut and hazelnut to similar products without such labelling.
- iii) to investigate the different types of allergen advisory labelling used in a sample of pre-packed processed food products purchased from UK retail outlets
- iv) to examine whether the suggested allergen advisory statements which are set out in the Best Practice Guidance (such as the FSA Guidance on Allergen Management) are being used by industry

## 1.4 Tasks

**Table 1: Tasks for the Project** – this table shows the 8 different tasks set out for the survey.

<b>Task NUMBER</b>	<b>Task DESCRIPTION</b>
<b>01</b>	Develop a robust sampling plan to investigate the frequency and level of allergen cross contamination across a range of pre-packed foods with and without allergen advisory labelling
<b>02</b>	Refinement and agreement of sampling and analytical strategy between the contractor, subcontractor and the FSA (see below)
<b>03</b>	Implementation of sampling programme
<b>04</b>	Quantitative analysis of samples using commercially available ELISA test kits, collation and interpretation of data
<b>05</b>	Undertake a review of the advisory labelling on purchased products and compare to the FSA Best Practice Guidance
<b>06</b>	Delivery of interim report at midpoint of survey
<b>07</b>	Presentation of collated survey results to agency
<b>08</b>	Delivery of final report

## **Task 01**

### **Develop a robust sampling plan to investigate the frequency and level of allergen cross-contamination across a range of pre-packaged foods with and without allergen advisory labelling**

A detailed sampling programme was designed specifically targeting those product categories which are known to present a higher risk of cross contamination. The rationale for the selection of specific categories will be based on published studies <sup>3, 4, 6</sup>, RSSL's experience gained from analysing different foods for residual allergens and technical knowledge obtained whilst working in different manufacturing environments.

The emphasis for categories selected will also be specifically linked to the allergens under investigation (gluten, milk, hazelnut and peanut).

## **Task 02**

### **Refinement and agreement of sampling and analytical strategy between the contractor, subcontractor and the FSA**

The categories selected and proposed sampling bias was reviewed with the Agency to ensure that this is aligned with any other data/information held by the Agency.

## **Task 03**

### **Implementation of sampling programme**

A phased sampling programme in a range of different geographic locations across the UK (primarily in Greater London and East Anglia but to include some products from Scotland, Northern Ireland and Wales) was undertaken. In order to ensure that samples could be analysed in accordance with the study guidelines, purchasing will be phased over an 8 month period.

## **Task 04**

### **Quantitative analysis of samples using commercially available ELISA test kits, collation and interpretation of data**

Using the decision tree in the FSA study protocol, the appropriate analytical test(s) will be performed using validated methods. For any sample matrices that have not previously been validated by RSSL, full matrix validation will be conducted. All analytical data will be collated, reviewed and compared to on-pack advisory statements. Any results which could constitute a potential food safety issue will be notified to the agency within 48 hours.

## **Task 05**

### **Undertake a review of the advisory labelling on purchased products and compare to the FSA Best Practice Guidance**

To record the different types of allergen advisory labelling used on food products and examine whether industry are following the FSA Best Practice Guidance.

## **Task 06**

### **Delivery of bi-weekly results and interim report at midpoint of survey**

Results and progress against sampling plan will be reported to the Agency on bi-weekly basis.

**Task 07****Presentation of collated survey results to Agency**

RSSL will present findings to the Agency on completion of sampling and analytical programme, which will include (but not be limited to) data interpretation, trends and key learnings.

**Task 08****Delivery of final report**

RSSL will deliver the final report to the Agency

## **2.0 Materials, Methods and Approach**

### **2.1 Materials**

R-Biopharm Ridascreen® Gliadin ELISA kit, AOAC approved, #R7001

R-Biopharm Ridascreen® Fast Milk ELISA kit, #R4652

ELISA Systems Hazelnut Residue ELISA kit, #ESHRD-48

Neogen Biokits Peanut ELISA kit, AOAC approved, #902048Q

ELISA Systems Peanut Protein Residue Detection Kit (ESPRDT-48)

R-Biopharm Cocktail Solution for use in conjunction with Gliadin ELISA kit, #R7016

Enhanced extraction solution for use in conjunction with Hazelnut Residue ELISA kit, #ESADDSOL

Consumables (e.g. 50ml and 15ml polypropylene tubes, 250ml sample pots, 1.7ml microtubes)

### **2.2 ELISA test kit validation**

The ELISA method was selected for this study for some of the following reasons:

- It detects allergenic proteins because antibodies are raised against target proteins from the allergen.
- ELISA is semi-quantitative within the standard range determined by each specific kit manufacturer and verified by a laboratory.
- ELISA is a well-recognised tool, is widely accepted by both the food industry and enforcement agencies as the current method of choice and has been in use for many years.
- ELISA is very sensitive and designed to detect allergenic proteins at very low levels (mg/kg).
- Testing time using ELISA ranges from a couple of hours to six hours (including extraction time) which means it is considered to be a cost efficient testing method.
- Samples can be diluted to extend the standard range of the tests, but this will increase the uncertainty of the results.
- Typical uncertainties range from 15 to 35% but are regularly re-calculated using current data.

For the target allergens chosen for this study, there are a wide variety of commercially available ELISA kits. RSSL has a UKAS Flexible Scope of Accreditation for allergen testing by ELISA and have validated numerous commercial ELISA kits for a wide range of allergens. During validation and through participation in extensive proficiency tests (i.e. FAPAS), certain test kits have been shown to perform better with certain matrices than others. The ELISA methods chosen for this project have been extensively validated to cover a wide range of different matrices for each of the target allergens.

The gluten, hazelnut and peanut ELISA kits deemed to be the most appropriate, and therefore chosen for use in this study, had been previously validated by RSSL and are currently RSSL's methods of choice for routine ELISA analysis. Due to a wide range of products sampled and analysed, the source of any potential milk contamination could not be known and therefore a new ELISA test kit that detects both casein and beta-lactoglobulin, which are the predominant milk proteins, (i.e. whole milk kit) were selected and validated for use.

As part of RSSL's UKAS Flexible Scope of Accreditation, a method for validating ELISA kits has been established, and only kits that meet the criteria set out in this method were used for the detection of allergens.

ELISA kits were assessed against the following criteria:

- **Reactivity and Specificity:**

Reactivity refers to the rate at which a chemical substance tends to undergo a chemical reaction in time. Specificity is the ability of the method to differentiate and quantify the analyte in the presence of other components in a sample matrix.

- **Recovery:**

Recovery is the detector response of an analyte in an assay obtained from a spiked sample compared to the detector response obtained from sample blanks. It also relates to the extraction efficiency of the method within the limits of variability.

- **Precision (Repeatability & Reproducibility):**

The precision of an analytical procedure expresses the closeness of the individual results between a series of measurements obtained from multiple sampling of the same homogeneous sample containing the analyte. The precision of a method will be assessed using the repeatability and reproducibility criteria:

- **Repeatability:**

The repeatability of the method will be demonstrated using the 'analyte-present' reference material assayed in quadruplicate by a single analyst on a given occasion. The mean result, Standard deviation and percentage coefficient of variation %CV will be calculated from the data obtained.

- **Reproducibility:**

Four replicates of the same 'analyte-present' reference material will be assayed by another analyst at different times using, where possible, a different batch of test kit and different reagents. The mean concentration, standard deviation and percentage coefficient of variation (%CV) will be calculated from the data obtained.

- **Linearity:**

A standard curve consists of a range of concentrations of an analyte linked by an appropriate mathematical relationship (Cubic spline, Linear Regression, Log-Logit, Spline, etc)

Standards of known concentration supplied with the respective test kits will be assayed in duplicate. The assay response (optical densities) of these standard solutions will be compared to those denoted by the kit manufacturer. Correlation of response versus concentration will be determined for each set of standard data using the appropriate statistical function. The acceptability of the standard curve will be based on the criteria specified by the test-kit manufacturer. For example curves constructed using Cubic Spline, will require a deviation of actual vs. expected fits to be <1.0%.



- Limit of detection and quantification (LOD and LOQ):

The LOD refers to the amount of analyte present in the sample above the “zero standard” that could be detected if the nominal extraction protocol is followed. This concentration should be significantly different from the zero standard. LOD is calculated as the mean concentrations read off the standard curve for negative controls + (X3) their standard deviation.

The LOQ is the lowest concentration interpolated from the standard curve that can be measured with acceptable accuracy and precision. The LOQ will be based on that specified by the test-kit manufacturer. Sample blanks (analyte-absent) will be spiked at this concentration for the analyte under investigation. The accuracy at LOQ will be determined by the % recovery obtained for each of the sample matrices. Acceptable recovery range is considered to be between 70-130%.

- Uncertainty of measurement:

All measurements are subject to uncertainty. The measurement of uncertainty associated with an analytical method takes into account various factors that could affect the performance of the method e.g. different analysts, different days and different equipment. The uncertainty of a method defines the range of results that could potentially be possible when a result is obtained. For example, during validation of a method, a sample with a true value of 1 is analysed a number of times by different analysts on different days, under all possible conditions. The results obtained are statistically analysed and the uncertainty is calculated from these results. If the uncertainty is calculated as 20%, a result of 1 would then be reported as 1 +/- 0.2.

Uncertainty of the method is measured using the standard deviation data obtained from the precision test (repeatability and reproducibility). Using a minimum of 10 data points from current analytical data (reproducibility and repeatability studies) the standard deviation of the mean is calculated. The Standard Deviation (SD) is then divided by the mean.

$$SD/Mean = \delta$$

In most measurements it is necessary to state the level of confidence related to the Calculated Standard Uncertainty. This level of confidence is obtained by multiplying the estimate of the SD ( $\delta$ ) by a coverage factor k. In accordance with the international practice UKAS recommended the factor k = 2 to be used. When the SD is multiplied by the factor k = 2, it is then referred to the Expanded Uncertainty and will give a confidence level of approximately 95%.

$$\delta \times 2 = \text{Expanded Uncertainty}$$

- Fitness for purpose and establishing reporting limits:

The fitness for purpose and the setting of the reporting limit for each kit was determined using the results from the validation work. The LOQ for certain sample types may differ, so a consistent reporting limit for a test is set to cover the full range of sample matrices.

The gluten kit has an LOQ of 5mg/kg as determined through validation; however due to the variability of protein denaturation, sample homogeneity and other

factors that could affect the protein levels in the sample, the reporting limit was set at the conservative level of 10 mg/kg gluten.

The milk kit showed sufficient recovery at the manufacturer's stated LOQ of 2.5 mg/kg, and when uncertainty data was taken into consideration, it was appropriate to set this value as the reporting limit.

The reporting limit of the hazelnut kit was set at 1 mg/kg. From the validation data, the theoretical reporting limit could be set at 0.5 mg/kg for most sample types, but a higher background with almond resulted in setting a reporting limit of 1 mg/kg to avoid the risk of false positives with samples containing almond. For peanut, the kit manufacturer's reporting limit of 1 mg/kg total protein was shown to be fit for purpose.

**Table 2: Validation Summary by Kit** – this table sets out the validation criteria for the four allergen test methods used in this survey

	<b>Gluten</b>	<b>Hazelnut</b>	<b>Milk</b>	<b>Peanut</b>
<b>LOD</b>	3 mg/kg (matrix dependent)	0.5 mg/kg (matrix dependent)	0.5 mg/kg (matrix dependent)	0.5 mg/kg (matrix dependent)
<b>LOQ</b>	5 mg/kg	0.5 mg/kg	2.5 mg/kg milk protein	0.5 mg/kg
<b>RSSL Reporting limit</b>	10 mg/kg gluten	1 mg/kg hazelnut protein	2.5 mg/kg milk protein	1 mg/kg whole peanut
<b>Standard range</b>	10-80 mg/kg	1 - 5 mg/kg	2.5 - 67.5 mg/kg	1 - 20 mg/kg
<b>Measurement of Uncertainty</b>	31%	13%	35%	25%
<b>In-house blank quality control material</b>	Ground white Basmati rice <LOD	Ground white Basmati rice <LOD	Ground white Basmati rice <LOD	Biscuit crumb (supplied with the kit)
<b>In-house positive quality control material (or IHRM)</b>	Wheat flour mixed into ground rice	Ground hazelnuts mixed into ground rice	Skimmed milk powder mixed into ground rice	Peanut liquid extract (NIST standard) supplied with kit, spiked into peanut free biscuit crumb supplied with kit
<b>Precision values over the relevant concentration range expressed as relative standard deviations</b>	Precision (repeatability / reproducibility CV <10%)	Precision (repeatability / reproducibility CV <10%)	Precision (repeatability / reproducibility CV <10%)	Precision (repeatability / reproducibility CV <10%)
<b>Duplicates</b>	All standard controls are run in duplicate and must have a CV <15%, all duplicate QCs must conform to the Shewhart chart rules.	All standard controls are run in duplicate and must have a CV <15%, all duplicate QCs must conform to the Shewhart chart rules.	All standard controls are run in duplicate and must have a CV <15%, all duplicate QCs must conform to the Shewhart chart rules.	All standard controls are run in duplicate and must have a CV <15%, all duplicate QCs must conform to the Shewhart chart rules.
<b>CRMs</b>	None	None	None	NIST peanut liquid extract supplied with kit
<b>Bias and recovery characteristics including relevant information on traceability</b>	70 - 130% recovery of spiked material in samples.	70 - 130% recovery of spiked material in samples.	70 - 130% recovery of spiked material in samples.	70 - 130% recovery of spiked material in samples.

## 2.3 Method Overview

Prior to assay, each sample was homogenised, aliquoted and then taken through an extraction process (specific to each kit being used). The specific kit protocols are displayed in Appendices 1.1 to 1.5. The extraction was then ready to be assayed.

Each kit was a sandwich type ELISA, which is based on an antigen-antibody reaction (see Figure 1).

The microtiter wells are coated with specific antibodies to the antigen (A). Sample solution and standards are added to respective antibody-coated wells

where the present antigen binds with the antibody during incubation (B). Any unbound antigen is then removed in a washing step.

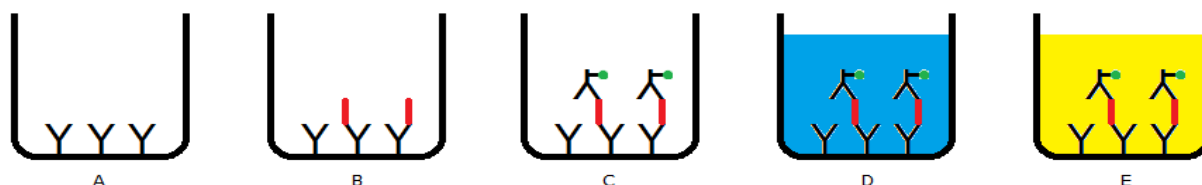
A second antibody conjugate is added and binds to the antibody-antigen complex. An antibody-antigen-antibody (sandwich) complex is formed (C). Any unbound enzyme conjugate is removed in a washing step.

Enzyme substrate is then added to the wells. Bound enzyme conjugate converts the substrate into a blue product (D).

Addition of the stop reagent leads to a colour change (E). The intensity of the colour is proportional to the concentration of the antigen.

Standards of known protein concentration were run in duplicate with each assay. These give absorbance readings that are used to produce a standard curve. Samples are then compared to this to obtain a result.

In-house positive quality controls are run with each assay to assess efficient extraction and consistency. Extraction control blanks are also run with each assay to detect any contamination.



**Figure 1. The steps in a sandwich type ELISA** – this figure depicts the separate steps in an ELISA assay described above

## 2.4 Deviations from the test method extraction procedure

Certain extraction procedures were slightly altered for two products. These were a cracker for milk and a bread mix for hazelnut. During the extraction procedure, the volume of extraction buffer was fully absorbed by the sample which prevented the extraction from being successful. The amount of extraction buffer on these specific occasions was therefore doubled and enabled the extraction procedure to be completed. The reporting limit for these few samples was therefore increased as a result but for each sample affected, the result was a “not detected” for those allergens. In the data spreadsheet, the analytical result was reported as “not detected” with an altered reporting limit but for the purposes of the data analysis, these results were considered to be not detected.

## 2.5 Quantification of Results

A variation to the original scope of the project was agreed for those samples where a result was reported above the top standard for any given allergen. As an example, if a result of >80 mg/kg was reported for a gluten test, that result value could be anything above 80 mg/kg. It was agreed that it was important to have a quantitative result for any sample for which this applied. This resulted in an additional 71 tests being carried out across the four allergens on a variety of products. The outcome of this additional analysis was that for each sample, a

quantitative result was obtained. The additional costs for this extension were reduced by efficiently analysing all positives in a small number of batches, analysing one sample of the duplicate until a result was obtained and then when the correct dilution was identified, analysing the second sample using that dilution.

## **2.6 Spike recovery**

For any matrices that have not been covered under the initial validation, a spike recovery is performed by adding in a set known amount of the analyte into the sample and measuring the % recovery of the analyte.

The purpose of a spike recovery procedure is to determine whether or not a particular sample matrix has any kind of inhibitory effects in the ELISA analysis which could potentially mask the presence of an allergen. It is essential to carry out spike recovery on any product which has not previously been tested using a specific ELISA test kit to ensure that the results obtained are neither inaccurate nor false, either false positive or false negative.

The test works by adding a known amount of the specific allergen to the control sample (the control sample should ideally be one which is known not to contain the allergen in question). This 'spiked' sample is then taken through the normal ELISA extraction and analysis procedure. The aim is to recover the equivalent concentration of the allergen as was originally added to the sample. The spike recovery, in most cases can only pass if the recovery of the allergen is between 70-130%. Anything which falls outside of this range will mean the particular sample type is not suitable for the specific ELISA analysis as some interference has taken place, producing incorrect results. This would mean any results obtained cannot be reported.

### **Results of spike recovery**

Over the course of the study, 43 samples failed the spike recovery test. Therefore a total of 86 samples out of the 1016 could not be reported with an analytical test result for some allergens. The highest numbers of spike failures overall were in the dry mix sauces, trail mixes and yoghurt product types. The distribution of spike failures was low for gluten and only in dried sauces, gravies, stuffing and mixes; spike failures for hazelnut were low and in dried sauces, gravies, stuffing and mixes; for milk there were many more and more evenly distributed across product types but higher in dried sauces, gravies, stuffing and mixes, cereals, cakes, beans and pulses; numbers of spike failures for peanut were higher and distributed across mixed pickles, chutneys and relishes, dried sauces, gravies, stuffing and mixes, crisps and snacks and high in the yoghurt category.

### **Discussion**

There is no common pattern for spike recovery failure in ELISA testing; however there are some ingredients that are more prone to failure such as fruits, vegetables, presence of polyphenols and strong colours and spices. All failures were reported as non-reportable results to the FSA. Advice was sought from the

kit manufacturers on resolving these interference issues but none were readily resolved. The number of failures demonstrated the importance of undertaking spike recovery, because without doing it, the results would have been incorrectly reported.

## **2.7 Peanut Cross-reactivity to Soya**

After all analytical testing had been completed, a suspected cross-reactivity to soya was discovered with the Neogen Biokits Peanut ELISA kit, Association of Analytical Communities (AOAC) approved, #902048Q, following an investigative analytical project RSSL conducted for a 3<sup>rd</sup> party client. RSSL contacted Neogen requesting an immediate investigation be carried out. RSSL provided Neogen with analytical data from soya ingredients (flour, meal and milk) which showed false positive results between 1 and 12 mg/kg peanut. As an immediate response to this, RSSL reviewed all the results from the survey that had shown a detectable peanut result and reviewed that data. This will be discussed fully below. All samples with a peanut not detected result with the Neogen peanut kit were unaffected by this issue. As a result of this incident, a review of the results' profile for all allergens and samples was undertaken and no other results were implicated.

As part of the validation by the original kit manufacturer, Tepnel BioSystems, and as detailed in their validation report of February 2003, a sample of soya flour was tested for cross-reactivity with the ELISA kit and all soya values were below the acceptable cut-off in all assays.

As part of RSSL's extensive database of samples analysed for allergens, different soya samples (flour and milk) showed no cross-reactivity using this ELISA kit during the early days of RSSL's testing service from 2005 to 2008. The results that RSSL obtained during this time concurred with the validation completed by Tepnel Biosystems.

Neogen Corporation bought Tepnel Biosystems in 2009 and as part of this acquired several lots of qualified antibody. The product line #902048Q has been produced by Neogen since that time.

This issue was discovered by RSSL because of the discussions held with the 3<sup>rd</sup> party client and their suspicions that the results reported to them were false positives. RSSL work through partnering with clients and building relationships, as a result of this, and a greater understanding of their manufacturing process and controls, the potential false positives were uncovered. The analysis conducted as part of this snapshot survey was undertaken in very different circumstances where no direct communication occurred between RSSL and either the manufacturer or the retailer. The combination of these circumstances and the lack of analysis of other soya samples for peanut during the course of this survey meant that the issue with cross-reactivity was not uncovered sooner.

RSSL requested that Neogen undertake an analysis to confirm RSSL's findings and, when confirmed, undertake a full root cause analysis to identify how this

occurred. The investigation by Neogen is included as an appendix (Appendix 3.1). A summary of the findings are as follows:

1. Antibody lots that had been previously qualified by Tepnel Biosystems did not undergo thorough QC testing to identify any changes from previous batches. When a new batch of antibody was commissioned by Neogen in April 2012, it was assumed by Neogen that the batch would be identical to previous batches. This was subsequently shown not to be the case. The exact changes or reasons have not been identified. Neogen did not receive any other customer complaints, so had no reason to suspect anything had changed.
2. Neogen should perform a comprehensive antibody characterisation when a new antibody is used; in this situation this testing was not performed. In the future, new batches of previously qualified antibody will be tested under the same quality parameters.
3. All other reagents in the kit were tested to ensure specifications were met and all passed the pre-determined criteria.
4. Neogen conducted some analysis to understand the scale of the issue and the range of soya derivatives that caused a cross-reactivity issue. The range of % soya that was used to assess the effect was at 1%, 10%, 25% and 50%. The result from the 1% soya level in their analysis was 1.3 mg/kg. Neogen inferred from this data that a result of about 1.3 mg/kg could be a false positive and be a consequence of soya present at about or greater than 1%. Unfortunately, no analysis was performed with soya levels between 0 and 1%, so in RSSL's opinion, this deduction is not robust. A level of 1% soya equates to 10,000 mg/kg which is more of an ingredient level, than a contamination level. So, in RSSL's opinion, any result obtained at or just above the LOQ should be investigated as a possible false positive. Neogen also concluded that because the result from the levels of soya in 10%, 25% and 50% resulted in responses of 2.0 to 2.1 mg/kg, showing a saturation effect above 10%, that any result obtained in a real sample above the level of 2.1 mg/kg would be a true positive for peanut, not a false positive because of the presence of soya. In RSSL's opinion, the subsequent analysis conducted by Neogen showed this not to be true. The initial analysis conducted by RSSL on 100% soya flour returned results of 10 – 12 mg/kg, demonstrating that the saturation level is greater than 2.1 mg/kg for soya false positives.
5. Neogen conducted some testing on a very limited number of batches of this ELISA kit (as more were not available), so it is impossible to understand the scale and variability of this cross-reactivity from the work conducted.
6. Neogen used their alternative ELISA kit for peanut, Veratox (Cat#8430) to confirm this cross reactivity was truly present with the Biokits ELISA.
7. Neogen's corrective action has been to inform RSSL of the issue (Appendix 3.2) and amend the test kit insert for future productions. They have informed all customers (Appendix 3.3) that any positive results should be considered suspect if the sample contains significant amounts of unprocessed soya flour and be confirmed using an alternative method. All samples that test as negative should be considered to be real results.

