

The Inexorable Rise of Food Hypersensitivity

We have all heard the media news reports of fatal allergic reactions to food – often takeaways, such as sandwiches, burgers or a curry. In this article, journalist Rosalind Whistance asks leading food safety expert **Dr Belinda Stuart-Moonlight**, **who in the article below sets out t**he reasons why the profile of food hypersensitivity is so high now, what is being done by regulators and the industry and whether we are likely to see an improvement in food safety in this regard over the next few years.

Meet Dr Belinda Stuart-Moonlight

RW: You are an award-winning, sought-after expert witness in food and infectious disease cases. How did you gain experience for this role?

BSM: I started out as a regulator, an environmental health officer in local government enforcement before taking up a junior research fellowship at King's College, University of London, where I examined microbial survival on food contact and structural surfaces in food preparation environments. For the last 20 years I have run my own business providing consultancy, training, auditing and expert witness services, mainly in food related sectors. I firmly believe that by continuing to undertake practitioner work, my expert witness work is better informed by current industry practice. As an expert witness, the majority of my instructions focus on food contamination risk and, in the last 18 months they comprise an unprecedented number relating to serious or fatal food allergy.

RW: What sort of cases have you undertaken historically as an expert witness?

BSM: I've been involved in criminal and civil cases and aim to maintain a 50:50 balance in producing reports for: i) the prosecution / claimant and ii) defence. The majority of my instructions require comprehensive reports and I produce approximately 15 per year. Some notable cases include large infectious disease outbreaks on cruise ships, fatal food poisonings, major pest infestations and the first ever norovirus prosecution under health and safety legislation. Here, I was appointed by the defence, and on receipt of my report, the prosecution was withdrawn (Exeter City Council v Mitchells & Butlers plc). Two of the higher profile allergy cases for which I have provided expert reports were R v Mohammed Khalique Zaman (re the Indian Garden restaurant in Easingwold, Yorks, heard in Teesside Crown Court), and R v Mohammed Abdul Kuddus, Harun Rashid and Royal Spice Takeaway Ltd (Oswaldwistle, Lancs, heard in Manchester Crown Court). There is discussion and reflection on these cases further in this article.

Food Hypersensitivity -Consequences Controls and Cases 1.0 What are the basic statistics for food hypersensitivity in the UK?

Food hypersensitivity includes food allergy, intolerance and Coeliac disease¹. Food allergy affects 1 - 2%of adults and 5 - 8% of children in the UK². Currently, it is estimated that approximately 2 million people in the UK live with a diagnosed food allergy and 600,000 (equating to 1 in 100) have Coeliac Disease¹. Individuals with intolerances add further to the food-hypersensitive population. Year-on-year rates of food hypersensitivity are increasing but the causes are not fully understood³.

2.0 What is the difference between food allergy, food intolerance and Coeliac disease?

Food allergy is where the body's immune system reacts to a seemingly harmless substance – in nearly all cases a protein, in food. Symptoms of food allergy⁴ include tingling or itching in the mouth, hives, swelling of the face, mouth, throat and other areas of the body, difficulty swallowing, wheezing, nausea, vomiting, diarrhoea and anaphylaxis. Food allergy can be life-threatening.

Food intolerance is an inability to process or digest certain foods, the most common being lactose intolerance, where there is a deficiency in the enzyme lactase to process lactose (sugar present in milk). Symptoms of food intolerance include tummy pain, bloating, wind, diarrhoea, skin rashes and itching. Food intolerance is not life-threatening.

Coeliac disease is an autoimmune condition that causes a complex inflammatory reaction following ingestion of gluten. It is not life-threatening but can cause severe weight loss and malnutrition.

Food hypersensitivity therefore encompasses three different types of physiological response to allergens (the proteins that trigger the reactions). In the case of food allergy, reactions tend to be very quick (within seconds or minutes) and in severe cases can be lifethreatening. In contrast, food intolerance and Coeliac disease may take some minutes or hours before symptom onset and they are not life-threatening.

