

Food allergy: innovation in advocacy, research and training to support and protect those at risk

Commentary (Volume 1) and Publications (Volume 2) submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy from Kingston University by

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I must also thank my parents; not only for bringing me into the world, but also for preventing me from leaving it on a number of occasions. They were early witnesses to the full panoply of allergic disease, dealing with all its manifestations without external support organisations, access to research, or specialist allergy clinicians. Their matter of fact explanations, practical care and balanced perspective shaped and equipped me with confidence and competence to support others. The continuing encouragement of my sisters and wider family is also recognised and appreciated.

The journey towards learning and advocacy would have been very different without the early champions who created and shaped the Anaphylaxis Campaign, and in particular David Reading OBE and Moira Austin, as well as many dedicated and committed Campaign colleagues with whom I have been privileged to work.

I should also recognise the generosity and patient teaching of many of our leading allergy scientists and clinicians, and particularly Dr Richard Pumphrey, Professor Jonathan Hourihane and Dr Pamela Ewan CBE, without whom significant research and advocacy would not have taken place. More recent collaborators include Professor Jane Lucas, Professor Julie Barnett, Professor René Crevel, Dr Paul Turner and Dr Lauri-Ann Van der Poel whose contributions in different research areas are substantial and influential.

One of my most enduring partnerships has been with the Allergy team at the Food Standards Agency. Particular mention must be made here of Sue Hattersley OBE, Dionne Davey and Dr Chun-Han Chan. The late Dorothy Cullinane was a committed food scientist and technologist who pioneered best practice for allergen control and consumer support. Good friends and partners, Graeme Kerr and Dr Lisa Ackerley

continue to support projects to shape interactive learning and standards for best practice.

My friend and colleague Dr Michael Walker deserves particular recognition as a disciplined and creative collaborator who, having trod this path before me, introduced me to Professor Declan Naughton, whose supervision and guidance are acknowledged and appreciated.

Lastly, my thanks are due to those individuals and families whom I have been privileged to know and be with, sometimes during their most difficult days. Their contribution to my own learning and to improving the lives of others is beyond measure.

Abstract

The profile of severe allergy and particularly food allergy has developed significantly since the early 1990s. The establishment of the Anaphylaxis Campaign in 1994 in the UK led to a serendipitous relationship between advocacy and research. Investigating the impact of food allergy through early member surveys informed Campaign initiatives and government and food industry policies, both to improve food information and the control of allergen risks, and access to specialist health care and the management of allergic emergencies. Their success in turn depended on individuals and organisations understanding their own roles in reducing allergy risks and being ready to work together to contribute to further research and advocacy. Collaborative and trusted partnerships within and beyond the UK continue to shape food and healthcare regulation and best practice, and contribute to standards for patient and consumer support, clinical and academic research. Formal and informal education and training, strategies to make scientific and clinical research accessible and applicable in food production and healthcare, and active use of social and other media shape knowledge and understanding for individuals at risk, those caring for them and those responsible for supplying their food.

There are elusive knowledge gaps and research questions which require further attention. Primary prevention of food allergy seems to be possible through protocols for early dietary intervention, but the longer-term allergy profile for these children is not yet known. Initiatives are underway to reverse food allergy through immunotherapy, both through supervised consumption of everyday foods and through pharmaceutically prepared up dosing for consumption or via the skin. The impact of severe allergy on quality of life indicates a need for tailored psychological support for some children, young people and adults.

The role of local and national food control bodies to advise and supervise food businesses in controlling and communicating the presence of food allergens is key to ensuring consumer protection for those at risk. Investigations following severe and fatal reactions which may have involved food allergy require a collaborative approach, the timely collection of samples (wherever possible), careful selection and use of appropriate legislation, analytical support and reporting.

Work continues to define allergen thresholds, and to understand their inter-relationship with symptom severity. Studies currently underway attempt to take into account some of the co-factors associated with severity. Progress towards the adoption and acceptance of allergen thresholds in food production and labelling, voluntarily or through regulation depends on improved stakeholder understanding and a high degree of trust, particularly for those making risk decisions about their own food, or food for those in their care.

List of abbreviations

| | |
|-----------------------|---|
| AAAAI | American Academy of Allergy, Asthma and Immunology |
| ACE inhibitors | Angiotensin converting enzyme inhibitors - Blood pressure medication |
| ADI | Acceptable daily intakes |
| AOAC | AOAC International (previously the Association of Official Analytical Chemists) |
| APA | Association of Public Analysts |
| ARfD | Acute Reference Dose |
| BRC | British Retail Consortium - Trade Association |
| BSACI | British Society of Allergy and Clinical Immunology |
| CCFL | Codex Committee on Food Labelling |
| CIEH | Chartered Institute of Environmental Health |
| CTSI | Chartered Trading Standards Institute |
| DBPCFC | Double Blind Placebo-Controlled Food Challenge |
| DfES | Department for Education and Science - previous name for UK government department |
| DG SANCO | Directorate General for Health and Consumer Protection European Directorate |
| DVD | Digital Versatile Disc |
| EAACI | European Academy of Allergy and Clinical Immunology |
| EAT | Enquiring About Tolerance Study |
| EC | European Commission / European Council |
| ED | Eliciting Dose |
| EFSA | European Food Safety Authority |
| EHO | Environmental Health Officer |
| EU | European Union |
| FAAM | Food Allergy and Asthma Meeting |
| FDf | Food and Drink Federation (UK Trade body) |
| FLS | Food Labelling and Standards Division |

| | |
|----------------|---|
| FODMAPs | Fermentable O ligo-, D i-, M ono-saccharides A nd P olyols Short chain fermentable carbohydrates |
| FPE | Food protein–induced enteropathy |
| FPIAP | Food protein–induced allergic proctocolitis |
| FPIES | Food protein–induced enterocolitis syndrome |
| FSA | Food Standards Agency |
| GMP | Good Manufacturing Practice |
| HCIMA | Hotel and Catering Industry Management Association |
| HCTC | Hotel and Catering Training Company |
| HRH | His / Her Royal Highness |
| HTF | Hospitality Training Foundation |
| IFST | Institute of Food Science Technology |
| IgA | Immunoglobulin A |
| IGD | Institute of Grocery Distribution |
| IgD | Immunoglobulin D |
| IgE | Immunoglobulin E |
| IgG | Immunoglobulin G |
| IgM | Immunoglobulin M |
| ILSI | International Life Sciences Institute |
| JECFA | Joint Expert Committee on Food Additives |
| LACORS | Local Authority Coordinators of Regulatory Services |
| LAED | Local Authority Enforcement Division |
| LEAP | Learning Early About Peanut Study |
| LEAP-On | Learning Early About Peanut Follow-on study |
| LOAEL | Lowest observed adverse effect level |
| MAFF | Ministry of Agriculture, Fisheries and Food |
| MOE | Margin of Exposure |
| MP | Member of Parliament |

| | |
|-----------------------|---|
| MSc | Master of Science |
| NBD | Neutralised, bleached, deodorised - Edible oil refinement process |
| NHS | National Health Service |
| NOAEL | No observed adverse effect level |
| Non-IgE-GI-FAs | Non-IgE-mediated gastrointestinal food-induced allergic disorders |
| OFSTED | Office for Standards in Education |
| OIT | Oral Immunotherapy |
| PAAM | Paediatric Allergy and Asthma Meeting |
| PAL | Precautionary Allergen Labelling |
| PhD | Doctor of Philosophy |
| QoL | Quality of Life |
| QRA | Quantitative Risk Assessment |
| REHIS | Royal Environmental Health Institute of Scotland |
| RfD | Reference dose |
| RIPH | Royal Institute of Public Health |
| RSPH | Royal Society of Public Health |
| safefood | Cross border food safety organisation on the island of Ireland |
| SBPCFC | Single blind placebo controlled food challenge |
| SOFHT | Society of Food Hygiene and Technology |
| TDI | Tolerable Daily Intake |
| TRACE | Study into peanut allergy in adults - thresholds and severity |
| TSC | Trial Steering Committee |
| TSI | Trading Standards Institute |
| TSO | Trading Standards Officer |
| UDEX OFSCI | UDEX business operating Optimum Foodservice Supply Chain Initiative information |
| VITAL | Voluntary Incidental Trace Allergen Labelling |
| WHO | World Health Organisation |
| WI | Women's Institute |

1 Introduction

M Hazel Gowland - Expert patient representative, researcher, lecturer and trainer specialising in food allergies

Background

Hazel Gowland has been allergic to nuts and peanuts since 1960 and has survived some severe reactions since. Her first degree was in French (with Management Studies) and after working in France and Germany, she qualified as a youth worker and secondary school teacher of modern languages and business studies. Since 1994 she has worked for and with the UK Anaphylaxis Campaign, a registered charity www.anaphylaxis.org.uk and independently to protect those at risk from severe food allergies through assessment, management and communication of allergy risks throughout the food supply chain and by campaigning for better access to diagnosis, allergen avoidance advice and symptoms management. Since 1988, she has investigated and recorded allergy-related deaths and 'near misses' and works at policy level to improve understanding of risk practice and behaviour, both among allergic people and food business operators. In 2000, she established Allergy Action – a sole trader organisation through which she undertakes research with a wide range of academic, regulatory and commercial bodies. She also develops materials and delivers lectures and training courses for many different audiences including university undergraduate and postgraduate students, food businesses, health care professionals, schools, nurseries, care personnel and families living with allergy.

A personal note

Living through a 1960s childhood, having severe early eczema, being exposed to peanut in the home environment and then having a severe reaction when first given it at the age of 14 months, being called Hazel and allergic to nuts, and following an unknown, but later all too familiar path through an atopic childhood, with associated asthma and some particularly severe reactions were all key circumstances which led to Gowland's work in allergy.

She was also shaped by a very matter of fact attitude to what was known to be a potentially life-threatening allergy from her parents and wider family. Although there were no food allergic people in their acquaintance, and only a few with asthma, their

explanations were clear and matter of fact. Gowland was never in any doubt that she might die from her allergy, but was also confident that she should be able to lead a normal life, learn languages (perhaps to ensure communication about her food allergies), take a variety of different jobs, live abroad, go to university, and find useful and fulfilling occupation.

This portfolio of published work includes:

- 29 journal papers, **P1-29**
- 12 abstracts for oral presentations or posters **A1-12**
- 4 book chapters **B1-4**
- 24 examples of other work in the public domain **W1-24**

(The published work is referenced **in purple** throughout.)

This work will be examined to illustrate the following themes:

- Investigating the impact of food allergies
- Developing partnerships with key stakeholders
- Shaping regulation and voluntary best practice
- Setting standards to reduce risks

Examples of the published work will also be used:

- To indicate the impact and career context of Hazel Gowland's work in food allergy
- To illustrate novel research methods and strategies and their impact on food allergy risks
- To illustrate the different roles undertaken and skills acquired by Hazel Gowland
- To demonstrate the relationships established to protect those with food allergies and intolerances

2 The research outputs

Key to research outputs:

P = Journal Paper, A = Abstract, B = Book Chapter, W = Other Work

* Peer reviewed

Literature is cited in Harvard style.