## **RSSL's Investigation**

RSSL reviewed all positive results (above the reporting limit of 1 mg/kg whole peanut or 0.25 mg/kg peanut protein) in this survey and identified 20 samples that had been recorded as containing peanut. The details of the samples affected are listed in Annex 1, Table 9. The vast majority of these 20 samples contained soya in some form as an intentional ingredient and all were therefore considered a possible incorrect result for peanut. This also suggested that the cross-reactivity issue started on or before July 2012 at the start of sampling for this survey.

## **RSSL's Next Steps**

### **DNA Testing**

To screen the positives for the presence of peanut DNA, RSSL have a UKAS accredited test for the detection of peanut DNA using PCR. It is a qualitative test with a validated detection limit of 1 mg/kg of whole peanut. The disputed 20 samples were all analysed using this method because it gave a rapid indication whether peanut was present or not. This then guided whether additional analysis was required. All samples, as part of the DNA test, undergo an inhibitor check and all passed as not containing inhibitors to the PCR analysis. All samples returned a result of not detected (<1 mg/kg whole peanut) except samples P12-04782-185 and P12-04782-186 which both tested positive for the presence of peanut DNA (>1 mg/kg whole peanut). A DNA PCR test result does not correlate directly with an ELISA Protein test result, so additional analysis using ELISA was warranted.

### **Additional ELISA testing**

The original scope of the survey was to undertake all analytical testing using ELISA and therefore because the DNA test results do not correlate to the absence or presence of peanut protein, for the results to be comparable between the four allergens, an alternative ELISA test for peanut was required in order to verify if the 20 samples that had shown a positive result were "real positives" or "false positives". Of the 20 samples identified for re-testing, the vast majority contained soya as an intentional ingredient. There are many different ELISA testing kits on the market for peanut. RSSL assessed a number that were available to use undertaking a limited validation exercise.

They were:

- R-Biopharm Ridascreen FAST Peanut Kit (R6202)
- Morinaga Peanut Protein ELISA Kit (161PE)
- Neogen Veratox Peanut Allergen Kit (8430)
- ELISA Systems Peanut Protein Residue Detection Kit (ESPRDT-48)
- Romer AgraQuant Peanut Assay Kit (COKAL0148)

The criteria that were assessed based on the sample types that had to be re-tested and the possible cross reactivities included:



- Limit of quantification (LOQ) and Limit of Detection (LOD) using a number of peanut free samples
- Recoveries from a limited number of different matrices to determine the practical LOQ at a level close to the published LOQ of the test kit.
- Cross reactivities, especially soya flour, soya bean meal, chocolate, carbohydrate mix, vegetable mix, legume mix (excluding soya and peanut), fruit mix, green pea and chickpea to determine specificity.
- QC material testing to determine the precision and accuracy.

The criteria for the choice of kit for the re-analysis had to fulfil no cross reactivity with the soya samples, even if there was a low level of background. This may be considered to be a non-cross reactivity by the ELISA kit manufacturers, but for this exercise, this was considered to be crucial. The kit that was selected for the re-analysis was the ELISA Systems Peanut Protein Residue Detection Kit (ESPRDT-48).

### **ELISA Systems peanut test kit**

The test kit passed the set of criteria for this repeat work. The reporting limit for the test was set at 1 mg/kg peanut protein which is equivalent to 4 mg/kg total peanut. The standard range for this kit is 1 to 15 mg/kg peanut protein. There were no cross reactivities observed with the sample types tested. The precision and accuracy were within the acceptable levels.

All the 20 samples were analysed using this ELISA test kit and all samples that had not been validated as part of this initial exercise were taken through the spiking recovery procedure. All samples passed this exercise, so the matrix types were validated. The samples were tested two times on separate occasions.

## **2.8 Sampling Strategy**

### **Task 01**

**Develop a robust sampling plan to investigate the frequency and level of allergen cross-contamination across a range of pre-packaged foods with and without allergen advisory labelling**

### **Task 02**

**Refinement and agreement of sampling and analytical strategy between the contractor, subcontractor and the FSA**

A detailed sampling plan was designed specifically targeting those product categories which are known to present a higher risk of cross contamination between products which contain allergens and those that do not. The rationale for the selection of specific product categories has been based on published studies <sup>3 - 12 and 24</sup>, RSSL's extensive expertise of analysing different foods for residual allergens and technical knowledge/expertise gained whilst working in a wide range of food manufacturing sites.

The emphasis for categories selected was also specifically linked to the allergens under investigation (gluten, milk, hazelnut and peanut) and the categories/manufacturing environments in which they are likely to be present. RSSL conducted an informal retail survey to help guide the sampling rationale.

A meeting was arranged with the FSA, RSSL and VTL to review and agree on the categories selected and proposed sampling bias to ensure that this was aligned with any other data or information available and not currently in the public domain (root cause analysis of recalls/withdrawals, information provided by consumer groups or trade federations <sup>24</sup>). A letter of 'intent to sample' was drafted and sent to all premises from which samples were to be taken.

A total of 508 products were purchased in duplicate (two samples with identical batch/production codes giving a total of 1016 samples) from a range of outlets including major and smaller national supermarkets and independent retailers (including convenience stores, health food shops, ethnic stores, service stations, newsagents etc.) mainly in two regions in the UK: Greater London and East Anglia with a small number of products from Scotland, Wales and Northern Ireland. The number of products purchased was an increase on the original sampling plan; the details of the variation are explained in the following sections.

The terms and hierarchy for sampling to help define each of the different stages of product selection was as follows:

- i) **Store selection** e.g. national supermarket, independent retailer
- ii) **Brand selection** e.g. supermarket own brand, name brands etc.
- iii) **Product categories** e.g. chilled/frozen desserts
- iv) **Product types** e.g. ice cream
- v) **Food selection** e.g. type of ice cream to be sampled – chocolate, vanilla etc.

## **Store selection**

Stores were intended to be selected according to data from Mintel Nov 2011 for food related sales:

**Table 3: Retailer Market Share Information from Mintel 2011** –Total Food sales in the UK in 2011 (£m) showing the % share between the 11 top listed retailers and the rest.

Rank	Retailer	Sales (£m)	%share
1	Tesco	40,766	31
2	J Sainsbury	21,102	16
3	Asda Group	20,546	16
4	Wm Morrison Group	16,479	13
5	Co-operative Group	7,520	6
6	Waitrose	4,700	4
7	Marks & Spencer (food)	4,499	4
8	Spar	2,843	2
9	Iceland Foods	2,334	2
10	Lidl	2,090	2
11	Aldi Stores	1,835	1
12	Other	4,200	3
		129,516	100

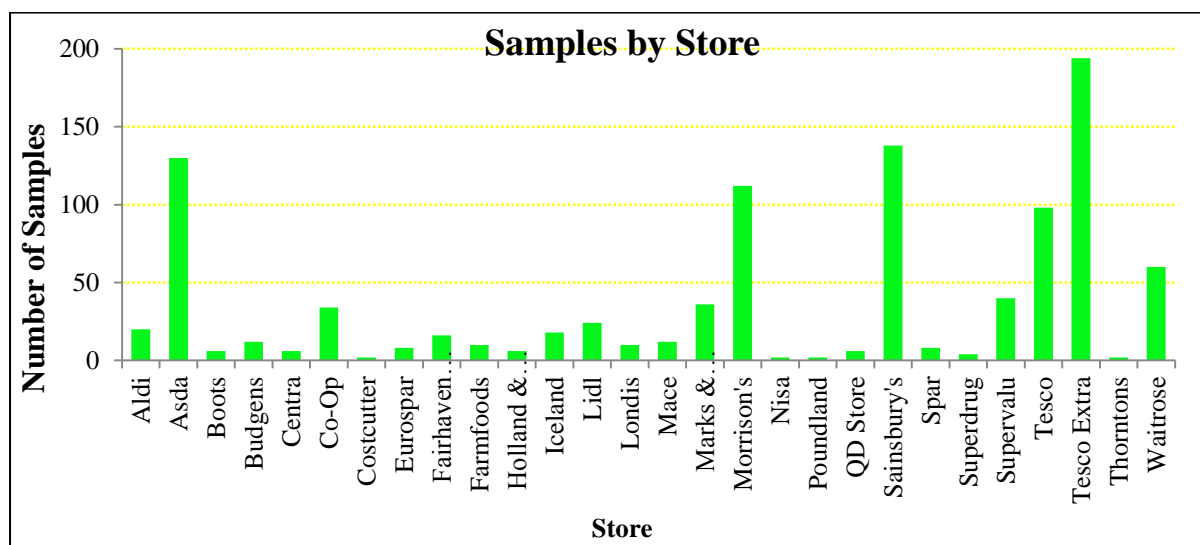
Others (independent retailers, ethnic supermarkets, newsagents, petrol stations and licensed street vendors) were also sampled.

Store selection aimed to mirror these proportions and all 12 product categories were spread across the range of retailers.

Some retailers use allergen advisory labelling more widely. This, at times, made product purchasing as per the retail market share proportions more challenging. The trigger for purchasing samples was the allergen labelling, not the store selection so these proportions were target figures only. VTL noted any difficulties or reasons to deviate from the agreed sampling plan. These data were not used in a formal statistical way, but if the sampling deviated from the original selection, these data were used as part of any possible reasons for that deviation.

It was planned that VTL would visit a town, and stores would be selected on the basis of what was available in that town. It was expected that they would be sampled in similar proportions as the market share showed. Smaller stores were selected initially in a location to ensure that an appropriate proportion of branded goods were sampled so that own label goods could be sampled from the larger retailers. This would also enable the appropriate balance between the smaller and larger retail outlets.

## Total samples split by store:



**Figure 2. The number of samples purchased split by store** – this figure shows where the 1016 samples were purchased from by store

Samples selected across the top four retailers (by volume) were sampled within 4% of the planned numbers from the agreed scope of work for store selection. The complexity in the choice of samples and the restrictions in sample selection were defined by the allergen status in the ingredients and the advisory labelling, not primarily on the store selection. Considering these constraints, sampling across retailers was within the parameters of the agreed scope of work. This demonstrates that VTL did not have any major difficulties in selecting samples from stores close to the parameters set out in the agreed sampling plan.

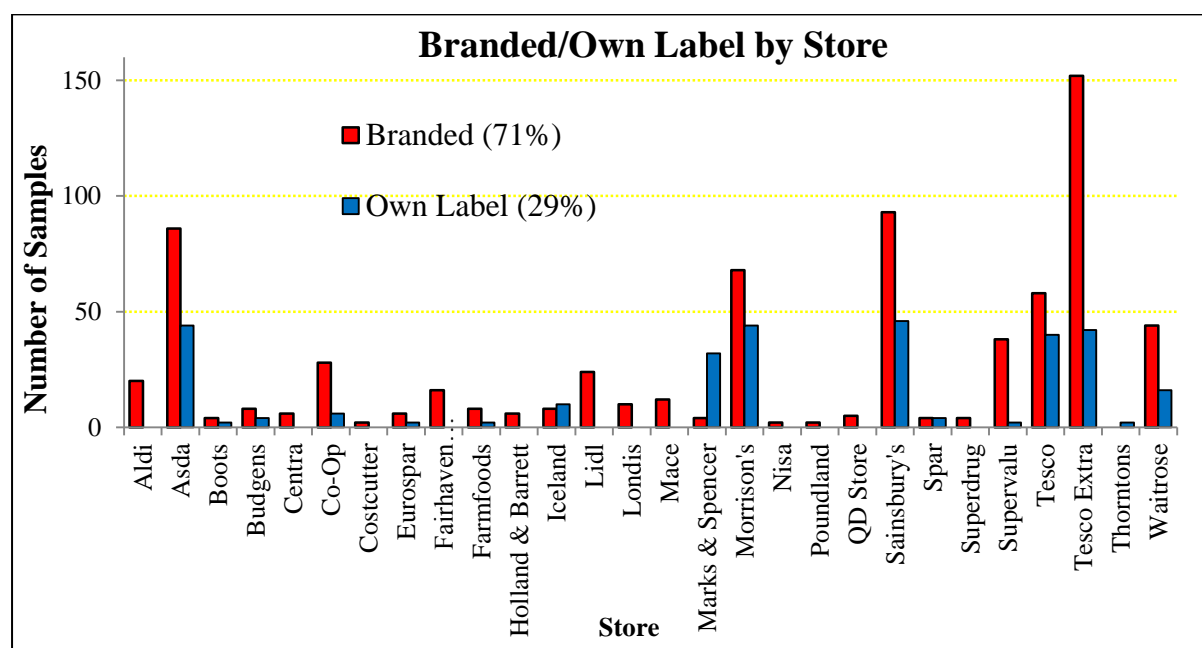
## Brand Selection

The decision on sampling proportions of own label versus branded products was based on data of food related sales from Mintel in 2011; 35% own label versus 65% branded. These figures were to be used as a guide and were adhered to as closely as possible.

## Results

The selection of products that were purchased in this survey were in the proportions of 29% own label versus 71% branded products. The figures that were suggested in the agreed sampling survey were only to be used as a guide because the selection driver was primarily the allergen status and advisory labelling. Only branded goods could be purchased from some stores (e.g. Aldi and Lidl). Less than half of the products sold in one of the major stores (Marks and Spencer) were branded, with figures of 89% own label versus 11% branded. All products sold by Thornton's were own label, therefore only one product was sampled in duplicate from this store.

The breakdown of branded versus own label by store is set out below in Figure 3:



**Figure 3. Split of samples by store and branded versus own label** – this figure shows the number of samples purchased from different stores and then split between branded samples and store own label samples

On occasion, the same brand in a product type was selected more than once, because the main focus for choice of sample was based on the allergen ingredient / advisory label, not the brand selection. This situation was avoided if at all possible, but had been identified as a possible risk in the original scope.

## Product selection

The stratification of product types in a category, and the allergen for comparison outlined in Annex 2 Table 10 was used as a guideline. RSSL monitored the sample choices throughout the survey and any adjustments required were discussed with the FSA.

The examples provided below were used as an explanation for the numbers of product types and allergen declarations. The decisions for each product type were based on similar reasoning throughout. Where available, unpublished data from an internal BRC-FDF survey conducted in 2011 <sup>24</sup> was used as a guideline for proportions of advisory statements. Additional data from RSSL's informal retail survey and RSSL's extensive experience in working with food manufacturers and retailers also helped to inform these decisions.

Many retailers / brands do not distinguish peanuts from specific tree nuts (e.g. it is rare to see "may contain brazil nuts"). It is more common to see "may contain

nuts and/or peanuts". It was therefore decided not to separate the categories of nuts and peanuts to ensure that sampling was not restricted.

For this survey, the use of "may contain wheat", "may contain barley", "may contain oats", "may contain rye" and "may contain gluten" were considered equivalent. All products made containing oats or oats themselves were tested for gluten as oats are often contaminated with gluten from wheat. The ELISA test used in this survey does not detect the gluten (avenin protein) in oats (Appendix 1.1).

Products were purchased in duplicate, meaning that two samples were purchased at the same time, from the same store, with the same date code / batch code where possible.

Products with advisory labelling and products without advisory labelling for the same allergen were considered comparable. On a few occasions, products with a positive "free-from" label were considered to be comparable to products with a "may contain" type label for that allergen.

Any additional allergens detailed in the advisory statement or the ingredients list that were outside the scope of this survey (eg. Crustaceans) were not taken into account during the selection of samples.

Below are two examples of how the product selections were made:

### **Example 1**

Flour (2) corn, rice or gluten-free flour – gluten

Product numbers of flour = 2. Product types of flour could be: corn, rice or gluten-free flour. The most likely allergen to have an advisory statement for these types of flour would be gluten. Therefore, ideally, one type of flour in duplicate could be sampled with a "may contain gluten" and the other comparable sample in duplicate with no advisory gluten statement.

### **Example 2**

Breakfast cereals (8) - 4 nuts/peanuts, 2 milk, 2 gluten.

Product numbers of breakfast cereals = 8. The internal BRC-FDF survey (2011)<sup>24</sup> showed that breakfast cereals had advisory statements for the following allergens in the following proportions: gluten 15.5%, peanut 12.5%, nuts 48.2% and milk 15.8%.

Therefore, of the 4 breakfast cereals for nuts/peanuts, 2 different types of breakfast cereal (e.g. corn base and puffed rice cereal) should be sampled in duplicate with a "may contain peanuts/nuts" and 2 comparable products in duplicate with no advisory peanut/nut statement, of the 2 breakfast cereals for milk, 1 in duplicate should be sampled with a "may contain milk" and 1 comparable product in duplicate with no advisory milk statement, of the 2 breakfast cereals for gluten, which would be breakfast cereals that either are

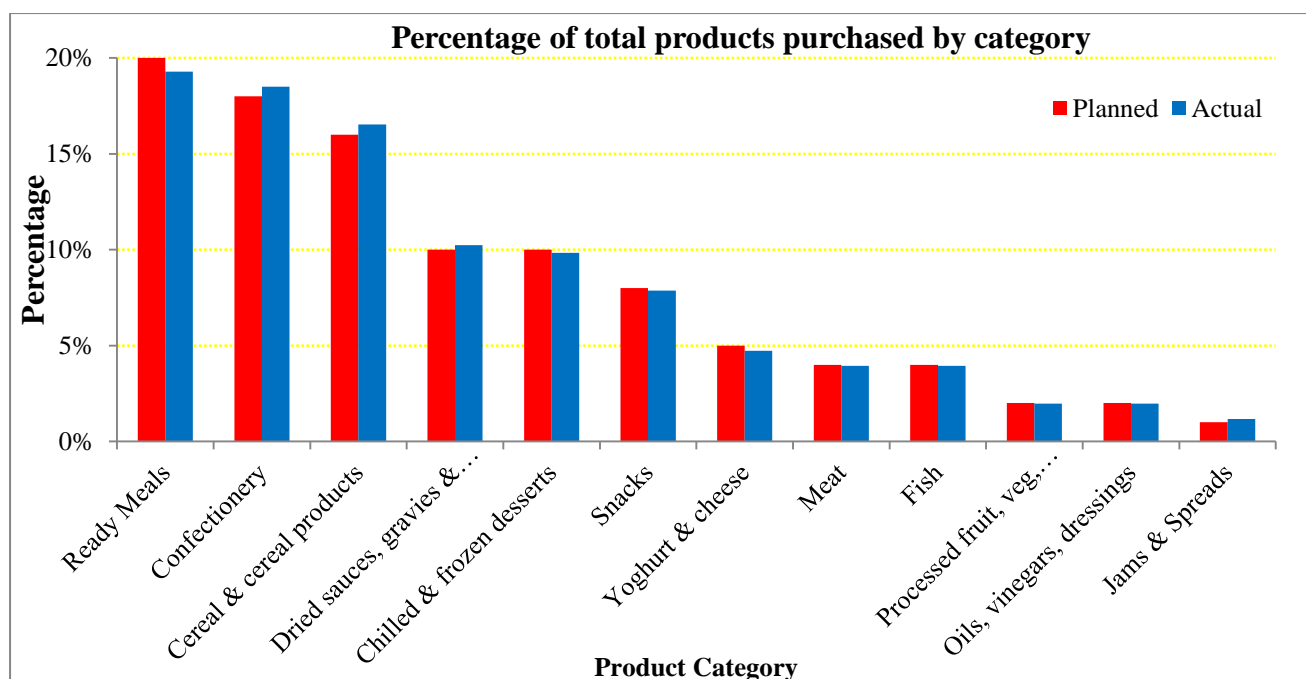
sold as gluten-free or do not contain gluten as an ingredient, 1 should be sampled in duplicate with a "may contain gluten" and 1 comparable product in duplicate with no advisory gluten statement.

### **Comparability of products**

Comparable products were considered to be from the same product type (e.g. 2 breakfast cereals) and be as similar as possible but they did not necessarily have to contain the same ingredients. For example, if a chocolate coated puffed rice breakfast cereal product was selected with a may contain nuts label, the best choice of a comparable product could be another chocolate coated puffed rice breakfast cereal without a may contain nuts label which did not have nuts listed as an ingredient. Alternatively if this was not possible a breakfast cereal (maybe a cornflake) without a may contain nuts label which did not have nuts listed as an ingredient. This selection in some cases was expected to be difficult and therefore time consuming, so the choice of comparable product was purposively not made too restrictive.

Products were ideally matched with their comparable product at the same time in case the comparable product was either too hard or impossible to find. This approach made matching comparable products together easier and also avoided wasted purchases and testing costs in the cases where a comparable product could not be found.

Ideally, for branded products, when a product from a brand (e.g. Kellogg's) had been selected from a product type (e.g. Breakfast cereals), that same brand should not be selected again for the same product type. However, for some product types with large sample numbers (e.g. Milk chocolate), sampling more than one product type from the same brand was allowed. For more detailed information provided to the sampling officers, a flow chart is displayed in Annex. 3, Figure 20.



**Figure 4. Comparison of actual product purchased against planned according to sampling plan** – this figure compares the numbers of products purchased against the sampling plan as a percentage by product category

All products from a given product category were sampled within 0.5% of the planned numbers when compared to the total overall numbers of products purchased. The total number of products purchased for the survey was 508 in duplicate (Total of 1016 samples). The reasons for any deviation from the agreed sampling plan are set out below, product category by product category.

Charts showing the comparison of actual product selection versus the sampling plan are shown in Annex 4.

