

ALLERGEN PRODUCT RECALLS – November 2016

Talbot Underwriting Ltd is one of the original and core businesses of the Validus Group, and operates within the Lloyd's Insurance Market through Syndicate 1183. With an expert team of highly skilled and experienced underwriters and a balanced, geographically diverse portfolio of business, Talbot has earned a reputation as an industry leading insurance and reinsurance specialist.

RQA is the leading global consultancy that specialises in the food, consumer product and automotive sectors. RQA helps businesses to develop product recall, crisis management and business continuity plans as well as train and test their product recall and crisis management teams. RQA consultants also advise during product recall incidents and can assist with the physical execution of the recall. RQA also work closely with the legal and insurance sectors, providing expert witness and consultancy services.

The Talbot/RQA Partnership

Talbot, leaders in product recall and contamination insurance, asked RQA to look into the trends in allergen recalls. Neil Evans, Senior Class Underwriter at Talbot explained, "Every year the food industry suffers from many allergen-related recalls in the US, Europe, Australia and elsewhere. Allergen recalls can be highly costly and can even result in company closures; highlighting the importance of product contamination insurance cover for balance sheet protection. We wanted to get a better understanding on where the allergen risks are in order to see how we can best support our food industry clients."

With brand protection being at the top of many CEO's concerns, Talbot is proud to be associated with one of the leading global firms in the Crisis Management space. RQA has been assisting clients throughout the world for the past 20 years in all areas of Crisis Management including incident response, risk mitigation and analysis and simulation training.

This paper addresses the following:

- Are allergen recalls increasing every year in US, Europe and Australia?
- What happened in 2015 that resulted in a spike in allergen-related recall numbers in all these regions? Was it the same event or different events?
- Why are there almost as many allergen recalls in the UK as reported across the entire EU?
- What products are most susceptible to allergen recalls?
- Which allergens are most commonly involved in recalls?
- What should food manufacturers do to reduce the risk of allergen contamination?

Executive Summary

It is clear from the statistics that allergen related product recalls are increasing. They are largely attributed to cross contamination in the factory and supply chain, or labelling errors (wrong label or erroneous allergen declarations). However, allergen-related recalls may also be caused by food fraud; deliberate contamination of an ingredient by a cheaper alternative which can have a massive impact on the global food industry. For example, it is widely believed that the motivation behind contaminating cumin with peanut protein (shells etc.) was fraud. That led to a large number of product recalls in the US in 2015. In fact, there were so many products containing contaminated cumin that the total US FDA recall figures were skewed in 2015.

Note: For lists of officially named allergens in US, Europe and Australia, go to Annex 1 of this article.

US FDA Allergen-related Recalls

First, let's look at the US situation. It is helpful to see the allergen-related recalls in context of the total number of recalls reported via the FDA system of Recall Enforcement Reports between 2013 and 2016.

Figure 1, shows the total number of separate product recall events whilst Figure 2 shows the total number of different products recalled. The total number of events have been increasing since 2014; with 725 estimated by the end of 2016, 20% higher than in 2015. In contrast, the number of different products recalled dropped in 2016 compared with 2015.

Figure 1 - US FDA Recalls – Events

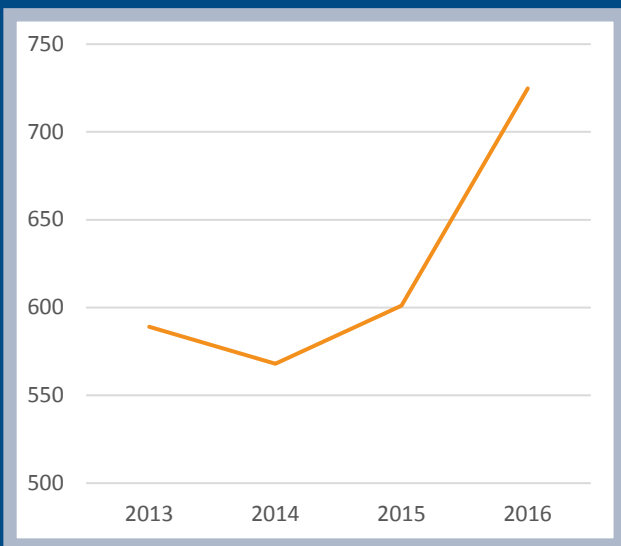
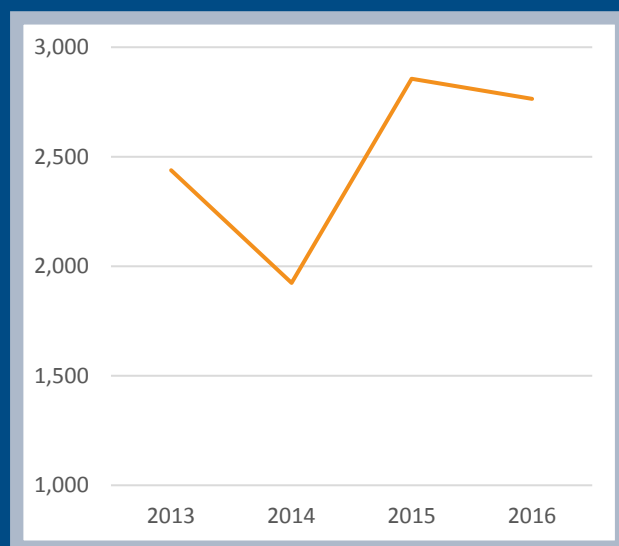


