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Analysis and critical comparison of food allergen recalls from the EU, USA, Canada, Hong Kong, Australia and New Zealand

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Abstract

As part of an EU-funded project (FP7) developing 'Integrated approaches to food allergen and allergy management' a database was constructed based on publicly available information on food allergen recalls in Europe, North America, Hong Kong, Australia and New Zealand. Over 2000 entries were made into the database. The database covers a 4-year period from 2011-2014 and each entry is categorised into food type (two different classifications), identified allergen and cause where indicated by the authorities. Across different authorities, by far the biggest incidence of undeclared allergens occurred in the food categories of prepared dishes and snacks (range, 12-53%), and cereals and bakery products (range, 14-25% of all recalls and/or alerts). The biggest incidence of undeclared allergens, according to the information from most authorities, occurred for milk and milk products (16-31% of all products with recall or alert), followed by cereals containing gluten (9-19%), soy (5-45%) and egg and egg products (5-17%). Although 42-90% of the products with recalls/alerts were explained as being 'Not indicated on the label' this is a generic explanation of cause and does not provide much insight into causes of the recall/alerts. However, 0-17% of products with recalls/alerts could be coded as caused by the unintended presence of an allergen as the probable result of cross-contact in production. Construction of the database of allergen recalls has provided some important lessons and recommendations

to the authorities are made in this paper in terms of harmonisation of the reporting of allergen recalls into a more standardised format.

Introduction

There are some differences in regulations across the world with respect to the number of foods that are designated as allergens. Ten regions of the world currently list between five and fourteen allergens with wheat/cereals, eggs, milk, peanuts and crustacean shellfish being common to all ten of the lists. Five lists contain eight common allergens, soy and fish occur in nine lists and tree nuts are in eight (Gendel, 2012; 2013). In addition to a legal requirement to label designated food allergens, when used as ingredients or processing aids, there is a general approach in requiring the food industry to take appropriate measures to protect vulnerable consumers from possible and unintentional presence of such allergens in food. Thus, even if countries such as Germany insist that such a precautionary warning is required only in the case of foods specifically targeted at allergic consumers, in most countries the food industry is expected to take precautions to minimise the risk of cross-contamination (cross-contact), or unintended allergen presence (UAP), which forms part of good manufacturing practice (GMP) and should involve specific allergen control measures (Taylor et al., 2006). It is this area of potential risk which has led to 'precautionary labelling' by manufacturers, which has had the effect of unnecessary labelling of some foods (Mills et al., 2004) and thereby reducing the availability of processed foods to vulnerable consumers.

A recent review has critically assessed precautionary labelling from a stakeholder perspective (Dunn Galvin et al., 2015), and there have been many investigations to establish when precautionary labelling has been used unnecessarily and also conversely the extent of contamination with designated allergens where there has been no such labelling (Food Safety Authority of Australia & New Zealand, 2010; FSAI, 2011; FSA 2011). A survey of over 20,000 unique products from 99 supermarkets in the USA found that 17% had precautionary labelling (Pieretti et al., 2009). A UK survey sampled a cross-section of pre-packed processed food products, both with and without allergen advisory labelling, and used ELISA to detect the presence of milk, gluten, peanut and hazelnuts. The UK survey included 508 products with and without precautionary labelling (254 of each) found gluten and milk in 3.3% and 2.1% of samples respectively, where the allergen was not present as an intentional ingredient and which did not carry precautionary labelling. However, in contrast, gluten, milk, hazelnut and peanut were not detectable in 19%, 18%, 44% and 45% of

samples which did carry an advisory label (Hirst, 2014). In a European study of cookies and chocolates, 569 samples were analysed for peanut and hazelnut content to compare analytical results with information provided on the product label. Chocolates were found to be much more likely to contain undeclared allergens than cookies, while, in both food categories, traces of hazelnut were detected at higher frequencies than peanut. The majority of chocolates carrying a precautionary label, tested positive for hazelnut, whereas peanut traces were not detected in 75% of the cookies carrying a precautionary label (Pele et al., 2007). Even if the use of PCR for detecting allergens is unable to detect the actual allergens, it should be noted that real-time PCR analysis of 229 commercial food products in Spain found that 29 (13%) contained pistachio or traces of pistachio without any indication on the label (López-Calleja et al., 2014). Thirty-eight food products from Ireland bearing peanut/nut allergen-related precautionary labelling were analysed for the presence of peanut, which was detected in only two of the products tested. No detectable levels of peanut were found in products that indicated peanut/nuts as a minor ingredient (Robertson et al., 2013). Of 1355 products examined in Australia, 65% had precautionary labelling for one or more allergens. The most commonly used labelling was for tree nuts (36.2%), peanuts (34.1%), sesame (27.5%) and egg (22.6%) (Zurzolo et al., 2013). In 2012, in the USA, only 8.6% of food products bearing advisory statements regarding peanut, and 37.5% having peanut listed as a minor ingredient were found to contain detectable levels of peanut ($>2.5 \text{ mg kg}^{-1}$ whole peanut). These rates and levels of peanuts found in products were similar to those tested in both 2005 and 2009. Nutrition bars with precautionary labelling contained the highest levels of peanut. Probabilistic risk assessment showed the risk of a reaction by peanut-allergic consumers from these products was significant but was brand specific (Remington et al., 2013).