### 1. Cereal and cereal products category

(Annex 4, Figure 21)

There were some amendments when progressing from the original sampling plan to the agreed sampling plan. These were:

- Muesli was excluded from the breakfast cereals because the method of manufacture of muesli was considered to be significantly different to that of the other product types in this category.
- Sandwiches were removed from the cereal product category and placed into the ready meals category as the method of manufacture of sandwiches was considered to be more similar to a ready meal, than to a cereal product.

The only product type that was not sampled in accordance with the agreed sample plan was the dried rice. This was oversampled by 2 products in duplicate in error, but no other categories were reduced to compensate for this.

Overall allergens for comparison were expected to be gluten (16 products), milk (18) and nuts/peanuts (48). They were sampled in the following numbers –



gluten (8), milk (20) and nuts/peanuts (56). The conclusion is that there were fewer products with gluten advisory statements sampled than expected and many more products with advisory statements for nuts /peanuts within this product category. The use of gluten advisory labelling was expected to be higher because products made with rice or maize would most likely be made in shared facilities with gluten.

## **2. Confectionery category**

(Annex 4, Figure 22)

The only product type that was not sampled in accordance with the agreed sample plan was the dark chocolate. This was oversampled by two sets (4 products in duplicate, 8 samples) in error but no other categories were adjusted down to compensate.

Overall allergens for comparison were expected to be gluten (14 products), milk (8) and nuts/peanuts (68). They were sampled in the following numbers – gluten (40), milk (8) and nuts/peanuts (46). The conclusion is that there were many more gluten advisory statements sampled than expected and as had been found in previous surveys <sup>3</sup> and <sup>24</sup> and slightly fewer for nuts / peanuts. The underuse of gluten advisory in other categories and the abundant use of gluten advisory in this category were used as an opportunity to oversample.

## **3. Chilled and frozen desserts category**

(Annex 4, Figure 23)

There were some considerable amendments from the original sampling plan to the agreed sampling plan which were:

- Cheesecakes – All products found had nuts as the allergen for comparison; none could be found for milk or gluten. Although there were some cheesecakes that did not contain gluten and some that did not contain milk as ingredients, there were no comparable products with the appropriate advisory labelling to choose from. Therefore, overall product numbers were reduced by two products (4 samples) within this product type to avoid only sampling one type of allergen for comparison.
- Gateaux – Products could not be found without nut advisory labels, so comparable products were very hard to find. Most products also contained gluten and often milk, so the numbers from this product type could not be sampled in accordance with the agreed sampling plan. It was agreed that an additional product type could be added (sorbets) and that some of the other product types (chilled mousse, fruit pies and ice cream) could be increased to ensure that the numbers for the overall product category were equivalent to the agreed sampling plan. Meringues were not affected as sufficient samples had been collected from this product type.
- Meringues are not sold chilled but considered to fit into this category of desserts.

Overall allergens for comparison were expected to be gluten (12 products), milk (10) and nuts/peanuts (28). They were sampled in the following numbers – gluten (2), milk (2) and nuts/peanuts (46). The conclusion is that there were fewer gluten and milk advisory statements sampled than expected and many more products with advisory labels for nuts / peanuts. This was particularly evident in the gateaux (including roulade) product type and represented the main issue throughout this category.

#### **4. Meat category**

(Annex 4, Figure 24)

All products were collected in accordance with the agreed sampling plan. Vegetarian sausages were not included in this product category; they were moved into the ready meals category as a separate product type as the method of manufacture was more similar to a ready meal.

Overall allergens for comparison were expected to be gluten (8 products), milk (4) and nuts/peanuts (8). They were sampled in the following numbers – gluten (0), milk (4) and nuts/peanuts (16). The conclusion is that there were no gluten advisory statements sampled, and many more products with advisory labels for nuts / peanuts.

#### **5. Fish category**

(Annex 4, Figure 25)

All products were collected in accordance with the agreed sampling plan. For fish pies and fish in sauce, the only allergen that was available to be used for comparison was nuts, so no comparable products were collected for gluten or milk.

Overall allergens for comparison were expected to be gluten (8 products), milk (8) and nuts/peanuts (4). They were sampled in the following numbers – gluten (0), milk (6) and nuts/peanuts (14). The conclusion is there were no gluten advisory statements sampled and many more products with advisory labels for nuts / peanuts.

#### **6. Ready meals**

(Annex 4, Figure 26)

All products were collected in accordance with the agreed sampling plan. The agreed plan differed from the original plan in order to include sandwiches (originally planned in the cereal and cereal product category) and meat alternatives (originally in the meat and meat product category) as it was agreed they fitted more closely within the ready meal category. Sampling in the Indian and Oriental product types resulted in more than one brand being sampled as a result of a limited number of brands in these product types. All sandwiches either contained gluten as an ingredient or if gluten was not present as an ingredient, did not carry a gluten advisory label.

Overall, allergens for comparison were expected to be gluten (24 products), milk (18) and nuts/peanuts (56). They were sampled in the following numbers – gluten (8), milk (6) and nuts/peanuts (84). The conclusion is that there were fewer gluten and milk advisory statements sampled than expected and many more products with advisory labels for nuts / peanuts than expected in this category. All of the four allergens are used widely in this category; the levels of advisory labelling for nuts / peanuts are much higher than that for milk / gluten. This category is also likely to employ extensive wet chemical cleaning during the manufacturing process and across the line.

## **7. Processed fruit, veg and pulses**

(Annex 4, Figure 27)

All products were collected in accordance with the agreed sampling plan. The only allergen for comparison that could be collected in the tinned fruit, tinned vegetables and tomatoes and tinned baked beans was nuts.

Overall allergens for comparison were expected to be gluten (6 products), milk (0) and nuts/peanuts (4). They were sampled in the following numbers – gluten (2), milk (0) and nuts/peanuts (8). The conclusion is that there were fewer gluten advisory statements sampled than expected and more products with advisory labels for nuts / peanuts than expected.

## **8. Jams and spreads**

(Annex 4, Figure 28)

All products were collected in accordance with the agreed sampling plan.

Overall, allergens for comparison were expected to be gluten (2 products), milk (0) and nuts/peanuts (4). They were sampled in the following numbers – gluten (0), milk (0) and nuts/peanuts (6). The conclusion is that there were no gluten advisory statements sampled and more products with advisory labels for nuts / peanuts. There was expected to be a low level of advisory labelling across this category; this was indeed the case.

## **9. Oils, vinegars and dressings**

(Annex 4, Figure 29)

All products were collected in accordance with the agreed sampling plan.

Overall, allergens for comparison were expected to be gluten (2), milk (2) and nuts/peanuts (6). They were sampled in the following numbers – gluten (0), milk (2) and nuts/peanuts (8). The conclusion is that there were fewer gluten advisory statements sampled than expected and more products with advisory labels for nuts / peanuts.

## **10. Dried sauces, gravies and mixes**

(Annex 4, Figure 30)

The only product type that was not sampled in accordance with the agreed sample plan was the gravy granules. This was oversampled by one product set in duplicate (4 products; 8 samples) but no other categories were adjusted down to compensate. Sampling in the dried stuffing mixes and the dried sauces product types resulted in more than one brand being sampled as a result of a limited number of brands in these categories.

Overall, allergens for comparison were expected to be gluten (20), milk (18) and nuts/peanuts (12). They were sampled in the following numbers – gluten (6), milk (18) and nuts/peanuts (28). The conclusion is that there were far fewer gluten advisory statements sampled than expected and many more nuts / peanuts.

## **11. Snacks**

(Annex 4, Figure 31)

All products were collected in accordance with the agreed sampling plan.

Overall, allergens for comparison were expected to be gluten (16 products), milk (12) and nuts/peanuts (12). They were sampled in the following numbers – gluten (8), milk (10) and nuts/peanuts (22). The conclusion is that there were far fewer gluten advisory statements sampled than expected and many more products bearing advisory labels for nuts / peanuts than expected.

## **12. Yoghurt and cheese**

(Annex 4, Figure 32)

All products were collected in accordance with the agreed sampling plan. All products in this category either contained milk as an ingredient or if milk was not present as an ingredient, did not carry a milk advisory label. Dairy free milk alternatives were selected as part of the dairy free yoghurt product type because of the similarity of the manufacturing process between these foods.

Overall, allergens for comparison were expected to be gluten (4 products), milk (4) and nuts/peanuts (16). They were sampled in the following numbers – gluten (2), milk (0) and nuts/peanuts (22). The conclusion is that there were slightly fewer products with gluten advisory statements sampled than expected, no products with milk advisory statements sampled and more products bearing advisory statements for nuts / peanuts sampled than expected.

## **Summary of sampling strategy**

The only product types that proved very difficult to sample were cheesecakes and gateaux. This was a result of a limited range of allergen advisory labelling for comparable samples. The only allergen available for comparison was nuts. Some brands were sampled more than once in a product type in order to collect the comparable products. Any products that were oversampled in error (8 products in duplicate) did not result in any category being reduced in product numbers.

Overall, allergens for comparison were expected to be gluten (132/500), milk (102/500) and nuts/peanuts (266/500). However, in actuality they were sampled in the following numbers – gluten (76/508), milk (76/508) and nuts/peanuts (356/508).

- 58% (76/132) of the products sampled had advisory labelling for gluten ,
- 74% (76/102) of the products sampled had advisory labelling for milk and
- 134% (356/266) of products sampled had advisory labelling for nuts/peanuts

This reflects the well-known, widespread use of advisory labelling for nuts and peanuts in general in the food production industry. The use of advisory labelling for gluten and milk is lower, despite their much wider use as ingredients across the selection of product categories in this survey. The very low use of advisory labelling for hazelnut was evident in this survey.

Without undertaking detailed discussions with manufacturers, RSSL are unable to ascertain the reason for why advisory labelling for allergens is used in the different product categories. Without these discussions, RSSL are also unable to ascertain why the use of advisory labelling for nuts / peanuts is more prevalent than advisory labelling for milk / gluten in this survey.

## **Task 03 Implementation of sampling programme**

VTL undertook a phased sampling programme over an 8 month period primarily in Greater London and East Anglia with some samples from Scotland, Wales and Northern Ireland. The first samples were collected in July 2012 and the final ones in March 2013. A break was taken in December 2012 in order to address inclement weather and allow for the Christmas holidays. Products were purchased and approximately 30 products in duplicate were delivered to RSSL every 2 weeks. All products were purchased by sampling officers following an agreed protocol and plan with as little duplication of product brand as possible. Sampling officers were professional people carefully selected for their relevant academic qualifications, organisational skills and the majority had experience of the food industry/food science.

All VTL staff were trained and were regularly appraised to ensure they had the competency to carry out the duties assigned to them. Project advice was available to the sampling officers by way of twenty four hour telephone access to the Projects Manager or another experienced member of the VTL management team. Products requiring special temperature storage conditions i.e. those that declare 'keep refrigerated', were handled throughout all transfer, storage and onward stages of the operation distribution chain at the recommended temperature range. Purchase details (including retailer information), product description, pack size, manufacturing code details (shelf life and batch codes), date and time of purchase, allergen ingredients and allergen advisory labelling were recorded on a Microsoft Excel spreadsheet (2007) if available. Each purchase was made following the agreed sampling protocol and was allocated a unique LIMS number.

Precautions were taken at all stages to ensure that cross contamination from allergens was prevented. Each sample was placed in a separate sampling bag during transportation and storage. Samples were inspected for any signs of damage and rejected if necessary. Sample deliveries were made to RSSL via a VTL approved carrier at times according to an agreed schedule (every 2 weeks). Regular reports (every 2 weeks) on the progress and status of the sampling and associated aspects of the project were sent via email to RSSL by VTL.

In accordance with the FSA Survey guidelines (<http://food.gov.uk/science/research/surveillance/guidefsatechsurv>), a letter from the FSA was sent to all relevant retail outlets, to advise them that samples had been taken from their premises in order to carry out the survey (Appendix 2.1). In addition, the head office of the British Retail Consortium (BRC) (e.g. Tesco, Asda and Sainsbury's) was sent an agreed general interested parties letter to inform their members of the timeframe of the survey and locations of where the sampling would be taking place (Appendix 2.2). A complete list of details for all samples purchased was sent to the FSA at the end of the sampling period.

The sampling started on 24<sup>th</sup> July 2012 and ended 5<sup>th</sup> March 2013. A practice sampling exercise was undertaken prior to the formal sampling in order to demonstrate that the sampling protocol could be followed correctly by VTL. This was shown to be the case without any requirement for changes to the original protocol.

Products were purchased in 16 lots with amounts for each lot varying from 4 products (the final lot) in duplicate to 50 products in duplicate. Samples were delivered to RSSL in accordance with the plan. One product was rejected as a result of damage in transit. Reports were issued to the FSA every 2 weeks, following the progress and status of sampling. Any products with a result above the reporting limit for a test were reported to the FSA as they were analysed.

All products were checked carefully for the comparability of the product pairs. On rare occasions, if comparability was not suitable, products were rejected and were re-purchased.

#### **Task 04**

#### **Quantitative Analysis of Samples**

Following sample delivery to RSSL, all pertinent labelling information was reconciled against the VTL/RSSL spreadsheet. All packaging was digitally scanned in high resolution and attached into LIMS. Confirmation of the analysis required for each product was made by RSSL, following the decision tree in the FSA protocol (<http://food.gov.uk/science/research/surveillance/guidefsatechsurv>), and reconciliation with the sampling rationale. Products were analysed within an appropriate timeline (taking account of 'Best Before' and 'Use By' dates) so that any positive results above the reporting limit for the test could be reported to the FSA.

## **Collation of Analytical Results**

The ELISA assay kit instructions were followed according to RSSL's SOPs and documented deviations, all of which have been previously validated. These may include deviations such as adjustments to sample weights and subsequent dilutions of samples.

An extensive array of IQCs, were used to demonstrate the performance of each and every ELISA assay. These included a blank extraction control, duplicate positive control samples, and duplicate kit standards. The acceptability of these IQCs is detailed in the materials and methods section (Table 2).

Results were reported to the FSA on a bi-weekly basis. Any result where the allergen was detected above the reporting limit for that test, were reported to the FSA as soon as possible, but within a maximum of two working days once the results were available. Progress against the sampling plan was also sent to the agency on a bi-weekly basis.

Results were reported in two formats to the FSA. This was as Certificates of Analysis generated through LIMS (accessible through Results Online, a secure internet based system) and the spreadsheet that was used to record ingredients and labelling declarations.

### **3.0 Results and discussion**

The results sections are divided into the following:

1. The analytical results of allergen testing
2. Review of advisory labelling
3. The results of the advisory labelling compared to the levels of allergen detected.

A full breakdown of the results can be found in annex 14. The letter sent to brand owners making them aware of their results from the survey can be found in annex 12 and their responses to the results can be found in annex 13.

#### **3.1 Results of the analytical testing**

##### **Objectives associated with section 3.1:**

(i) to investigate the frequency and level of allergen cross-contamination in a sample of pre-packed processed food products with advisory labelling for the following 4 food allergens; milk, cereals containing gluten, peanut and hazelnut

(ii) to investigate the frequency and level of allergen cross-contamination in a sample of pre-packed processed food products that lack advisory labelling (but are similar to products bearing such statements) for the following 4 food allergens; milk, cereals containing gluten, peanut and hazelnut

##### **Analytical testing**

All analytical results were recorded as part of the survey in an excel spreadsheet. Any products that had failed the spike recovery test were not included in the data analysis and any results that had been originally reported as >top standard for the assay, were quantified and the final numerical result was the one used for the data interpretation. The results were then categorised into three levels of total protein, shown in Table 4.

The three levels selected were non-detectable using the reporting limit of the test, up to 20 mg/kg protein and greater than 20 mg/kg protein. The non-detectable for peanut was altered to <1 mg/kg to include the results from the ELISA Systems tested samples and the up to 20 adjusted to >1 mg/kg but <20 mg/kg. These are shown as follows:



**Table 4: Categorisation of the levels of allergen into three groups used for data analysis** – this table shows the three groups of allergen protein level used for data analysis – non-detectable was allergen not detected above the reporting limit which varies for each allergen, up to 20 mg/kg which is the level from the reporting limit up to 20 mg/kg and the third category of greater than 20 mg/kg for each allergen

<b>Allergen</b>	<b>Non-detectable</b>	<b>Up to 20mg/kg protein</b>	<b>Greater than 20 mg/kg protein</b>
Gluten	<10 mg/kg	>10mg/kg but <20 mg/kg	>20 mg/kg
Milk Protein	<2.5 mg/kg	>2.5 mg/kg but <20 mg/kg	>20 mg/kg
Hazelnut Protein	<1 mg/kg	>1 mg/kg but <20 mg/kg	>20 mg/kg
Peanut Protein	<1 mg/kg	>1 mg/kg but <20 mg/kg	>20 mg/kg

The choice of level was made in order to be able to compare results across the four allergens. The results for the peanut tests for the majority of the results were converted from the kit reporting units (Neogen Biokits) of whole peanut into peanut protein (by dividing the results of whole peanut by 4 because peanut is approximately 25% protein). The results for the 20 samples tested with the ELISA Systems kit were reported as peanut protein, so no additional conversion was required. The decision to use 20 mg/kg as a cut off between two levels was made based on the quantitative ranges of the kits used in the study and to ensure data was comparable across the four allergens. There are no internationally agreed legal labelling limits for the use of advisory labelling for the four allergens used in this study.

### **Peanut retesting**

Of the 20 samples that were re- tested for peanut protein, only two returned a positive result above the reporting limit. These were the samples with the RSSL Ref codes P12-04782-185 and P12-04782-186 with results of 11 and 18 mg/kg peanut protein respectively. The remaining 18 samples tested did not return a positive result above the reporting limit of 1 mg/kg peanut protein and the results for these were recorded as such. The results from this ELISA kit concurred with the results from the DNA testing conducted. For the samples that were tested originally with the Neogen Biokits peanut test, all non-detectable results were recorded as <0.25 mg/kg peanut protein; with the ELISA Systems kit the 18 non-detectable results were recorded as <1 mg/kg peanut protein. The previous results with the Neogen Biokits for the two positive samples were 12 and 19 mg/kg peanut protein which is very consistent with the results from the ELISA Systems kit.

### **Total number of test results recorded**

A total of 508 products were purchased in duplicated (1016 samples). Each sample was analysed for all allergens that were not present as an ingredient, regardless of whether there was advisory labelling present on the product.

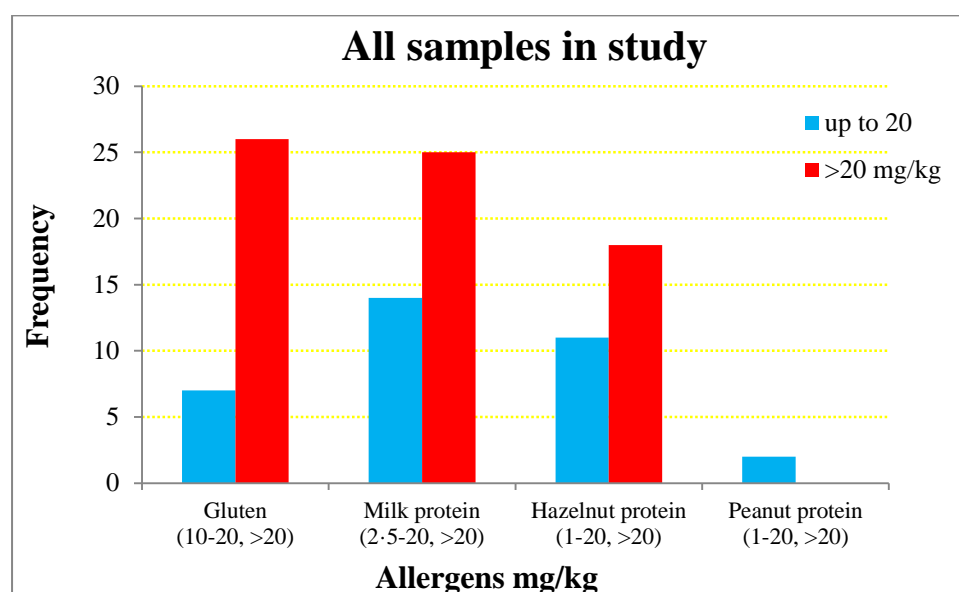
The total number of results for each allergen is shown in Table 5.

**Table 5: Total number of test results recorded** – this table shows for each allergen the total number of test results (excluding spike failures) separated out into results where allergen was not detected, where allergen was detected above the reporting limit for the test which when these two are added together shows the total number of tests.

Allergen	Number of test results when allergen not detected	Number of test results when allergen was detected	Total number of test results recorded
Gluten	509	33	542
Milk	435	39	474
Hazelnut	959	29	988
Peanut	948	2	950

This shows that on average of the 2954 tests recorded, there were 2.9 test results per sample. The original estimation of the number of tests per sample was 3 per sample.

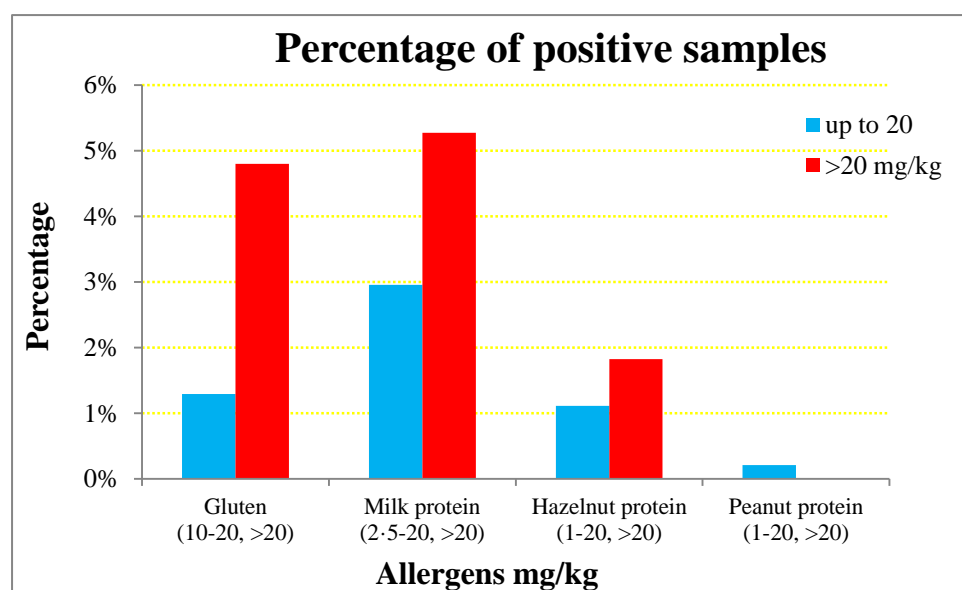
The following chart (Figure 5) shows the number of samples (with and without advisory labelling) for each allergen in the 'up to 20 mg/kg protein' and the 'greater than 20mg/kg protein' category.