Fig 2. - US FDA Recalls - Products



But that is not the complete picture. In 2015 there was a widespread contamination of cumin with peanut that resulted in 259 different products recalled through 47 different recall events. This was sufficient to cause a spike in the total recall numbers in 2015. Therefore, to see the underlying trend, we can look at the total data without the contribution from the 2015 cumin incident. Figure 3 shows the total number of recall events (without cumin contaminated peanut) and Figure 4 shows the total number of products recalled without the cumin incident.

Figure 3 – FDA All Recalls – Events without cumin

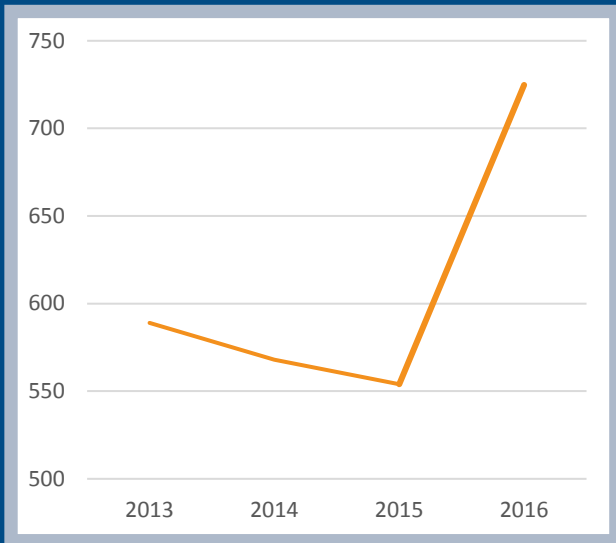
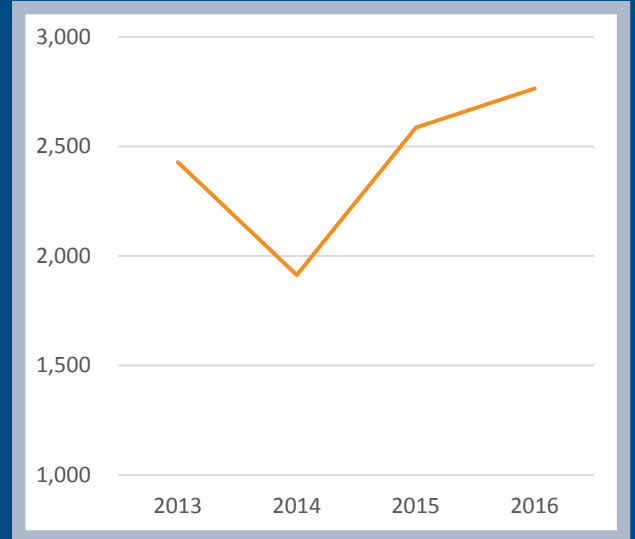


Figure 4 - FDA All Recalls – Products without cumin



Excluding the cumin incident, the underlying numbers of products recalled have been increasing since 2014 and there was a particularly large increase in recall events in 2016. This shows how large an impact a major allergen contamination incident can have; especially when a basic ingredient is contaminated.

You can see from Figures 5 and 6 that if we don't include the cumin incident, the allergen-related recalls have also been increasing since 2013. In fact, the number of allergen-related recall events and the number of recalled products has almost been increasing linearly. We can almost predict that if there are no major widespread allergen contamination incidents, there will be around 340 product recall events related to allergens in 2017.