3.0 What are the risks associated with food allergy?

In rare cases, the allergic reaction becomes severe and causes anaphylaxis that can lead to death. Symptoms of anaphylaxis include swollen tongue, breathing difficulties, tight chest, trouble swallowing or speaking and a drop in blood pressure. Individuals who are severely allergic need to carry epinephrine auto-injectors such as the Epi-Pen, for rapid administration upon experiencing anaphylactic symptoms. Risks include i) not having the auto-injector readily available, ii) not administering the auto-injector properly and ii) receiving too small a dose – all three risks have contributed to recent food allergy fatalities.

4.0 To how many foods are people hypersensitive?

There are 14 foods responsible for the majority of reactions in the European food- hypersensitive population. These foods are considered key allergens that are defined in legislation for provision of specific information; they comprise:

1. **celery** (includes stalks, leaves, seeds, celeriac and celery salt, e.g. used in stocks and soups)

2. cereals containing **gluten** (includes wheat, rye, barley and oats, e.g. used in breads, cakes, couscous, pastry, soup, cereal-dusted products)

3. **crustaceans** (includes crabs, lobsters, prawns, scampi, e.g. shrimp paste)

4. **eggs** (found in a wide variety of products including cakes, mayonnaise, and foods brushed with egg glaze. Egg white is used as a processing aid in cocktails)

5. **fish** (can be unexpected in products such as pizzas, relishes, salad dressings, stock cubes and Worcestershire sauce)

6. **lupin** (includes lupin seeds and flour, and can be found in bread, pastries and pasta)

7. **milk** (found in dairy products including butter, cream, cheese, milk powders, yogurts, sauces, powdered soups and foods glazed with milk)

8. **molluscs** (includes mussels, land snails, squid and whelks and are found in a range of products, such as fish stews and oyster sauce)

9. **mustard** (includes liquid, powder and seeds often used in breads, curries, marinades, meat products, dressings, sauces, soups, etc.)

10. **tree nuts** (includes almond, hazelnut, walnut, cashew, pecan, Brazil, pistachio, macadamia and Queensland nuts, used in a variety of products including breads, biscuits, nut oils, sauces, curries and stir fries)

11. **peanuts** (can be found in a variety of products including biscuits, cakes, curries, desserts, sauces, groundnut oil and peanut flour). NB peanuts are considered separately from tree nuts, as they grow below the ground.

12. **sesame seeds** (can be found in bread, breadstick, hummus, sesame oil, tahini and as a sprinkle on various sweet and savoury products)

13. **soya** (can be found in various products including bean curd, edamame beans, miso paste, texturized soya protein, soya flour, tofu)

14. **sulphur dioxide** (used as a preservative in dried fruit, meat products, soft drinks, vegetables, wine, beer)

The foods that a population in one part of the world are allergic to can differ from those to which a population in a different region of the world is allergic. The list of key allergens requiring specific declaration information in the EU is thus different from that in the US and Australia. As with many aspects of food hypersensitivity, the reasons for this variation are not fully understood.

The most common foods that elicit hypersensitivity reactions in European populations are milk, egg, wheat, fish and nuts⁶.

5.0 How do allergens get into food?

Allergens enter food in three ways: 1. as an ingredient

2. as a processing aid (substances used to help achieve qualities in a food product such as sulphur dioxide used as a preservative and antioxidant in dried fruit, soft and alcoholic beverages)

3. through cross contact (formerly known as crosscontamination, where the allergen is inadvertently or accidentally transferred into a food that does not contain it as an ingredient. For instance, the transfer of a sesame seed on a baking tray used firstly for a batch of sesame- containing rolls then, through insufficient cleaning, the remaining sesame seed attaches to a non-sesame-containing batch.)

6.0 What are the realities of living with an allergy?

Writing in the Guardian, Sophie Ankle, an allergy sufferer, sums up living with an allergy⁷:

"Living a life with food allergies can feel like you're walking through a minefield. It means having to call up restaurants in advance to see if it's possible to eat there, and then feeling like a nuisance every time you have to grill a stumped waiter about how certain foods are prepared. It means developing a habit of meticulously reading through every single ingredient list, and becoming an expert at studying any allergen guide handed to you. And it means checking, double checking, and then living with the fear that you haven't checked enough and that any oversight can, in severe cases, cost you your life.