**Figure 5. Number of samples for each allergen in the two results categories when allergen was detected** – this figure shows the separation of results into the "up to 20 mg/kg allergen protein" and the "greater than 20 mg/kg allergen protein" for the four allergens.

The following chart (Figure 6) shows the percentage of samples (with and without advisory labelling) for each allergen in the 'up to 20 mg/kg protein' and

the 'greater than 20mg/kg protein' category as a percentage of the overall sample numbers.



**Figure 6. Percentage of samples for each allergen in the two results categories when allergen was detected** – this figure shows the separation of results into the “up to 20 mg/kg allergen protein” and the “greater than 20 mg/kg allergen protein” for the four allergens compared to the total number of tests recorded (excluding spike failures).

The overall percentage of samples with and without advisory labelling with allergen above the detectable limit (excluding spike failures) is as follows: -

- 6.1% of samples tested for gluten (33/542)
- 8.2% of samples tested for milk (39/474)
- 2.9% of samples tested for hazelnut (29/988)
- 0.2% of samples tested for peanut (2/950)

The vast majority of test results for all allergens showed a not detectable result. The distribution of all tests showed that more tests were undertaken for hazelnut followed by peanut, followed by gluten and then milk. For all of the allergens except peanut, there were more results recorded at the >20 mg/kg level than in the up to 20 mg/kg level. There were no results recorded for peanut at all in the >20 mg/kg level.

Table 6 shows the highest levels of allergen detected in total protein across the snapshot of sample result.

**Table 6: Highest recorded results by allergen** – this table shows the highest level of allergen detected for the four allergens detailing the results from the duplicate pair of samples.

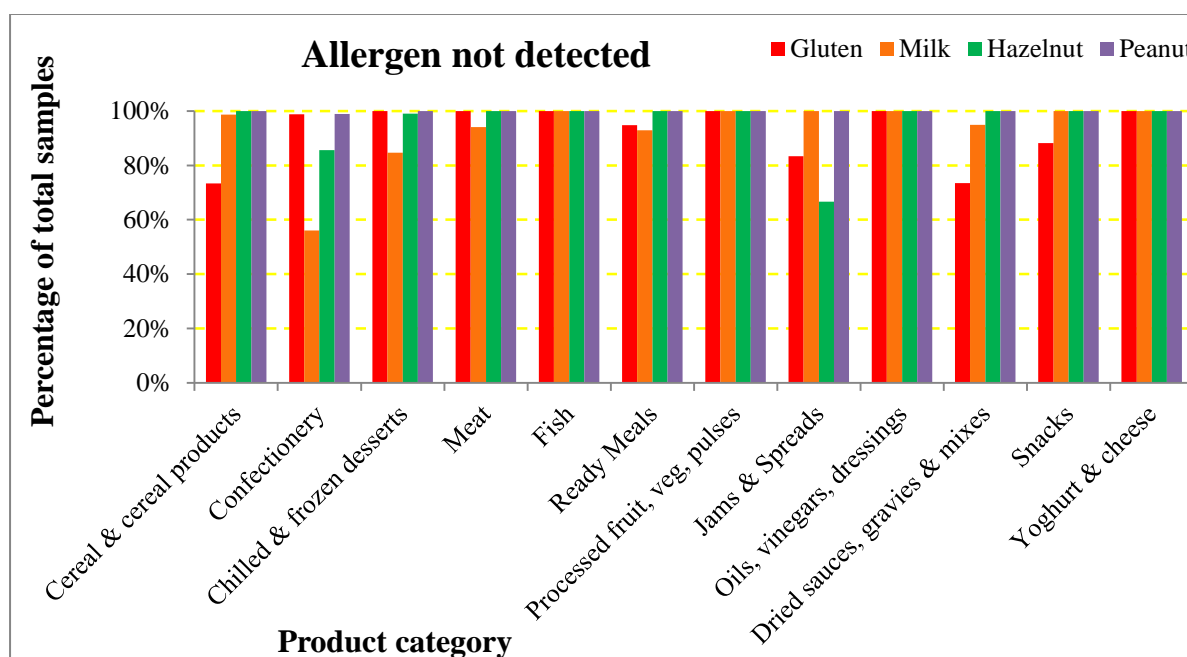
<b>Allergen</b>	<b>Result from duplicates (mg/kg) protein</b>	<b>RSSL Ref No</b>	<b>Product</b>	<b>Product Type</b>
<b>Gluten</b>	155	P12-04781-137	Meridian Organic peanut butter & oat bar	Cereal and cereal products/ cereal bar
	210	P12-04781-138	Meridian Organic peanut butter & oat bar	Cereal and cereal products/ cereal bar
<b>Milk</b>	4100	P12-04782-25	Asda Dark chocolate	Confectionery / Dark Chocolate
	4400	P12-04782-26	Asda Dark chocolate	Confectionery / Dark Chocolate
<b>Hazelnut</b>	170	P12-04782-85	Balance Milk chocolate (38% cocoa) with stevia - no sugar added	Confectionery / Milk Chocolate
	170	P12-04782-86	Balance Milk chocolate (38% cocoa) with stevia - no sugar added	Confectionery / Milk Chocolate
<b>Peanut</b>	11	P12-04782-185	Bon Bon Buddies One Direction milk chocolate egg with choc bars	Confectionery / Milk Chocolate
	18	P12-04782-186	Bon Bon Buddies One Direction milk chocolate egg with choc bars	Confectionery / Milk Chocolate

## Results of analytical testing where allergen was not detected

Overall the following percentage of samples (both with and without advisory labelling) were found to have no detectable allergen (excluding spike failures): -

- 93.9% of samples tested for gluten (509/542)
- 91.8% of samples tested for milk (435/474)
- 97.1% of samples tested for hazelnut (959/988)
- 99.8% of samples tested for peanut (948/950)

The following chart (Figure 7) displays the number of samples that had no detectable allergen as a percentage of the total number of tests carried out for that allergen in that product category. For example in the cereal and cereal product category, there were 30 samples tested for gluten; of these 8 samples tested positive, therefore 22 samples were not detected. Consequently  $22/30=73.3\%$  samples were not detected of those analysed. Any samples that failed the spike recovery test were removed from the number of samples tested so that only "successful" sample tests were included. For example in the dried sauces, gravies and mixes product category, there were 36 samples tested for gluten but 2 failed the spike recovery test, so only 34 of them were "successful". Of those 34, 9 samples were detected as positive for gluten, so 25 samples were not detected. Consequently,  $25/34=73.5\%$  were not detected of those samples successfully tested.



**Figure 7. The percentage of samples where no allergen was detected by product category** - this figure shows the number of samples that had no detectable allergen as a percentage of the total number of tests carried out for that allergen in that product category.

The type of allergen detected varied according to the product category. The product category where the allergens were detected in the highest numbers is as follows: -

- Gluten was detected in 27% of cereal and cereal products tested for gluten (73% of products in this category did not contain undeclared gluten)
  - Milk was detected in 44% of confectionery products tested for milk (56% of products in this category did not contain undeclared milk)
  - Hazelnut was detected in 38% of jams and spreads tested for hazelnut (67% of products in this category did not contain undeclared hazelnut)
  - Peanut was detected in 1% of confectionery products tested for peanut (99% of products in this category did not contain undeclared peanut)
- For gluten, the next highest percentage of non-detectable results by product categories were dried sauces, gravies and mixes (73.5%), jams and spreads (83.3%), snacks (88.2%), ready meals (94.7%) and confectionery (98.8%) with the remainder at 100%. Consequently the detectable rates by product category were dried sauces, gravies and mixes (26.5%), jams and spreads (16.7%), snacks (11.8%), ready meals (5.3%) and confectionery (1.2%) with the remainder at 0%.
  - For milk the next highest percentage of non-detectable results by product category were chilled and frozen desserts (84.6%), ready meals (92.9%), meat (94.1%), dried sauces, gravies and mixes (94.9%), cereal and cereal products (98.6%) with the remainder at 100%. Consequently the detectable rates by product category were chilled and frozen desserts (15.4%), ready meals (7.1%), meat (5.9%), dried sauces, gravies and mixes (5.1%), cereal and cereal products (1.4%) with the remainder at 0%.
  - For hazelnut the next highest percentage of non-detectable results by product category were confectionery (85.5%), chilled and frozen desserts (99%) with the remainder at 100%. Consequently the detectable rates by product category were confectionery (14.5%), chilled and frozen desserts (1%) with the remainder at 0%.
  - For peanut the only category with detectable results was confectionery with all the remainder at 100% of non-detectable results. Consequently the detectable rates by product category for confectionery was 1% with the remainder at 0%.

By product category, the highest percentage of tests where allergen was detected was confectionery with 1.2% of gluten, 44% of milk, 14.5% of hazelnut and 1.1% of peanut tests returning a detected result. In fact, only confectionery as a product category returned some positive tests for each of the four allergens.

### **Reportable positive allergen test results above the detectable level by product category**

In this section of the report we have investigated the number of positive results per product category and per allergen. Please see Annex 6 for a breakdown of product types with each product category e.g. cereal and cereal products included both breakfast cereals and cereal bars as product types.

## 1. Cereal and cereal products category:

Number of products purchased in the category- 84

Number of samples purchased in the category- 168

### Table to show the total number of tests performed in the cereal and cereal product category

Allergen	Total samples tested (excluding spike failures)
Gluten	30
Milk	70
Hazelnut	164
Peanut	162

#### Gluten

Only 4 samples (from 2 products in duplicate) in the breakfast cereals product type showed positive gluten results above the reporting limit for the test. These were all samples of oats which were agreed as part of the original scope of the survey would be tested for gluten. This is because the risk of cross contamination with other cereals is high. The test kit used for this survey does not detect the protein contained in oats (avenin), so a positive result demonstrates a cross contamination from a cereal containing gluten other than from oats. The labelling regulation for the definition of cereals containing gluten includes oats, wheat, rye, barley, spelt, kamut and their hybridised strains <sup>22</sup>. The levels ranged from 21 to 38 mg/kg. Two of the 4 samples (1 product) carried an advisory label for gluten.

Only 4 samples (from 2 products in duplicate) in the cereal bar product type showed detectable gluten results. The levels ranged from 17 to 210 mg/kg. These products contained oats as ingredients and so the positive results demonstrates a cross contamination from a cereal containing gluten other than oats because the test kit does not detect avenin proteins. Two of the 4 samples (1 product) carried an advisory label for gluten.

There were two samples of cereal bars (P12-04781-99 and P12-04781-100) which contained oats as the only cereal ingredient. These should have been tested for gluten but due to an error on RSSL's part, they were not. All other samples that contained oats as an ingredient, other than those detailed above, also contained other sources of cereals as ingredients and therefore were not tested for gluten.

#### Milk

Only 1 sample in the bread / bread rolls product type showed a detectable milk result. The level detected was 3.9 mg/kg. The duplicate in that pair showed a result of not detectable at the reporting limit of 2.5 mg/kg. The product carried an advisory label for milk.

#### Peanut

There were no products with detectable levels of peanut in this category.

### Hazelnut

There were no products with detectable levels of hazelnut in this category.

### Spike failures

18 samples failed the spike recovery test in this category for milk so no result was reportable for these samples. These were in the following product types; flour 2, breakfast cereals 8, ambient, stable cakes 4 and savouries 4.

## **Discussion**

Gluten was the most frequently found allergen in the cereal and cereal products category.

There was no difference in levels of gluten between the breakfast cereals that carried a gluten advisory label and those that did not. For the cereal bars the levels of gluten found for products with advisory label were at least 5 times higher than those that were not. However, there was only a very small sample size so it is not possible to draw definitive conclusions. Milk was almost completely non-detectable in this category. Hazelnut and peanut cross-contamination was not detected at all in this category, in products with and without an advisory label. The results of no detectable levels for peanuts or hazelnuts in this category could suggest that these allergens are well managed and the cleaning methods effective or that the nature of the snapshot survey and the possibility of the heterogeneous contamination may have resulted in either a lower detectable frequency or indeed a higher one.

In RSSL's experience, the use of dry cleaning in this category and the challenges of shared equipment and environmental cross contamination could help to explain the findings but without a detailed investigation with the specific manufacturers, it is impossible to corroborate this.

## **2. Confectionery category**

Number of products purchased in the category- 94

Number of samples purchased in the category- 188

### **Table to show the total number of tests performed in the confectionery product category**

Allergen	Total samples tested (excluding spike failures)
Gluten	160
Milk	50
Hazelnut	166
Peanut	178

### Gluten

Only 2 samples (from 1 product) in the milk chocolate product type showed detectable gluten levels. The levels detected were 51 and 53 mg/kg in the duplicate pair of samples. There was an advisory label for gluten.



### Milk

Only 4 samples (from 2 products) in the sweets product type showed detectable milk levels. The levels detected were 14 and 12 mg/kg in the duplicate pair. There was an advisory label for milk.

There were 18 samples (from 9 products) in the dark chocolate product type that showed detectable levels of milk. The levels ranged from 4.3 to 4400 mg/kg. All carried an advisory label for milk. Only 2 samples (from 1 product) in the white chocolate product type showed detectable levels of milk and this was in a specialist vegan chocolate bar. There was an advisory label for milk.

### Hazelnut

There were 6 samples (from 3 products) in the dark chocolate product type that showed detectable levels of hazelnut. The levels ranged from 17 to 78 mg/kg. All carried an advisory label for nuts. There were 18 samples (from 9 products) in the milk chocolate product type that showed detectable levels of hazelnut. These ranged from 1 to 170 mg/kg with more in the >20 mg/kg than in the up to 20 mg/kg range. All carried an advisory label for nuts.

### Peanut

Only 2 samples (from 1 product) in the milk chocolate product type showed detectable peanut levels. The levels detected were 11 and 18 mg/kg in the duplicate pair. There was an advisory label for peanut.

### Spike failures

Four samples failed the spike recovery test in this category for peanut so no result was reportable for these samples. These were in the milk chocolate product type and all were fruit flavoured chocolate. Interference with fruit flavours in chocolate, in our experience, is a common issue with allergen ELISA testing.

## **Discussion**

The only product in this category with a detectable level of gluten carried an advisory label for gluten. Milk was clearly frequently detected in the dark chocolate product type from low to very high levels but there were no instances of this without advisory labelling and this issue has been widely reported over recent years and is a result of cross-contamination due to manufacturing methods therefore the high use of advisory labelling is expected. Milk cross contamination is known to be a result of the same lines being used for the production of milk and dark chocolate. The level of milk contamination varies within batches, and could explain the variation in the results obtained.

Hazelnuts were also frequently detected in the dark and milk chocolate product types but again always with an advisory label highlighting. The challenges of removing cross contact risks associated with tree nuts and peanuts is also well known. This is heterogeneous cross contamination and as a result it can be difficult to manage the small particulate contamination to ensure the removal of particles from shared equipment and environment. As a result cross contamination risks remain high however it is likely that the allergen would not be detected in the vast majority of products. Therefore, advisory labelling is

often warranted on such products. Without a detailed investigation, it is not possible to reach definitive conclusions as to the frequency and levels of cross contamination found. Peanut was detected rarely and carried an advisory label.

### **3. Chilled and frozen desserts category**

Number of products purchased in the category- 50

Number of samples purchased in the category- 100

#### **Table to show the total number of tests performed in the chilled and frozen desserts product category**

<b>Allergen</b>	<b>Total samples tested (excluding spike failures)</b>
<b>Gluten</b>	<b>56</b>
<b>Milk</b>	<b>26</b>
<b>Hazelnut</b>	<b>100</b>
<b>Peanut</b>	<b>100</b>

#### Gluten

There were no products with detectable levels of gluten in this category.

#### Milk

Only 1 sample in the fruit pies product category showed a detectable milk result. The level was 2.6 mg/kg. The duplicate was not detectable. There was no advisory label for milk.

There were 3 samples in the sorbet product type that showed detectable levels of milk. They were 2.7 mg/kg in duplicate for a duplicate pair which did carry an advisory label for milk and 29 mg/kg and not detectable for a duplicate pair which did not carry an advisory label. This product was a pack of several fruit flavoured lollies and all samples were composited to make a homogeneous sample containing all of the constituent components.

#### Hazelnut

Only 1 sample in the cheesecake product type showed detectable levels of hazelnut. The level was 1 mg/kg and the duplicate in the pair was not detectable. There was an advisory label for nuts.

#### Peanut

There were no products with detectable levels of peanut in this category.

### **Discussion**

Milk was detected occasionally in this product category and not always with an advisory label. The detection of milk in products without advisory labelling may present a risk to milk allergic individuals. These along with all other positive sample results were reported to the FSA for full risk assessment and necessary follow up with individual companies. Gluten was not detected at all; hazelnut only once and at a very low level close to the reporting limit of the test and with an advisory label and peanut not at all.

#### 4. Meat and meat products category

Number of products purchased in the category- 20

Number of samples purchased in the category- 40

##### **Table to show the total number of tests performed in the meat and meat product category**

Allergen	Total samples tested (excluding spike failures)
Gluten	10
Milk	34
Hazelnut	40
Peanut	40

##### Gluten

There were no products with detectable levels of gluten in this category.

##### Milk

Only 2 samples (from 1 product) in the ham product type showed detectable levels of milk. They were 5.5 and 6.6 mg/kg in a duplicate pair. There was an advisory label for milk.

##### Hazelnut

There were no products with detectable levels of hazelnut in this category.

##### Peanut

There were no products with detectable levels of peanut in this category.

#### **Discussion**

The only detectable product with milk was a breaded ham, which is a common ingredient in this product type. Again, the advisory label was present. There was no detectable gluten, hazelnut or peanut in this product category. The absence of detectable gluten in this category that uses it as a common ingredient in breaded products could, in RSSL's experience suggest that it is well managed and the cleaning of shared equipment effective, probably through wet cleaning. Without a detailed investigation with the specific manufacturers, it is impossible to verify this.

#### 5. Fish and Fish products category

Number of products purchased in the category- 20

Number of samples purchased in the category- 40

**Table to show the total number of tests performed in the fish and fish product category**

<b>Allergen</b>	<b>Total samples tested (excluding spike failures)</b>
<b>Gluten</b>	<b>8</b>
<b>Milk</b>	<b>22</b>
<b>Hazelnut</b>	<b>40</b>
<b>Peanut</b>	<b>40</b>

Gluten

There were no products with detectable levels of gluten in this category.

Milk

There were no products with detectable levels of milk in this category.

Hazelnut

There were no products with detectable levels of hazelnut in this category.

Peanut

There were no products with detectable levels of peanut in this category.

**Discussion**

No detectable results for any allergens were found in this category despite gluten and milk being common ingredients in the value added and breaded products in this category. The absence of detectable gluten in this category that uses it as a common ingredient in breaded products could, in RSSL's experience suggest that it is well managed and the cleaning of shared equipment effective, probably through wet cleaning. Without a detailed investigation with the specific manufacturers, it is impossible to verify this.

**6. Ready meals category**

Number of products purchased in the category- 98

Number of samples purchased in the category- 196

**Table to show the total number of tests performed in the ready meals product category**

<b>Allergen</b>	<b>Total samples tested (excluding spike failures)</b>
<b>Gluten</b>	<b>76</b>
<b>Milk</b>	<b>84</b>
<b>Hazelnut</b>	<b>196</b>
<b>Peanut</b>	<b>196</b>

Gluten

Only 2 samples (from 1 product) in the meat alternatives product type showed detectable levels of gluten. They were 12 and 14 mg/kg in a duplicate pair. They carried an advisory label for gluten.

Only 2 samples (from 1 product) in the Indian product type showed detectable levels of gluten. They were 21 and 25 mg/kg gluten in the duplicate pair. They did not carry an advisory label for gluten however the results were only marginally above the legal labelling for "gluten free" <sup>23</sup>.

#### Milk

There were 4 samples (from 2 products) in the sandwiches product type that showed detectable levels of milk. They ranged from 11 to 52 mg/kg milk. None contained an advisory label for milk.

There were 2 samples (from 1 product) in the Indian product type that showed detectable levels of milk. They were 41 and 45 mg/kg milk in a duplicate pair. There was no advisory label for milk.

There were 2 samples (from 1 product) in the sandwich product type that did not contain milk as an ingredient (P12-04786-157 and P12-04786-158) and should have been tested for milk. They were not and this was an error on RSSL's part. They did not carry an advisory label for milk.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures

2 samples (from 1 product) failed the spike recovery test in this category for milk so no result was reportable for these samples. These were in the meat alternatives product type.

### **Discussion**

Milk and gluten were the two allergens detected in this category. The Indian product type showed levels of detectable milk and gluten without advisory for either. The detection of milk and gluten in products without advisory labelling may present a risk to allergic individuals. These along with all other positive sample results were reported to the FSA for full risk assessment and necessary follow up with individual companies. The results of no detectable levels for peanuts or hazelnuts in this category despite their extensive use could suggest that these allergens are well managed and the cleaning methods effective or that the nature of the snapshot survey and the possibility of the heterogeneous contamination may have resulted in either a lower detectable frequency or indeed a higher one. Without a detailed investigation of the specific manufacturers, it is impossible to verify this.

## 7. Processed Fruit, veg and pulses category

Number of products purchased in the category- 10

Number of samples purchased in the category- 20

### Table to show the total number of tests performed in the fruit, veg and pulses product category

Allergen	Total samples tested (excluding spike failures)
Gluten	18
Milk	16
Hazelnut	20
Peanut	20

#### Gluten

There were no products with detectable levels of gluten in this category.

#### Milk

There were no products with detectable levels of milk in this category.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures

4 samples (from 2 products) failed the spike recovery test in this category for milk so no result was reportable for these samples. These were in the dried beans and pulses product type.

## Discussion

No detectable results for any allergens were found in this category. This could be a result of the simplicity of the manufacturing process in this category and the common use of single source ingredients; although some ingredients would be at risk from cross contamination in the supply chain. Although it is also possible that the nature of a snapshot survey and the heterogeneous nature of cross contact from some allergens may have led to these results.