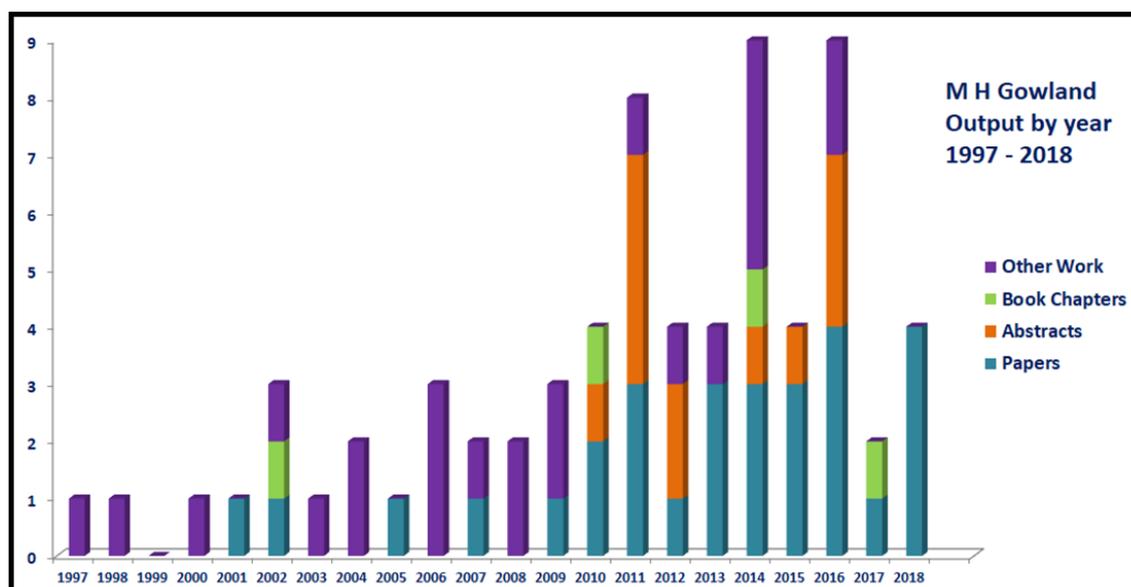


Figure 1: M H Gowland Output by year 1997 - 2018

Papers in journals P1 – P29

The number of citations has been noted (where recorded) for all journal papers.

A co-author has certified Hazel Gowland's contribution for journal papers wherever possible, (See **Appendix 1**) and an estimate has been made of her percentage contribution to the project and the publication.

P1 - 2001

Gowland, M. H. (2001). Food allergen avoidance - the patient's viewpoint. *Allergy*, 56 (Supp. 67), pp. 117–120. *

This paper was written at the request of the European Academy of Allergy and Clinical Immunology (EAACI) following an invitation to speak at their symposium in Venice in 2001. The purpose was to present the patient's perspective of living with food allergy

and associated atopic conditions to an audience of European allergy clinicians. (Sole author)

This paper has been cited 51 times on Google Scholar and 27 times on Wiley Online and CrossRef. (Accessed 31st March 2018)

P2 – 2002

Gowland, M.H. (2002). Food allergen avoidance: Risk assessment for life. *Proceedings of the Nutrition Society*, 61 (1), pp. 39–43. *

This paper was written at the invitation of the (UK and Ireland) Nutrition Society following a presentation at their meeting in Coleraine in 2001. The audience were primarily academic and clinical practitioners in nutrition and dietetics. (Sole author)

This paper has been cited 34 times on Google Scholar and 19 times on the Cambridge University press website, Cambridge Core. (Accessed 31st March 2018)

P3 – 2005

Derby, C.J., Gowland, M.H., Hourihane, J.O'B. (2005). Sesame allergy in Britain: A questionnaire survey of members of the Anaphylaxis Campaign. *Pediatric Allergy and Immunology*, 16 (2), pp. 171–175. *

This paper summarised the results of a member survey about the impact of sesame allergy amongst adult and children members of the Anaphylaxis Campaign.

Gowland devised, designed, distributed and collected the survey questionnaires. Derby collated and analysed the survey data. Derby and Gowland both contacted subjects to elicit further data and followed up queries. Hourihane provided clinical insight and oversaw the data analysis and reporting. All three contributed to writing and editing the final paper.

(Certified by C J Derby) (Gowland's contribution c 40%)

It has been cited 30 times on Wiley Online Library. (Accessed 31st March 2018)

P4 – 2007

Pumphrey, R. S. H. and Gowland, M. H. (2007). Further fatal allergic reactions to food in the United Kingdom, 1999-2006. *Journal of Allergy and Clinical Immunology*, 119 (4), pp. 1018–1019. *

This letter to the editor by Dr Richard Pumphrey and Hazel Gowland was proposed by the leading international Journal of Allergy and Clinical Immunology following publication of Pumphrey's earlier longitudinal review of fatal food reactions to which Gowland had contributed informally. Pumphrey's clinical database of severe and fatal reactions and Gowland's informal records of fatal reactions to foods collected from families and inquests were cross-matched, reviewed, summarised and updated. Both authors contributed equally to writing and editing the publication.

(Gowland's Contribution c 50%)

This letter has been very widely cited with 443 citations on Google Scholar. (Accessed 31st March 2018)

P5 – 2009

Gowland, M.H. (2009). Food allergies. *Perspectives in Public Health*, 129 (2), pp. 62–63.*

This was a review article for the journal of the Royal Society of Public Health. (Sole author)

P6 - 2010

Madsen, C.B., Crevel, R., Chan, C.H., Dubois, A.E.J., DunnGalvin, A., Flokstra-de Blok, B.M.J., **Gowland, M.H.**, Hattersley, S., Hourihane, J.O'B., Nørhede, P., Pfaff, S., Rowe, G., Schnadt, S., Vlieg-Boerstra, B.J. (2010). Food allergy: Stakeholder perspectives on acceptable risk. *Regulatory Toxicology and Pharmacology*, 57 (2010), pp. 256–265.*

This was a position paper from the EU-funded Europrevall Integrated Project on food allergy which involved regulators (Chan, Hattersley), allergy clinicians (Dubois, Hourihane, Vlieg-Boerstra), food scientists/toxicologists (Madsen, Crevel, Pfaff), social scientists and psychologists (DunnGalvin, Flokstra-de Blok, Nørhede, Rowe) and expert patients / consumers (Schnadt and Gowland). The purpose was to review progress towards agreed allergen thresholds which could be used by the food industry and supported by regulators to protect consumers at risk. Gowland's roles were a) to present and to represent the consumer / patient interest, b) to support ethics and the patient perspective for related studies and c) to contribute to writing and editing the final paper.

(Certified by R W R Crevel) (Gowland's contribution c 8%)

This paper has 29 citations on Science Direct (Elsevier). (Accessed 31st March 2018)

P7 – 2010

Monks, H., **Gowland, M.H.**, Mackenzie, H., King, R., Lucas, J.S., Roberts, G. (2010). How do teenagers manage their food allergies? *Clinical & Experimental Allergy*, 40 (10), pp. 1533-1540. *

Gowland was expert project adviser on this study into teenager behaviour relating to food allergies conducted by Monks, a fourth year medical student at Southampton University. Mackenzie is a research psychologist who provided expertise in developing the study questionnaire and data interpretation, Roberts and Lucas are university professors and consultant paediatric allergy physicians and King is a paediatric allergy nurse. Their teenage clinic patients were the study subjects. Gowland contributed to the study ethics and questionnaire, reviewing the data and co-writing and editing the paper.

(Certified by Professor J S Lucas) (Gowland's contribution c 10%)

This paper has 60 citations on Wiley Online Library. (Accessed 31st March 2018)

P8 - 2011

Leftwich, J., Barnett, J., Muncer, K., Shepherd, R., Raats, M.M., **Hazel Gowland, M.**, Lucas, J.S. (2011). The challenges for nut-allergic consumers of eating out. *Clinical and Experimental Allergy*, 41 (2), pp. 243–249. *

This paper was one of a series of publications from the Food Standards Agency funded project conducted by the University of Surrey, then Brunel University and then the University of Bath with the University of Southampton. The project aimed to understand the behaviour of consumers with peanut and tree nut allergies and those buying food for them. This paper examined issues when eating out. Barnett is a professor of health psychology who led the project, Leftwich and Muncer are psychology researchers, Shepherd and Raats are experienced consumer behaviour expert academics, Lucas is a paediatric allergy physician and professor who provided clinical insight. Gowland's roles included a) representing the consumer / patient interest for project ethics and data interpretation, b) briefing all project participants at the scoping stage to understand the key research issues, c) training the researchers to conduct interviews, d) reviewing the results and e) contributing to the project reports and publication writing and editing.

(Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has 24 citations on Wiley Online Library. (Accessed 31st March 2018)

P9 – 2011

Barnett, J., Leftwich, J., Muncer, K., Grimshaw, K., Shepherd, R., Raats, M.M., **Gowland, M.H.**, Lucas, J.S. (2011). How do peanut and nut-allergic consumers use information on the packaging to avoid allergens? *Allergy*, 66 (7), pp. 969–978. *

This paper was one of the publications from the Food Standards Agency funded project conducted by the University of Surrey, then Brunel University and then the University of Bath. The project aimed to understand the behaviour of consumers with peanut and tree nut allergies and those buying food for them. This paper examined issues when buying prepacked foods. Barnett is a professor of health psychology who led the project, Leftwich and Muncer are psychology researchers, Shepherd and Raats are experienced consumer behaviour academics, Lucas is a paediatric allergy physician and professor who provided clinical insight.

Gowland's roles included a) representing the consumer / patient interest for project ethics and data interpretation, b) briefing all project participants at the scoping stage to understand the key research issues, c) training the researchers to manage the accompanied shop and interviewing subjects, d) reviewing the results and e) contributing to the project reports and publication writing and editing.

(Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has 38 citations on Wiley Online Library. (Accessed 31st March 2018)

P10 – 2011

Barnett, J., Muncer, K., Leftwich, J., Shepherd, R., Raats, M.M., **Gowland, M.H.**, Grimshaw, K., Lucas, J.S. (2011). Using "may contain" labelling to inform food choice: A qualitative study of nut allergic consumers. *BMC Public Health*, 11 (734), pp. 1-9. *

This paper was one of the publications from the Food Standards Agency funded project conducted by the University of Surrey, then Brunel University and then the University of Bath and supported by the University of Southampton. The project aimed to understand the behaviour of consumers with peanut and tree nut allergies and those buying food for them. This paper examined issues when buying prepacked foods carrying 'may contain' labelling. Its purpose was to provide evidence for policy development by the FSA and other regulators, as well as food suppliers and consumers. Barnett is a professor

of health psychology who led the project, Leftwich and Muncer are psychology researchers, Shepherd and Raats are experienced consumer behaviour academics, Grimshaw is an experienced clinical and research dietitian, Lucas is a paediatric allergy physician and professor. Both Grimshaw and Lucas provided clinical and practical insight.

Gowland's roles included a) representing the consumer / patient interest for project ethics and data interpretation, b) briefing all project participants at the scoping stage to understand the key research issues, c) providing expertise on 'may contain' labelling and nut / peanut allergic consumer behaviour, d) reviewing the results and e) contributing to the project reports and publication writing and editing.

(Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has 27 citations on Springer - BMC Public Health. (Accessed 31st March 2018)

P11 – 2012

Barnett, J., Botting, N., **Gowland, M.H.**, Lucas, J.S. (2012). The strategies that peanut and nut-allergic consumers employ to remain safe when travelling abroad. *Clinical and Translational Allergy*, 2 (12), pp. 1-7. *

This paper was one of the publications from the Food Standards Agency funded project conducted by the University of Surrey, then Brunel University and then the University of Bath. The project aimed to understand the behaviour of consumers with peanut and tree nut allergies and those buying food for them. This paper examined the particular challenges faced by these people during travel abroad, including avoiding nuts and peanuts on journeys, finding safe food and accessing medical support in other countries

Botting was a medical student during the research period. Barnett is a professor of health psychology who led the project and Lucas is a paediatric allergy physician and professor who provided clinical and practical insight.

Gowland's roles included a) providing expert patient / consumer about living with a nut / peanut allergy, b) reviewing the study data on travel and staying abroad, and c) contributing to the project reports and publication writing and editing.

(Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has 13 citations on Springer. (Accessed 31st March 2018)

P12 - 2013

Barnett, J., Vasileiou, K., **Gowland, M.H.**, Raats, M.M., Lucas, J.S. (2013). Beyond Labelling: What Strategies Do Nut Allergic Individuals Employ to Make Food Choices? A Qualitative Study. *PLoS ONE*, 8 (1), pp. 1-7.*

This paper was one of the publications from the Food Standards Agency funded project conducted by the University of Surrey, then Brunel University and then the University of Bath. The project aimed to understand the behaviour of consumers with peanut and tree nut allergies and those buying food for them. This paper examined the additional strategies employed to avoid nuts and peanuts when buying food. It presented evidence for policy development by the FSA and other regulators, as well as informing food suppliers and consumers.