"It is a burden people like myself have no choice but to carry, we simply have to learn how to cope. But it's made even harder when people fail to give us relevant information. Take Leon for example, whose cofounder and chief executive John Vincent advised diners with severe allergies to think carefully before choosing to eat at the health-conscious joint. In a blog post, he wrote: 'the idea that Leon could cause harm to one of its guests is horrifying. And we therefore ask those of you with serious allergies to consider carefully whether to choose to dine with us.' "

The realities of living with an allergy are thus about a lack of choice, being seen as the odd one out and the constant fear that food may be contaminated. From research and analysis of cases, it has been identified that young people (16-24-year-olds) are particularly at risk. This recognition has caused the Food Standards Agency to engage in the 'Easy to ASK' campaign, which follows the prompt 'Always ask about allergies, **S**peak up, **K**eep safe^{'8}.

7.0 What is the regulatory landscape for food hypersensitivity?

7.1 Introduction

The regulatory landscape in respect of allergen control and information has changed significantly in the last 20 years. For example, prior to 2012, eight foods were required to be identified as allergenic ingredients, whereas the number is currently 14. More recently, change has been gaining pace, particularly following specific incidents such as the death of Natasha Ednan-Laparouse. Natasha consumed a Pret a Manger baguette that contained sesame but was not required to have a label identifying its ingredients because it was prepacked for direct sale, a type of food exempt from such labelling. This exemption is now closing following Foods Standards Agency (FSA) consultation and the Food Information (Amendment) (England)) Regulations 2019 (SI 2019 No. 1218) will come in to force on 1st October 2021.

To an expert witness, there is a distinct challenge resulting from the current rapid pace of change. Consumers are much more familiar with allergen issues now because of media coverage. This means that in jury trials, jurors are likely to automatically apply the allergen climate of today (with knowledge of exemptions often unhelpfully referred to as 'loopholes', fatalities and lessons learned) when listening to evidence about issues that occurred maybe three years ago, in any event prior to some of the knowledge-giving incidents that have occurred in the interim. Indeed, even three years ago, business systems, expectations and awareness were quite different. This means that jurors may well expect higher standards of food businesses than were the industry norm at the time.

Within general food law there is an overarching requirement that food is not unsafe. Food intended for a food-hypersensitive individual will need to be free from certain ingredients, processing aids or contaminants to avoid a potential reaction. Notwithstanding, given that the 14 key allergens are safe for non-hypersensitive individuals, foods that are safe for some people may be unsafe for others. Food-hypersensitive individuals can identify any of the 14 key allergens in prepacked food by consulting the label, but for non-prepacked foods or those prepacked for direct sale, such as in sandwich bars, the information must be available and easily accessible.

7.2 Mandatory particulars for 14 allergens

Article 9 1 of Regulation EC 1169/2011⁹ requires, inter alia, to provide specific information (termed 'mandatory particulars'), namely detail of any ingredient or processing aid derived from 14 allergens that are identified within Annex II. These allergens (products and products thereof) are: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame, sulphur dioxide, lupin and mollusc (please see section 4 above for further details).

Article 12 1 of Regulation EC 1169/2011 requires that the mandatory information "shall be available and shall be easily accessible..."

7.3 Prepacked Food – Food inside a wrapper

Article 12 2 of Regulation EC 1169/2011 requires that the mandatory information in the case of prepacked food, "shall appear directly on the package or on the label attached thereto."

The requirements regarding pre-packaged foods are therefore quite straightforward whereby on the label any one of the 14 key allergens, if present as an ingredient or processing aid, is highlighted in a defined way – usually in bold font.

7.4 Non-Prepacked Food – Restaurants, bars, buffets etc

Article 12 5 of Regulation EC 1169/2011 indicates that in the case of non-prepacked food, the provisions of Article 44 shall apply.

Article 44 1 of Regulation EC 1169/2011 indicates that, inter alia, where food is offered for sale to the final consumer without packaging, the mandatory information (14 allergens) must still be available.

Article 44 2 of Regulation EC 1169/2011 indicates that EU Member States may adopt national measures concerning the means through which the mandatory information is to be made available and, where appropriate, their form of expression and presentation.

The UK took up this Article 44 option via The Food Information Regulations 2014¹⁰ in respect of nonprepacked food to specify how compliance might be satisfied within the catering / hospitality sector. It introduced some flexibility in how allergen ingredient information can be provided.

Regulation 5 (1) of The Food Information Regulations 2014 enables food business operators to make available the allergenic ingredient information "by any means the operator chooses, including, subject to paragraph (3), orally".