## 8. Jams and spreads category

Number of products purchased in the category- 6

Number of samples purchased in the category- 16

### Table to show the total number of tests performed in the Jams and spreads product category

Allergen	Total samples tested (excluding spike failures)
Gluten	12
Milk	8
Hazelnut	12
Peanut	12

#### Gluten

There were 2 samples (from 1 product) in the savoury spread product type that showed detectable levels of gluten. They were 23 and 24 mg/kg gluten in a duplicate pair. There was no advisory label for gluten however the results were marginally above the legal labelling for "gluten free" <sup>23</sup>.

#### Milk

There were no products with detectable levels of milk in this category.

#### Hazelnut

There were 4 samples (from 2 products) in the sweet spread product type that showed detectable levels of hazelnut. They ranged from 66 to 120 mg/kg hazelnut. They all carried an advisory label for hazelnut.

#### Peanut

There were no products with detectable levels of peanut in this category.

## Discussion

No detectable milk was found in this category. The product in which the gluten was detected did not carry an advisory label. No peanut was detected but the hazelnut was, but both products carried an advisory label. This cross contamination of hazelnut was not unexpected as it was found in the chocolate spread product types. Hazelnuts would be a commonly used ingredient in this production environment and there would be challenges associated with the cleaning practices and controlling cross contamination.

## 9. Oils, vinegars and dressings category

Number of products purchased in the category- 10

Number of samples purchased in the category- 20

### Table to show the total number of tests performed in the Oils, vinegars and dressings product category

Allergen	Total samples tested (excluding spike failures)
Gluten	20
Milk	16
Hazelnut	20
Peanut	16

#### Gluten

There were no products with detectable levels of gluten in this category.

#### Milk

There were no products with detectable levels of milk in this category.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures

4 samples (from 2 products) failed the spike recovery test in this category for peanut so no result was reportable for these samples. These were in the mixed pickles, chutneys and relishes product type. This is not unusual given the matrix interference issues.

## Discussion

No detectable results for any allergens were found in this product category. The products in this category are usually highly refined, derived from allergens rather than containing the allergens themselves as highly refined oils would contain no protein.



## 10. Dried sauces, gravies and mixes category

Number of products purchased in the category- 52

Number of samples purchased in the category- 104

### Table to show the total number of tests performed in the dried sauces, gravies and mixes product category

Allergen	Total samples tested (excluding spike failures)
Gluten	34
Milk	80
Hazelnut	102
Peanut	92

#### Gluten

There were 7 samples (from 4 products) in the dry mix sauces and seasoning mixes that showed detectable levels of gluten. These ranged from 23 to 66 mg/kg gluten. One duplicate pair showed results of 66 mg/kg and not detectable. Three of the 7 samples carried an advisory label for gluten and 4 did not carry advisory labelling. There were 2 samples (from 1 product) in the dried stuffing mixes that showed detectable levels of gluten. They were 21 and 23 mg/kg in a duplicate pair. There was no advisory label for gluten.

#### Milk

There were 8 samples (from 4 products) in the dry mix sauces and seasoning mixes that showed detectable levels of milk. They ranged from 4 to 31 mg/kg milk. Two of the 4 products carried an advisory label for milk.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures:

- 2 samples (from 1 product) failed the spike recovery test in this category for gluten so no result was reportable for these samples. These were in the dry mix sauces and seasoning mixes product type.
- 16 samples (from 8 products) failed the spike recovery test in this category for milk (so no result was reportable for these samples). 14 were in the dry mix sauces and seasoning mixes product type and 2 were in the gravy granules product type.
- 2 samples (from 1 product) failed the spike recovery test in this category for hazelnut (so no result was reportable for these samples). These were in the dry mix sauces and seasoning mixes product type.
- 12 samples (from 6 products) failed the spike recovery test in this category for peanut (so no result was reportable for these samples). These were in the dry mix sauces and seasoning mixes product type.

These spike failures are not always predictable or expected, but these results clearly show the value of undertaking this procedure to reduce the risk of false reporting.

## Discussion

The positive results for gluten and milk demonstrate the common use of this ingredient in this category and as a result there is a likelihood of cross contamination with these allergens in this product category. The uneven distribution of gluten in some products and the challenges of dry cleaning in shared equipment environments could also help to explain these results. The large number of spike failures in this category across the allergens is probably as a result of the interferences caused by colours, herbs and spices, which in RSSL's experiences can cause problems. This is demonstrated by the majority occurring in the dry mix sauces and seasoning mixes product type.

### 11. Snacks category

Number of products purchased in the category- 40

Number of samples purchased in the category- 80

#### Table to show the total number of tests performed in the snacks product category

Allergen	Total samples tested (excluding spike failures)
Gluten	68
Milk	60
Hazelnut	80
Peanut	60

#### Gluten

There were 4 samples (from 2 products) in the trail mixes and Bombay mix product type that showed detectable levels of gluten. They ranged from 28 to 32 mg/kg gluten. 2 of the 4 samples (1 product) carried an advisory label for gluten.

There were 4 samples (from 2 products) in the corn snacks / tortilla chips product type that showed detectable levels of gluten. They ranged from 11 to 14 mg/kg gluten. 2 of the 4 samples carried an advisory label for gluten.

Milk There were no products with detectable levels of milk in this category.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures:

- 4 samples (from 2 products) failed the spike recovery test in this category for milk so no result was reportable for these samples. They were all in the trail mix and Bombay mix product type.
- 16 samples (from 8 products) failed the spike recovery test in this category for peanut so no result was reportable for these samples. 2 samples were in the potato crisps product type, 12 samples were in the trail mix and Bombay mix product type and 2 samples were in the corn snacks and tortilla chips product types.

## Discussion

Products in this category are likely to be manufactured on shared equipment, with products containing gluten. Therefore the results obtained for gluten most likely reflect this risk of contamination and the challenges associated with dry cleaning that is common in this product category and the results are therefore not surprising. The results of no detectable levels for peanuts or hazelnuts in this category despite their extensive use could suggest that these allergens are well managed and the cleaning methods effective or that the nature of the snapshot survey and the possibility of the heterogeneous contamination may have resulted in either a lower detectable frequency or indeed a higher one.

The large number of spike failures in this category across the allergens is probably as a result of the known interferences caused by colours, herbs and spices. This is demonstrated by the majority occurring in the trail mix and Bombay mix product type.

## 12. Yoghurt and cheese category

Number of products purchased in the category- 52

Number of samples purchased in the category- 104

### Table to show the total number of tests performed in the yoghurt and cheese product category

Allergen	Total samples tested (excluding spike failures)
Gluten	48
Milk	8
Hazelnut	48
Peanut	34

#### Gluten

There were no products with detectable levels of gluten in this category.

#### Milk

There were no products with detectable levels of milk in this category.

#### Hazelnut

There were no products with detectable levels of hazelnut in this category.

#### Peanut

There were no products with detectable levels of peanut in this category.

#### Spike failures

14 samples (from 7 products) failed the spike recovery test in this category for peanut so no result was reportable for these samples. 10 samples were in the yoghurt fruit flavoured product type, 4 samples were in the fresh cottage cheese and processed cheese spreads product type.

#### **Discussion**

No detectable results for any allergens were found in this product category. Although not conclusive, it may be possible that the probable common use of wet cleaning in this category could correlate with the lack of undeclared detectable allergens. The large number of spike failures in the yoghurt product types was probably as a result of fruit and flavourings. A number of these spike failures occurred in pro-biotic yoghurts which were also commonly flavoured and it is unknown if the failure was due to the flavourings or the presence of the probiotics.

#### **Summary Discussion for allergen analytical results**

Based on the results of this snap shot survey, it would suggest that there is a lack of correlation between the presence of milk, gluten, hazelnut or peanut (as a result of cross contamination) and the use of advisory labelling. Nor was there a correlation between allergen presence and product categories. This will be explored in this section 3.3.

This was a snapshot survey and due to design, numbers in some categories are not truly representative of the UK retail market. However these results highlight the challenges of different cleaning systems. A dry cleaning system does not involve the use of water or any aqueous substance and may involve either the use of a vacuum, high pressure air system or a system of using a dry purging material like salt or sugar. Another non-aqueous system of cleaning is used widely in the chocolate industry where liquid chocolate mass could be used as a flushing material to remove residues of the previous product. Dry cleaning is often used because the use of water would increase the risk of microbiological contamination.

A wet cleaning system will involve the use of water, sometimes heated and sometimes including the addition of chemicals to increase the effectiveness of the cleaning regime. The cleaning choices would normally be determined by the environment in which the product is being manufactured and often there are predictable similarities between manufacturers. Chocolate production usually involves purging or flushing, dry mixes usually involves dry cleaning or brushing and ready meals, meat and fish production usually involves a wet chemical clean.

The results demonstrate that in certain product categories dry cleaning systems appear to present more risk of cross contamination e.g. the cleaning of chocolate production lines. As it is not possible to use wet cleaning systems in these production environments, the risk of cross contamination needs to be considered when undertaking a risk assessment and deciding on the need for

advisory labelling. These comments are based on RSSL's experience in the food manufacturing environment, but without a detailed investigation of specific manufacturers, these suggestions are impossible to verify.

The allergen that was detected the fewest number of times was peanut, with only one product in duplicate showing positive levels in the confectionery category (1.1% of tests). Hazelnut was detected more frequently than peanut but in only a few categories; confectionery (14.5% of tests), chilled desserts (1% of tests) and sweet spreads (33.3% of tests). It is used widely as an ingredient in these categories and with the exception of chilled desserts; there would be likely challenges of dry cleaning as a means of allergen control. Both gluten and milk were detected across a broader range of categories (6 out of 12 product categories for both gluten and milk) than either hazelnuts or peanuts.

The levels detected for milk were more varied ranging from under 20mg/kg, a few between 20mg/kg and 100 mg/kg right up to the high thousands of mg/kg, all in confectionery.

There were a number of spike recovery failures in certain product categories and this is probably as a result of interferences especially by colours, herbs and spices. The failures shown in this survey emphasise the importance of this matrix validation to prevent either false positive or false negative result reporting.

Although the frequency of gluten cross contamination was high (when compared to peanut and hazelnut contamination), the levels detected for gluten were lower overall (all under 60 mg/kg), except for 2 duplicate products with >100 mg/kg in the cereals and cereal products category. The percentage of detectable positive results for gluten per category were 26.7% in cereals, 26.5% in dried sauces, 16.7% in jams, 11.8% in snacks, 5.3% in ready meals and 1.2% in confectionery. There were 7 samples below the 20 mg/kg which is below the threshold set for the labelling of 'gluten free'. The percentage of detectable positive results for milk were 44% in confectionery, 15.4% in chilled desserts, 7.1% in ready meals, 5.9% in meats, 5.1% in dried sauces and 1.4% in cereals.

The wider spread of detectable gluten and milk across categories compared to the hazelnuts and peanuts, based on RSSL's experience in the food manufacturing industry is probably a reflection that the risk from nuts and peanuts has been well publicised and more tightly managed in the food industry over a longer period of time than for milk and gluten. Clearly, without a detailed investigation of the specific food manufacturing sites, this is RSSL's opinion it is not possible to draw definitive conclusions. Some of the issues with allergen detected in some categories could be the result of cleaning challenges in a dry system. There were fewer positives for gluten than expected in some categories such as meat and fish where breaching is a common practice; this could suggest that gluten control is well managed in these areas. The issues with milk detected in the confectionery industry are well known and understood and all products with milk detected in this survey carried advisory labelling.



## 3.2 Review of Advisory Labelling

### Objectives associated with section 3.2:

(iii) To compare the level of food allergens in a sample of pre-packed processed food products with advisory labelling for milk, cereals contain gluten, peanut and hazelnut to similar products without such labelling.

### Overview

As part of the survey, one of the objectives was to examine whether the suggested allergen advisory statements which are set out in the FSA Best Practice Guidance<sup>1</sup> are being used by industry. RSSL carried out a review of all product labels and advisory statements.

### Review of the range of advisory labels used

There was a wide range of advisory labels used on the products selected for this survey. They were broadly grouped into the following categories of advisory labelling:

1. A simple "contains" message: where the allergen has been listed as an ingredient but that this additional information is contained in an allergens statement and under current regulations is voluntary and re-enforcing the message.
  - a. Contains A, B and C
  - b. This product contains A, B and C
  - c. Allergens: contains A, B and C
2. A "contains" message with extra information about the source of the allergen
3. A "contains" message with either extra warning or just an allergen list without distinction between ingredient level or advisory level
4. A simple "may contain" message:
  - a. May contain A, B or C
  - b. May contain traces of A, B or C
5. A "may contain" message with additional information
6. A simple "contains" message with a "may contain" following
7. A "may contain" message with a "contains" message following

There was also a wide variety that did not naturally fit into any of the categories above. These are not displayed in any particular order but shown in Table 7.

**Table 7: Other advisory labels** – this table shows the additional advisory labels that did not use the wording in the statements above

Advisory Label
Made in premises which produce nut products
May contain traces of wheat and barley due to farming practices
Contains wheat, milk. Produced on a line handling soya and in a factory handling egg, hazelnut but on a different line.
Packed on a production line that also packs nuts, seeds and cereals that contain gluten. Therefore cannot be guaranteed nut, seed or gluten free

Contains milk, wheat, gluten, soya. Recipe: No nuts. Ingredients: Cannot guarantee nut free. Factory: Product made in nut free area, but nuts used elsewhere.
Contains: milk, wheat, gluten. This product contains no nuts. However, we cannot guarantee the ingredients used are nut free.
Contains eggs, wheat, oats, gluten. Not suitable for cow's milk and sesame allergy sufferers due to manufacturing methods used.
Contains wheat, gluten. Manufactured in a nut free environment.
Contains gluten. Manufactured on equipment that processes products containing milk, soy and in a plant processing tree nuts, egg.
Contains gluten/milk. Manufactured in a factory that handles nuts and seeds.
Contains soya, milk. May contain nuts, cereals. This product contains milk due to the unavoidable cross contamination from milk chocolate made on the same manufacturing line.
Contains: milk. Recipe: No nuts. Ingredients: Cannot guarantee nut free. Factory: Before being prepared for manufacture of this product, the equipment was previously used to make products containing nuts. Product may contain traces of soya.
Nut free, dairy free, gluten free, egg free.
Contains milk and soya products. May contain traces of hazelnuts, almonds and peanuts due to shared equipment.
Contains milk and soya. Not suitable for nut or wheat gluten allergy sufferers due to manufacturing methods.
Contains milk. Dietary advice: suitable for vegetarians. Gluten free
Contains milk, soya. Recipe contains cashew nuts. May contain traces of other nuts
This recipe contains gluten, egg, fish and milk. We made it in a busy working kitchen so it may also contain traces of nuts and sesame.
Any allergies? I contain celery. I've been known to hang around near nuts, peanuts and sesame seeds and I may contain them as well.
Food fact: This product may contain traces of nuts and seeds. Allergen advice: Contains - egg, gluten, milk and soya. Manufactured on a site that also handles celery, fish, molluscs, mustard, nuts, peanuts and sulphites.
Contains wheat, gluten & barley. Produced in a factory which handles milk powder. Not suitable for people with nut allergy.
This product is manufactured in a factory which uses sesame seeds, lentils, wheat & nuts. Therefore this product may contain trace allergens. This product contains peanuts.
Don't munch if you are allergic to soyabeans & sesame seeds.
Our packing house handles nuts and seeds.
Contains nuts and peanuts. In our makery, we use soya, cows milk and sesame seeds. We can't be absolutely sure they won't find their way into this bar.
Some chocolates contain nuts and soya, but all chocolates contain milk and traces of nuts and soya
May contain traces of soya. Manufactured under controlled conditions in our own factory in which no nuts are ever used.
Contains dairy. May contain nut traces. Vegetarian. Free from gluten, soya, GM, colouring and preservatives. Made in a factory where peanuts & sesame seeds are used.
Contains: hazelnuts, almonds, milk, soya. May contain: other nuts. Some chocolates contain nuts. All chocolates may contain parts of or traces of nuts.
Allergy advice: see list of ingredients
Allergy advice: Contains egg and milk. Produced in a factory that handles wheat gluten, soya, Nuts (cashew), sesame and mustard. Mycoprotein is high in protein and fibre. This may cause intolerance in some people.
This baby is good for everyone
No Nuts but packed in a cave where nuts and seeds are kept



## Grouping advisory labels

This work has clearly demonstrated that there is a wide variety of advisory labels currently in use. For the purposes of this survey, it was necessary to group the statements into categories to interpret the data more easily and to compare the level of allergens found with the advisory label (objective 3). In addition category numbers were also assigned to each group for presentation in graphical forms.

This survey did not look to establish the strategies employed by the allergic consumer when interpreting the risk associated with allergen advisory labelling. However when interpreting the data from this report it is useful to note that there have been previous studies <sup>17</sup> which have detailed the choices made by consumers with food allergy and the “rules of thumb” they may use when purchasing or consuming food (Barnett *et. al.* (2011)). This published study looked to understand what the main criteria are for food choices and what strategies they use when selecting food, including their approach to risk assessment using advisory labelling. It was clear from this study that the strategies employed by allergic consumers or parents of allergic children employ vary depending on a number of factors including previous experience, sensory information and preferences for the product. Other strategies were based on whether the food was perceived as high or low risk, trust on the information source and also the allergy information on the pack. Therefore advisory labelling is not the only information that is used by consumers to assess whether the allergic consumer will choose to purchase or eat a particular product.

**Table 8: Categories of advisory labels** – this table shows the wording of the different categories and the number associated with that wording to allow the data to be presented more easily in graphical form

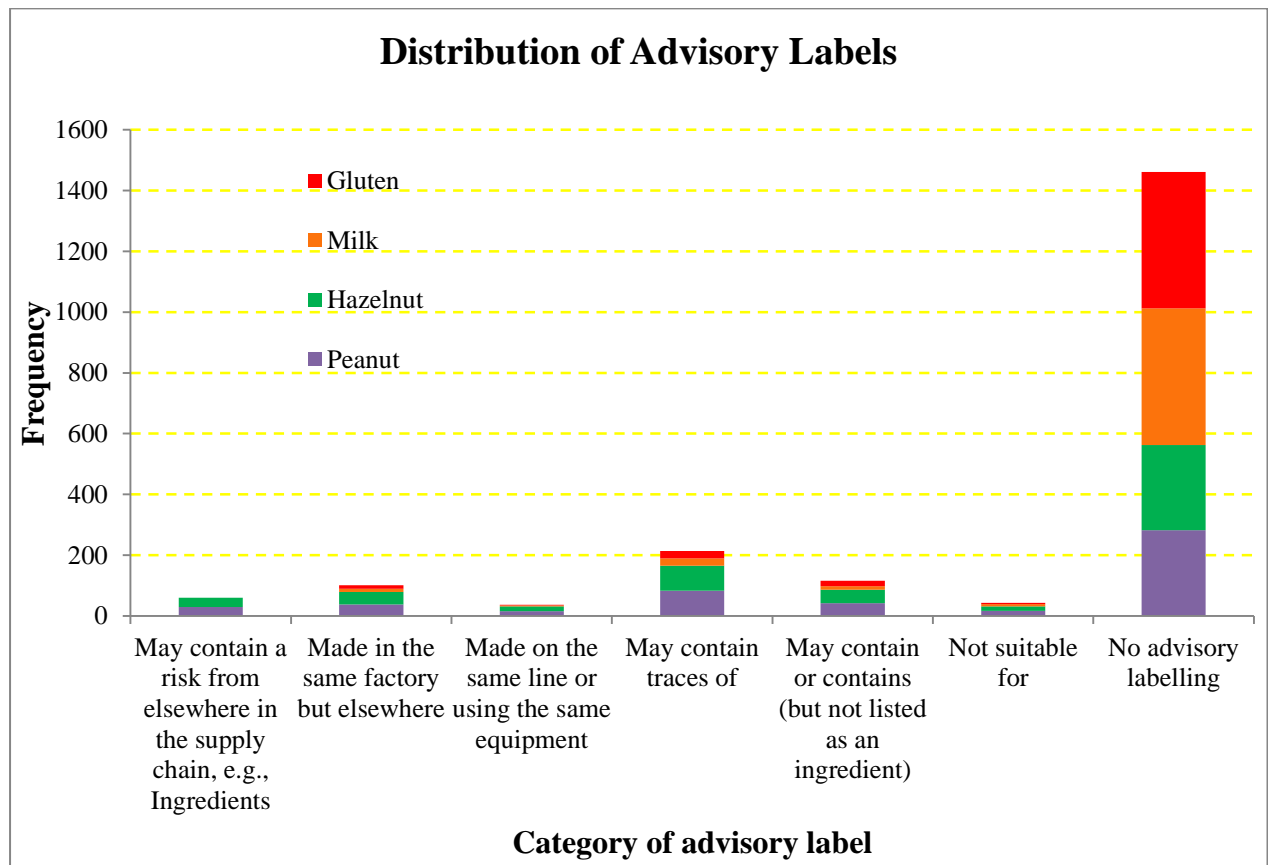
Categories of Advisory Labels	Category number
No advisory labelling	7 or 0
Not suitable for	6
May contain or contains (but not listed as an ingredient)	5
May contain traces of	4
Made on the same line or using the same equipment	3
Made in the same factory but elsewhere	2
May contain a risk from elsewhere in the supply chain, <i>e.g.</i> , Ingredients	1

The category of “No advisory label” covers two situations; those where the allergen is present as a deliberate ingredient and so no advisory label is required (0) and those where the allergen is not present as a deliberate ingredient and there is no advisory label present (7).