Figure 5 – FDA Allergen recalls

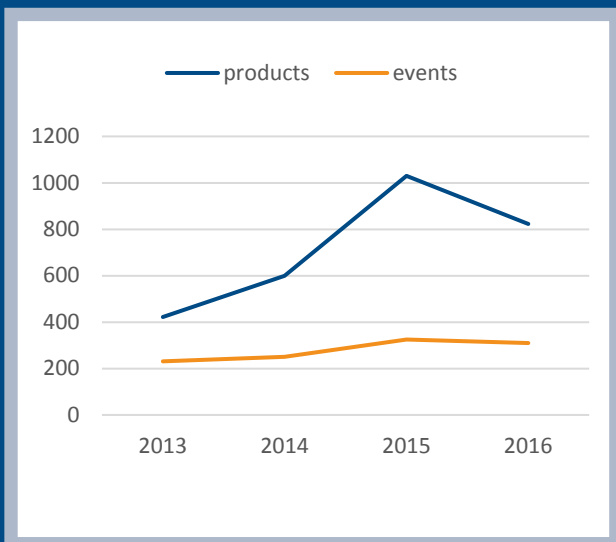
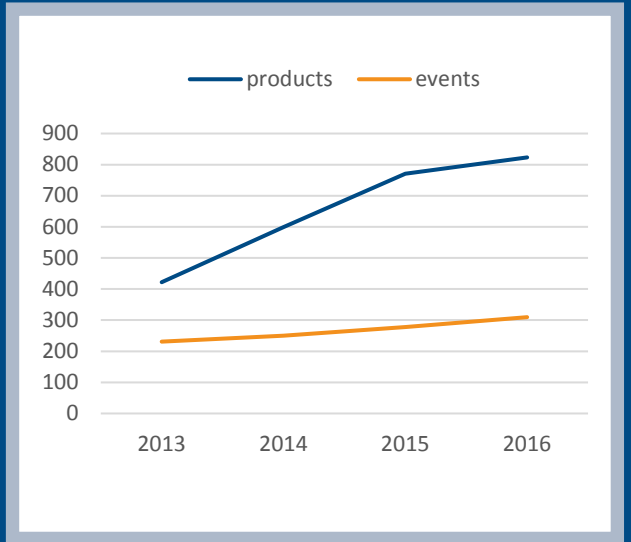


Figure 6 – FDA Allergen recalls without cumin



It is also possible to analyse the USFDA enforcement reports to identify which allergens are the cause of the recalls. The numbers of allergen-related recall events are shown in Figure 7 and the number of recalled products is in Figure 8.