From these surveys there are clear indications of unnecessary labelling when allergens are not present, and conversely a breakdown in Good Manufacturing Practice (GMP) allowing unidentified contamination of processed foods with allergens (an alternative explanation may be that companies judge that the risk associated with the residual allergen concentration to be too low to warrant precautionary labelling). A survey of food control practices in the food industry was conducted in 2010 by the US Food & Drug Administration (Gendel et al., 2013). This study was based on physical inspection of 463 food facilities of varying size ($<\$1\text{M}$ to $>\$25\text{M}$ turnover) across a wide geographical distribution. Important gaps were identified in allergen control measures with approximately 20% of facilities not declaring all major food allergens used, and approximately 30% of the facilities not

adequately protecting products from cross-contact during production. These results were consistent with an earlier survey using self-reporting on a voluntary basis (Taylor et al., 2006). There is however no shortage of useful guidance for food processors as to the components of an effective allergen control plan (Food and Drink Europe, 2013; Jackson et al., 2008; Food allergy research and resource program, 2008).

Information concerning failures to implement effective allergen control measures and failures in labelling on the part of the food industry can be gleaned from allergen recalls. However, despite allergen recall information being publically available in the USA, Canada, Australia & New Zealand, Ireland and the UK, the only systematic analysis of recall data has to date been carried out in the USA. An analysis of 659 recalls in 1999 in the USA found 36% of products contained one or more undeclared allergens with 34 consumers reporting allergic reactions. Ingredient-statement omissions and errors, manufacturing equipment cross-contact, and errors by ingredient suppliers or manufacturing firm employees contributed to these recalls (Vierk et al., 2002). The Reportable Food Register in the USA collects mandatory reports from industry and voluntary reports from public health officials related to foods that represent serious health risks (US Food & Drug Administration, 2010). From 2009 to 2012, reports of undeclared allergens increased from 30% to 40% of all reports. The five food types that were most often involved in food allergen recalls were bakery products, snack foods, candy, dairy products and dressings, with bakery products accounting for almost as many food allergen recalls as all of the other top five foods combined (Gendel et al., 2014). To understand why food allergen recalls in the USA have continued to occur at a high rate, information was obtained from the FDA recall database on each food allergen recall that occurred from 2007 to 2012. The food type, allergen, root cause, and mode of discovery for each food allergen recall have been tabulated (Gendel & Zhu 2013). Bakery products were the most frequently recalled food type, and milk was the most frequently undeclared major food allergen (Malyukova et al., 2012). Use of the wrong package or label was the most frequent problem leading to food allergen recalls (Gendel & Zhu 2013). It was found that labelling errors are frequently caused by the use of incorrect, outdated or damaged data files in computerised on-site label printing systems. It seems that the move towards printing labels during manufacture or directly on packaging has created new opportunities for errors and omissions. Several recalls were caused by an employee clicking on an old (outdated and incorrect) version of a label file when loading data into a printer system. In other cases, a label file generated at a central corporate location was used at a remote production site without checking to see if the ingredients actually being used

matched those on the label (Gendel et al., 2014). Controls therefore need to be in place to ensure that the correct data or template files are used and that these files have not been corrupted.

As part of iFAAM which is an EU-funded project developing 'Integrated approaches to food allergen and allergy management' it was recognised that a wider analysis of allergen recalls could provide a useful resource in identifying common problems in the food industry (<http://www.inflammation-repair.manchester.ac.uk/iFAAM/>). A user-friendly searchable database was therefore constructed and populated with recall data from 2011-2014 using publically available information from the EU, Ireland, UK, USA, Canada, Australia, New Zealand and Hong Kong. The work reported in this paper is based on an analysis of the recalls entered into this iFAAM database, providing statistical insights into the prevalence of recalls of different food types, prevalence of different food allergens in recalls and alerts, and causes of recalls, examining as well any differences between geographical regions of the world. The analysis of recall information provided by different authorities in different parts of the world has identified differences in categorisation of food-types, differences in data reporting and differences in the vocabularies explaining causes of recalls. Recommendations have therefore been made in this paper as to how some harmonisation in reporting recalls could improve the effectiveness of allergen management and the value of recall/alert data as a learning resource.

Materials & methods

Data sources

Data sources identified were the food allergen alerts publicly available from the Rapid Alert System for Food and Feed (RASFF) of the European Commission, and those published on the website of selected European (UK Food Standards Agency, Food Safety Authority of Ireland) and non-European food safety authorities (US Food & Drug Administration (FDA), US Department of Agriculture Food Safety and Inspection Service (USDA FSIS), Canadian Food Inspection Agency (CFIA), Australia and New Zealand Food Standards, Hong Kong Centre of Food Safety). All the identified sources were searched for food allergen alerts from January 2011 to December 2014.

The RASFF database contains information on food and feed alerts notified by EU Member States, including the details of the notification (reason, country, date, etc.), type (food or feed), product category (e.g. cereals and bakery products, or cocoa or cocoa preparations, coffee and tea, etc.), hazard (e.g. presence of allergens, heavy metals,

GMO/novel food, etc.), the nature of the problem leading to the alert (e.g. the allergen was found in the food product but not indicated on the label, a product mislabelled as a different product), and the action taken, as well as allergen concentration (when provided). Food allergen alerts were identified by selecting the “Allergens” category in the hazard section of the RASFF. To enable a comparison with other datasets, alerts related to unauthorised sulphite use were independently collected, as they are not counted as “Allergens” within the RASFF database.