Regulation 5 (3) of The Food Information Regulations 2014 provides that where a food business operator intends to make available the particulars (allergenic ingredient information on the 14 specified allergens) relating to the relevant food orally, the operator must indicate that details of allergenic substance(s) or product(s) can be obtained by asking a member of staff.

Regulation 5 (4) of The Food Information Regulations 2014 provides that in instances outlined in 5 (3), the particulars "must be given:

a) on a label attached to the food, or

b) on a notice, menu, ticket or label that is readily discernible by an intending purchaser at the place where the intending purchaser chooses that food". Guidance on the interpretation and practical implementation of the requirements can be found in the FSA document 'Food allergen labelling and information requirements under the EU Food Information for Consumers Regulations No 1169/2011: Technical Guidance (April 2015)'.¹¹

Paragraph 79 of the Guidance states:

"Allergen information for non-prepacked food can be communicated through a variety of means to suit the business format of the FBO [food business operator]. The requirement is to provide information about the use of allergic ingredients in a food. The provision does not require food businesses to provide a full ingredients list. Where food businesses choose for this information to not be provided upfront in a written format (for example allergen information on the menu or foods sold by a butcher or delicatessen), the food business should use clear signposting to direct the customer to where this information can be found, such as asking members of staff. In such situations there must be a statement that can be found on food menus, chalkboards, food order tickets, food labels or webpages (see Regulation 5 (4) of the Food Information Regulations 2014)".

Paragraph 81 of the Guidance states:

"All mandatory allergen information, on menus or signpost statements to where it could be found, should be easily accessible and visible, and clearly legible to the final consumer regardless of whether they have a food allergy or not."

The requirements regarding pre-packaged foods are, therefore, that information regarding 14 key allergens when used as ingredients or processing aids must be available and easily accessible. A food business operator can choose how to make the information available but if this is orally, there must be signposting to indicate the availability of the information.

One issue that will be tested in a forthcoming case is the question of who is responsible to initiate a discussion about the allergenic ingredients - the individual ordering food or the business which has the information available but does not place it in front of customers unless asked. The decision will have far reaching implications for the industry should there be no onus on the customer. For instance, pubs and restaurants would have to ask about the allergy needs of every customer every time a food or drink is ordered.

7.5 Food that is Prepacked for Direct Sale (PPDS) – Food that is wrapped on the site of making and sale but does not require a label

The sandwich purchased by Natasha Ednan-Laparouse falls under the umbrella of non-prepacked foods and, in particular, the classification 'prepacked for direct sale' (PPDS). Regulations do not specifically define PPDS. Regulation EC 1169/2011 Article 2 2 (e) defines 'prepacked' and states that 'prepacked food does not cover foods packed on the sales premises at the customer's request or prepacked for direct sale'. The FSA Technical Guidance¹¹ provides examples of PPDS foods (at paragraph 74):

"... meals prepacked in a canteen for consumption on or off the premises, cheese or meat sold loose from a delicatessen counter, bread or pies sold at bakeries or meat and meat products at butchers and packed at the consumer's request."

The Gov.UK website¹² provides a further indication that states:

"...Put simply, PPDS foods are foods that are packed on the same premises from which they are being sold, before they are offered for sale. These might include a packaged salad or baguette from a shop that was made by staff earlier in the day, packaged in the kitchen and then placed on a shelf for customers to purchase."

PPDS foods therefore are sold in a wrapper that does not require a label with ingredient information. Incidents have happened where, for instance, the consumer assumed that the absence of a label meant the absence of risk (on the basis that there was no allergen information). In another case, the customer followed the label signpost and asked for ingredient information, but the wrong information was provided despite the business having all relevant staff training and competence systems in place. Given the tragic outcomes of such situations, the exemption of PPDS from the requirement to label will cease next year in England, Wales and Northern Ireland when full labelling will be required. Scotland is taking longer to consider the impact of alternatives.