Barnett is a professor of health psychology who led the project, Vasileiou is a psychology researcher, Raats is a professor of psychology with experience in consumer behaviour and Lucas is a paediatric allergy physician and professor who provided clinical insight.

Gowland's roles included a) providing expert patient / consumer insight about living with a nut / peanut allergy, b) suggesting additional strategies which consumers may use c) reviewing the study data and d) contributing to the project reports and publication writing and editing. (Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has 7 citations on the PloS One and Scopus. (Accessed 31st March 2018)

P13 – 2013

Cochrane, S.A., **Gowland, M.H.**, Sheffield, D., Crevel, R.W.R. (2013). Characteristics and purchasing behaviours of food-allergic consumers and those who buy food for them in Great Britain. *Clinical and Translational Allergy*, 3 (31), pp. 1–8. *

This project was commissioned by Unilever, a leading food manufacturer, and undertaken by Mintel, a leading market research organisation. Its purpose was to characterise food-allergic consumers in Great Britain and find out more about the foods they avoid as well as how they manage and report their reactions. An online consumer research survey targeted at a wide demographic was designed with a filter question which aimed to focus upon those people experiencing symptoms typical of 'true' food allergy.

Cochrane and Crevel are research scientists with expertise in toxicology, allergen risk management and allergy consumer behaviour whilst Sheffield provided expertise in statistical analysis for data collection and reporting. Gowland provided expert consumer, patient and ethical insight throughout the project, guidance on structuring the questions and interpreting the results, and contributed to publication writing and editing.

(Certified by R W R Crevel) (Gowland's contribution c 15%)

This paper has 14 citations on Springer - Clinical and Translational Allergy (Accessed 31st March 2018)

P14 – 2013

Gowland, M.H. (2013). Reactions, Regulation and Risk: Protecting consumers with food allergies and intolerances. *Perspectives in Public Health*, 133 (6), pp. 306-307. *

This article was commissioned by the journal of the Royal Society for Public Health. Its purpose was to update a wide public health audience, and particularly those involved in food safety and health and safety on new food allergy regulation and how to support consumers at risk. (Sole author)

This article has 3 citations on CrossRef. (Accessed 31st March 2018)

P15 – 2014

Muraro, A., Hoffmann-Sommergruber, K., Holzhauser, T., Poulsen, L.K., **Gowland, M.H.**, Akdis, C.A., Mills, E.N.C., Papadopoulos, N., Roberts, G., Schnadt, S., Van Ree, R., Sheikh, A., Vieths, S. (2014). EAACI Food Allergy and Anaphylaxis Guidelines. Protecting consumers with food allergies: Understanding food consumption, meeting regulations and identifying unmet needs. *Allergy*, 69 (11), pp. 1464–1472.*

This publication was one of a series of papers from the European Academy of Allergy and Clinical Immunology which aimed together to promote awareness of the issues facing those with food allergies and to propose initiatives to reduce allergy risks.

Muraro, Akdis, Papadopoulos, and Roberts are allergy physicians, Hoffmann-Sommergruber, Holzhauser, Poulsen, Mills, Van Ree and Vieths are research scientists, Sheikh is a physician and epidemiologist. Schnadt and Gowland acted as expert consumer / patient researchers and advocates.

Gowland was invited to contribute to this publication a) as an expert food allergic patient / consumer, b) as an established consumer researcher, c) to provide expertise in food allergen management and food regulation and d) to contribute to shaping and editing the title and the publication.

(Gowland's Contribution c 8%)

This article has 32 citations on Wiley Online Library. (Accessed 31st March 2018)

P16 – 2014

Le, T.M., Kummeling, I., Dixon, D., Barreales Tolosa, L., Ballmer-Weber, B., Clausen, M., **Gowland, M.H.**, Majkowska-Wojciechowska, B., Mustakov, T., Papadopoulos, N.G., Knulst, A.C., Potts, J., Stukas, R., Burney, P. (2014). Low preparedness for food allergy as perceived by school staff: A EuroPrevall survey across Europe. *Journal of Allergy and Clinical Immunology: In Practice*, 2 (4), pp. 480–482.*

This publication was commissioned through the EU-funded Europrevall Integrated Project examining the preparedness of schools in different countries to manage food allergies. The project was led by Le (physician and researcher) and Kummeling (epidemiologist) supported by Dixon, Potts and Stukas who undertook the data analysis supervised by Burney at Imperial College, London. Allergy physicians (Barreales Tolosa,

Ballmer-Weber, Clausen, Majkowska-Wojciechowska, Mustakov, Papadopoulos and Knulst) led recruitment, questionnaire translation and data collection in different countries.

(Gowland's contribution c 5%)

This publication has 3 citations on Scencedirect / Elsevier. (Accessed 31st March 2018)

P17 – 2014

Walker, M., **Gowland, H.** (2014). Food allergy - A forensic perspective. *Food Science and Technology (London)*, 28 (3), pp. 33-36.

This article was written for the Journal of Food Science and Technology, for which the primary audience is food scientists and technologists, and also public analysts, regulators and food industry consultants with an interest in food integrity and reducing food risks. Walker was acting as a Subject Matter Expert for a major UK-wide review into food supply chains conducted by Professor Chris Elliott, to which Gowland also gave evidence – see **W18**. Walker and Gowland have monitored the forensic aspects of food allergy evidence and prosecutions since 1996 and this work continues.

(Certified by Dr M J Walker) (Gowland's contribution c 45%)

P18 – 2015

Gowland, M.H., Walker, M.J., (2015). Food allergy, a summary of eight cases in the UK criminal and civil courts: Effective last resort for vulnerable consumers? *Journal of the Science of Food and Agriculture*, 95 (10), pp. 1979–1990.*

Walker and Gowland reviewed court cases involving food allergy in the UK. Selections were made to represent prepacked and non-prepacked foods, fatal and non-fatal reactions and criminal and civil action. Gowland had been involved in some of the investigations, as well as supporting some of the individuals and families involved so was able to supply detailed insight into the circumstances of each case. As an analytical chemist (and previous Public Analyst) with experience in food legislation and preparing court evidence, Walker provided the forensic context. This publication reached a multi-disciplinary audience which included a) food allergic consumers and representative patient / consumer organisations, b) the analytical and food technical community c)

national and local regulators, d) food businesses including manufacturers, retailers and caterers and e) lawyers and others involved in public protection and civil litigation.

(Certified by Dr M J Walker) (Gowland's contribution c 55%)

This publication has 8 citations on Wiley Online Library. (Accessed 31st March 2018)

P19 – 2015

Turner, P.J., **Gowland, M.H.**, Sharma, V., Ierodiakonou, D., Harper, N., Garcez, T., Pumphrey, R., Boyle, R.J. (2014). Increase in anaphylaxis-related hospitalization but no increase in fatalities: An analysis of United Kingdom national anaphylaxis data, 1992-2012. *Journal of Allergy and Clinical Immunology*, 135 (4), pp. 956–963. *

This collaborative project involved the allergy and immunology physicians managing the UK Fatal Anaphylaxis Registry in Manchester (Sharma, Harper, Garcez and Pumphrey) and those from Imperial College, London (Turner, Ierodiakonou and Boyle) who have a major research interest in the severity of allergic reactions. Gowland's contributions were as follows: a) collection and scrutiny of data about UK fatal allergic reactions since 1988 with Dr Pumphrey and then with Drs Boyle and Turner, b) analysis of hospitalisation admissions data in England associated with allergy c) case by case examination of symptoms and cause and d) editing the publication.

(Certified by Dr P J Turner) (Gowland's contribution c 20%)

This publication has 122 citations on Scopus. (Accessed 31st March 2018)

P20 – 2015

Walker, M., **Gowland, H.** (2015). Food fear. *Chemistry & Industry*, 79, p28.

The primary audience for this article is the food technological and analytical community, though it is also of interest to food regulators and the wider food industry. Gowland describes health risks associated with food allergies in Great Britain and the need to label foods correctly to reduce inadvertent allergen consumption and consequential reactions. Walker focuses on analytical methods to detect food allergens using enzyme-linked immunosorbent assay, polymerase chain reaction, and mass spectrometry.

(Certified by Dr M J Walker) (Gowland's contribution c 40%)

P21 - 2016

Walker, M.J., Burns, D.T., Elliott, C.T., **Gowland, M.H.**, Mills, E.N.C. (2016). Is food allergen analysis flawed? Health and supply chain risks and a proposed framework to address urgent analytical needs. *The Analyst*, 141, pp. 24–35.*

This publication in *The Analyst* involved a collaboration between analytical chemists (Burns and Walker) and biologists (Elliott and Mills) with expertise in food allergens, food fraud, the food supply chain, food regulation and forensics. Gowland devised a survey of the analytical community on allergen-related activity and contributed to the final publication.

(Certified by Dr M J Walker) (Gowland's contribution c 10%)

This publication has 12 citations on CrossRef and RSC Journals. (Accessed 31st March 2018)

P22 – 2016

Turner, P., Baumert, J.L., Beyer, K., Boyle, R., Chan, C., Clark, A., Crevel, R., DunnGalvin, A., Fernandez-Rivas, M., **Gowland, M. H.**, Grabenheinrich, L., Hardy, S., Houben, G. F., Hourihane, J. O'B., Muraro, A., Poulsen, L. K., Pyrz, K., Remington, B. C., Schnadt, S., van Ree, R., Venter, C., Worm, M., Mills, E. N. C., Roberts, G., Ballmer-Weber, B. K. (2016). Can we identify patients at risk of life-threatening reactions to food? *Allergy*, 71 (9), pp. 1241–1255. *

Following work to establish food allergen thresholds for different allergens, across different ages, populations and within different food matrices, it was recognised that people reacting to the same amount of allergen might have markedly different symptoms. Further work to better understand the impact and possible severity of symptoms continues. This publication for the European Academy of Allergy and Clinical Immunology (EAACI) involved a large consortium of allergy physicians, regulators, food scientists (toxicologists, protein chemists, analysts), dietitians, psychologists and consumer / patient representatives. Gowland's role was to represent the consumer / patient interest and to provide expertise from recording and examining life-threatening reactions to food. She also contributed to writing and editing the publication.

(Certified by Dr P J Turner) (Gowland's contribution c 5%)

This publication has 10 citations on PubMed and 23 on Wiley Online Library.

(Accessed 31st March 2018)

P23 – 2016

Begen, F., Barnett, J., Payne, R., Roy, D., **Gowland, M. H.**, Lucas, J. S. (2016). Consumer Preferences for Written and Oral Information about Allergens When Eating Out. *PloS One*, 11 (5), pp. 1-12.*

Following the previous project (See **P8 - P12** above) to understand consumer behaviour relating to buying food for people with nut and peanut allergies, the UK Food Standards Agency commissioned a team led by Professor Julie Barnett (previously at Surrey and Brunel Universities and now at Bath University) to assess how people with a range of food avoidance needs (food allergies, intolerances and coeliac disease) across the UK cope with finding safe food before and after the implementation of new food labelling legislation in December 2014. The focus was on non-prepacked foods including catering. Begen, Barnett and Roy are health psychology researchers, Payne provided expertise in consumer research, devising the survey, recruiting and interviewing the subjects, and Lucas is an allergy physician who helped with characterising subjects and providing clinical insight.

As previously, Gowland acted as expert project adviser, devising and shaping the methodology, developing the survey questions and interview strategies, reviewing the data, reporting, and co-writing the publications.

(Certified by Professor J S Lucas) (Gowland's contribution c 15%)

This paper has been cited 3 times on Scopus. (Accessed 31st March 2018)

P24 – 2016

Turner, P.J., **Gowland, M.H.** (2016). Precautionary allergen labelling: NO MORE TRACES! *Allergy*, 71 (10), pp. 1505-1507. *

This letter to *Allergy*, the journal of the European Academy of Allergy and Clinical Immunology followed an international survey undertaken by a consortium of patient / consumer groups in different countries. Its purpose was to provide background information and expertise to a mainly clinical audience about 'may contain' labelling and consumer / patient / physician perception of the relative risks of allergen cross contamination as indicated by precautionary labelling. Gowland co-wrote and edited the publication.