Among European food safety authorities, the UK Food Standards Agency (FSA) and Food Safety Authority of Ireland (FSAI) publish food safety alerts on their webpage. FSA disseminates information on food alerts, product withdrawals and recalls, including food allergen recalls, with an online archive searchable back to 2011. FSA allergen recalls cover the information on the food product (name, pack size and “use by” date), the identified risk, the cause of the recall, the FSA advice to consumer and the action taken by the company. FSAI lists recent (since 2009) food product recalls, including food allergen recalls. Details (name of the product, best before date, batch and size), the allergen found, the reason for withdrawing the product from the market are also provided.

The FDA has an archive of food allergen recalls which goes back to 2004 covers all foods except meat, poultry and egg products. The USDA FSIS regulates meat, poultry and egg products in the US, and has a recall archive that goes back to 1994. Archives were screened to identify and collect allergen alerts. Recall alerts report the description of the food product (batch, code, size, best before date), the problem that led to the alert, the distribution status, the company recalling the product, and when an adverse effect has occurred.

In the CFIA dataset, food alerts and recalls are organised according to category and reason (e.g. the type of allergen), and are accessible from a direct navigation tool bar. For most of allergen types, data are available back to years 2006-2007. Alerts were screened to identify those related to allergen presence. Information reported in the recalls includes the food product details (name, code, size), recalling firm, allergen, involved batches, occurrence of adverse reactions, reason for recalling the product.

Food recalls since 2010 are available from the Australia and New Zealand Food Standards database. Alerts were screened to identify those related to allergen presence. They include the details of the product (name, package description and size, best before date), the recalling firm, country of origin, reason for recall, distribution status.

Finally, the Hong Kong Centre of Food Safety archive contains food alerts since 2006. Alerts were screened to identify those related to allergen presence. Alerts report

information on the food product, the risk that led to issuing the alert and the action taken by the Centre for Food Safety.

A database was developed using Microsoft Access containing in total twenty-one fields (Table 1).

Design of database and selection of fields

At the European level, food alert notifications are sent when food which may present a serious risk is available on the market and when rapid action is required. Food products involved in the alerts were coded in the database using the RASFF product categorisation (Table 2) and the Reportable Food Registry (RFR) categories of the FDA as reported by Gendel and Zhou (2013) (Table 4). These two systems were applied to compare different outputs and highlight potential limitations, which are implicit in any categorisation system. For alerts involving more than one product, each food product was added as a single record. Conversely, when multiple allergens were found in the same food product, each allergen was added as a discrete product/allergen record.

Allergen categories identified in Regulation (EU) No. 1169/2011 (i.e. cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame, sulphur dioxide and sulphites, lupin, and molluscs) were used to code the allergen found in the food product. Where more detailed information as to a specific allergen within a category was provided, this information was added as a separate field. For example, if a tree nut was specified as being hazelnut this was recorded. On a few occasions when allergen concentration data was provided this was also added into a separate field.

Both the type of notification and the action undertaken by the food company were coded based on the RASFF categorisation system according to Regulation (EU) No 16/2011, which distinguishes between an alert (a notification of a risk that requires or might require rapid action in another member country), a border rejection (a notification of a rejection of a batch, container or cargo of food or feed as referred to in Article 50(3)(c) of Regulation (EC) No 178/2002), information (a notification of a risk that does not require rapid action in another member country), information for attention (an information notification related to a product that: (1) is present only in the notifying member country; or (2) has not been placed on the market; or (3) is no longer on the market) and information for follow-up (an information notification related to a product that is or may be placed on the market in another member country). For the selected data sources, except RASFF, the notification type was designated to be in most cases an "alert". Similarly, to categorise the action taken by the company, RASFF codes were used (i.e. destruction, import not authorised, informing

authorities, informing recipients, no action taken, no stock left, official detention, product recall or withdrawal, prohibition to trade – sales ban, public warning – press release, recall from consumers, re-dispatch, relabelling, return to consignor, seizure, withdrawal from recipient(s), withdrawal from the market). Such detailed information is not available for sources other than RASFF. border rejections are included in the database, but have been excluded from further analysis as the affected products did not reach the final consumer.

For the country of origin of the food product, in some cases the alert text provided specifications as to the origin of raw materials or the place of product packaging. When available, the number of lots involved in the recall was added. In some cases the alerts' text included several or all lots produced in a certain time period without giving any specifications on the number of lots ("not quantifiable") was indicated. If available, the number of adverse reactions was reported.

Since the database which was constructed contained in addition to RASFF alerts, also alerts from the UK FSA and FSAI, it might happen that an alert launched by the national food safety authority was already present in the RASFF. Such alerts, when they could be identified, were marked as duplicate.

Finally, the cause of each food alert was classified according to a coding vocabulary developed firstly, using terms from RASFF alerts and in the FSA recalls and, secondly, new terms that were introduced during the course of data entry to reconcile with terms used by other food safety authorities (Table 4). The coding system was required due to fact that problems leading to a food alert are diverse and that each food safety authority may use a different type of categorization or indication for the cause of the alert.