The category of “may contain or contains (but not listed as an ingredient)” includes the very infrequent situation where milk is present as a cross contaminant in dark chocolate, not listed as a deliberate ingredient but present

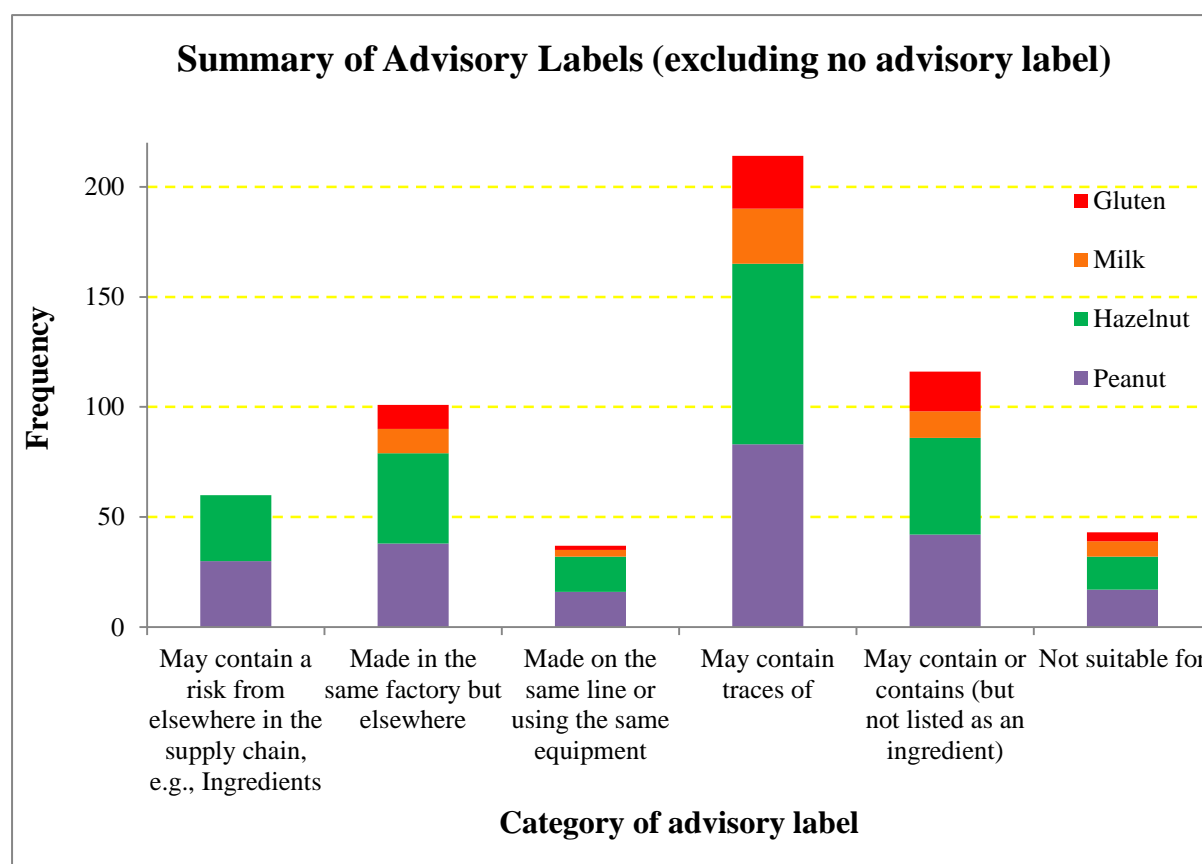
at a high level. The use of contains (but not listed as an ingredient) was not used for any other allergens.

The following chart (Figure 8) shows the distribution of the categories of advisory labels across all products.



**Figure 8. The distribution of advisory labels across all products** – this figure shows the spread of the categories of advisory labels per allergen across all of the 508 products in this survey.

The following chart (Figure 9) has the category of “no advisory label” removed to allow a clearer representation of the frequency of advisory labelling.



**Figure 9. The distribution of advisory labels (except no advisory label) across all products** - this figure shows the spread of the categories of advisory labels per allergen across all of the 508 products in this survey with the exclusion of the “no advisory label category” for clearer graphical display.

## Discussion

The objective for the review of the range of advisory labels was to assess how closely food labels followed the guidance from the FSA <sup>1</sup>. The guidance suggests that advisory labelling should be brief and factual and easy to translate into other languages. The two phrases suggested by the FSA are:

- May contain X
- Not suitable for someone with X allergy.

The frequency of these two statements as a percentage of the total number of advisory statements, when used, across the snapshot survey averaged over the four allergens was:

- May contain X = 20.6% (228/1106)
- Not suitable for someone with X allergy = 7.2% (80/1106)

The frequency of these two statements for the four allergens as a percentage of the total advisory statements, when used, per allergen in sample numbers was as follows:

- Gluten
  - May contain X = 32.1% (36 / 112)
  - Not suitable for someone with X allergy = 3.6% (4 / 112)
- Milk
  - May contain X = 18.9% (20 / 106)
  - Not suitable for someone with X allergy = 13.2% (14 / 106)
- Hazelnut
  - May contain X = 19.3% (88 / 456)
  - Not suitable for someone with X allergy = 6.6% (30 / 456)
- Peanut
  - May contain X = 18.6% (84 / 432)
  - Not suitable for someone with X allergy = 7.4% (32 / 432)

Whilst some products examined as part of this snapshot survey, clearly have followed the guidance, there are also a great many that have diverged from the principles of the FSA guidance.

There is also a wide divergence in the level of information between different allergens.

The most frequently used advisory labels were 'may contain traces'. The second most frequently used was 'may contain' or 'contain'.

For gluten and milk, there were no instances of the advisory label of "may contain a risk from elsewhere in the supply chain" applied, but for hazelnuts and peanuts, this was common with a total of 30 products of the 508 for each allergen of peanut and hazelnut. Overall the levels of any type of advisory label applied for peanuts and hazelnuts was 55% of the total number of products for each and those for milk and gluten was 11% for each.

This survey showed that the frequency of advisory labelling for gluten and milk were similar to each other (at 11% each) and much lower than that for peanut and hazelnut (or nuts) therefore; considering milk and gluten; only the advisory label of "May contain or "contains" (but not listed as an ingredient)" was higher for gluten than for milk. For all other categories, the numbers were higher for milk than for gluten. The category of "not suitable for" with milk was displayed on 7 products compared to only 4 for gluten. Overall the most common advisory labels for milk and gluten were "May contain traces of" and "May contain or contains (but not listed as an ingredient)".

Considering hazelnut and peanut secondly; the choice of advisory label was more evenly distributed across the categories but the most commonly used overall were "May contain traces of" and "May contain" or "contains". (but not listed as an ingredient)" with "May contain traces of" being used about 16% of the time for each allergen.

This survey does not seek to address how the variety of descriptions of production environments is interpreted by the consumer or how the consumer

understands or makes a judgement of the different levels of risk that may be present in each one from the statement. This survey is instead measuring the levels of allergen detected and comparing them to the different advisory statements as well as assessing the variety of statements used for the different allergens on the broad scope of pre-packed foods covered.

### 3.3 Review of frequency and level of allergen cross contamination of products with and without advisory labelling

#### Objectives associated with section 3.3:

(iv) To investigate the different types of allergen advisory labelling used in a sample of pre-packed processed food products purchased from UK retail outlets

#### Review of the amount of different allergens detected with the advisory labelling applied

Overall there were 75 samples (from 39 products) that contained a detectable level of allergen that carried an advisory label for that allergen and the allergen was not present as an ingredient. In the cereal and cereal products category in samples that contained oats as a declared ingredient, the detection of gluten was from a cross contamination from a cereal other than oat. These were split in the following numbers per allergen:

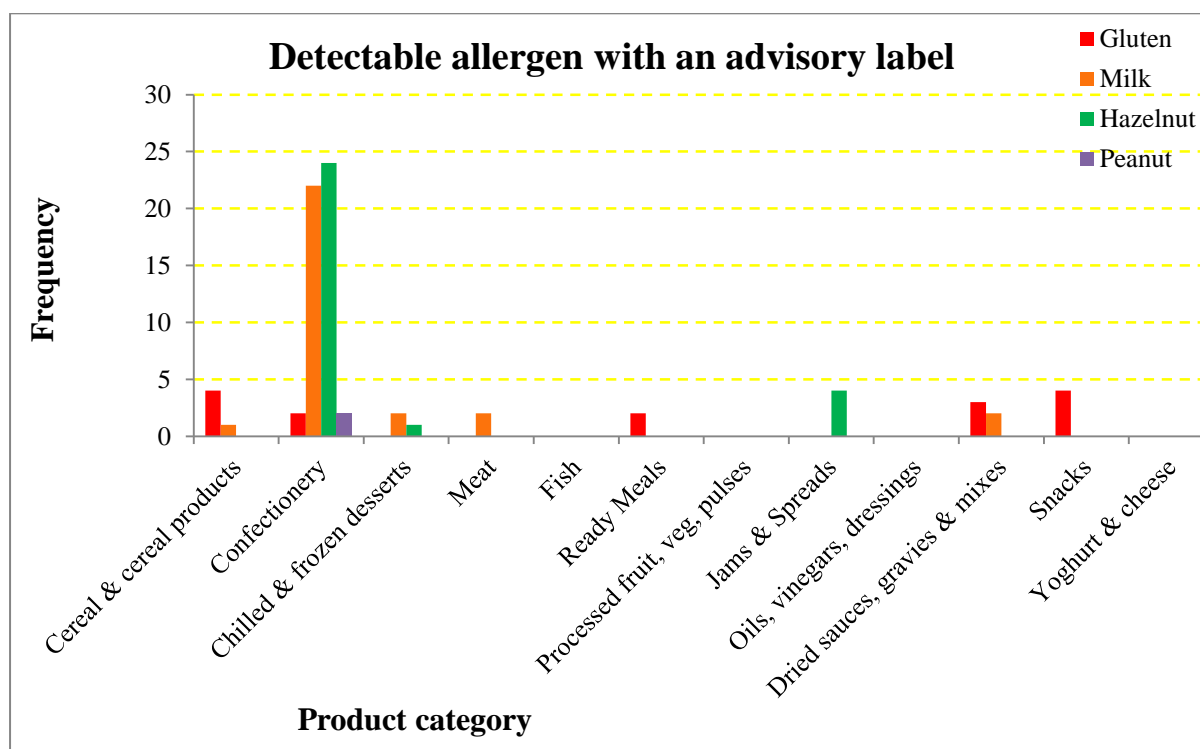
Gluten 15 samples (from 8 products)

Milk 29 samples (from 15 products)

Hazelnut 29 samples (from 15 products)

Peanut 2 samples (from 1 product)

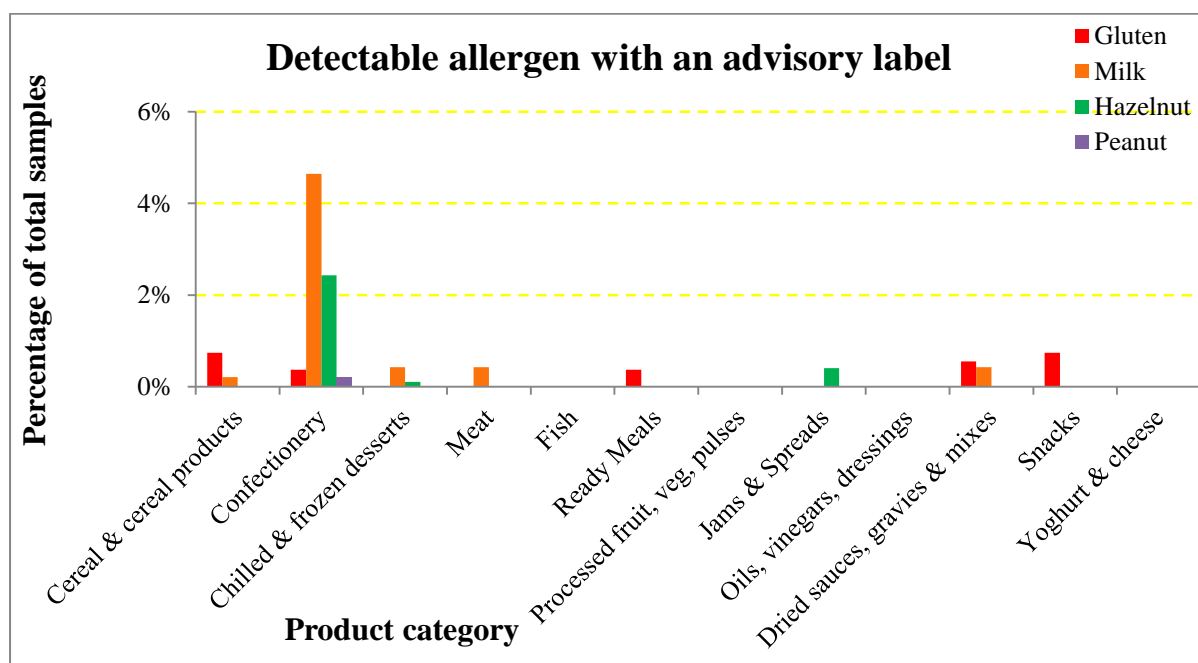
The split of allergens present above the detectable level where an advisory label was used by product category are shown in Figures 10 and 11.



**Figure 10. The split of detectable allergen in sample numbers across the product categories with advisory labelling** – this figure shows the number

of samples for each allergen across the product categories where an advisory label was present.

The following chart (Figure 11) shows the numbers of detectable allergens in sample numbers per product category as a percentage of all samples tested for that allergen within each category:



**Figure 11. The split of detectable allergen in sample numbers across the product categories with an advisory labelling as a percentage of all samples tested within a category** – this figure shows the percentage of samples for each allergen across the product categories where an advisory label was present.

### **Review of the amount of different allergens detected without the advisory labelling applied**

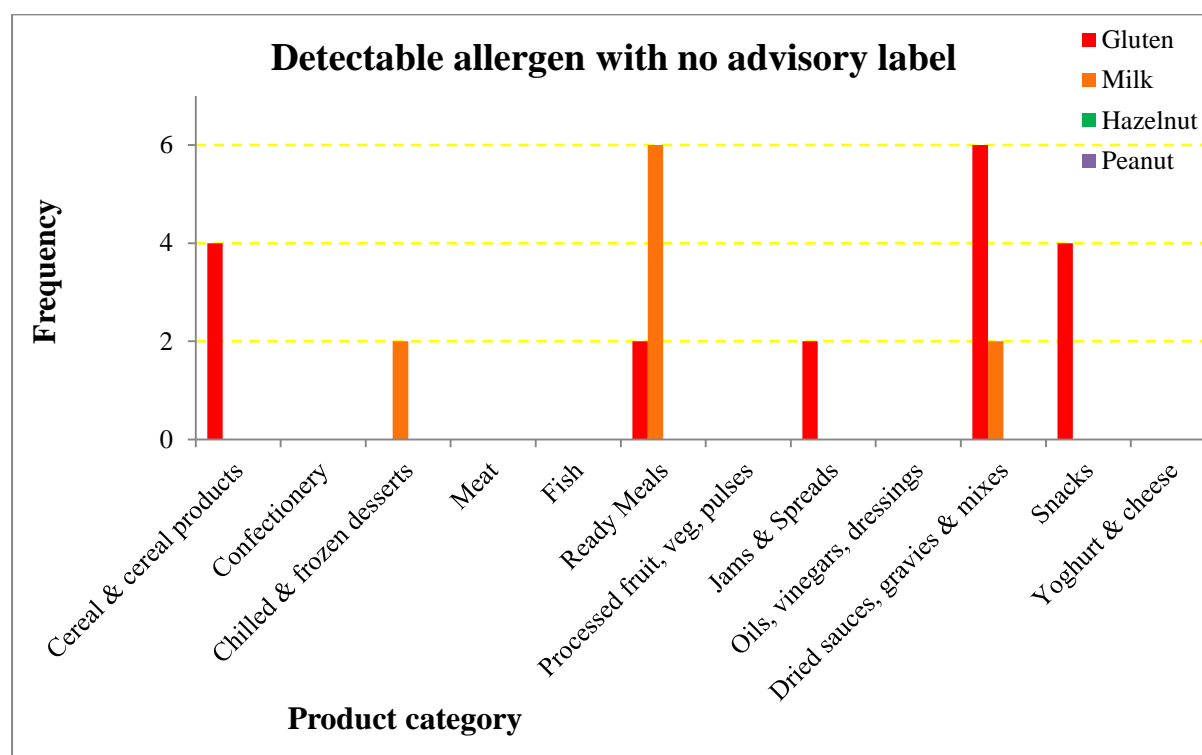
Overall there were 28 samples (from 15 products) that contained a detectable level of allergen that carried no advisory label for that allergen. In the cereal and cereal products category in samples that contained oats as a declared ingredient, the detection of gluten was from a cross contamination from a cereal other than oat. These were split in the following numbers per allergen:

Gluten 18 samples (from 9 products)  
 Milk 10 samples (from 6 products)  
 Hazelnut 0 samples  
 Peanut 0 samples

Of these 28 products, the following charts show the split by product category.

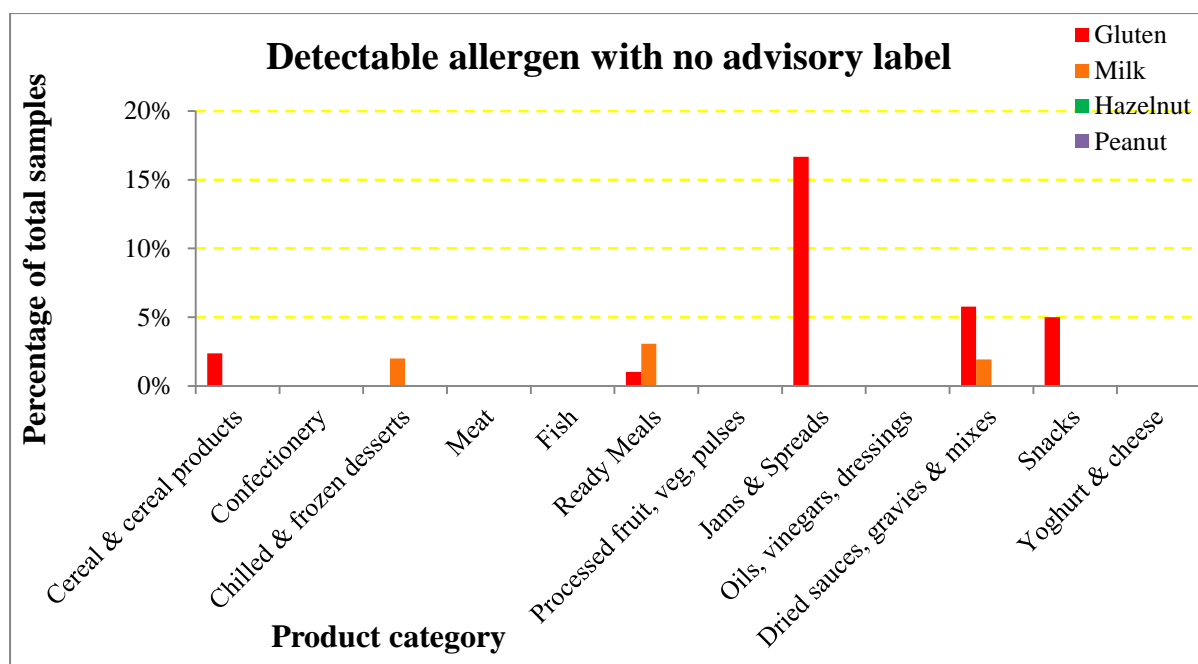


The split of allergens present in sample numbers above the detectable level where no advisory label was used by product category are shown in Figures 12 and 13.



**Figure 12. The split of detectable allergen in sample numbers across the product categories with no advisory labelling** – this figure shows the number of samples for each allergen across the product categories where no advisory label was present.

The following chart (Figure 13) shows the numbers of detectable allergens in sample numbers per product category as a percentage of all samples tested within each category:



**Figure 13. The split of detectable allergen in sample numbers across the product categories with no advisory labelling as a percentage of all samples within a category** – this figure shows the percentage of samples for each allergen across the product categories where no advisory label was present.

## Discussion

Only milk and gluten were detected in products without advisory labelling. Hazelnut and peanut were not detected in any products in this survey where no advisory label was applied.

Results where the allergen was found above a detectable level and no advisory label was applied, presents the highest level risk to the allergic consumer. The product category where, as part of this snapshot survey, this happened most frequently in numbers of samples was the ready meal category (4 products, 8 samples) and the dried sauces, gravies and mixes category (4 products, 8 samples). The other categories with detectable allergen and no advisory label were snacks (2 products, 4 samples), chilled and frozen desserts (1 product, 2 samples) and jams and spreads (1 product, 2 samples). There were 2 products (4 samples) in the cereal and cereal products category where gluten from a non-oat source was detected where the only cereal declared was oat. No other categories were found to contain detectable allergen without advisory labelling.

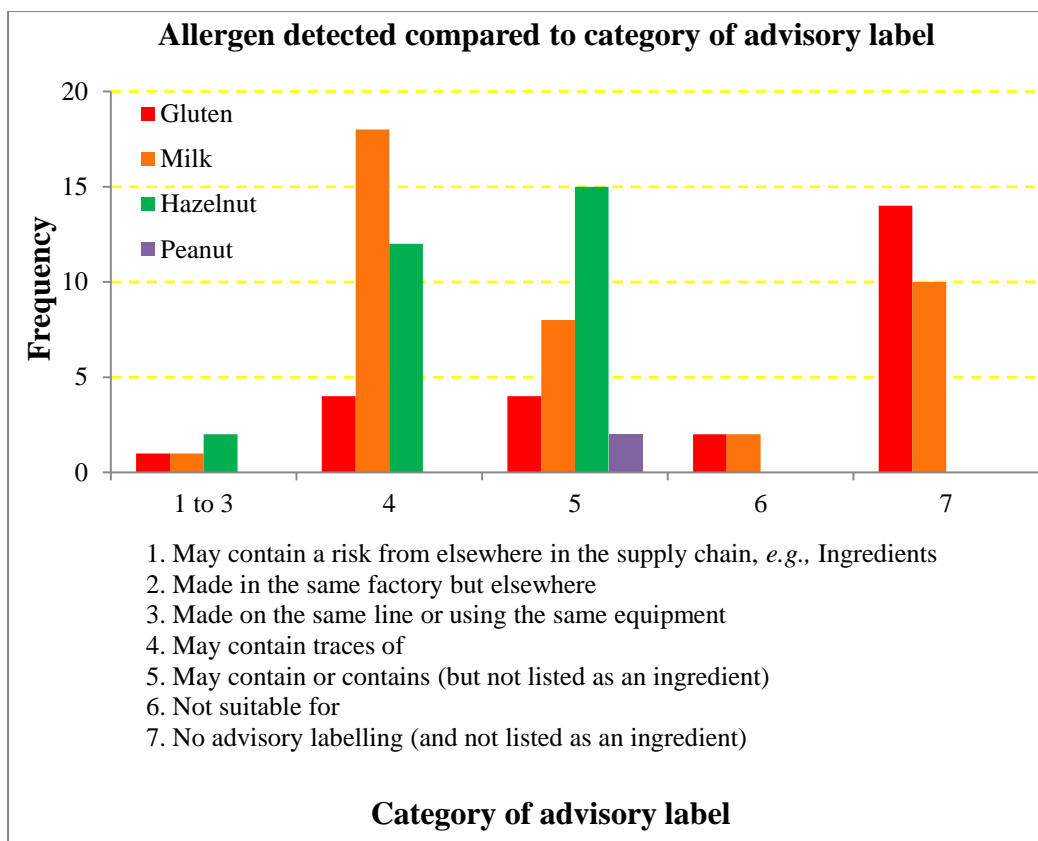
The category with the highest percentage of instances for gluten were jams and spreads (16.7%), followed by dried sauces, gravies and mixes (5.8%, 5.9% if spike failures excluded), then snacks (5%), cereals (2.4%) and then ready meals (1%). The categories with the highest percentage of instances for milk were ready meals (3.1%), followed by chilled and frozen desserts (2.0%) and then dried sauces, gravies and mixes (1.9%, 2.3% if spike failures excluded). Each of the instances where allergen was detected will be discussed per product

category in the following sections. It must be noted that for some of these categories, sample numbers were small so conclusions based on the results must be cautious.