7.6 Cross contact (inadvertent contamination) and precautionary labelling

Other than general food law requirements, there are no specific legal provisions for precautionary labelling in prepacked or non-prepacked foods. Historically, some manufacturers used 'may contain' indiscriminately as a form of disclaimer but nowadays, through risk analysis, it is feasible to identify the risk of cross contact, minimise it and then provide the customer with products that have integrity of precautionary labelling. In practice, despite the theory of risk analysis being sound, threshold levels are the current challenge. Most allergy experts consider a threshold should be no lower than ED01 (Eliciting Dose 1%); this is the amount of an allergenic substance in mg of protein below which adverse reactions are unlikely in the majority of the allergic population. Some may ask why tolerate any risk at all? If manufacturers were required to work to an even more stringent level, the risk may not exist, the allergic population would have a significantly reduced availability of goods and warnings would arguably be devalued. There is therefore a tension and some data uncertainty around thresholds.

Caterers also have a particular challenge in respect of precautionary labelling. While larger catering and hospitality businesses are getting to grips with allergen matrices that identify ingredients and possible contaminants in dishes and beverages, smaller businesses are at a significant technical disadvantage.

8.0 Allergens not amongst the 14 key allergens

There are approximately 200 different food substances to which people are allergic aside from the 14 key allergens; for instance tomatoes, kiwi and strawberries. In theory, the presence of one of these allergens in a food offered to an allergy sufferer would be unsafe, particularly if they were likely to suffer a severe reaction. General food law requires that food is safe and of the nature, substance and quality demanded by the customer. Notwithstanding, if a restaurant were to receive an enquiry / request regarding the need for the absence of a particular ingredient not among the familiar 14 key allergens, they may not realise the gravity of such enquiry / request and that a person's life may depend upon it. I am aware of just such a situation that occurred recently in relation to a lemon, where the customer was hospitalised, thankfully they made a full recovery. Currently, there is no specific legislation or comprehensive guidance in this part of the allergy arena. It will be interesting to see whether in the future it, too, becomes subject to stricter control as awareness is raised of the magnitude of the impact of such customer demands.

9.0 How are regulators managing to assess risk and prioritise inspections and interventions?

Regulator interventions are defined in and guided by Food Law Codes of Practice and Practice Guidance. These set out a framework for inspections, the frequency of which are conducted on a risk-based basis. Unfortunately, the presence of allergens in food falls into two different fields of inspection, which are often conducted by two different regulators, depending on location. The question of ingredient information is dealt with as a food standards matter and, in most areas, regulated by Trading Standards Officers. The question of cross contact and inadvertent contamination by poor practices is dealt with as a food hygiene matter and is regulated by Environmental Health and Food Safety Officers. This means that in areas with county and district/borough/city councils, a food business may be inspected by two different council bodies at different times, looking at different aspects of allergen management. In unitary authorities, London Boroughs and Metropolitan Boroughs, one regulator, namely environmental health departments, usually conducts both inspections.

In practice, this has sometimes meant that businesses (and even regulators) are confused as to which authority and regulator is responsible for interventions over which aspects of allergen management – ingredient information or ingredient control.

There is a wide variation in approach to regulatory inspections in respect to allergens. Some environmental health departments use checklists to assist in examining risk, whereas others do not. Some conduct separate allergen compliance inspections, whilst others include allergen management within the food standards or food hygiene inspection. Some take an educative approach with businesses that are struggling to manage allergens effectively, whereas others take a harder line of enforcement.

Based upon what is evident within criminal allergen case instructions plus what I have learned from providing workshops for regulators and industry, the somewhat disparate regulatory approach to allergen management results in businesses with similar histories and compliance standards experiencing a wide variety of interventions.

Case Studies

R v Mohammed Khaliq Zaman, Teesside Crown Court

Zaman was found guilty of gross negligence manslaughter and was given a six-year prison sentence after selling a takeaway curry containing peanuts to Mr Paul Wilson, who was known to be severely allergic to peanuts since the age of seven. The conviction and sentence were subsequently found to be safe at appeal.

Zaman was the owner of a chain of five curry houses in the north Yorkshire area. Financially, the business was struggling. It had an overdraft of £200,000 at the start of 2013 that rose to £300,000 by the end of the year. Zaman was under pressure to cut outgoing costs. It was found that this was likely to have been the reason that he chose to substitute ground peanut for the more expensive ground almond used in curry sauces in the restaurant.