Results and discussion

Total numbers of allergen recalls

A summary of the total number of recalls, and recalled product/allergen combinations (total number of recalled products, with multiple counts in case of several allergens), entered into the database from all sources is given in Table 5. From the RASFF system, a total number of 435 food-allergen notifications were identified for the four years 2011-2014, of which 266 were alerts, corresponding to 294 recalled product/allergen combinations. As alerts are a sub-set of notifications, which apply to a food where there is potential for a serious health risk, and as the food is still on the market, rapid action is required to protect consumers, which normally involves a food recall. Therefore, for consistency with the other sources which have focussed on allergen recalls, only RASFF alerts were used for this analysis. For

the same period the UK (FSA) reported 252 allergen recalls (526 recalled product/allergen combinations) through their website, and 70 recalls (149 recalled product/allergen combinations) were notified by Ireland (FSAI). A total of 43 duplicate entries were identified as occurring in RASFF, where a recall was initiated in the UK and notified to RASFF. However, duplicate entries could only be identified when the detailed product description on RASFF was an exact match to the product description in the allergen recall by the national authority. This was not the case for recalls initiated in Ireland. During the 4 year period the UK notified RASFF 43 alerts and Ireland on 14 alerts that products were on the market containing undeclared allergens. These recalls did not necessarily give rise to duplicate entries, as the recall might not qualify for RASFF notification if the risk were not deemed serious (or *vice versa*, if the product was only marketed to another EU country, and not sold in the home market).

The differences in the number of notifications to RASFF by different authorities is interesting and cannot be explained by the relative size of different countries, as Germany and France only notified 7 and 4 alerts respectively, compared to the UK which notified 43 alerts, whilst relatively small Cyprus made 11 notifications. Slovenia made 18 alert notifications, Italy 23, Slovakia 18 Sweden 11 and Spain 13. It is not clear whether the number of notifications is due to a proactive policy with respect to the authorities in giving allergens a priority, or vigilance by the food industry to the problem of allergens and therefore being more conscious of the need to make recalls and notify the authorities. All of the 11 alerts from Cyprus were official controls based on analytical data where levels of milk, hazelnut, almond, soya and celery ranging from 8 mg kg⁻¹ for milk in broth of vegetable in grains to 987.6 mg/kg of milk in chicken soup were reported. In contrast for the UK, of the 43 alerts only 10 were based on analytical results ranging from 4 mg kg⁻¹ of peanuts in ground almonds to >1024 mg kg⁻¹ for milk in truffles.

A total of 453 alerts were entered into the database identified from the FDA online records (1591 recalled product/allergen combinations), whilst USDA FSIS records yielded an additional 128 alerts (378 recalled product/allergen combinations). A total of 860 alerts were retrieved for the same period from Canada (CFIA) (3273 recalled product/allergen combinations), with Australia and New Zealand reporting 77 recalls (218 recalled product/allergen combinations), which could be identified as food allergen related, while Hong Kong (CFS) only reported 9 recalls (12 recalled product/allergen combinations). There is no obvious relationship between the number of allergen recalls/alerts and the size of the population in the area under consideration, as the EU population is 1.5 times greater than

the USA, and 14 times bigger than Canada, but Canada had about three times more recalls than were notified through RASFF. There were no evident trends in recorded numbers of recalls over the 4 year period, apart from those recalls from Canada where recorded food allergen alerts were significantly higher in 2014 than previous years.

In terms of recalled product/allergen combinations (recalled products), the trends are similar, although the RASFF dataset has approximately the same number of alerts and product/allergen combinations, whereas in other datasets a single alert/recall has involved, on average, multiple products and allergens.

Allergens responsible for product recalls

The most reliable information, which can therefore be used to aggregate data from different authorities and make comparisons, is the notification of the allergen responsible for the food recall. The food recalls and alerts listed by allergen are shown in Table 6, where it can be seen that the total numbers for allergens for each authority in all cases exceeds the total number of recalls. This is explained by the high incidence of multiple allergens responsible for individual recalls (including multiple allergens of the same category, such as hazelnut and almond), and by several products in a single recall. For RASFF there were only 22, a small proportion, of reports of multiple allergens, with 266 alerts. In contrast for the FDA there were 453 alerts, with 99 reporting multiple allergens. Milk and milk products are cited as food allergens of concern in 31% (CFIA), 16% (USDA-FSIS) of the recalled products, with RASFF's having 29% and FDA's 30% as shown in Table 6. This is consistent with an analysis of recalls in the USA from 2002-2012, where milk was found to be the most frequently undeclared major food allergen (Gendel and Zhu, 2013; Malyukova et al., 2012). However, in another publication looking only at the fiscal year 1999 undeclared egg accounted for the greatest number of recall actions (38%) in the USA (Vierk et al., 2002). These undeclared egg product recalls involved foods that contained mayonnaise made from eggs as an ingredient in which the ingredient statement declared "mayonnaise" but not "eggs."