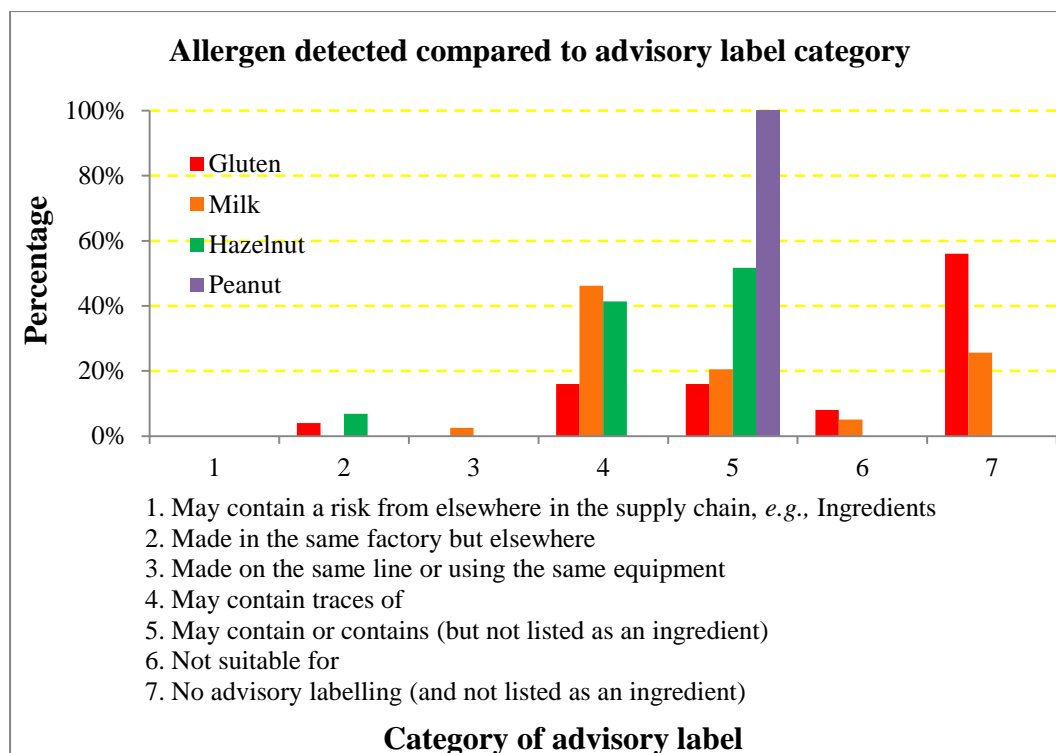
It is important to note that only gluten and milk were detected in products where no advisory label was applied, and hazelnut and peanut were not detected in products without any advisory label. The reasons for this may be that peanut and hazelnut can often be present as fragments as cross contaminants whereas gluten and milk are more likely to be homogeneously distributed; therefore the probability of detecting a heterogeneous contamination in a snap shot survey such as this is lower. Another reason is that, according to the results of this survey precautionary labelling for peanut and hazelnut (55%) are used much more frequently than that for milk and gluten (11%), so the probability of detecting the allergen without an advisory label for peanut and hazelnut is much lower. In RSSL's experience another reason could be that the allergen management for peanuts and hazelnuts has been in use for far longer than that for milk and gluten. Historically, peanuts and tree nuts (along with sesame, fish and crustaceans) have been considered to be the highest allergen risk for cross contact, followed by egg, milk, wheat and gluten in the medium risk and mustard, celery and sulphites in the low category. However RSSL have found through their experience, that more recently, milk and egg were re-assigned to the highest level by some retailers/ manufacturers.

### **Review of the amounts of different allergens detected with the advisory label applied**

The charts (Figures 14 and 15) shows the distribution of allergen detected when compared to the categories of the advisory statements. For some charts, categories 1 to 3 have been collated and for ease were condensed.



**Figure 14. The distribution of detectable allergen when compared to the category of advisory labelling (with categories 1, 2 and 3 combined)** – this figure shows the spread of the four allergens in sample numbers when detected above the reporting limit with the range of different advisory label categories. For ease of graphical depiction, the numbers of samples in categories of “may contain a risk from elsewhere in the supply chain”, “made in the same factory but elsewhere” and “made on the same line or using the same equipment” have been combined.

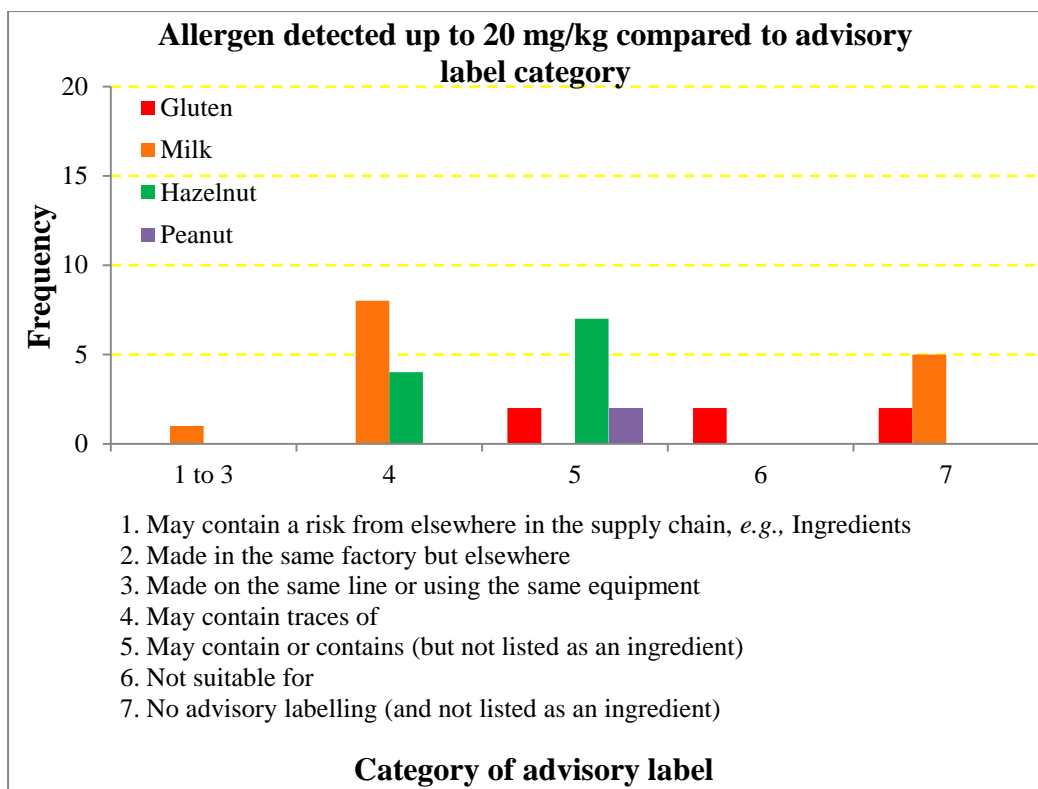


**Figure 15. The distribution of detectable allergen when compared to the category of advisory labelling as a percentage of the total number of detectable allergens per allergen** - this figure shows the spread of the four allergens when detected above the reporting limit as a percentage of the total number of detectable allergens per allergen compared to the range of different advisory label categories. The only sample with detectable peanut had an advisory label of “may contain” and therefore 100% of the peanut detectable results are within this category of advisory label.

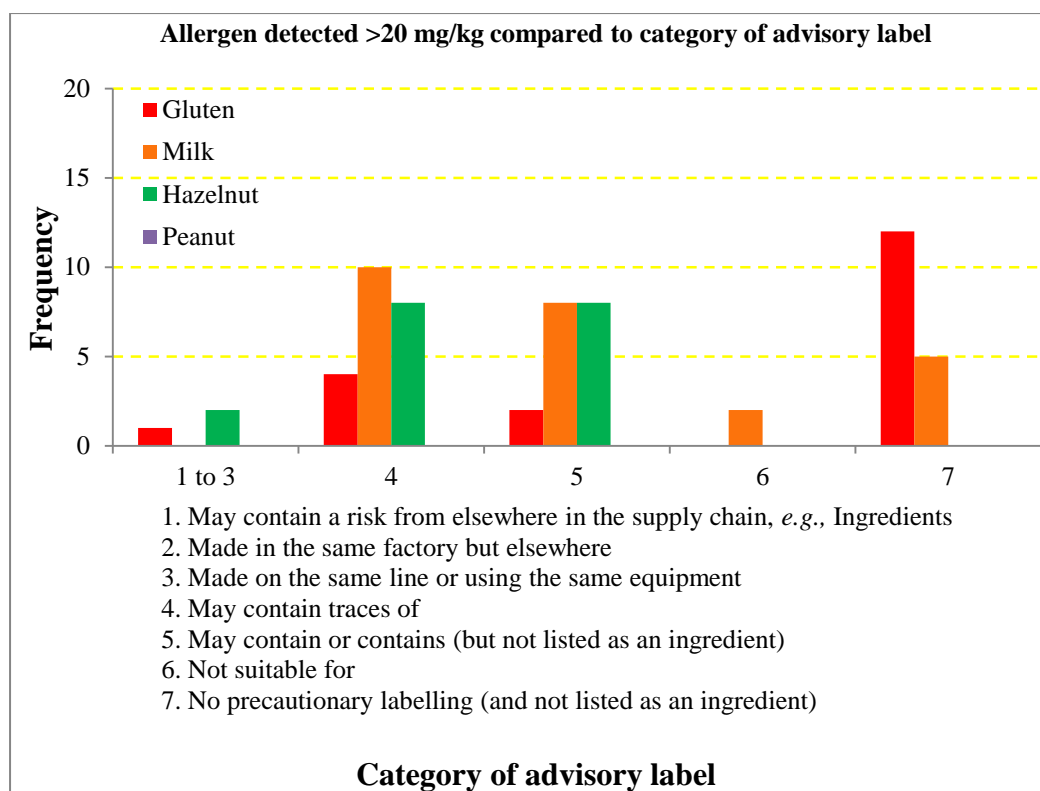
The charts show that overall the majority of times that allergen was detected, the products carried the “may contain traces” or “may contain” advisory label category, or no advisory labelling at all.

Hazelnut was only detected with 3 types of advisory label: “made in the same factory but elsewhere”, “may contain traces” or “may contain”, but the majority of instances were split between the “may contain” and “may contain traces”. For gluten and milk, the spread across categories of advisory label were broader. **It is important to note that the sample numbers across some categories are quite small and the possible heterogeneous nature of cross contamination by some allergens may skew the pattern of results.**

The following charts (Figures 16 and 17) split the results of detectable allergen into the 2 groups of detected but up to 20 mg/kg and >20 mg/kg per allergen.



**Figure 16. The distribution of detectable allergen up to 20 mg/kg when compared to the category of advisory labelling (with categories 1, 2 and 3 combined) )** – this figure shows the spread of the four allergens in sample numbers when detected above the reporting limit but < 20mg/kg detected with the range of different advisory label categories. For ease of graphical depiction, the numbers of samples in categories of “may contain a risk from elsewhere in the supply chain”, “made in the same factory but elsewhere” and “made on the same line or using the same equipment” have been combined.



**Figure 17. The distribution of detectable allergen > 20 mg/kg when compared to the category of advisory labelling (with categories 1, 2 and 3 combined)** – this figure shows the spread of the four allergens in sample numbers when detected at a level >20mg/kg detected with the range of different advisory label categories. For ease of graphical depiction, the numbers of samples in categories of “may contain a risk from elsewhere in the supply chain”, “made in the same factory but elsewhere” and “made on the same line or using the same equipment” have been combined.

### **Summary Discussion of allergen detected above the reporting limit with categories of advisory labelling**

From the data collected in this snapshot survey, there is a lack of evidence that there is an association between the used of allergen advisory labelling and the type of allergen detected for any of the four allergens and across the product categories. In addition there was no evidence that there was an association between the amount of allergen found in the product and the type of advisory labelling.

It is clear that there were many more occasions when gluten and milk were detected, sometimes with no advisory labelling, whereas for peanut and hazelnut were not detected without advisory labelling.

In RSSL’s experience, milk and gluten are more likely to be present as homogeneous contamination whereas peanut and hazelnut are more likely as heterogeneous contamination. The results from this snapshot survey appear to support this theory and could suggest that some heterogeneous contamination

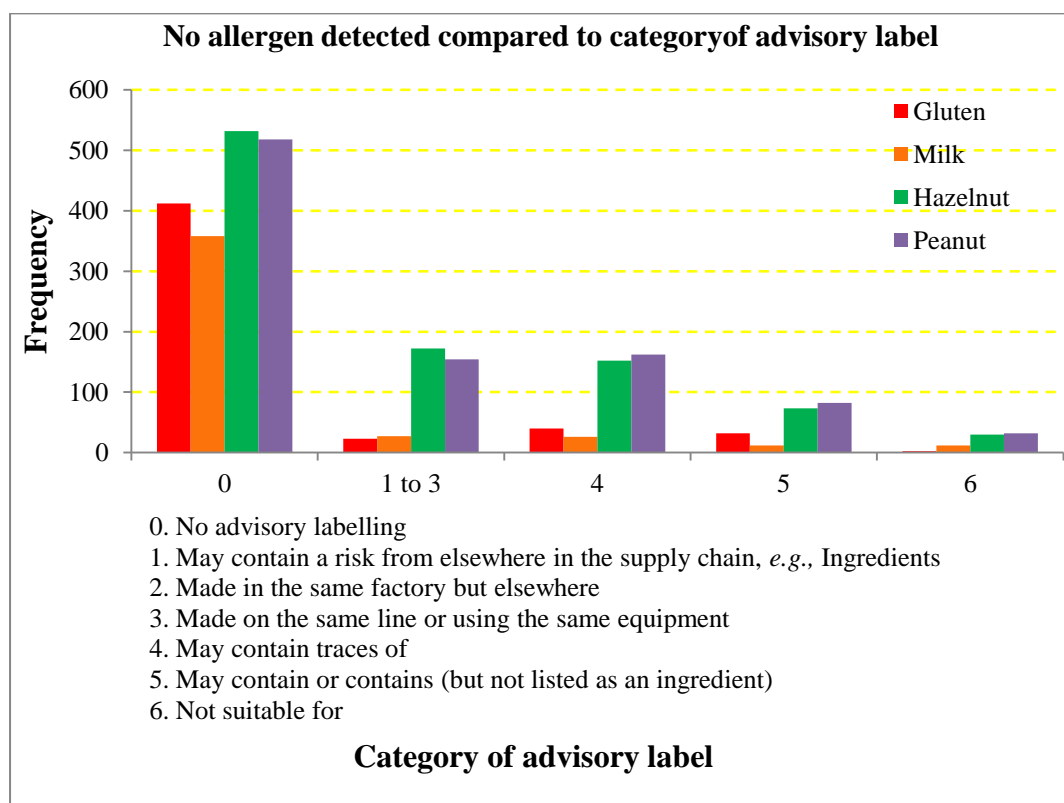
may have resulted in either a lower detectable frequency or indeed a higher one. Without detailed investigations, this is impossible to verify.

The levels of allergen detected at either a lower level (up to 20g/kg) or a higher level (>20mg/kg) did not show any direct correlation with the category of advisory label applied. The most common advisory label applied to products that did contain undeclared allergen were "may contain" or "may contain traces" or no advisory label at all. For the allergens gluten, milk and hazelnut the higher level of >20mg/kg was detected more frequently than at the lower level of up to 20mg/kg. In RSSL's experience, in terms of cleaning challenges where dry cleaning as a method would be more common practice, there appeared to be more undeclared allergen detected especially in the categories of confectionery, dry sauces and snacks. The only product that contained peanut through cross contamination and also contained undeclared hazelnut and gluten but carried "may contain" for all three allergens.



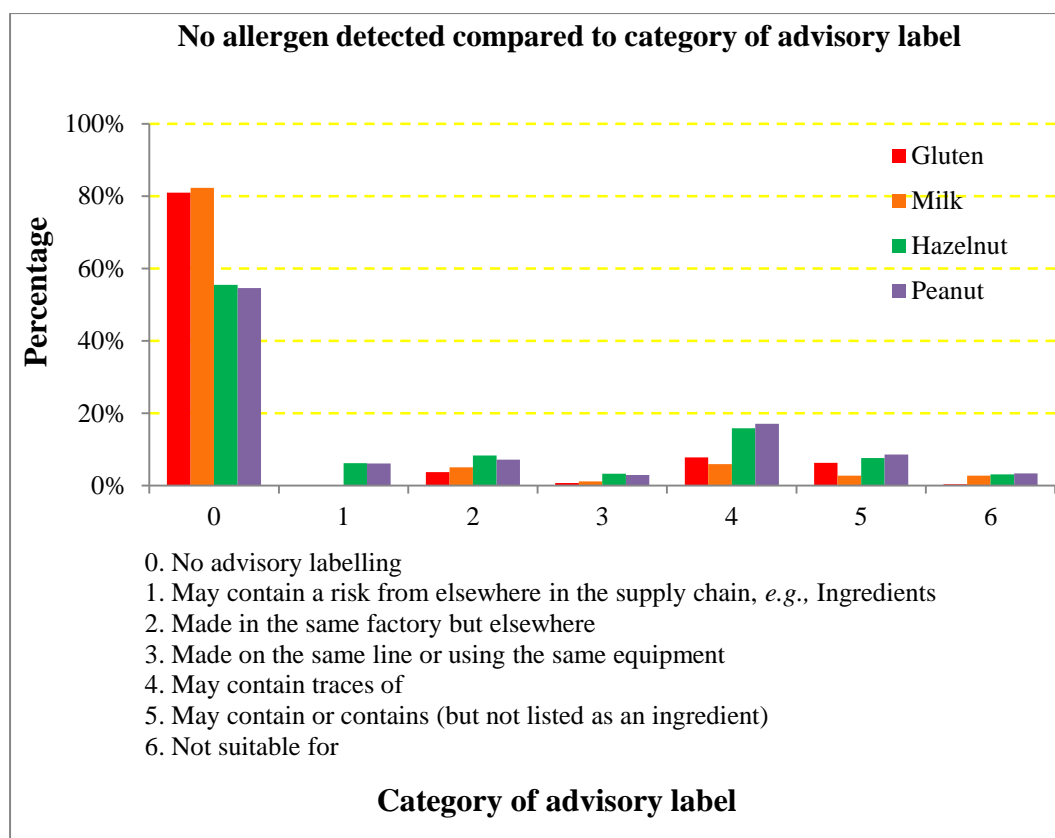
## Review of results of products containing no detectable allergen with the category of advisory label applied

The following charts (Figures 18 and 19) shows the distribution of results when allergen was not detected as compared to the category of advisory label applied, if at all. All samples were only tested for the allergen when the allergen was not declared as an ingredient.



**Figure 18. The split of allergen not detected with the different categories of advisory labelling (with categories 1, 2 and 3 combined)** – this figure shows the spread of the four allergens in sample numbers when not detected with the range of different advisory label categories. For ease of graphical depiction, the numbers of samples in categories of “may contain a risk from elsewhere in the supply chain”, “made in the same factory but elsewhere” and “made on the same line or using the same equipment” have been combined.

The following chart (Figure 19) shows the distribution as a percentage of the total number of tests per allergen.



**Figure 19. The split of allergen not detected with the different categories of advisory labelling as a percentage of the total number as tests per allergen** - this figure shows the spread of the four allergens when not detected above the reporting limit as a percentage of the total number of non-detectable allergens per allergen compared to the range of different advisory label categories.

#### Gluten

81% of products where no gluten was detected carried no advisory labelling at all. The next most common category of advisory label used where gluten was not detected was "may contain traces" with 8%, followed by "may contain" with 6%. The other categories of advisory label used where gluten was not detected were 4% in the "made in the same factory but elsewhere" and 1% in "made on the same line". There were no products that did not contain gluten that carried the advisory label of "may contain a risk from elsewhere in the supply chain".

#### Milk

82% of products where no milk allergen was detected carried no advisory labelling at all. The next most common category of advisory label used where no milk was detected was "may contain traces" with 6%, followed by the "made in the same factory but elsewhere" with 5%. The other categories of advisory label used where no milk was detected were "may contain" with 3%, was "not suitable for" with 3% and 1% in "made on the same line". There were no products that did not contain milk that carried the advisory label of "may contain a risk from elsewhere in the supply chain".

### Hazelnut

56% of products where no hazelnut allergen was detected carried no advisory labelling at all. The next most common category of advisory label used where no hazelnut was detected was "may contain traces" with 16%, followed by the "made in the same factory but elsewhere" with 8% and "may contain" with 8%. The other categories of advisory label used where no hazelnut was detected were "may contain a risk from elsewhere in the supply chain" with 6%, "made on the same line" with 3% and "not suitable for" with 3%.

### Peanut

55% of products where no peanut allergen was detected carried no advisory labelling at all. The next most common category of advisory label used where no peanut was detected was "may contain traces" with 17%, followed by the "may contain" with 9%, "made in the same factory but elsewhere" with 7%. The other categories of advisory label used where no peanut was detected were "may contain a risk from elsewhere in the supply chain" with 6%, "made on the same line" with 3% and "not suitable for" with 3%.

## **Discussion of results with no detectable allergen with and without advisory labelling**

The most common category of advisory label for all four allergens where they were not detected was for no advisory label at all, but there was a large difference between milk/gluten (milk 82%, gluten 81%) and hazelnut/peanut (hazelnut 56%, peanut 55%). For all four allergens, the next most common category of advisory label was "may contain traces" where no allergen was detected.

The high number of products that were tested and contained no detectable undeclared allergen and did not carry any type of advisory labelling could be a reflection of the degree to which food manufacturers have allergen management under good control in RSSL's opinion. It also shows the high number of products that the allergic consumer could perceive to be safe for them to consume but this snapshot survey was not designed to address this specific issue. The results shown from this survey are only a snapshot in time of the industry. They are not representative and should not be used by consumers to assess the risk or safety associated with particular products.