Figure 7 - FDA Allergen recalls - Events

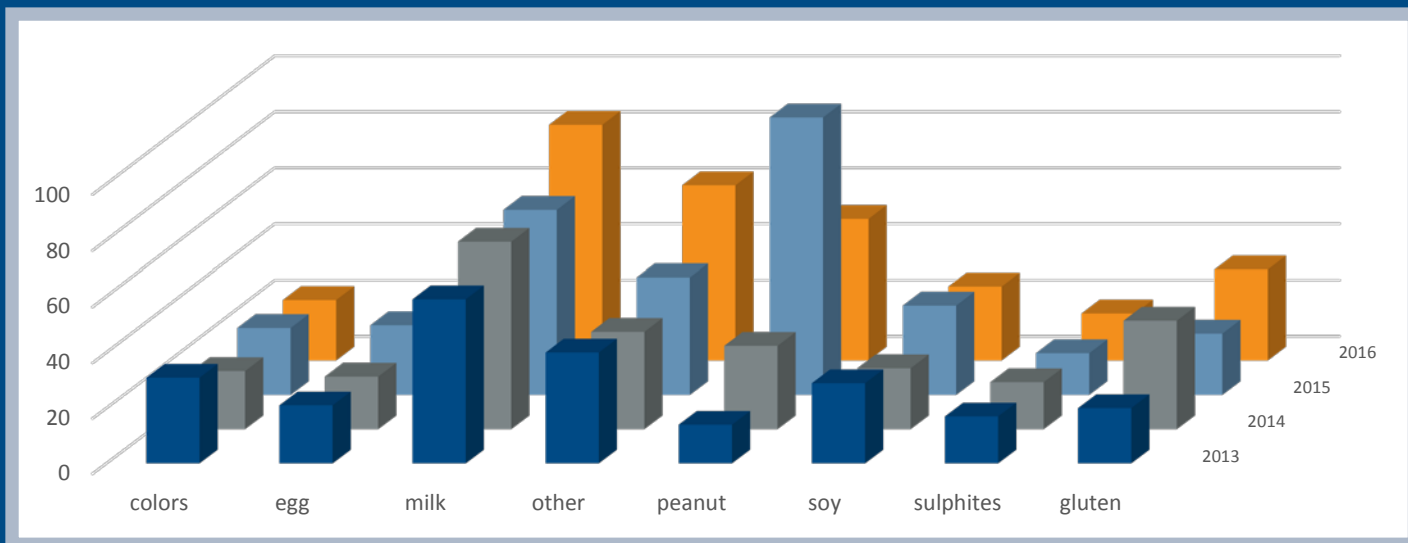
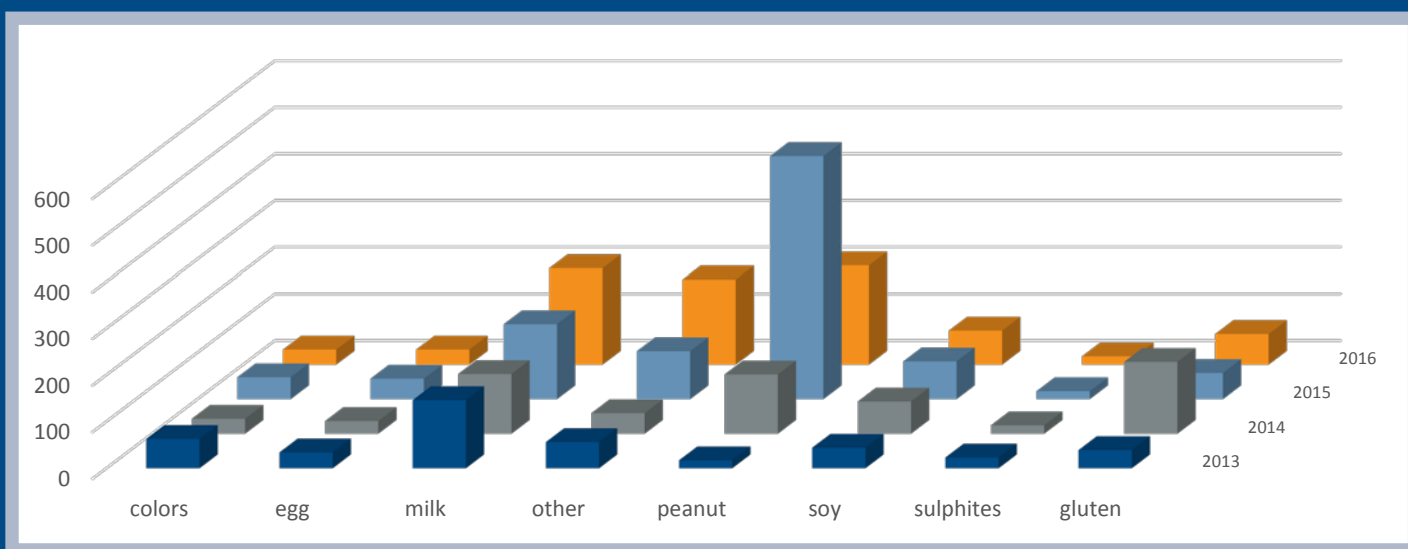


Figure 8 - FDA Allergen Recalls – Products



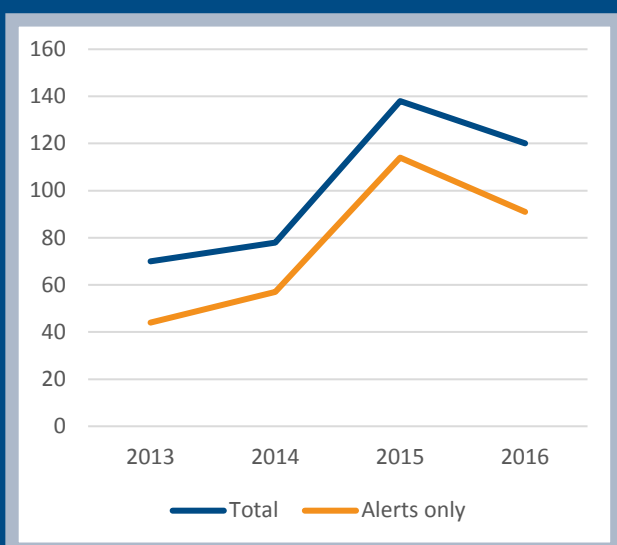
As would be expected, peanut and milk are the two most common allergens that cause product recalls. These are used as ingredients in a wide range of food products and so the high number of recalls reflect their broad usage across the food industry. Peanut and milk are then followed by soy and gluten, including wheat (the allergen, intolerance and other health factors relating to wheat and gluten are considered together) and then egg and colors and sulphites. (Note: although sulphites are not listed as one of the 8 main food allergens by the FDA, it is known that people may be sensitive or have an allergic type response and so it has been included in these data). Of the main 8, fish, shellfish and tree nuts do not occur in the recall data in significant numbers to warrant individual listing here. They are included in the “other” category along with “not specified”.