Cereals containing gluten were associated with 17-19% of the recalled products in EU-based datasets (RASFF, FSA, FSAI), with 18% in the USDA-FSIS dataset, with 14% in the Canadian dataset, and 9% for the FDA. With the exception of Australia and New Zealand (44%) and Hong Kong (50%), nuts were mentioned in only 3-10% of the recalled products from other individual authorities. Peanuts accounted for 11% of the FDA recalled products, and 4% of EC's RASFF (7% in the UK dataset, and none in Ireland). Eggs were linked with 5-17% of the recalled products. Celery was mentioned in only 3-5% of recalls in EU

databases (RASSF, FSA & FSAI) and is not listed as an allergen by other authorities and therefore is not reported. Sesame was linked to 2% of RASSF products with an alert, and 3% of Canadian recalled products. Soya was associated with 45% of the USDA-FSIS products with alerts, and between 5 and 17% from other authorities. Sulphites were reported in 20% of FSA products with alerts, but FDA and USDA-FSIS only reported 3% and 1% respectively.

Causes of allergen recalls

There has been no consistent system of reporting the causes of allergen recalls even by a single authority. There are differences in the 'form of words' used by one authority over the course of the four years under study. In many instances the recall has been a voluntary one initiated by the food industry and the authority has only passed on the information provided to them. To overcome these difficulties, in Table 4 we have proposed a coding of 'Causes' to provide a consistent approach, and this coding was developed based on the different descriptions of causes found in the various recalls. Only one coding of the cause has been used in the database for each recalled product, but there is a hierarchy such that if a specific cause is reported such as 'Unintended presence' this coding has been used, even though it is self-evident that the allergen is also 'Not indicated on the label'. In fact 'Not indicated on the label' is an explanation of the recall encompassing several causes including 'Labelling error', 'Unauthorised or undeclared sulphites' and 'Allergic reaction', causing some overlap. The cause was often found to be given as 'Labelling error' with no explanation, whereas 'Wrong label' means that the product has been mislabelled, which is similar to 'Packaging error' where a totally wrong package has been used for the product. 'Unauthorised or undeclared sulphites' relates only to sulphites and indicates that sulphur dioxide or sulphite containing food additives, or residues thereof, were found in food products in which the use of such food additives is not authorised, or they were not declared. It is notoriously difficult to associate an allergic reaction with a specific food product, but in those instances, predominantly from the FDA, where a reaction has been recorded this has been coded separately, even though the cause may be any of the other reasons listed in the coding.

Excluding the limited dataset from Hong Kong's CFS, it can be seen from Table 7 that 42-90% of the alerts and recalled products were explained as being 'Not indicated on the label'. The second major cause associated with recalled products (0-20%) was presence of sulphites in a food in which use of sulphite-containing food additives is not permitted in the relevant jurisdiction, or was not declared. 0-17% of the products were recalled because of

unintended presence as a result of cross-contact or possibly analysis of the product indicating the presence of an allergen. Gendel and Zhu (2013) reported that for the USA the use of the wrong package or label was the most frequent problem leading to food allergen recalls in an analysis of data from 2007-2012. For snack foods in the USA, there have been several recalls for chocolate-coated snack bar products that carried “dairy-free” or “vegan” labels (Gendel et al., 2014). In many cases, these snack bar products were made on shared equipment that was also used to manufacture products with milk chocolate i.e. the cause was identified as being due to cross-contact.

In the same databases, an allergic reaction was associated with recalled products (notably, 4% of Canada’s alerts). A false label claim (presumably a false free-from claim, e.g. milk free) was linked to products with an alert in most datasets (up to 15% in the case of Ireland). When information was available, packaging error was reported in some datasets in up to 1-13% of the recalled products. The use of incorrect allergen advice (e.g., allergen advice box) has resulted in recalled products in the UK (26%), Ireland (20%), and in the US (FDA, 8%). The practice of allergen advisories, which is voluntary, is discontinued in the EU, as it conflicts with new legislation (Food Standards Agency, 2015).

In terms of making future recalls and alerts more useful in informing better allergen management practice”, a more precise and consistent coding of the causes would be extremely helpful for the analysis of datasets. Agreement between authorities and the food industry as to a harmonised coding of causes would enable risk assessment resources to be appropriately focussed on priority areas.

Assignment to food categories

The system used by RASFF for classification of products into 29 food and beverage categories is comprehensive, but with a particular emphasis on raw materials. Most problems with allergen recalls arise when the food product has been processed. For example the food categories ‘Meat and meat products’ and ‘Poultry and poultry products’ are good for indicating the main component is an animal product. However, where recalls are concerned, the alert invariably relates to a processed meat or poultry product of one type or another and is unlikely to relate to raw meat. For example, a pork sausage (raw or cooked) containing an undeclared allergen will be classified as ‘Meat and meat products’ with no indication that the meat has been minced, mixed with other ingredients, perhaps cooked then packaged for sale. Cross-contact, a contaminated ingredient or a packaging error might be responsible for the allergen recall, but unless specifically stated in the recall, this cannot be gleaned as a potential cause from the product classification. Nor if there are a number of

allergen recalls from sausages can this be readily identified as a pattern. To gain a better insight into the types of food processing operations where the most recalls arise, a better system of categorisation is really needed.