The results show a difference (81-82% vs. 55-56%) between the number of advisory labels used for milk and gluten compared to those used for hazelnut and peanut when no allergen was detected. The use of advisory labelling for nuts and peanuts appears to be more widely used. This is despite the survey demonstrating that nuts and peanuts being less frequently used as an ingredient than milk or gluten. We also know that the cross contamination of hazelnut and peanut would be more heterogeneous than that for milk or gluten and may go some way to explain why there are many more advisory labels for nuts where no allergen was detected.

## **Summary Discussion of the review of frequency and level of allergen cross contamination of products with and without advisory labelling**

Overall the frequency of the use of advisory labelling when no allergen was detected was much higher for hazelnut (45% 427/959) and peanut (45% 430/948) than for gluten (19% 77/435) and milk (19% 97/509). This pattern was repeated for the processed fruit, jams and oils categories but reversed for the cereals, fish, ready meals and dried sauces categories. The category of advisory label – “not suitable for” where no allergen was detected was used for all four allergens but more commonly for peanut and hazelnut than for gluten or milk. The “may contain traces” was the most commonly used advisory label for all four allergens. The frequency of no advisory labelling was highest for milk when not detected and was in the confectionery, chilled desserts, jams, oils and yoghurts categories. Of course for some of these categories, milk is a common ingredient. The frequency of no advisory labelling was highest for gluten when not detected and was in the meat category.

Peanuts and hazelnuts are more likely to be present as heterogeneous or particulate contamination so could help to explain the frequency of products that carry an advisory label but did not contain the allergen. This survey also only tested a snapshot of products; albeit in duplicate from the same batch, but heterogeneous contamination, by its very nature is not evenly distributed and may go some way to explain/support the results. It is clear from other work <sup>3, 4, 5, 6 and 24</sup>, that the use of advisory labelling for nuts/peanuts is much more widespread generally, but in this survey not consistently across all product categories. Without a detailed investigation, this cannot be verified.

Cereals and cereal products category – The only notable detected allergen was gluten when present as a cross contamination of non-oat gluten in oats. However, the levels of advisory labelling applied across this category were very high, especially for hazelnuts and peanuts and across all categories of advisory groups. The presence of peanut and hazelnut as declared ingredients in the range for this survey was low (<5%) and many products did not carry advisory labelling for them, and they were not detected in any products. There were several products that could not be tested for milk because of poor spike recovery validation.

Confectionery category – More allergens were detected across the range in this product category than any other but never without an advisory label. It was the only category where peanut was detected and in the same duplicate product as hazelnut and gluten (all with advisory labelling). Hazelnut was commonly detected in milk and dark chocolate where they were tested in 75% of products and milk was commonly detected in dark chocolate, often at high levels. The issues with milk contamination in dark chocolate are well known and the challenges of non-wet cleaning in this sector also well-known but without detailed investigation of the manufacturing sites, the reasons cannot be verified. The use of advisory labelling for milk is consistent with the frequency it was detected i.e. low frequency of advisory labelling when no allergen detected. This was not the case for peanut where the frequency of advisory labelling was high, the detection was low and only 5% contained peanut as a declarable allergen.

Chilled and frozen desserts category – The level and spread of detectable allergen was low for this category. Except for one single sample, not present in the duplicate sample when milk was detected >20mg/kg, no other allergen was detected above 20mg/kg. Gluten was not detected at all. There was a low frequency of advisory labelling for gluten and an absence for advisory labelling for milk in this product category when no allergen was detected. However, the frequency of advisory labelling for peanut and hazelnuts was very high, but the allergens were only detected in a single of a duplicate product for hazelnut just above the reporting limit of the test. This presence of peanut / hazelnuts in this product category as ingredients for this snapshot survey was 0% and wet cleaning would be the method of choice for allergen control in RSSL's experience. Without a detailed investigation, it is impossible to verify the reasons behind these findings.

Meat category– Only milk was detected as an undeclared allergen in a duplicate product of 2 samples. The frequency of advisory labelling for milk was very low; correlating with the detectable allergen results. This was also true for gluten where no products that did not contain gluten carried an advisory label for them despite the low level of products tested for gluten (25%) indicating the high levels as gluten as an ingredient in the products sampled in this survey. This was not the case for peanut / hazelnuts where the use of advisory labelling was high despite the lack of any detectable, non-declared allergen and no products that contained either hazelnut or peanut as an ingredient. Without a detailed investigation of the manufacturing practices, the reasons behind these findings cannot be verified.

Fish category– No undeclared allergens were detected in this category at all. Wet cleaning would be common in this category in RSSL's experience, as in the meat category and the use of gluten and slightly less so milk in value added products quite common. The use of peanut / hazelnuts in this category as ingredients was 0% and the use of advisory labelling was slightly lower than for meats when no allergen was detected. Without a detailed investigation of the manufacturing practices, the reasons behind these findings cannot be verified.

Ready meals category – Milk and gluten were detected in very few products in this category; no hazelnut or peanut were detected despite all 100% being tested. The milk detected in the sandwiches did not carry any level of advisory labelling. The use of advisory labelling did not appear to correlate with the levels of the four allergens used as ingredients in the samples selected in this product category. Gluten and milk were common ingredients in the products sampled in this survey but the use of advisory labelling was considerably lower than that for peanut and hazelnut. Peanut and hazelnut were not present as deliberate ingredients in any products sampled but the use of advisory labelling for these two allergens was high. Wet cleaning would be the most likely method of allergen control in RSSL's experience and the few cases of allergen detected, except in a vegetarian sausage for gluten, carried no advisory label. Without detailed investigations, it is impossible to understand the reasons for these findings.

Processed fruit, veg and pulses category– This category showed no detectable allergens and the use of advisory labelling for milk and gluten is very low. The use of advisory labelling for peanut and hazelnut is high, despite no products in

this category containing them as declared ingredients. The products in this category are mainly single ingredient products but with possibly complex supply chains and challenges with the regions from which they are sourced. The probable use of wet cleaning could help in allergen control in this category. The use of advisory labelling for peanut and hazelnut does not correlate with their use as ingredients or cross contaminants in this survey, albeit with fairly small sample numbers but without detailed investigations, it is not possible to corroborate these suggestions.

Jams and spreads category - This small category showed a relatively high proportion of undeclared allergen cross contamination. The gluten detected in yeast extract was just above 20mg/kg and no advisory label present. The hazelnut detected was all at >20mg/kg in chocolate spreads where wet cleaning would not be common in RSSL's opinion. All products were tested for gluten, hazelnut and peanut as they were not present as ingredients. This was the only category where there was no advisory label applied for milk or gluten where allergen was not detected, despite the risk of cross contact with gluten evident.

Oils, vinegars and dressings category - No products in this category contained gluten, hazelnut or peanut as ingredients and no undeclared allergens were detected. This could suggest a high degree of control or low risk of cross contact in RSSL's opinion but without detailed investigations, it is impossible to verify. The use of advisory labelling, especially for hazelnuts when they were not detected were high, despite the absence of hazelnuts or peanuts as ingredients in the products sampled in this category for this snapshot survey. The risk of cross contact from allergens in this category would be expected to be low in RSSL's opinion because of the highly refined nature of the products and the use of wet cleaning, so the abundance of advisory labelling does not correlate with the results but again without a detailed investigation of the manufacturing sites, this cannot be verified.

Dried sauces, gravies and mixes category - Milk was detected in a few products in this category, despite it being an uncommon ingredient in the products sampled in this survey. Gluten was detected more frequently but was a far more common ingredient. Neither hazelnut nor peanut was a declared ingredient in any product in this product category but the use of advisory labelling where allergen had not been detected was widespread, especially for peanut and hazelnut. Restrictions with wet cleaning may be one reason why the use of advisory labelling is high but it is not clear if the abundant use of advisory labelling for peanut and hazelnut correlates with their apparent low use as ingredients in this product category. Without detailed investigations, it is impossible to verify these suggestions. There were a high number of spike recovery failures in this category, especially for milk and gluten so those results are non-reportable.

Snacks category - Gluten was the only non-declared allergen as a cross contamination detected in this category. However, the abundance of advisory labelling did not correlate with this in RSSL's opinion. There was far more advisory labelling for hazelnut, even more than peanut. Wet cleaning may not be common practice across this whole category in RSSL's opinion, so the levels of advisory labelling may reflect that to an extent but without detailed investigations, this cannot be verified.

Yoghurt and cheese category – There were no cases of detected allergen in this category. This category was unusual as gluten, hazelnut and peanut were not present as declared ingredients in any products. However, the only allergen for which advisory labelling was not applied and allergen not detected was milk in the milk-free alternatives. A reason for this could be due to the higher levels of manufacturing controls applied to support a milk-free claim in RSSL's opinion. Again, without detailed investigation, these suggestions cannot be verified. The use of advisory labelling for the other allergens, especially peanut and hazelnut was common. There were 14 spike recovery failures for peanut probably as a result of matrix interference from fruit, which meant that 30% of peanut test results could not be reported.

It is clear that in most product categories the use of advisory labelling for peanut/hazelnuts (55% for each of all samples) is much more common than for gluten or milk (11% for each of all samples). There are few product categories and few allergens where the profile of advisory labelling correlates to the detectable allergen results from this survey. It could be expected that in product categories where the use of a certain ingredient in that category is high, you might expect to see a higher degree of advisory labelling on similar products but, of course, without detailed investigations, this cannot be verified. The exceptions to this suggestion are hazelnut and milk in confectionery, gluten and milk in chilled desserts, milk and gluten in meat.

The nature of the sampling strategy for this survey had an effect on the representative profile of products selected. Therefore, the frequency of the four allergens present as deliberate ingredients, and then any correlation to the amount of advisory labelling applied to similar products in that category should be analysed with caution. The choice was determined by many factors and especially the presence of the duplicate pairs; one with and one without advisory labelling for any given allergen. The nature of cross contamination from peanuts and hazelnuts is more likely to be as particulate heterogeneous contamination versus that from milk and gluten which is more likely to be homogeneous in RSSL's opinion, so the abundance of advisory labelling for peanut and hazelnut compared to the frequency of their detection may be a result of the unrepresentative sample size and distribution in this survey. Without detailed investigations of the specific manufacturing sites, this is impossible to corroborate.

## **4.0 Main conclusions**

This nationwide 'snap shot' survey has sampled a cross-section of pre-packed processed food products in the UK, with and without allergen advisory labelling, and has determined the presence and levels of milk, cereals containing gluten, peanut and hazelnut. The survey aimed to gain a better understanding of the type of allergen advisory labelling used on pre-packed processed foods sold in the UK. It also aimed to quantify the levels of allergens present in the food as a result of cross contamination and establish whether the type of advisory labelling used was related to the level of allergen present.

Although there has been research focussing on the range of advisory statements used by manufacturers and retailers <sup>2, 3, 4, 5, 6, 19,24</sup>, there has not previously been a comprehensive study linking the levels of undeclared allergen to advisory statements across a broad range of foods sold in the UK. This survey sought to address this issue.

### **Limitations of the survey**

The snapshot nature of this survey has meant that it is not representative of the entire UK retail market and as a result, it is difficult to extrapolate these findings to the UK retail market as a whole.

It is important to recognise that advisory labelling for some products and some allergens (heterogeneous or particulate contamination), may be used to indicate the sporadic presence of allergen. This may mean that for a snapshot survey such as this, the levels detected may not be a true representation of the risk of unintentional presence of that allergen.

The choice of allergens in this survey, the range of foods and the numbers of samples across this broad range of product categories has resulted in some limitations of the statistical significance of the data. However, this survey was intended to be a broad snapshot, rather than a definitive analysis. The way in which samples were chosen in comparable pairs (one with and one without advisory labelling for one of the four allergens selected) has also had an impact on how representative the products sold in the UK were during this time, especially in examining the range of ingredients in different product categories.

The product sampling for the survey was undertaken from July 2012 to March 2013. The EU FICR (1169/2011)<sup>22</sup> was published in October 2011 and as a result food labels have required change and as such this could have promoted a review and revision of advisory labelling over the period of the sampling and beyond.

### **Sampling and methods**

Sampling was undertaken with very little deviation from the original protocol. 508 products were purchased in duplicate (1016 samples) against the target of 500 products (1000 samples). The main deviation was in chilled and frozen desserts where gateaux could not be found without nut advisory labels, so a new product type of sorbet was introduced to fill the product numbers in that category.



Products were tested for allergens using ELISA methods. This was chosen because it is currently the method of choice for allergen detection by industry and regulatory bodies. It is relatively quick and cost effective to undertake and the results are semi- quantitative. All results above the reporting limit were quantified. There were issues with one peanut ELISA kit (Neogen Biokits) as cross reactivity with soya was identified. An alternative kit (Elisa Systems) and method (PCR) was used successfully to overcome this issue.

There were a total of 86 of the 1016 samples that failed the matrix spike recovery validation testing and therefore, in those instances no data are available. This emphasises the importance of this type of matrix validation. If this validation had not been conducted, there is a risk that incorrect results could have been reported.

## **Key findings of the survey**

### **Allergen cross contamination**

#### **Objectives**

- to investigate the frequency and level of allergen cross-contamination in a sample of pre-packed processed food products, with and without advisory labelling for the following four food allergens; milk, cereals containing gluten, peanut and hazelnut.
- to compare the level of food allergens in a sample of pre-packed processed food products with and without advisory labelling for milk, cereals contain gluten, peanut and hazelnut to similar products without such labelling.

#### **Key findings**

- The percentage of samples (both with and without advisory labelling) with detectable allergen that were not present as intentional ingredients, as a percentage of total tests, were as follows:

Gluten - 6.1% (33/542),  
Milk - 8.2% (39/474),  
Hazelnut - 2.9% (29/988),  
Peanut - 0.21% (2/950).

The numbers of occasions when cross-contamination was detected was higher for gluten and milk than for peanut and hazelnut. There were more allergens present as cross contaminants in the confectionery category than any other category, but all products carried an advisory label. This highlights the challenging nature of cross contact in this category and the need for industry to remain vigilant and undertake risk assessments and alert allergic consumers appropriately to the risk of cross contamination.

- The percentage of samples with detectable allergens that were not present and no advisory label as a percentage of the total tests were as follows:

Gluten 3.3% (18/542)

Milk - 2.1% (10/474)  
Hazelnut - 0% (0/988)  
Peanut - 0% (0/950)

Only gluten and milk were detected as cross contaminants in products where no advisory label was applied. Hazelnut and peanut were not detected in products without any advisory label. These results could suggest that cross contamination for hazelnut and peanut is well controlled by manufacturers but this would require further detailed investigation. However this is only a snapshot survey and results are probably due, in part, to the risk of contamination with peanut and hazelnut as particulates (heterogeneously distributed in the food product) rather than being distributed equally (homogenous distribution), as is more likely with gluten or milk contamination. Therefore given the sample size, it would have been difficult to detect both peanut and hazelnut as cross contaminants in these products.

These results differ from previous studies. The FSAI study (2011) <sup>3</sup> showed that 2% of samples that did not carry advisory labelling contained detectable peanut compared to 0% in this study. The study in the USA by Hefle *et al* (2007) <sup>4</sup> showed that 7% of products with a peanut advisory label contained peanut at similar detectable levels. This compares with 0.21% in this current study. Other studies in the USA <sup>4, 6</sup>, showed that the levels of allergens detected with and without advisory labelling was much higher than in this current study. This may suggest that the UK food manufacturing industry has a greater degree of allergen control for cross contact than in the previous studies cited but additional investigations would be required to support and verify this.

- The percentage of samples with no detectable allergen present and no advisory label present as a percentage of the total tests were as follows:

Gluten - 81% (412/509)  
Milk - 82% (358/435)  
Hazelnut - 56% (532/959)  
Peanut - 55% (518/948)

- The percentage of samples with no detectable allergen present and advisory label present as a percentage of the total tests were as follows:

Gluten - 19% (97/509)  
Milk - 18% (77/435)  
Hazelnut - 44% (427/959)  
Peanut - 45% (430/948)

The number of samples with no detectable hazelnut or peanut but with advisory labelling was just below 50%. This is probably, in part due to peanut and hazelnut being present as fragments as cross contaminants (heterogeneous) whereas gluten and milk could be more likely to be homogeneously distributed. Therefore the probability of detecting a heterogeneous contamination in this survey was low.

Another reason is that advisory labelling for peanut and hazelnut (55%) are used much more frequently than that for milk and gluten (11%), so the probability of detecting the allergen without an advisory label for peanut and hazelnut is much lower. However, without further investigations and discussion with food manufactures both of these assumptions cannot be verified.

- Based on this small sample size, there was little evidence that the wording of the allergen advisory label reflected the level of cross contamination found (for any of the four allergens across any product category) e.g. there was no difference in the level of cross contamination between those products labelled as 'may contain' vs 'may contain traces'.
- The highest levels of allergen detected were milk protein in the dark chocolate product type in the confectionery category. The only product that contained all three other allergens as cross contact contamination, when milk was present as an ingredient was a milk chocolate egg, but advisory labelling was present for all of these three allergens.
- In some product categories (such as cereals and cereal products) the presence of peanut / hazelnut as ingredients was low (<5%). Equally these allergens were not detected as cross contaminants in these categories with many products not carrying advisory labelling. Conversely, in confectionery, peanut was present in 5% of products as an ingredient, but advisory labelling was common and only one product contained peanut as a cross contaminant in duplicate samples. The snapshot nature and the sampling strategy of this survey, of course, limits any general conclusions that can be drawn from results such as this.
- Hazelnut was detected more frequently than peanut as cross contaminants but in only a few categories; confectionery (14.5% of tests in confectionery for hazelnut), chilled desserts (1% of tests) and sweet spreads (33.3% of tests). Both gluten and milk were detected across a broader range of product categories than either hazelnuts or peanuts with 6 out of the 12 categories. The levels detected for milk varied from under 20mg/kg, up to 4400 mg/kg; the highest levels were all found in the confectionery product category. The levels detected for gluten were lower overall (all under 60 mg/kg), except for two duplicate products with >100 mg/kg in an oat bar (the cereals and cereal products category).

The percentage of positive results for gluten per category were 26.7% in cereals, 26.5% in dried sauces, 16.7% in jams, 11.8% in snacks, 5.3% in ready meals and 1.2% in confectionery.

The percentage of positive results for milk were 44% in confectionery, 15.4% in chilled desserts, 7.1% in ready meals, 5.9% in meats, 5.1% in dried sauces and 1.4% in cereals.

The wider spread of detectable gluten and milk across categories compared with hazelnuts and peanuts could be a reflection of the fact that the risk of cross contact from nuts and peanuts has been well publicised and more tightly managed in the food industry over a longer period of time in RSSL's opinion

than for milk and gluten. However, there were fewer positives for gluten than RSSL would have expected in some product categories such as meat and fish where breasting is a common practice; this could suggest that gluten control is well managed in these areas. Although without detailed investigations into the specific manufacturing sites, this is impossible to verify.

- Some of the issues with allergen detected in some categories could be the result of cleaning challenges. In a dry system there is more risk of cross contamination and. in RSSL's opinion, product categories using dry cleaning systems are more likely to use allergen advisory labelling on products. A good example of where dry cleaning systems are used and cross contamination is difficult to manage is the confectionery industry. The high levels of cross contamination of milk in dark chocolate are well understood and as expected all products with detectable milk carried advisory labelling, suggesting that industry recognises this issue and are taking the necessary precautions to alert the consumer to this risk. Again, without further work, these suggestions cannot be verified.

## **Review of advisory labelling commonly used**

### Objectives

- to investigate the different types of allergen advisory labelling used in a sample of pre-packed processed food products purchased from UK retail outlets
- to examine whether the suggested allergen advisory statements which are set out in the Best Practice Guidance (such as the FSA Guidance on Allergen Management) are being used by industry

### Key findings

- This survey did demonstrate that there was a wide variety of different statements used across the product categories. The most frequently used advisory labels were 'may contain traces' (38%). The second most frequently used was 'may contain' (20.6%).
- The FSA guidance on the use of advisory labelling suggests the statements of:
  - "may contain X"
  - "not suitable for someone with X allergy".
- The frequency of these two statements across the snapshot survey averaged over the four allergens was:
  - "may contain X" – 20.6% (228/1106)
  - "not suitable for someone with X allergy"- 7.2% (80/1106)

## 5.0 Further work

Further work could be divided into two areas; additional analysis on the data already collected and new opportunities that have arisen as a result of this survey.

### **Additional analysis:**

- Analysis on the comparability of results from the duplicate samples. This could help to inform the uniformity or not of allergen contamination. It could also be used to assess the repeatability of ELISA analysis for allergens.
- Analyses on the types and frequency of advisory labelling across the different retailers, both when allergen cross contact was detected and when not.
- Analyses to compare the use of advisory labelling and allergen cross contact detection between smaller and larger manufacturers.
- Analyses on the use of advisory labelling between own label and branded products.

### **New research:**

- A more comprehensive survey of product categories where there was a high incidence of allergen cross-contamination based on the results in this survey could be done. It would potentially involve using higher sample numbers and remove the bias of comparable sampling. Suggestions from this survey could include gluten in oat products, milk and hazelnut in confectionery, hazelnut and gluten in jams and spreads, gluten in snacks and all four allergens for dried sauces, gravies and mixes. However the risk of cross contamination in these food categories is already well known, and food manufacturers appear to be alerting the consumer to this risk, therefore this work may be of lower value than other suggestions.
- A detailed investigation on the use of advisory labelling from the manufacturer's perspective. This could be achieved through interviews with a range of manufacturers across the industry.
- A survey with unbiased sampling with respect to advisory labelling for peanuts and tree nuts in the chilled and frozen desserts and ready meal categories. This could give a more realistic representation of the use of these ingredients in these categories and therefore a truer picture of the frequency of advisory labelling compared to the presence of allergen through cross contact.
- A survey to understand how allergen cross contamination is assessed by food manufacturers and retailers and therefore to analyse how and when advisory labelling is used.
- A repeat of this survey following the introduction of the Food Information for Consumers Regulation <sup>22</sup> to understand if the change in labelling has had any impact on the levels of allergen cross contact and types of advisory labelling applied.
- A survey to assess some other allergens of interest in food production and public health, this could include egg.
- Following the introduction of the Food Information for Consumers Regulation <sup>22</sup>, a survey to assess the levels of unintentional allergen presence (both deliberate and non-deliberate) in foods sold non pre-packed (loose).



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