EU RASFF Allergen-related Recalls

The first thing to realise when looking at the EU “recall” data is that the numbers are actually quite low when compared with the recall events reported via the US FDA. This is not due to any major difference in perception of allergens or how they are controlled. The reason is because a large number of recalls in Europe related to allergen contamination or mislabelling are not reported via the European Rapid Alert System for Food and Feed (RASFF). Instead reporting of allergen recalls is normally limited to the individual member country within the EU where the products are being sold. For example, by the end of 2016 there will have been around 120 notifications related to allergens reported across the EU via RASFF whereas, during that same period there will have been around 100 reported in the UK alone. Of those 100 UK alerts, only around 15 were reported to RASFF. In other words over 80 allergy recalls in UK were not reported to RASFF. When the UK Food Standards Agency was asked about this, they replied as follows: “*We will issue a notification via the RASFF system if there is distribution outside of the UK and involves an incident in breach of EU legislation.*” Which suggests that most allergen recalls do not involve products distributed cross border.

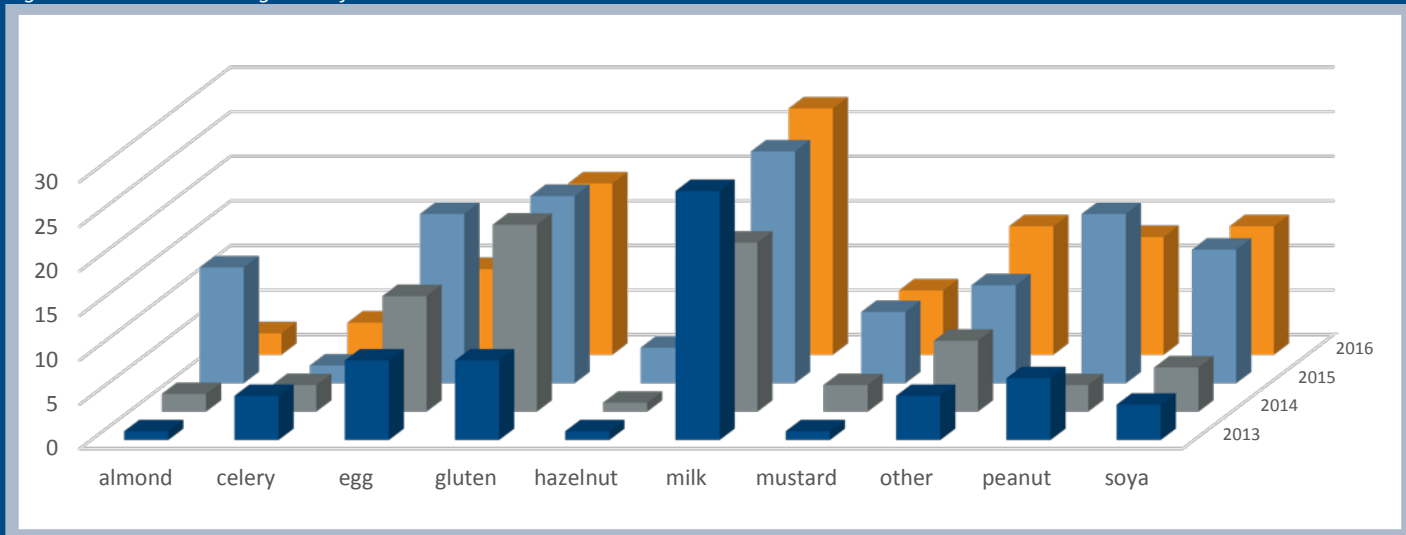
If we then look at the EU RASFF data reported under the hazard category “allergens”, it can be seen in Figure 9. that there was a peak in the number of notifications 2015 (like in the US). Even so, the number of total notifications in 2016 is still 50% higher than the number in 2014. Also, the peak seen in 2015 is not due to a large single event (as with peanut-contaminated cumin in the US). Instead, there was just an increase in the number of individual or smaller events. It is also worth noting that in the EU, typically more than 75% of all allergen category RASFF notifications are designated as “alert”. An “alert” is issued if a product represents a serious risk and is on the market. For definitions of all EU notification types, please go to Annex 2.