In the design of the database some consideration was given to inclusion of fields using more elaborate food classifications such as LanguaL™ (<http://www.langua.org/>) or the EFSA FoodEx2 (<http://www.efsa.europa.eu/en/datex/datexfoodclass>) food classification system, but these were found to be too detailed for the information publicly available and might still not yield the groupings of food types sought in making a data analysis of allergen recalls. Alternative systems are those used for trade purposes, such as the Combined Nomenclature.

With RASFF notifications, mostly the foods have been correctly assigned to their appropriate categories. However, problems seem to arise in deciding when a product should be classed as 'Confectionery' or whether it is a 'Cocoa product', or whether it should be classed as 'Cereals and bakery products'. For example, 'orange-flavoured chocolate biscuits' and 'chocolate almond cookies' are categorised in two alerts as confectionery, whereas elsewhere 'chocolate biscuits' are more correctly categorised as 'cereals and bakery products'. Both 'milk chocolate' and 'dark chocolate' have been categorised as 'confectionery', but in other alerts 'chocolate for cooking' and 'milk chocolate' have been categorised as 'Cocoa and cocoa preparations, coffee and tea'. In one place a 'chocolate muffin mix' is categorised as 'Confectionery' rather than 'Cereals and bakery products'. 'Surimi sticks' and 'crab sticks' are mostly correctly assigned as 'Fish and fish products' although in some instances this imitation crab product has been wrongly assigned as 'Crustaceans and products thereof'. 'Undeclared shrimp in fish stew' has been categorised as 'Prepared dishes and snacks' whereas arguably it should have been 'Fish and fish products'.

The system of 17 food categories used by the FDA and shown in Table 3 is helpful in that the descriptions enable a consistent approach to assignment to categories and there is a useful separation of some processed foods. Soups are separate from sauces, and composites usefully covers products like sandwiches, which appear as either 'Prepared dishes and snacks' or 'Other food products – mixed' in the RASFF classification. As the descriptions are quite specific and there are only 17 categories, this means that many foods have inevitably been categorised as 'Other' (Miscellaneous). It was also found to be particularly difficult to classify traditional foods imported from Asia (China, Vietnam) using the food categories designed around Western foods.

Distribution of allergen alerts among the RASFF categories of foods is shown in Table 8. From the aggregated totals 'Prepared dishes and snacks' and 'Cereals and bakery products' were the food categories most frequently reported in allergen recalled products at 27% and 21% respectively, with confectionery (9%) and 'Soups, broths, sauces and condiments' occurring in 7% of recalled products. These food categories are unsurprising as they all involve preparation from a range of ingredients with consequent risks of cross-contact or contaminated ingredients. This is consistent with an analysis of FDA recalls between 2007 and 2012 bakery products were the most frequently recalled food type (Gendel and Zhu, 2013). For the USA a more detailed analysis of recalls has shown that within the bakery products category, cookies and cakes were the most often reported food types. Within the candy products category (confectionery), a large number of recalls were caused by the presence of undeclared milk in products containing dark chocolate (Gendel et al., 2014).

Looking at the individual authorities a similar pattern emerges with 'Cereals and bakery products' associated with 24% of RASFF food products with alerts, 14% (FSA), 18% (FSAI), 22% (FDA), 25% (CFIA) and 15% (FSANZ) of the alerts. Cocoa and cocoa preparations, coffee and tea (including chocolate) was associated with 14% (FSANZ) and 11% (RASFF) recalled products, but less than 7% in other cases (only 4% in the case of the FDA). Confectionery was reported in 10-21% of the products with alerts in most databases. As expected given the agency's remit, meat products were associated with 37% of USDA-FSIS recalled products, and 5-1% of the recalled products in all other databases. Prepared dishes represented 53% of the USDA-FSIS recalled products, 20% in the FSA and FSAI databases, 18% in FSANZ's datasets, and 25% in US FDA's and 28% in Canada's CFIA's. They represented 12% of the RASFF recalled products. Some alerts included multiple products; therefore more than one food category could be present in the same alert.

Distribution of allergen alerts among the FDA categories of foods is shown in Table 9. From the aggregated totals 'Bakery' and 'Meals' were the food categories most frequently reported in allergen recalled products at 20% and 15% respectively, with 'Candy' (12%) and 'Snack' occurring in 8% of recalled products. These food categories broadly reflect the "Prepared dishes and snacks", "Cereals and bakery products", and "Confectionery" of the RASFF system. 16% of the recalled products could not be classified using FDA categories.

In detail, FDA categories allow for separating the broader "Cereals and bakery products" into "Bakery" (20%), "Breakfast cereal" (1%) and "Pasta" (2%), and to conclude that "Bakery" is, as expected, the most relevant category (11%, FSA – 24%, CFIA). This

applies also to “Prepared dishes and snacks”, which is in part similar to “Meals” (15%) and “Snacks” (8%). On the other hand, RASFF categories are more detailed in that they treat separately cocoa and cocoa preparations from other categories, and differentiate seafood and types of meat.