(Certified by Dr P J Turner) (Gowland's contribution c 30%)

This publication has 4 citations on Wiley Online Library. (Accessed 31st March 2018)

P25 – 2017

Begen, F.M., Barnett, J., Barber, M., Payne, R., **Gowland, M.H.**, Lucas, J.S., (2017). Parents' and caregivers' experiences and behaviours when eating out with children with a food hypersensitivity. *BMC Public Health*, 18 (38), pp. 1-10. *

Following the previous project (See **P8 - P12** above) to understand consumer behaviour relating to buying food for people with nut and peanut allergies, the UK Food Standards Agency commissioned a team led by Professor Julie Barnett (previously at Surrey and Brunel Universities and now at Bath University) to assess how people with a range of food avoidance needs (food allergies, intolerances and coeliac disease) across the UK cope with finding safe food before and after the implementation of new food labelling legislation in December 2014. Contributors' roles were as in **P23** above. As expert project adviser, Gowland provided insight into eating out with food hypersensitive children, reviewing the data, reporting, and co-writing the publications.

Evidence from the survey and interviews indicated particular challenges for people eating out with children with food hypersensitivity. The publication brings these issues to the attention of allergy clinicians, regulators, food businesses and families, and may help to shape practice and policy.

(Certified by Professor J S Lucas) (Gowland's contribution c 10%)

This publication has 1 citation on CrossRef. (Accessed 31st March 2018)

P26 – 2018

Begen, F.M., Barnett, J., Payne, R., Gowland, M.H., DunnGalvin, A., Lucas, J.S. (2018). Eating out with a food allergy in the UK: Change in the eating out practices of consumers with food allergy following introduction of allergen information legislation. *Clinical & Experimental Allergy*, 48 (3), pp. 317–324.*

Following the previous project (See **P8 - P12** above) to understand consumer behaviour relating to buying food for people with nut and peanut allergies, the UK Food Standards Agency commissioned a team led by Professor Julie Barnett (previously at Surrey and Brunel Universities and now at Bath University) to assess how people with a range of food avoidance needs (food allergies, intolerances and coeliac disease) across the UK cope with finding safe food before and after the implementation of new food labelling legislation in December 2014. Contributors' roles were as in **P23** and **P25** above. Psychologist DunnGalvin provided expert input on Quality of Life assessment for food allergy and intolerance. Once again, Gowland acted as expert project adviser, devising and shaping the methodology, developing the survey questions and interview strategies, reviewing the data, reporting, and co-writing the publications.

(Certified by Professor J S Lucas) (Gowland's contribution c 10%)

P27 – 2018

Walker, M.J., **Gowland, M.H.**, Points, J. (2018). Managing Food Allergens in the U.K. Retail Supply Chain. *Journal of AOAC International*, 101 (1), pp. 45–55.

AOAC International (previously the Association of Official Analytical Chemists) is an internationally recognised non-profit organisation engaged in scrutinising and publishing standardised scientific analytical methods. A special edition of the AOAC Journal included papers on a range of allergen-related subjects, of which this was one. Walker provided the perspective of an analytical chemist and referee analyst, and experience from his forensic roles assessing risks, developing methods and reporting results to courts, Points is an experienced food scientist who has set industry standards and undertaken allergen risk assessment and management for a leading UK retailer. Gowland's early research into UK retail foods for the Food Standards Agency (see **W4**),

and on-going partnership with food manufacturers and retailers also contributed. The publication describes influences on the UK food retail market which have led to the integration of allergen controls throughout the supply chain, and examines individual retailer policies and strategies to deal with the on-going challenge of providing information to food allergic and intolerant consumers, precautionary allergen labelling, and the effective management of associated product recalls and alerts.

(Certified by Dr M J Walker) (Gowland's contribution c 20%)

P28 – 2018

Dubois, A.E.J., Turner, P.J., Hourihane, J., Ballmer-Weber, B., Beyer, K., Chan, C.-H., **Gowland, M.H.**, O'Hagan, S., Regent, L., Remington, B., Schnadt, S., Stroheker, T., Crevel, R.W.R. (2018). How does dose impact on the severity of food-induced allergic reactions, and can this improve risk assessment for allergenic foods? *Allergy*, 2018 (00), pp. 1-10.*

This paper followed a project (managed by ILSI Europe – an industry supported science organisation) which brought together representatives from different stakeholder interests to review and update understanding, not just on food allergen thresholds (dose) but also on the impact of allergic reactions (severity). Allergy physicians were represented by Dubois (who led the project and writing the paper), Turner, Hourihane, Ballmer-Weber and Beyer. Their experience of managing clinical food allergy challenges for both adults and children contributed significantly to the understanding of severity, and the impact of co-factors. O'Hagan, Stroheker and Crevel represented the industry regulatory and scientific community, having a particular interest in working towards the practical implementation of allergen thresholds in the food supply chain. Chan represented the regulatory perspective – both for food safety and food labelling. Remington brought expert scientific insight. Regent and Schnadt represented patient / consumer groups in EU member states. Gowland contributed to the concept and conduct of the research; in particular a) data on perceived and actual reaction severity from her own and other people's 'near miss' and fatal reactions, b) consumer research experience c) risk modelling (including Figure 1 in the paper), and d) to editing the final paper.

(Certified by R W R Crevel) (Gowland's contribution c10%)

P29 – 2018

Barnett, J., Begen, F. M., **Gowland, M. H.**, Lucas, J. S., (2018). Comparing the eating out experiences of consumers seeking to avoid different food allergens *BMC Public Health* 2018 18, pp. 1263-1275. * Published November 16th, 2018

Abstracts for oral presentations and conference posters A1-12

A1 - 2010

Cochrane, S. A., **Gowland, M. H.**, Sheffield, D., Crevel, R. W. R., (2010). An online survey of food allergic consumers and people buying for such individuals in the UK. *EAACI 2010 Congress Programme – London, UK*, Abstract for poster 1043, p157.

This poster was first presented at the EAACI Congress in London in 2010 from the project commissioned by Unilever and undertaken by Mintel. (See also **P13** above). Gowland was project adviser and reviewed and edited the final poster.

(Gowland's contribution c10%)

A2 – 2011

Gowland, M. H. (2011). How to manage food allergy in restaurants, cafeterias and fast food outlets? Oral presentation EAACI Food Allergy and Anaphylaxis Meeting (FAAM) Venice 2011. *Clinical and Translational Allergy*, 2011, 1 (Suppl 1), S21. *

Gowland was invited to give an oral presentation on food allergy risks and controls at this EAACI international food allergy and anaphylaxis meeting as part of a workshop for a multi-disciplinary audience including consumer / patient representatives, allergy clinicians, food industry representatives, food scientists and regulators.

A3 – 2011

Gowland, M. H., Walker, M. J. (2011). *Food allergy, a summary of recent cases in the criminal and civil courts of the UK* Poster EAACI Food Allergy and Anaphylaxis Meeting (FAAM) Venice and BSACI 2011. *Clinical and Translational Allergy*, 2011, 1 (Suppl 1) O1.*

Gowland and Walker have collected data about food regulation and court cases relating to food allergy since 1996, and continue to do so. This poster described a sample of recent cases and was presented at the EAACI international food allergy meeting in Venice and the UK BSACI meeting in 2011. Further work was described in P17 and P18 above.

This abstract has 3 citations on CrossRef.

A4 – 2011

Gowland, M. H., (2011). How to tackle allergies at school. Abstract 2337780 for Oral presentation EAACI PAAM Barcelona (2011). *Clinical and Translational Allergy*, 2011, 1(Suppl 1), S21. * See http://www.eaaci-paam2011.com/scientific_programme/thursday/5375/Page.html - Accessed May 6th, 2018.

As a previous school teacher with considerable experience in advising on allergen management in schools, Gowland was invited to the EAACI international paediatric anaphylaxis and allergy meeting in Barcelona to make this presentation as part of a workshop for a multi-disciplinary audience including consumer / patient representatives, allergy clinicians, food industry representatives, food scientists and regulators.

A5 – 2011

Gowland, M. H., (2011). Eating out in a restaurant: (Abstract 2337781 for Oral presentation) EAACI PAAM Barcelona 2011. *Clinical and Translational Allergy*, 2011, 1(Suppl 1), S21. * See http://www.eaaci-paam2011.com/scientific_programme/saturday/5378/Page.html - Accessed May 6th, 2018.

As an expert patient and food industry consultant advising on allergen management in catering and other food outlets, Gowland was invited to the EAACI international paediatric anaphylaxis and allergy meeting in Barcelona to make this presentation as part of a workshop for a multi-disciplinary audience including consumer / patient representatives, allergy clinicians, food industry representatives, food scientists and regulators.

A6 – 2012

Botting, N., Barnett, J., Gowland, M. H., Lucas, J. S., (2012). The problems that peanut and tree nut allergic people encounter when travelling abroad. *Clinical & Experimental Allergy*, 42 (12), p. 1831. *

The research team involved in P11 above also presented this poster at the UK BSACI meeting in 2012 for allergy health care professionals. Gowland reviewed the travel data and edited the poster.

(Gowland's contribution c10%)

A7 – 2012

Gowland, M. H., Ledford, C. L., Austin, M. M., (2012) Which food allergies are most common in the UK? Using Anaphylaxis Campaign member data and case files to indicate prevalence. *Clinical & Experimental Allergy*, 42 (12), pp. 1834–1835. *

From 1999 (as food adviser to the Anaphylaxis Campaign), Gowland collected and collated data from membership records about the number of campaign members avoiding particular foods. This included both allergens for which there was specific labelling regulation and other food allergens. These data were of particular interest to the food industry and regulators for horizon-scanning and future planning. Ledford continues to maintain the member database and Austin was the campaign's information manager from 1997-2017. Gowland prepared the poster and presented it at the UK BSACI meeting.

(Gowland's contribution c50%)

A8 – 2014

Turner, P. J., Sharma, V., Tang, M. L. K., Gowland, M. H., Harper, N., Garcez, T., Pumphrey, R., Boyle, R. J., (2014). Age as a Risk Factor for Fatal Food-Induced Anaphylaxis: An Analysis of UK and Australian Fatal Food Anaphylaxis Data. *Journal of Allergy and Clinical Immunology*, 133 (2), Suppl. AB19. *

Turner prepared and presented this poster at the international American Academy of Allergy, Asthma and Immunology (AAAAI) meeting in the USA in 2014. Gowland's primary contribution was background detail of fatal food anaphylaxis cases in the UK collected from 1988.

(Gowland's contribution c 10%)

A9 – 2015

Walker, M., Gowland, H. (2014). Deadly fraud – Food allergen substitution in the food chain. *Clinical and Translational Allergy*, 5 (Suppl 3), p. 137. *

Gowland and Walker prepared and presented this poster at the 2014 EAACI international food allergy and anaphylaxis meeting in Dublin. Related publications for

this project are **P18, P20** and **P21** above as well as **W18**, Gowland's evidence to the Elliott Review of food supply networks.

(Gowland's contribution 40%)

A10 – 2016

Boer, R.D., Hunter, H., Stedman, C., Chalmers, R., **Gowland, M.H.**, Van der Poel, L.-A. (2016). Precautionary allergen labelling (PAL) - nuts about getting it right. Poster 130, BSACI Meeting 2016. *CLINICAL AND EXPERIMENTAL ALLERGY*, 46, p. 1669. *

Gowland advised Dr Lauri-Ann van der Poel and the dietetics team at Guy's and St Thomas Hospitals / King's College London for this poster about an intelligent digital portal tool for healthcare professionals designed to help food allergic consumers make informed choices when buying foods, and in particular biscuits, confectionery, cereal bars and breakfast cereal for people with nut / peanut allergies. Gowland also edited the poster which was presented at the UK BSACI meeting.