Figure 9 – EU RASFF Allergen Notifications



Breaking the EU RASFF data into types of allergen it can be seen in Figure 10 that the major allergens involved in product recalls are milk then gluten (including wheat). Interestingly, in 2015 there was a higher than “typical” number of notifications for almond, egg and peanut. Although there is no clear reason why this was the case; it just appears that there were more allergen issues in 2015.

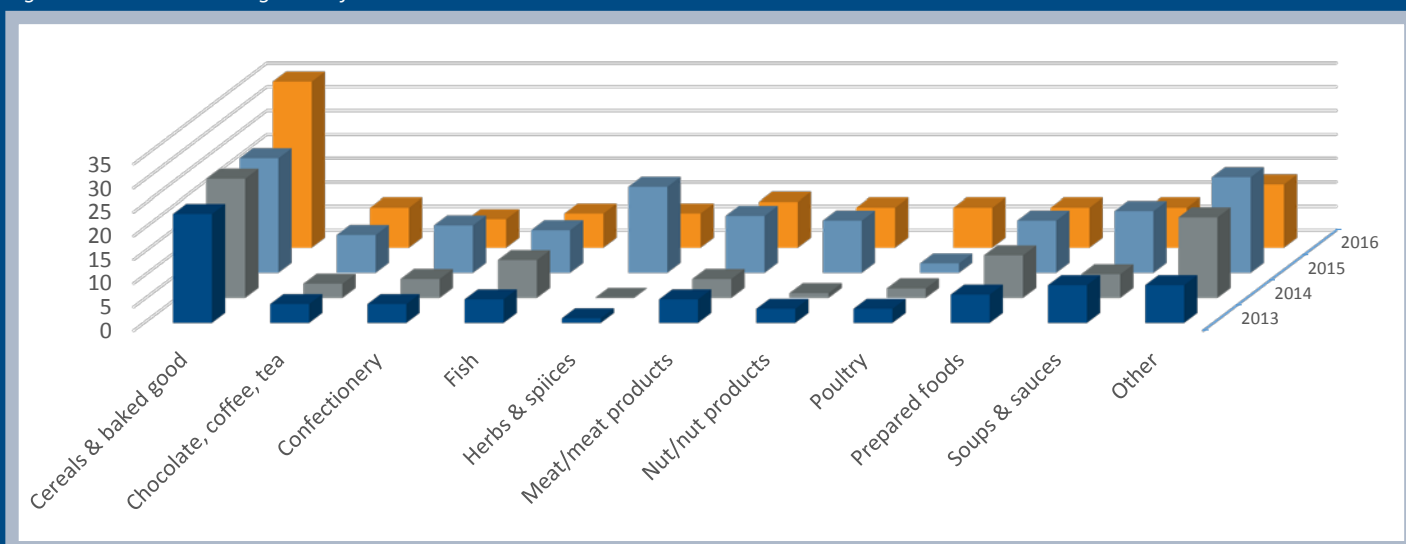
Figure 10 - EU RASFF Allergen Notifications



Let’s also look at the food products involved in these allergen related notifications. Cereals and baked goods are by far the largest category with 29% of all allergen notifications in 2016. This category includes items such as pasta, cookies, cereal bars, biscuits, muesli, etc.

Each of the other food product categories named in Figure 11 represent around 5 – 8% of the total notifications.