Conclusions and recommendations

The publically available information concerning allergen recalls by national authorities in the UK, Ireland, USA, Canada, Australia and New Zealand is primarily intended to alert consumers who may have purchased the product that it has been withdrawn. The RASFF is primarily a mechanism to communicate between one national authority and another concerning a product that should be withdrawn, or originates from a third country and is a cause for concern. In both cases the information provides reassurance to consumers that both industry and authorities are vigilant to concerning the presence of undisclosed allergens. The allergen recall data is potentially a rich source of information that could be harnessed to improve prevention measures. For this it is necessary to understand which the most common allergens are causing recalls and alerts, which food types are frequently a problem and the underlying causes. Although unsurprisingly we have found that ‘Prepared dishes and snacks’ and ‘Cereals and bakery products’ are the two groups of foods where allergen recalls occur most frequently, a better classification of foods is necessary in order to be able to ‘drill down’ and identify whether any specific food processing operations might be identified as a common source of contamination. The most common cause as a failure to disclose the allergen on the label does not provide helpful insights as to the real cause. The biggest incidence of undeclared allergens occurred for milk and milk products, followed by cereals containing gluten, egg and egg products and soybeans. Adoption by the authorities in Europe and in other countries of a harmonised approach to reporting the details with respect to allergen alerts, particularly identifying the cause would be enormously helpful for future data collection and in identifying priorities for improving risk management of allergens in the food industry.

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Table 1. Database fields and description of their content

Database field	Description
Food description	Description of the product as reported in the alert text
RASFF category	Category of the food product in the RASFF system
JFP category	Category assigned according to the system of Gendel & Zhu (2013)
Allergen	Allergen found in the food product subject of the food alert
EU allergen category	Allergen category according to the Regulation (EC) 1169/2011
Single allergen	A single or multiple allergens were present in the food product object of the food alert
Concentration	The concentration of the allergen (mg/kg – ppm)
Source	The authority publishing the food alert
Month	The month of notification of the food alert
Year	The year of notification of the food alert
Notification type	Type of notification as coded in the RASFF system
Action taken	The action undertaken by the food company involved in the food alert as coded in the RASFF system
Country	Country launching the alert
Origin	Country of origin of the food product
Cause	The problem that caused the food alert
Company	Name of the company producing and/or distributing the food of interest
Lots	The number of commercial lots involved in the alert
Illness	Number of adverse reactions reported
Code	Identification code of the food alert as recorded in the RASFF or by the safety authority
Duplicate	The alert is present in the RASFF database and in the archive of the national authority(only for UK FSA and FSAI)

Table 2. RASFF food product categories.

RASFF product categories
Alcoholic beverages
Animal by-products
Bivalve molluscs and products thereof
Cephalopods and products thereof
Cereals and bakery products
Cocoa, cocoa preparations, coffee and tea
Confectionery
Crustaceans and products thereof
Dietetic foods, food supplements, fortified foods
Eggs and egg products
Fats and oils
Feed additives
Fish and fish products
Food additives and flavourings
Fruits and vegetables
Gastropods
Herbs and spices
Honey and royal jelly
Ices and desserts
Meat and meat products (other than poultry)
Milk and milk products
Natural mineral water
Non-alcoholic beverages
Nuts, nut products and seeds
Other food products / mixed
Poultry meat and poultry meat products
Prepared dishes and snacks
Soups, broths, sauces and condiments
Wine

Table 3. RFR US-FDA food product categories and description of their content

RFR of the FDA (Gendel and Zhou 2013)	Description
Bakery	Bread, pastry, cookies, cakes
Beverage	Drinks and drink mixes
Breakfast cereal	Boxed cereals, granola, instant cereals
Candy	Chocolates, confections, sweets
Composite	Sandwiches, wraps, egg rolls, samosas, and similar products
Dairy	Milk-based products, spreads, dips
Dressing	Sauces, salad dressings, pasta sauces, gravies
Imitation milk	Soy milk, almond milk, rice milk, other milk alternatives
Meals	Frozen dinners, packaged multicomponent meals
Other	Miscellaneous
Pasta	Pasta, macaroni, noodle products
Produce	Vegetables, fresh herbs, raw agricultural commodities
Salad	Deli salads, bagged salads, fruit salads
Seafood	Fish and fish-based products
Snack	Snack foods, pretzels, chips, novelty, trail mix, granola bars
Soup	Canned, refrigerated, dry, ramen, and packaged soups and soup mixes
Supplement	Vitamins, dietary supplements, and related products

Table 4. The different codes used to categorise the problem that led to the alert

Code	Description of the problem that led to the alert
Not indicated on label	Allergen undeclared in the label, Insufficient labelling
Packaging error	Use of a wrong packaging
Wrong allergen advice	Allergen listed among the ingredients but not on the separate allergen box
Wrong label	Product mislabelled as another totally different product
Unintended presence	Presence of the allergen, Traces of the allergen, Possible contamination, Cross-contamination, Cross-contact
False label claim	Label claiming allergen-free but actually containing the allergen
Labelling error	Labelling error (with no specification of the type of error)
Allergic reaction	Occurrence of an allergic reaction
Unauthorised or undeclared sulphites	Presence of unauthorised or undeclared sulphites

Table 5. Alerts and recalls (recalled product/allergen combinations, in brackets) in the dataset, by year and source.