(Gowland's contribution c10%)

A11 – 2016

Gowland, M.H., Stratford, L.J., Austin, M.M. (2016). Can I help you? - Horizon-scanning allergy priorities using enquiries to the Anaphylaxis Campaign. Poster 132, BSACI Meeting 2016. *CLINICAL AND EXPERIMENTAL ALLERGY*, 46, pp. 1669–1670. *

From 1997, the Anaphylaxis Campaign has collected details of enquiries made by letter, phone and more recently email and social media. These provide a useful indicator for current concerns and priorities for people living with allergy risks. As food adviser to the Anaphylaxis Campaign, Gowland collected and collated data provided by information manager Austin and her assistant Stratford, prepared the poster and presented it at the UK BSACI meeting.

(Gowland's contribution c40%)

A12 - 2016

Gowland, M.H., Walker, M.J. (2016). Food allergy law and consumer protection - an update from UK courts. Poster 133, BSACI Meeting 2016. *CLINICAL AND EXPERIMENTAL ALLERGY*, 46, p. 1670. *

Following research leading to the publication of **P18, P27** and **A3** above, Gowland and Walker continue to support investigations following severe and fatal allergic reactions and to examine cases in the UK courts. In 2016, a key prosecution led to the conviction and imprisonment of a caterer following a food allergy death. This poster presented at the BSACI meeting presented factors associated with taking legal action in such cases.

(Gowland’s contribution c50%)

| Journal Impact factors – accessed April 5th 2018 | Impact Factor | Year | Papers and Abstracts | | | | | | | |
|---|---------------|--------|----------------------|-----|-----|-----|-----|-----|-----|-----|
| M H Gowland’s papers P1-29 and Abstracts A1-12 | | | | | | | | | | |
| Journal of Allergy and Clinical Immunology | 13.081 | 2016 | P4 | P19 | A8 | | | | | |
| Allergy | 7.361 | 2018 | P1 | P9 | P15 | P22 | P24 | P28 | A1 | |
| Pediatric Allergy and Immunology | 3.775 | 2017 | P3 | | | | | | | |
| Proceedings of the Nutrition Society | 4.421 | 2016 | P2 | | | | | | | |
| Perspectives in Public Health | 0.919 | 2016 | P5 | P14 | | | | | | |
| Regulatory Toxicology and Pharmacology | 2.221 | 2017 | P6 | | | | | | | |
| Clinical & Experimental Allergy | 5.587 | 2016 | P7 | P8 | P26 | A6 | A7 | A10 | A11 | A12 |
| BMC Public Health | 2.265 | 2018 | P10 | P25 | P29 | | | | | |
| Clinical and Translational Allergy | 3.239 | 2 year | P11 | P13 | A2 | A3 | A4 | A5 | A9 | |
| PLoSOne | 2.806 | 2016/7 | P12 | P23 | | | | | | |
| Journal of Allergy and Clinical Immunology: In Practice | 5.317 | 2017 | P16 | | | | | | | |
| Food Science and Technology (London) | 1.12 | 2014 | P17 | | | | | | | |
| Journal of the Science of Food and Agriculture | 2.463 | 2018 | P18 | | | | | | | |
| Chemistry and Industry | 0.182 | 2016 | P20 | | | | | | | |
| The Analyst | 3.885 | 2016 | P21 | | | | | | | |
| Journal of AOAC International | 1.05 | 2015 | P27 | | | | | | | |

Figure 2: Impact factors of journals in which Gowland’s work has been published

Book chapters B1 - B4

B1 – 2002

Gowland, M. H., (2002). Food Allergen Risk Management - A matter of Life or Death. In V. Emerton, ed., *Food Allergy and Intolerance Current Issues and Concerns*, 1st ed. Leatherhead Food Research Association / Royal Society of Chemistry, pp. 81-92.

This book was written for food industry and scientific audiences to present the proceedings of an international food allergy conference. This was also an early example of Gowland's role as a 'hub', bringing together and developing partnerships with key stakeholders involved in allergen risk assessment, management and control. These included leading allergy clinical researchers, food scientists and technologists, regulators and consumer / patient support organisations.

B2 - 2010

Gowland, M. H., (2010). Chapter 7: Allergen Management and Control in the Food Service Industry. In: J. Boye, ed., *Allergen Management in the Food Industry*. 1st ed. Hoboken, New Jersey: Wiley, pp. 167-204.

This book was published by the Canadian government (Health Canada) in association with Wiley. As an experienced expert adviser to a range of catering businesses, and as a food allergic individual, Gowland was invited to contribute the chapter on foodservice – catering and buying non-prepacked foods.

B3 – 2014

Gowland, M. H., (2014). Chapter 7: In: Flanagan, S. (ed.) *Handbook of Food Allergen Detection and Control*. 1st ed. Cambridge UK. Woodhead Publishing, pp. 133-160.

This book is a handbook for the food industry. Its primary audience is food technologists, scientists, suppliers, manufacturers, retailers and regulators. Gowland was invited to contribute this chapter, presenting and classifying the range of consumers avoiding different allergens and the reasons why they do so. The chapter summarises the impact of different conditions, including data about fatal and 'near miss' reactions, the foods people are avoiding, risk factors in food supply, communicating information about ingredients and the possible inadvertent presence of other allergens, changes in consumer behaviour, particularly regarding allergen consumption to prevent allergy in

early life, the new Food Information Regulation and resources available to support best practice.

B4 – 2017

Walker, M. J., **Gowland, M. H.** (2017). Chapter 24: Food Allergy: Managing Food Allergens. In: Yiu Chung Wong, ed., *Analysis of Food Toxins and Toxicants*. 1st ed. Hong Kong: Wiley, pp. 711-742.

This book was commissioned by the Government Laboratory in Hong Kong in association with the publisher, John Wiley. As an international publication with contributors from around the world, its primary audience is the food analytical community, as well as food industry representatives, scientists, technologists, policymakers and regulators.

Walker and Gowland were commissioned to write this definitive and up to date chapter on food allergens, including current developments in allergen and allergy management. Gowland provided expert input on recent changes in food labelling, progress on establishing allergen thresholds in light of improved understanding of reaction severity, and the impact of food allergy and related conditions on quality of life.

(Gowland's contribution c30%)

Other work and achievements **W1 - W24**

W1 – 1997

MAFF – (1997) Be Allergy Aware – government allergy awareness initiative for caterers: Joint Project Adviser and media (radio and TV) **Hazel Gowland**

W2 – 1998

The Katherine Baker Appeal – project to collect funds with the Bradford and Bingley Building Society, and Boots the Chemist and engage with schools and nurseries to send out videos about Anaphylaxis: Project Manager – **Hazel Gowland**

W3 – 2000

BBC Radio 4 Food Programme **Hazel Gowland** Finalist: Campaigner / educator for the first awards in 2000

W4 – 2002

Research study and report

Food Standards Agency UK (2002) ‘May Contain’ Labelling – The Consumer’s Perspective **Hazel Gowland**, Allergy Action for the Anaphylaxis Campaign. Food Standards Agency, London. Ref: FSA/0582/0502

W5 – 2003

Allergy - the unmet need - Diagram on Page 22 by **M H Gowland** Royal College of Physicians Working Party on Allergy. Earlier versions prepared for meeting in 1998 with the Minister for Public Health, and used in Ewan, P. (2000).

W6 – 2004

The Provision of Allergy Services – House of Commons Health Committee 6th Report of Session 2003-04, Volume 1 Diagram **W5 – 2003** above from RCP Allergy: the unmet need - by **M H Gowland** (2003) re-used in report – Page 20. House of Commons

W7 – 2004

Investigating deaths from allergen-induced anaphylaxis and asthma. Dr Richard Pumphrey and **Mrs Hazel Gowland**. The Coroners' Society of England and Wales Annual Report

W8 – 2006

Voluntary food industry guidance – Guidance on Allergen Management and Consumer Information. Food Standards Agency Voluntary Guidance FSA/1064/0606 **M H Gowland** - member of working group

W9 – 2006

SoFHT award-winning (Best New product) and RIPH accredited DVD training tool *Allergy awareness: an introductory pack for food handlers.* **Hazel Gowland** and Dr Lisa Ackerley allergytraining.com

W10 – 2006

Food Standards Agency – creating and managing the delivery of online pre-course learning and 49 interactive workshops for 1043 local authority food standards and food safety officers throughout the UK. **Hazel Gowland** and Dr Lisa Ackerley

W11 – 2007

House of Lords Science Committee on Allergy. Evidence to enquiry **Hazel Gowland**

W12 - 2008

Irish cross-border food safety project for safefood to deliver online pre-course learning and interactive workshops to 295 EHOs, 12 Public Analyst laboratory staff and 172 catering lecturers Online and workshop content - also two conferences. **Hazel Gowland** and Dr Lisa Ackerley

W13 - 2008

Voluntary food industry guidance The Provision of Allergen Information for Non Pre-packed Foods. Food Standards Agency Voluntary Guidance **M H Gowland** member of working group. FSA/1226/0108 Food Standards Agency

W14 - 2009

Food Allergy training course for James Watt College Hazel Gowland (Allergy Action) and Graeme Kerr

W15 – 2009

Living with Allergy - Lecture on the MSc in Allergy at Southampton University delivered on every course since. Hazel Gowland for University of Southampton School of Medicine

W16 – 2011

Qualification in Allergy Awareness: REHIS Joint Award. Hazel Gowland and Graeme Kerr. Royal Environmental Health Institute in Scotland partnership

W17 – 2012

New food allergy guidance published for caterers. Hazel Gowland for Sustain - the alliance for better food and farming for the London 2012 Olympics

W18 – 2013

Food supply networks: integrity and assurance review - Elliott Review. Note of Meeting with Hazel Gowland DEFRA - UK Government report by Professor Chris Elliott

W19 - 2014

Updated and revised DVD training tool Allergy awareness: an introductory pack for food handlers. Hazel Gowland for allergytraining.com

W20 - 2014

Food fraud: the dangerous allergens lurking in the supply chain. Michael Walker and Hazel Gowland. The Guardian

W21 - 2014

New EU allergy rules could mean life or death this Christmas. The Guardian Hazel Gowland

W22 - 2014

Film - 12 days before Christmas - Hazel Gowland Vimeo film about the resources for the new Food Information Regulation <https://vimeo.com/114715790>

W23 - 2016

Imperial College School of Medicine, London - Lecture on MSc / PG certificate in **Allergy: Risk Management in Food Allergy**: Regular lecturer on these courses **Hazel Gowland**

W24 - 2016

British Hospitality Association, *Industry Guide to Good Hygiene Practice*. Guide to compliance with Regulation (EC) 853/2004 on the Hygiene of Foodstuffs and HACCP. 2016. **Chapter 4 - Allergens** - **Hazel Gowland** and working group members.