When he changed his customary order from almond to peanut powders his wholesale supplier warned him to make clear the change of nut to his customers. However, this was not done and just three weeks before Paul Wilson died another customer, Ruby Scott, suffered an allergic reaction from food bought from one of his other restaurants. Her reaction had been communicated to Zaman so he was aware of the problem, but peanut-contaminated meals continued to be served.

Zaman's defence was that he wasn't present in the restaurant on the evening when Mr Wilson had bought his takeaway meal; that he'd taken reasonable steps, and that he had been let down by his staff and by his supplier. Both the waiter who took the order and the chef, who was an illegal citizen, absconded before trial, making the examination of some evidence related to communication during the transaction difficult.

Paul Wilson died at home, alone, on 30th January 2014. Evidence presented at trial included the fact that he must have asked for a peanut-free dish because a carton lid in which the meal had been served bore the indication 'no nuts'. Results from stomach contents and leftover takeaway elements confirmed that he had consumed considerable peanut protein in the tikka masala curry sauce.

Zaman was found guilty of manslaughter and six

charges of contravening food safety requirements including selling unsafe food (Article 14 EC178/2002) and selling food not of the substance demanded by the customer (Section 14 Food Safety Act 1990). In addition, he was found guilty of employing individuals subject to immigration control and perverting the course of justice.

R v Harun Rashid and Mohammed Abdul Kuddus and the Royal Spice Takeaway, Manchester Crown Court

Megan Lee, 15, died after eating a takeaway from the Royal Spice Takeaway ordered from the Just Eat website on 30th December 2016. A mixed order was placed for her and her friend's different dishes and a note was included on the website order made at the time that referred to 'prawns and nuts'. Unfortunately, the system was unsophisticated and not foolproof, there was no clarification call from the restaurant, and on delivery no indication, such as a note on relevant packaging, as to which dishes contained nuts or prawns.

On eating, Megan had a slight reaction and took the antihistamine Piriton, but three hours later had a severe asthma attack. She was put on life support but died two days later, on 1st January 2017.

Environmental Health and Trading Standards Officers visited the Royal Spice and observed poor practices, including no system for recording or managing allergen requests, and because there was no evidence from the meal she consumed, asked the business to make replica dishes to those ordered by Megan Lee. The replica meal contained peanut protein present through cross contact due to poor practices.

Reflections from the two cases

The two cases are interesting to compare on a number of levels. Paul Wilson's allergy was severe: he had an autoinjector. Megan Lee's was mild, she did not have an autoinjector. They had both taken precautions in specifying their needs yet did not receive safe food. Judge Higginbottom said of Zaman of the Indian Garden that his negligence was "gross" and behaviour "appalling", while Mrs Justice Yipp in the Royal Spice case marked the two men as "incompetent" and "not bad men". The conviction of Kuddus was later quashed. Another difference was in the regulatory approach to the two events; the Indian Garden was not immediately closed by regulators, while the Royal Spice was. Common threads include that both were small businesses, they lacked understanding of food safety systems and staff training. Staff did not understand the importance of allergen information requests and were not competent at managing to produce food free from allergens when such requests were made.

If one were to carry out a root cause analysis of the two incidents, it is likely that the majority of contributory factors in both cases are still present today in a significant number of smaller catering and take away food businesses. For this reason, it is my view that these will not be the last gross negligence manslaughter cases for food allergen incidents.

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for Public Health and the Institute of Food Science and Technology and is a member of the Academy of Experts. Her early career saw her working as an EHO in local government enforcement before taking up a Junior Research Fellowship at King's College, University of London. Here, she looked at influences on survival of pathogenic bacteria on various food environment surfaces. Her laboratory results were used to comment on the suitability of legislation to control risk in this area.

For the last twenty years Belinda has run her own business providing consultancy, training, auditing and expert witness services. She has a wealth of experience in food safety in the manufacturing, catering and retail sectors and is highly respected in her professional community. As an expert witness, her instructions include food contamination, infectious intestinal disease and increasingly, injury and death from food allergy. She works in the criminal and civil arenas with a split of roughly 50:50 prosecution/claimant to defence.

Belinda's approach is pragmatic and plain speaking. She is regularly commissioned to deliver workshops and presentations to industry and regulators for the Food Standards Agency, Chartered Institute of Environmental Health and ABTA. She is known for her inimitable enthusiasm for food safety and makes technical and scientific concepts accessible.