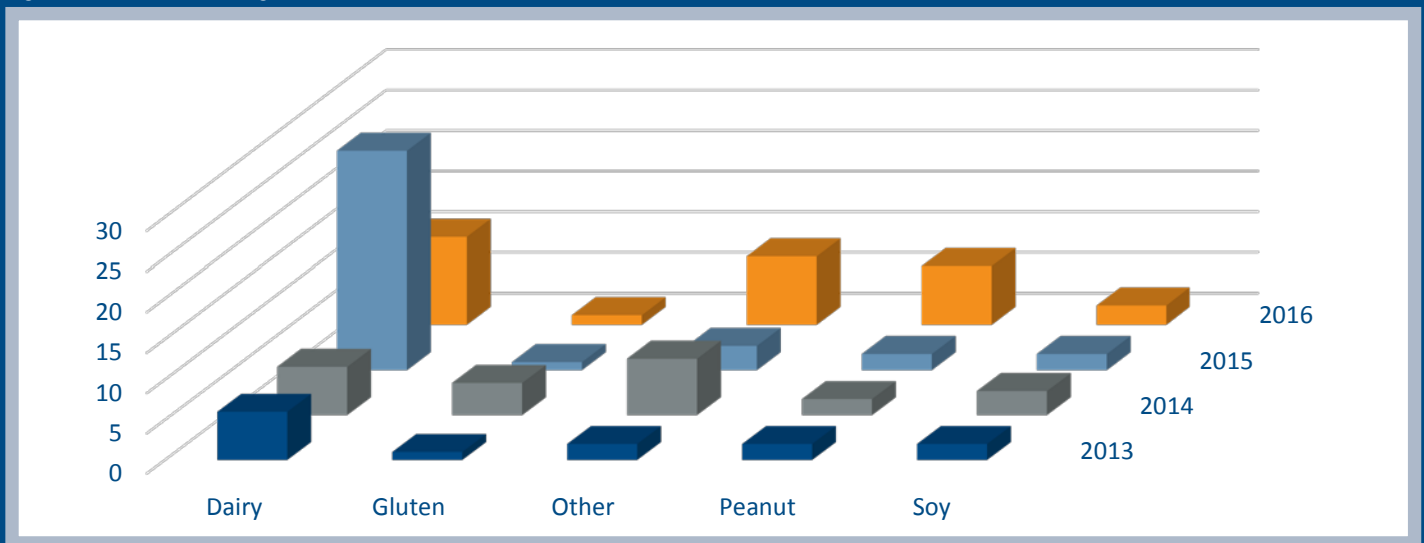
Figure 11 - EU RASFF Allergen Notifications - Foods



Finally, the EU RASFF data also allows us to analyse how the notifications originated. In the case of allergen related notifications in 2016, almost 40% resulted from “official control on the market”, over 35% from “company’s own checks” and over 15% from “consumer complaints”. It is always best if the company can identify the fault before it leaves their control within the supply chain and certainly before reaching consumers.

Australia Allergen-Related Recalls

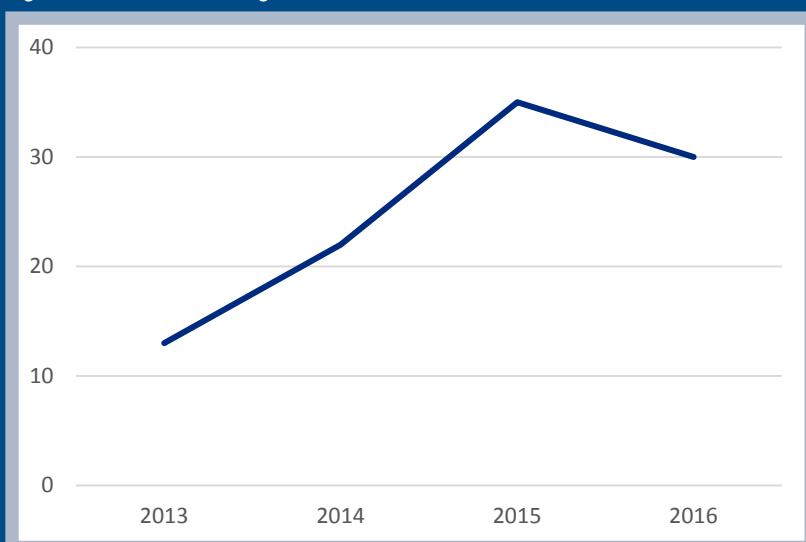
Figure 12 – Australia Allergen Recalls



According to Food Standards Australia New Zealand (FSANZ), over 30% of all food recalls in the past 10 years have been due to undeclared allergens.

These allergen-related product recalls in the food & groceries section of Product Safety Australia are shown in Figure 12. As with the US and Europe, there is an increasing upwards trend, with a spike in 2015. In the case of Australia, the spike in 2015 was due to several coconut milk, coconut juice drinks, and coconut powder products being recalled due to the presence of undeclared dairy allergen. In fact, there were over 20 recalls related to this issue. This spike can also be seen in Figure 13.

Figure 13 – Australia Allergen Recalls



Each year, dairy is the cause of most allergen-related recalls with gluten, peanut and soy also impacting in low numbers. The “other” category includes crustacean, fish, other nuts, egg etc.

Conclusions:

Why are allergen recalls so concerning?