3 Career progression

Mrs M Hazel Gowland BA, PGCE, MSoFHT, MREHIS, FIFST, FRSPH

Expert patient representative, researcher, lecturer and trainer specialising in food allergies

Also Food Adviser - UK Anaphylaxis Campaign (registered charity) since 1994

Website: www.allergyaction.org

Employment

Sole Trader – Allergy Action since 2000

- Working for and with the Anaphylaxis Campaign as Food Adviser and independently as Allergy Action for the Food Standards Agency, the Universities of Southampton, Manchester, Surrey, Bath and Imperial College London, and project partners including the Laboratory of the Government Chemist, Hygiene Audit Systems and the Royal Environmental Health Institute of Scotland and many food manufacturers, retailers, caterers and other food suppliers
- Previously secondary school teacher and youth leader
- UK, France and Germany: hotels and restaurants, food manufacture, language teaching, office administration and children’s holiday camps

Key activities

- **2016 Contributed to the Allergens section** of the new *Industry Guide to Good Hygiene Practice Catering Guide* – British Hospitality Association
- **2016 Lecturer on the MSc Allergy course** - Imperial College Medical School, London
- **2014 Member of International Life Sciences Institute (ILSI) Expert Group:** Severity of allergic reactions to foods; work to assess allergen thresholds
- **2014 Examiner for the Royal Society of Public Health (RSPH)** – developing qualification: *Level 2 Qualification in Identifying and controlling Food Allergy Risks*

- **2014 Advising HM Coroners and the police**, particularly on issues relating to food labelling and failed allergen avoidance – Also **Expert Witness**
- **2014 Wrote and produced information video** on the resources available to implement allergen controls required in the new Food Information Regulation <https://vimeo.com/114715790> (**W22 – 2014**)
- **2013 Project Adviser – FSA funded study** – Bath and Surrey Universities: How do food allergic and intolerant consumers make food choices when eating out? – the impact of the new Food Information Regulation
- **2013 Lecturer on Allergy Academy courses** – Guy’s and St Thomas Hospitals, and King’s College London
- **2012 Consultancy work** for leading food businesses to review the impact of the Food Information Regulation 1169/2011 EC and implement additional controls and guidance
- **2012 Expert Trainer** – delivering training materials and advice to food safety trainers and consultants to implement the new Regulation 1169/2011 EC
- **From 2012 Member of Trial Steering Committee** for TRACE study into the *Extrinsic factors of allergic reactions* – FSA funded and coordinated by Addenbrooke’s Hospital, Cambridge and St Mary’s Hospital / The Brompton Hospital, London
- **2012 EAACI** (European Academy of Allergy and Clinical Immunology) Annual Meetings and Food Allergy Summer Schools: **Faculty member**
- **2012 NHS Scotland** Briefing clinicians and delivering training workshops to catering and nursing staff
- **2012 Developing E-learning** on food allergies with Dr Lisa Ackerley
- **2012 Expert adviser to the Food Standards Agency** on implementing food legislation in practice
- **2012 Royal College of Paediatrics and Child Health** – tutor on food allergy training course for paediatricians
- **2011 Royal Environmental Health Institute of Scotland** Joint Award in Allergy Awareness for food handlers, nursery, school and hospital staff

- **From 2009 Lecturer on the MSc in Allergy** (University of Southampton School of Medicine) ‘Living with Allergy’ and ‘Lessons learned from bereaved families’
- **From 2008 Laboratory of the Government Chemist – project adviser** - development of analytical methods for the presence of food allergens. Research with Dr Michael Walker on court cases relating to food allergies
- **From 2004 Support for investigations into fatal anaphylaxis cases:** undertaking family liaison, working with Dr Richard Pumphrey and Manchester clinical colleagues.
- **From 2003 to date** Media work – Advising programme producers, undertaking live and recorded interviews, work with the BBC and independent broadcasters and newspaper / website journalists to raise public awareness of Food Allergy
- **April 2000** BBC Radio 4 Food Programme Awards – Finalist – Campaigner / Educator
- **1994 - 2000** – Member of the National Executive of the Anaphylaxis Campaign

Qualifications:

BA (Hons), French – Leeds University, 1982

Youth Leader’s Certificate – London Borough of Hillingdon 1984

Postgraduate Certificate in Education – University of Hertfordshire, 1985

Member of the Society of Food Hygiene and Technology from 2004

Member of the British Society of Allergy and Clinical Immunology from 2009

Fellow of the Institute of Food Science and Technology from 2014

Member of the Royal Environmental Health Institute of Scotland from 2014

Fellow of the Royal Society of Public Health from 2018

Table 1: Gowland's Career Progression by theme

| | Gowland's career Progression | Key to Output | | | | |
|----------------|--|---|--|--|--|--------|
| Timeline | Protecting consumers with food allergies | P = Journal Paper | A = Abstract | B = Book Chapter | W = Other Work | |
| (Not to scale) | Investigating impact | Developing partnerships | Shaping Regulation and Best practice | Setting standards to reduce risk | Skills developed | Output |
| 1988 | Collecting details of fatal reactions | | | Data collection and management | Fatal allergy data collection and analysis | |
| 1994 | Recruiting subjects for peanut oil study | Anaphylaxis Campaign member | MAFF Codex Food Labelling Milk and egg | Ethical aspects of leading a patient / consumer member organisation. | Questionnaire development and survey management | |
| 1995 | Milk and egg survey | Anaphylaxis Campaign representative, speaker, executive member | | Taking notes from people who have had reactions | Bereavement and pastoral support | |
| | | Allergy clinicians at Great Ormond Street, Southampton General, St Thomas', St Mary's London, Addenbrooke's, Cambridge and Manchester Central Hospitals | | | Preparing slides for different audiences | |
| | | British Allergy Foundation - later Allergy UK | | | Public speaking - preparing and delivering presentations | |
| | Listening to food allergic individuals | Coeliac UK | | Setting up and managing databases | Completing and reviewing reaction records | |
| | Collecting data about reactions | | Replying to MAFF consultations | Clear and accessible language | Networking | |

| | | | | | | |
|------|--|--|--|---|--|----|
| | Early sesame survey | MAFF - officials | MAFF Codex Food Labelling Sesame | Timely and collaborative response to member, media and colleague enquiries and requests | Managing a patient / support organisation | |
| 1996 | Learning from early contacts - food manufacturers and caterers | Food industry contacts - manufacturers, retailers, caterers, technologists, professional and scientific associations | | Pastoral advocacy and supporting bereaved families | Research and advocacy - Collaboration with clinicians and scientists | |
| | Early site visits to factories, catering operations | Journalists - print, radio, television | | Integrity of patient support activities | Press liaison - writing, interviews - tv and radio | |
| | Further site visits - schools, nurseries, care scenarios | Consumer champions | Setting learning aims and objectives for chefs, front of house and other food handlers | Setting learning aims and objectives for chefs, front of house and other food handlers | Literature reviews | W1 |
| | | Dr Lisa Ackerley and Hygiene Audit Systems | | Website content | Allergy Action website, building, designing, managing | |
| | The relationship between allergy and the pharmaceutical industry | Cranfield University | | | Understanding and working with the pharmaceutical sector | |
| 1997 | Further sesame allergy survey | Coroners, bereaved families | | | Attending inquest, family support | |
| | Manufacturing controls for food allergens | Institute of Food Science and Technology | IFST Good Manufacturing Practice - Dealing with allergens | Trusted authoritative consultancy | Consultancy work including training | |

| | | | | | | |
|------|--|---|---|--|--|---------|
| | Review of personal allergy history for conference and publications | European allergy clinicians, journal editors, scientists | Close partnership with Food Standards Agency | | Writing abstracts and first journal paper | |
| 1998 | Mapping allergy care pathways | Meeting with Minister of Public Health, work with Nutritionists | | | Responding to reviewer comments | |
| | Survey of community pharmacists into readiness to deliver adrenaline auto-injectors | Royal Pharmaceutical Society of Great Britain | The 'Red Book' for pharmacists | Allergy management in professional standards for community pharmacists | Writing information leaflets for Katherine Baker Project and Boots the Chemist | W2 |
| 2000 | | BBC Radio 4 Food Programme Awards Finalist | Replying to FSA consultations | | Setting up and running a small business | W3, P1, |
| | Reviewing the life-long impact of food allergy and related conditions - personal perspective | | | Clear and accurate food labelling | Devising research methodologies Presenting research data | P2, W4 |
| | Presenting the consumer and patient perspective - also understanding of different food industry perspectives | Leatherhead Food Research Association | Call for more recognition of information and food safety needs of consumers with allergies and intolerances | | First Book Chapter | B1 |
| 2001 | 'May contain' report into shopping for people with nut and peanut allergies | Royal College of Physicians | | Research ethics | Giving written and oral evidence | W5 |
| | | European Academy of Allergy and Clinical Immunology | | | Speaking at international conference | |
| 2002 | | | | | Modelling – presenting novel research methods | |

| | | | | | | |
|------|---|--|--|--|---|-------------|
| 2003 | Data collection on patient care pathways | | Giving evidence for House of Commons Report into Allergy | | Producing graphical illustrations for advocacy and training | W6, W7 |
| | | Anaphylaxis Campaign Strategic Review of partnerships and identification of potential partners | | | Reviewing activity and Strategic Planning | |
| | | | | | Tender application for training programmes | P3 |
| 2004 | Data collection for House of Commons report | | | | Project management - training programme | W8, W9, W10 |
| 2005 | Full sesame allergy survey | | Shaping FSA guidance for consumers with allergies and intolerances | | Conference and events management | |
| 2006 | | | | Content of Allergytraining DVD Training Pack | Film making - script writing, editing, production, managing actors, sourcing music, artwork, locations, marketing, online sales, ethics | |
| | | | | | Creating online learning materials and project logistics UK and Ireland | |
| | | British Retail Consortium (BRC) and Food and | | | Writing industry guidance in FSA working group | |

| | | | | | | |
|------|--|--|--|--|--|--------------|
| | | drink Federation (FDF) | | | | |
| | Data collection for House of Lords Report | | Giving evidence for House of Lords Report into Allergy | | Giving oral evidence | P4, W11 |
| | | | | | Interactive CPD training workshops | |
| 2007 | Review of fatal food reactions 1999-2007 | | | Allergy audits for catering operations | Reviewing fatal food reactions | |
| | | | Discussing EU Labelling at French conference | | Addressing French clinicians' conference | |
| 2008 | | Work to set up the UK Fatal Anaphylaxis Registry with Central Manchester Hospitals | | Ethics and working methods for the UK Fatal Anaphylaxis Registry | Building collaborative research teams | |
| | | | | | Submitting applications for research funding | P5, W14, W15 |
| | | | | | Designing and presenting study posters | |
| | | LGC - Laboratory of the Government Chemist - developing analytical methods | | | Project adviser - development of analytical methods for the presence of food allergens. Research on court cases relating to food allergies | |
| 2009 | In-depth FSA study into wide range of issues related to living with nut / peanut allergy | Allergy and Hygiene Systems Ltd - Graeme Kerr - Training partner in Scotland | Short course in Allergy Awareness | Making learning accessible, Supplying practical learning tools | Preparing publications collaboratively | P6, P7, |

| | | | | | | |
|------|--|--|---|---|--|------------------------------|
| | | Southampton University Medical School | | | Lecturer on the MSc in Allergy at Southampton University | |
| 2010 | Reviewing allergen management and controls in foodservice | Health Canada and Wiley | Presenting the need for further consumer information for people eating out and buying non-prepacked foods | Population Consumer research with Mintel and Unilever | Book chapter Allergen Management and Control in the Food Service Industry. | B2, A1 |
| 2011 | Reviewing food allergen controls in NHS Scotland | Royal Environmental Health Institute of Scotland | Support for Environmental Health Officers in Scotland to control allergy risks | Royal Environmental Health Institute of Scotland Joint Award in Allergy Awareness for food handlers, nursery, school and hospital staff | Risk assessment and training for hospitals | P8, P9, P10, A2, A3, A4, W16 |
| | Research into how to make the new legislation practical and helpful for businesses and consumers | | Expert adviser to the Food Standards Agency on implementing food legislation in practice | Writing accessible exams for food handlers to ensure competence | Faculty member: EAACI Summer School for allergy clinicians – Vienna | P11, A5, W17 |
| 2012 | | Royal College of Paediatrics and Child Health | | Improved understanding of food allergies for paediatric clinicians | Royal College of Paediatrics and Child Health – tutor on food allergy training course for paediatricians | P12, P13, P14, A6, A7, W18 |
| | Extrinsic factors of allergic reactions TRACE Study - looking at peanut allergen thresholds and understanding symptom severity | Addenbrooke's Hospital, Cambridge and St Mary's Hospital / The Brompton Hospital, London | | Member of Trial Steering Committee for TRACE Study - Project integrity and ethics | Acting as Trial Steering Committee member for clinical research | |