Year	RASFF	FSA	FSAI	FDA	USDA-FSIS	CFIA	CFS	FSANZ
2011	75 (82)	82 (103)	20 (34)	126 (563)	41 (115)	146 (456)	0 (0)	21 (80)
2012	72 (80)	71 (175)	14 (26)	107 (466)	29 (56)	159 (404)	3 (3)	13 (26)
2013	50 (54)	46 (108)	12 (45)	118 (283)	25 (60)	212 (832)	4 (7)	16 (29)
2014	69 (78)	53 (140)	24 (44)	102 (279)	33 (147)	343 (1581)	2 (2)	27 (83)
Total	266 (294)	252 (526)	70 (149)	453 (1591)	128 (378)	860 (3273)	9 (12)	77 (218)

Table 6. Products in alerts and recalls in the dataset, by EU allergen type and source.

	RASFF	FSA	FSAI	FDA	USDA- FSIS	CFIA	CFS	FSANZ
Celery	15	23	5	-	-	-	-	-
Cereals containing gluten	49	102	26	147	67	465	-	19
Crustaceans	2	8	-	23	1	48	-	-
Egg and egg products	24	28	18	237	45	372	2	15
Fish and fish products	5	10	3	24	17	46	-	1
Milk and milk products	85	128	42	478	62	1018	3	40
Molluscs and mollusc products	2	1		-	1	9	-	
Mustard and mustard products	8	14	2	-	-	395	-	-
Not an EU allergen	-	-	-	35	-	12	-	-
Nuts and nut products	25	39	11	162	10	117	6	95
Peanuts and peanut products	13	35	-	169	-	145	-	-
Sesame seeds and sesame products	5	5	-	2	-	96	-	11
Soybeans and soy products	26	27	13	274	170	229	1	26
SO ₂ and sulphites	35	106	29	40	5	321	-	11
Total	294	526	149	1591	378	3273	12	218

Table 7. Products with alerts and recalls in the dataset, by cause and source.

Cause	RASFF	FSA	FSAI	FDA	USDA	CFIA	CFS	FSANZ
Allergic reaction	-	-	2	35	7	121	-	-
False label claim	6	12	23	16	1	12	-	4
Labelling error	-	2	-	48	-	-	-	13
Not indicated on label	252	219	63	955	341	2813	12	180
Packaging error	2	46	20	53	11	3	-	7
Unauthorised or undeclared sulphites	6	106	-	40	-	318	-	-
Unintended presence	28	26	2	264	1	3	-	14
Wrong allergen advice	-	104	39	124	-	-	-	-
Wrong label	-	11	-	56	17	3	-	-
Total	294	526	149	1591	378	3273	12	218

Table 8. Products with alerts and recalls in the dataset, by RASFF food category and source.

Food categories	RASFF	FSA	FSAI	FDA	USDA- FSIS	CFIA	CFS	FSANZ
Alcoholic beverages	4	12	-	2	-	6	-	2
Cereals and bakery products	71	72	27	349	-	814	3	32
Cocoa, cocoa preparations, coffee and tea	32	31	8	70	-	136		31
Confectionery	31	109	7	170	-	217	5	32
Crustaceans and products	6	6	-	12	-	18	-	-
Dietetic foods, food supplements, fortified foods	11	3	9	168	-	24	1	10
Eggs and egg products	-	-	-	-	-	5	-	-
Fats and oils	2	-	-	-	-	11	-	-
Fish and fish products	12	9	1	8	-	23	-	9
Food additive, flavouring	1	-	-	-	-	1	-	-
Fruits and vegetables	18	34	1	25	-	30	-	3
Herbs and spices	4	-	-	44	-	60	-	1
Honey and royal jelly	-	-	-	-	-	5	-	-
Ices and desserts	6	4	8	79	-	52	-	6
Meat and meat products	13	28	8	-	138	191	-	2
Milk and milk products	3	21	33	29	-	9	-	-
Molluscs and mollusc products		-	3	7	-	2	-	-
Non-alcoholic beverages	1	3	-	18	-	129	-	2
Nuts, nut products, seeds	7	15	2	15	-	90	-	32
Other food product/mixed	8	2	4	70	-	258	1	-
Poultry meat, poultry products	6	10	-	-	31	73	-	8
Prepared dishes and snacks	35	104	30	397	202	919	2	40
Soups, broths, sauces	23	63	8	128	7	200	-	8

and condiments								
Total	294	526	149	1591	378	3273	12	218

Table 9. Products with alerts and recalls in the dataset, by FDA food category and source.

Food categories	RASFF	FSA	FSAI	FDA	USDA-FSIS	CFIA	CFS	FSANZ
Bakery	54	60	20	326	-	775	2	27
Beverage	4	15	-	36	-	169	-	2
Breakfast cereal	6	14	-	13	-	33	-	2
Candy	43	127	14	226	-	302	5	60
Composite	1	11	-	126	-	145	-	
Dairy	3	22	33	31	-	14	-	
Dressing	19	59	8	121	6	204	-	4
Imitation milk	-			4	-	21	-	2
Meals	19	38	19	26	162	648	2	29
Other	76	66	33	200	205	448	2	27
Pasta	3	8	4	17	-	105	-	2
Produce	13	25		26	-	22	-	
Salad		8		23	2	59	-	
Seafood	19	17	4	27	-	45	-	9
Snack	27	49	5	193		227	-	10
Soup	6	4		28	3	33	-	
Supplement	1	3	9	168		23	1	10
Total	294	527	149	1591	378	3273	12	218