The reaction to allergens, even at very low levels can cause serious health effects and occasionally be fatal. It is essential for foods to be labelled accurately so that consumers can make informed decisions about what they eat in order to manage and prevent allergic reactions. There are strict laws in most territories relating to labelling of allergens and non-compliance due to cross contamination or labelling errors results in product recalls.

Managing Allergens

This is a lengthy topic, but essentially relates to training, up to date knowledge of regulatory requirements, risk assessment, supply chain controls and quality assurance. Some top level points are listed here.

- Food manufacturers and distributors should have an effective allergen management plan and train their staff on food allergen risks.
- Allergen management is a comprehensive, site-wide system. It should be based upon a sound risk assessment and include all areas such as raw materials, packaging, equipment, cleaning supported by validation and audit.
- The supply chain should be risk assessed for vulnerabilities to contamination and fraud.
- As well as operators understanding allergen risks, managers should know the regulations for the country where the product is destined.
- Finally, there must be a process of approval and sign-off to ensure the label is correct. Too many products are recalled because the wrong label was put on the product!

It is only by ensuring these measures are 100% robust across the industry that the number of allergen related recalls will start to reduce.

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November 2016
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ANNEX 1 – FOOD INGREDIENTS THAT MUST BE DECLARED AS ALLERGENS

US FDA List

Food Allergen Labeling and Consumer Protection Act identifies eight foods or food groups as the major food allergens. They are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans.

These eight foods, and any ingredient that contains protein derived from one or more of them, are designated as “major food allergens” by FALCPA.

Also, note from FDA:

More than 160 foods have been identified to cause food allergies in sensitive individuals. However, the eight major food allergens identified by FALCPA account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.

Ref: Food Allergen Labeling and Consumer Protection Act (FALCPA) 2004

EU List

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:

- (a) wheat based glucose syrups including dextrose
- (b) wheat based maltodextrins
- (c) glucose syrups based on barley
- (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin

2. Crustaceans and products thereof

3. Eggs and products thereof

4. Fish and products thereof, except:

- (a) fish gelatine used as carrier for vitamin or carotenoid preparations
- (b) fish gelatine or Isinglass used as fining agent in beer and wine

5. Peanuts and products thereof

6. Soybeans and products thereof, except:

- (a) fully refined soybean oil and fat
- (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources
- (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources
- (d) plant stanol ester produced from vegetable oil sterols from soybean sources

7. Milk and products thereof (including lactose), except:

- (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin
- (b) lactitol

8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*),

pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin

9. Celery and products thereof

10. Mustard and products thereof

11. Sesame seeds and products thereof

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

13. Lupin and products thereof

14. Molluscs and products thereof

Ref: Regulation (Eu) No 1169/2011 Of The European Parliament And Of The Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

Australia List

According to FSANZ, most food allergies are caused by the following foods and these must be declared on the food label whenever they are present as ingredients or as components of food additives or processing aids, however small the amounts present in the food.

- Eggs
- Fish
- Milk
- Peanut
- Sesame
- Shellfish
- Soy
- Tree nuts
- Wheat

Gluten-containing cereals need to be declared on the label so people with Coeliac Disease and cereal allergies can identify these products. Gluten-containing cereals include wheat, rye, barley, oats and hybrid strains of these cereals (e.g. triticale).

ANNEX 2 - DEFINITIONS

What type of RASFF notifications are there? The definitions below have been taken from the RASFF 2015 Annual Report prepared by the European Commission.

An **'alert notification'** or **'alert'** is sent when a food, feed or food contact material presenting a serious risk is on the market and when rapid action is or might be required in a member country other than the notifying country.

An **'information notification'** concerns a food, feed or food contact material for which a risk has been identified that does not require rapid action either because the risk is not considered serious or the product is not on the market at the time of notification.

A **'border rejection notification'** concerns a consignment of food, feed or food contact material that was refused entry into the Community for reason of a risk to human health and also to animal health or to the environment if it concerns feed.

Following a RASFF notification, members of the network can transmit **'follow-up' notifications** which refer to the same consignments and which add information to the original notification such as information on hazards, product traceability or measures taken.

An original notification that was transmitted through the RASFF can be **withdrawn** by the Commission in agreement with the notifying country if the information upon which the measures taken are based turns out to be unfounded or if the transmission of the notification was made erroneously.

ANNEX 3 – NOTES ABOUT THE DATA

The 2016 figures are extrapolated from January to October data.

If multiple allergens are listed as the cause of a recall, the one listed first is included in these data.

Data is sourced from official sites in US, EU, UK and Australia.

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