| | | | | | | |
|------|--|--|--|--|--|-------------------------------|
| 2013 | | | | Expert Trainer – delivering training materials and advice to food safety trainers / professionals to implement the new Regulation 1169/2011 EC | Adapting materials to include new regulation and for different audiences | P15, P16, P17, W19, W20, W21, |
| | | | | Consultancy work for leading food businesses implementing additional controls and guidance | | |
| | | Allergy Academy - Guy's and St Thomas' clinical training programme | London 2012 Olympics – allergy risk assessment for on-site caterers | Food allergy risk assessment for Sustain for the London 2012 Olympics | Lecturer on Allergy Academy courses – Guy's and St Thomas Hospitals, and King's College London | |
| | FSA funded study: How do food allergic and intolerant consumers make food choices when eating out? | Surrey, Brunel, Bath and Cork Universities and Creative Research Ltd | Study to examine impact of Food Information Regulations 1169/2011 EC | Informing policy from consumer behaviour research looking into eating out with food allergies and intolerances | Project Adviser – the impact of the new Food Information Regulation | |
| 2014 | ILSI working group: Severity of allergic reactions to foods; work to assess allergen thresholds | Member of International Life Sciences Institute (ILSI) Expert Group | Impact review Food Information Regulation 1169/2011 EC | | Understanding symptoms severity | A8 |
| | Review of consumer attitudes to allergens in food for book chapter | RSSL Editor Simon Flanagan | | Consumer attitudes to allergens in food. Chapter 7. Handbook of Food Allergen | Contributing chapter on consumer attitudes to allergens in foods | B3 |

| | | | | | | |
|------|---|--|---|---|--|-----------------------------|
| | | | | Detection and Control. | | |
| | | Royal Society of Public Health | | Royal Society of Public Health (RSPH) – developing qualification: Level 2 Qualification in Identifying and controlling Food Allergy Risks | Examiner for accredited qualification: RSPH Level 2 - creating question bank | P18, P19, P20, |
| | Further fatal reactions and lessons learned | H M Coroners and others investigating fatal allergic reactions | Reviewing legislation which may be applicable following fatal reactions | Modelling investigation protocols into food allergy reactions | Properly interested person and expert witness for fatal allergic reactions | |
| | Reviewing the effectiveness of materials available to implement the new Food Information for Consumers Regulation | | Wrote and produced information video on the resources available | Practical implementation of allergen controls required in the new Food Information Regulation | Making an awareness cartoon video and uploading to Vimeo | W22 |
| 2015 | Further investigation into consumer behaviour following the Food Information for Consumers Regulation | University of Bath, Creative Research Ltd | | | Lecturing on MChemA Public Analysts Training course | P21, P22, P23, P24, A9 |
| 2016 | Further understanding of severity of allergic reactions | Imperial College London | | | Lecturer in MSc in Allergy at Imperial College | P25, A10, A11, A12, B4, W23 |
| | Review of current best practice in catering and regulatory context | British Hospitality Association | Contributed to the Allergens section of the new <i>Industry</i> | Contributed to the Allergens section of the new <i>Industry</i> | Updating understanding of managing food allergies in | W24 |

| | | | | | | |
|------|--|--------------------------|---|---|---|---------------------|
| | | | <i>Guide to Good Hygiene Practice</i> Catering Guide | <i>Guide to Good Hygiene Practice</i> Catering Guide | catering businesses | |
| 2017 | Re-examining food allergen regulations worldwide | | International oversight of food allergen regulation and controls | Food Allergy: Managing Food Allergens Chapter 24 of Analysis of Food Toxins and Toxicants. | Writing book chapter with Dr Michael Walker | P26, P27, P28 |
| 2018 | Allergy in adolescents | EAACI Task Force partner | Codex working group incorporating allergen management into Food Hygiene | | Online teleconferences, meetings and live data handling, webinars | (P29) |

4 Allergy and associated conditions – Discussion

Gowland's role in allergy has always included support and advocacy for people sensitive to medication and insect stings as well as food. She has taken histories, undertaken investigations, provided support and worked on coroner's investigations for people who suffered fatal reactions to medication, bee and wasp stings. For some people, anaphylaxis may be idiopathic – ie with no known cause, or perhaps triggered by exercise alone, or with co-factors. She is committed to improving access to specialist allergy healthcare and diagnosis, and ensuring that injectible adrenaline is available and accessible to those who may need it, whatever may trigger their symptoms. Training courses and management protocols developed and delivered by her always recognise the needs of anybody who may have a severe reaction, whether from medication, insect stings, food or other cause.

At the same time, her work to improve the identification and control of food allergens continues to benefit those with a range of conditions; primarily food allergy, food intolerance and coeliac disease, as well as other less common conditions which require food allergen avoidance.

4.1 Food allergen avoidance

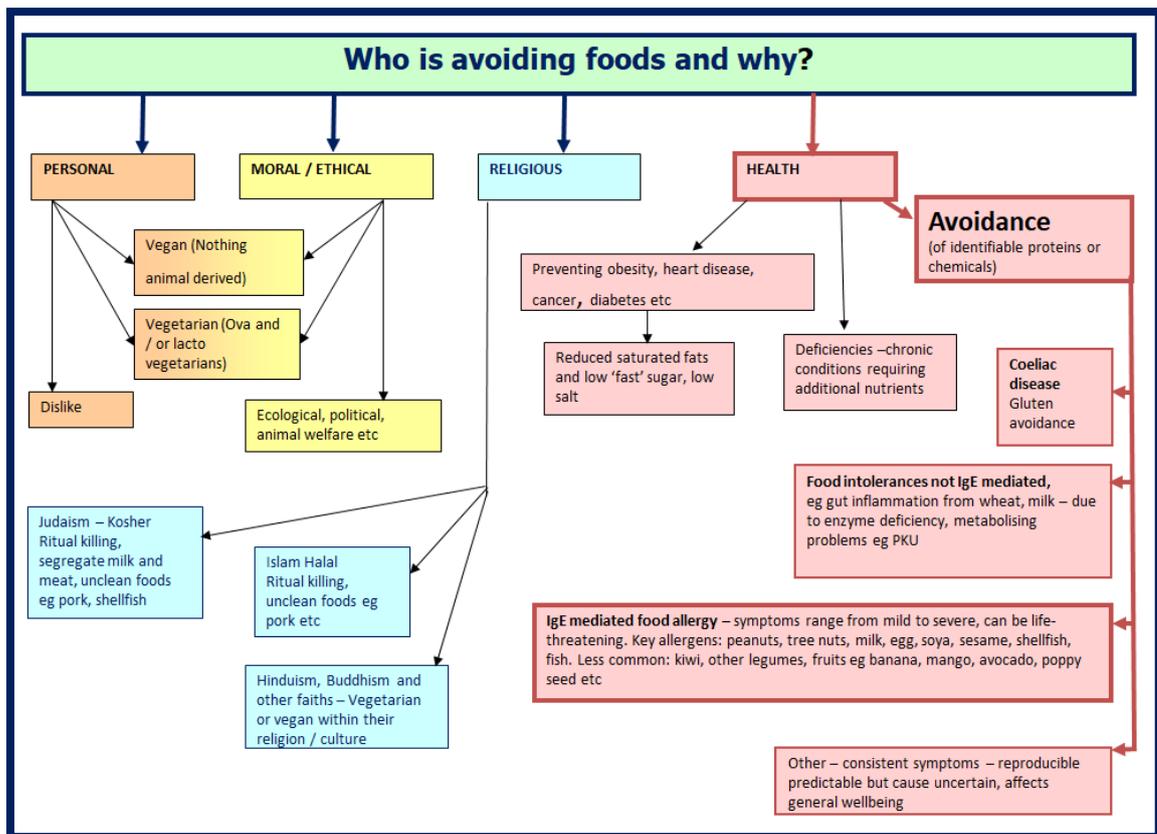


Figure 3: Who is avoiding foods and why? (Published in book chapter B2 – 2010)

Gowland used the diagram (Figure 3) in her training courses from 2000 – 2008 to help food business staff understand food allergy, food intolerance and coeliac disease in the wider context of all the food avoidance requests they receive from customers.

Although more is understood now about some of the medical conditions associated with food hypersensitivity, and this information is more effectively communicated to students through the use of images and photos, this simplified format helped staff to appreciate and address the potential risk to health associated with different dietary requests.

4.2 Food hypersensitivity

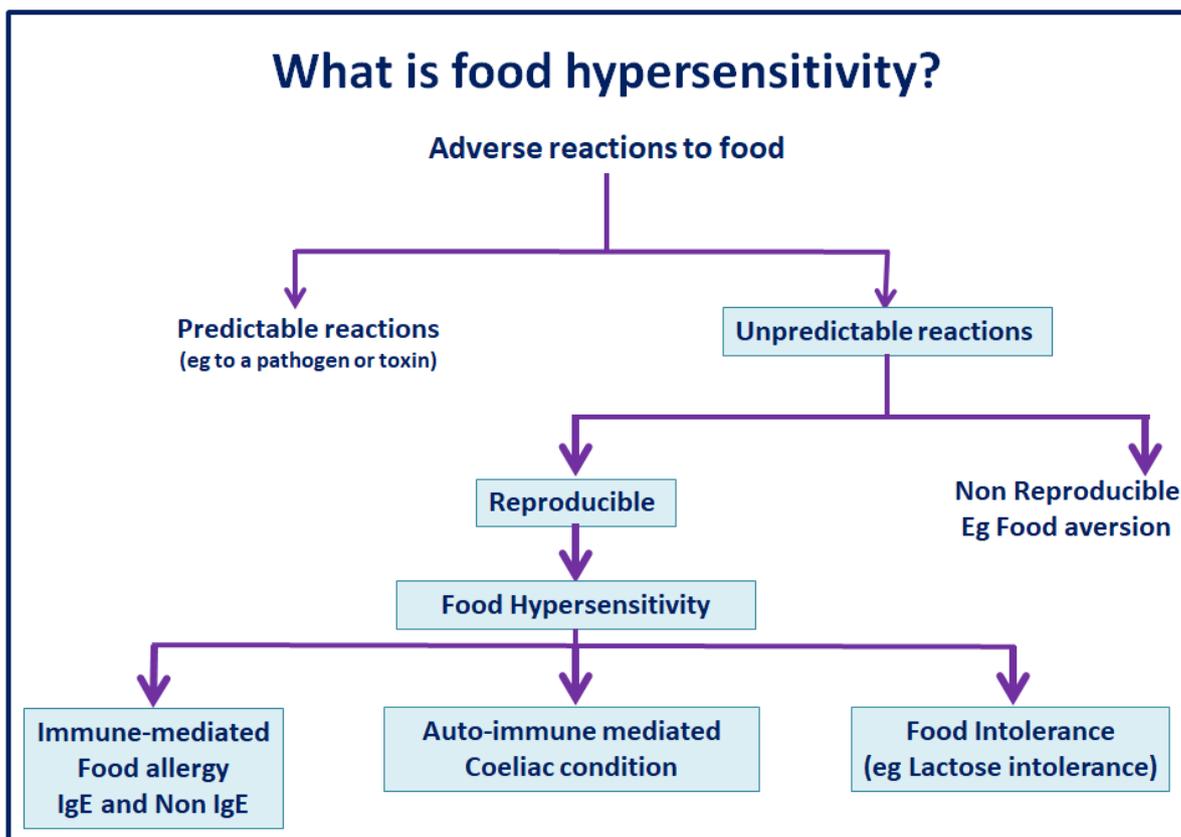


Figure 4: Food hypersensitivity

(Much of section 4 from this point and section 5 are abridged from the book chapter Walker, M. J., [Gowland, M. H.](#) (2017). Chapter 24: Food Allergy: Managing Food Allergens. In: Yiu Chung Wong, ed., *Analysis of Food Toxins and Toxicants*. 1st ed. Hong Kong: Wiley, pp. 711-742. [B4 – 2017](#)).

People may suffer a range of adverse reactions to food (Figure 4). Anybody who consumes food containing a large number of *Salmonella* enterobacteria will become ill. Other reactions to food are not predictable and will not affect everybody. Until a reaction happens, the person affected does not know that it *will* happen. If such reactions occur almost every time the person eats that food, their reactions are 'reproducible'. Food hypersensitivity is the general term for such reproducible adverse reactions to particular foods, defined more formally as: 'objectively reproducible symptoms or signs initiated by a defined stimulus at a dose tolerated by 'normal' subjects' (Johansson *et al.*, 2001).

There are many forms of food hypersensitivity. One of these is 'allergy', a term introduced in 1906 by Clemens von Pirquet (1874–1929) (Igea, 2013). 'Food allergy' is

a hypersensitivity to food protein(s) involving the immune system. The immune system ensures human survival by producing antibodies to recognise, fight and help to destroy harmful antigens such as parasites, bacteria or viruses. Antibodies are immunoglobulin glycoproteins produced by plasma cells (white blood cells). There are five main isotypes: IgA, IgD, IgE, IgG, and IgM, (Schroeder and Cavacini, 2010). Food allergy is mediated by immunoglobulin E, IgE, discovered in 1967 (Johansson, 2016).

4.2.1 Food Allergy

Food allergy develops in two separate stages: a) sensitisation and b) elicitation of signs and symptoms. Sensitisation occurs in susceptible individuals as the development of an immunological response to specific food proteins. It is possible for somebody to be sensitised ie produce allergen specific IgE, sIgE without allergic symptoms. Food allergy is therefore defined as the sensitisation and elicitation of an adverse reaction on subsequent exposure. This means that individuals sensitised to a food protein who consume or have other contact with it may experience symptoms. These are caused by IgE cross linking with allergenic epitopes leading to the release of potent inflammatory mediators such as histamine from tissue mast cells and peripheral basophils. IgE mediated food allergy involves acute symptoms, generally within 2 hours of ingestion of the provoking food, and sometimes within minutes. Symptoms include lip tingling, nausea, diarrhoea, vomiting, pruritus (itch), erythema (red rash), asthma, urticaria (hives, a raised, itchy rash), and angioedema (swelling caused by fluid released from the circulatory system to protect the organs). The most severe allergic reaction is anaphylaxis which can become life threatening (see section 4.4 below).

4.2.2 Oral allergy or pollen-food allergy syndrome

Some people have oral allergy or pollen-food allergy syndrome. They are sensitised (via the respiratory system) to pollen proteins which are similar in size and shape to certain fruit and vegetable proteins leading to IgE binding. Symptoms may include localised mouth itching and intermediate gastrointestinal hypersensitivity.

4.2.3 Other mechanisms

Mixed IgE and cell-mediated mechanisms are involved in chronic conditions such as atopic dermatitis, also known as eczema and also in eosinophilic gastro enteropathies, such as eosinophilic esophagitis and eosinophilic gastritis. Non-IgE-mediated

gastrointestinal food-induced allergic disorders (non-IgE-GI-FAs) account for an unknown proportion of food hypersensitivity and include food protein–induced enterocolitis syndrome (FPIES), food protein–induced allergic proctocolitis (FPIAP), and food protein–induced enteropathy (FPE). Non-IgE-GI-FAs have considerable overlap among themselves and with eosinophilic gastro enteropathies. FPIES is probably the most actively studied non-IgE-GI-FA, potentially because of acute and distinct clinical features. FPIAP remains among the common causes of rectal bleeding in infants, while classic infantile FPE is rarely diagnosed. The most prominent clinical features of FPIES are repetitive emesis (vomiting), pallor, and lethargy; chronic FPIES can lead to failure to thrive. FPIAP manifests with bloody stools in well-appearing young breast-fed or formula-fed infants. Features of FPE are non-bloody diarrhoea, malabsorption, protein-losing enteropathy, hypoalbuminemia, and failure to thrive. Non-IgE-GI-FAs have a favourable prognosis; the majority resolve by 1 year in patients with FPIAP, 1 to 3 years in patients with FPE, and 1 to 5 years in patients with FPIES, with significant differences regarding specific foods. Much work remains to be done to understand these conditions (Sicherer and Sampson, 2010, Burks *et al.*, 2012, Järvinen and Nowak-Węgrzyn, 2013, Caubet *et al.*, 2014, Nowak-Węgrzyn, *et al.*, 2015). See also Heiner syndrome, milk-induced pulmonary disease in infants (Moissidis *et al.*, 2005).

4.2.4 Coeliac disease and ‘food intolerance’

Food hypersensitivity also includes auto-immune conditions such as coeliac disease (Kennedy and Feighery 2000) and the spectrum of conditions grouped together as ‘food intolerance’. Food intolerance includes pharmacological effects of food components, eg vasoactive amines such as histamine, non-coeliac gluten sensitivity, enzyme and transport defects, eg lactose intolerance, the potential adverse effects of some food additives eg tartrazine, annatto, sulphites, benzoic acid, and short chain fermentable carbohydrates (FODMAPs) (Lomer, 2015).

The primary focus of Gowland’s work to reduce risks from food allergens and support patients and consumers has been IgE mediated food allergy, an increasing global health problem with considerable associated morbidity (Prescott and Allen, 2011, Nwaru *et al.*, 2014, Chan *et al.*, 2015a).

4.3 Food Allergy Prevalence

Food allergy may persist from childhood or follow newly acquired sensitisation in adulthood. Some childhood food allergies eg to milk, egg, soya, or wheat are often outgrown, whereas allergies to tree nuts or peanut in children beyond age 6-7 tend to persist. Allergies to fish or crustacean shellfish, which most commonly develop in adulthood, usually persist. Hence the prevalence of food allergy varies, data may be lacking and studies exhibit heterogeneity. The double-blind, placebo-controlled food challenge (DBPCFC), the most reliable indicator of allergy to a food, has proved difficult to apply in many prevalence studies (Burks *et al.*, 2012).

Rona *et al.*, (2007) first identified the main problems in prevalence studies; out of 934 articles identified by these authors from 1990 onwards, only 51 were appropriate for inclusion in their prevalence meta-analysis. Information sources were classified into 5 categories: self-reported symptoms, specific IgE positive, specific skin prick test positive, symptoms combined with sensitisation, and food challenge studies. The high prevalence of self-reported food allergy compared with objective measures was also noted.

Nwaru *et al.*, (2013) studied the prevalence and epidemiology of food allergy in 25 countries of Europe in a systematic review of the literature 2000 – 2012. The protocol, search strategy, inclusion and exclusion criteria and key terms were defined. The numbers of new cases of the various IgE-mediated, non-IgE-mediated or combination causes of food allergy that occur during a given period in a defined population were studied as:

- Incidence rate: The number of new cases of food allergy that occur during a given period per unit of person-time;
- Cumulative incidence: The number of new cases of food allergy that occur during a given period per the population at risk;

Prevalence data were collected as:

- Point prevalence: the proportion of the population that has experienced food allergy at a specific time;
- Period prevalence: the proportion of the population that has experienced food allergy during a given period, and
- Lifetime prevalence: the proportion of the population that at some point in their life will have experienced food allergy.

Seventy-five eligible articles (56 primary studies) were included and most of the studies were graded as at moderate risk of bias (Nwaru *et al.*, 2014). There were significant differences between self-reported and other categories. Self-reported pooled lifetime prevalence of food allergy was 17.3% (95% CI: 17.0 – 17.6) accompanied by a self-reported point prevalence of 5.9% (95% CI: 5.7 – 6.1). However the point prevalence of sensitisation to one or more foods also differed with category as shown in Table 2.

Table 2: Point Prevalence to \geq allergen by diagnostic category (from Nwaru *et al.*, 2014)

| Assessed by | Point Prevalence | 95 % Confidence Interval |
|-----------------|------------------|--------------------------|
| Specific IgE | 10.1 % | 9.4–10.8 |
| Skin prick test | 2.7 % | 2.4–3.0 |
| Food challenge | 0.9 % | 0.8–1.1 |

Both self-perception and allergic sensitisation (specific IgE) are known to substantially overestimate the actual frequency of food allergy (FA). Overall the data reported by Nwaru *et al.*, appear to indicate that food allergy affects some 1 – 2% of adults and some 5 – 6 % infants and children in Europe. However more studies are needed. Prevalence was greater in north-western Europe than in southern Europe. While the incidence of FA appeared stable over time, there was some evidence that the prevalence may be increasing.

Prevalence of food allergy to specific foods in Europe was investigated again showing significant heterogeneity across fewer studies, Table 3, (Nwaru, 2014b). Allergy to cow’s milk and egg was more common among younger children, while peanut, tree nut, fish, and shellfish were more common among older children.

Table 3: Overall pooled estimates for all age groups lifetime prevalence of allergy

| Food | Self-reported lifetime prevalence allergy, mean and 95 % Confidence Interval | Lifetime prevalence of food challenge defined allergy, mean and 95 % Confidence Interval |
|------------|--|--|
| Cow's milk | 6.0 % (5.7 – 6.4) | 0.6 % (0.5 – 0.8) |
| Egg | 2.5 % (2.3 – 2.7) | 0.2 % (0.2 – 0.3) |
| Wheat | 3.6 % (3.0 – 4.2) | 0.1 % (0.01 – 0.2) |
| Soya | | 0.3 % (0.1 – 0.4) |
| Peanut | 0.4 % (0.3 – 0.6) | 0.2 % (0.2 – 0.3) |
| Tree Nuts | 1.3 % (1.2 – 1.5) | 0.5 % (0.08 – 0.8) |
| Fish | 2.2 % (1.8 – 2.5) | 0.1 % (0.02 – 0.2) |
| Shellfish | 1.3 % (0.9 – 1.7) | 0.1 % (0.06 – 0.3) |

Sicherer and Sampson suggested that food allergy in the USA probably affects nearly 5% of adults and 8% of children, with growing evidence of an increase in prevalence (Sicherer and Sampson, 2014).

Mahesh *et al.*, reported food allergy sensitisation prevalence (sIgE estimation for 24 common foods) among South Indian adults of 26.5% (Mahesh *et al.*, 2016), but actual food allergy was far less common.

Australia appears to have some of the highest global prevalence of food allergy of up to 10% in young children (Prescott *et al.*, 2013). These authors conducted a global survey in 2012 to collect information from all the national member societies of the World Allergy Organization, and some of their neighbouring countries, (total $n = 89$). More than half of the countries surveyed (52/89) did not have any data on food allergy prevalence. Only 10% (9/89) of countries had accurate food allergy prevalence data, based on oral food challenges, (OFC). The remaining countries had data largely based on parent-reporting of a food allergy diagnosis or symptoms, recognised to overestimate the prevalence of food allergy.

Food allergy in Asia has been reviewed based on the literature published between 2005 and 2012 (Lee *et al.*, 2013). The overall prevalence of food allergy in Asia was found to be somewhat comparable to that in the West with egg and cow's milk allergy the two most common food allergies among young children and infants. However, by contrast, shellfish allergy rather than peanut allergy is the most prevalent in Asia, in part due to the abundance of seafood in the diet. Lee *et al.*, (2013) suggest that house dust mite tropomyosin may be a primary sensitiser. Differences also exist within Asia. Wheat allergy, though uncommon in most Asian countries, is the most common cause of anaphylaxis in Japan and Korea, and is increasing in Thailand.

In large and rapidly emerging societies of Asia, such as China there are documented increases in food allergy. The prevalence of oral food challenge (OFC), proven food allergy is around 7% in pre-schoolers, comparable to the reported prevalence in European regions. Comparison of cross-sectional data collected in 1999 and again in 2009 at the same clinic in Chongqing, China, showed a two-fold increase in the prevalence of food allergy, from 3.5% to 7.7% ($p = 0.017$), and skin prick tested, (SPT), sensitisation, from 9.9% to 18.0% ($p = 0.02$). The overall prevalence of challenge-proven food allergy in 0 to 1 year-old children in Chongqing, China was 3.8%, (Chen *et al.*, 2011).

The prevalence rates of adverse food reactions including food allergy were found to be 8.1% (parent-reported) and 4.6% (doctor-diagnosed) in Hong Kong (Leung *et al.*, 2009). The six leading causes of were shellfish (15.8%), egg (9.1%), peanut (8.1%), beef (6.4%), cow's milk (5.7%), and tree nuts (5.0%). When compared with children born and raised in Hong Kong, children born in mainland China had statistically significantly lesser prevalence. The authors concluded adverse food reactions including food allergy are a common atopic disorder in Hong Kong pre-school children, and prevalence rates are comparable to those in Caucasians. Chan *et al.* (2015b) summarising what is known about food allergy prevalence in Hong Kong noted 'probable' food allergy in 2010 in children aged 7 – 10 was 2.8% while in 2012 the prevalence of food allergy in children from birth to 14 years old was 4.8% of which shellfish was by far the commonest alongside egg, milk, peanut and fruits (Chan *et al.*, 2015b). Children with food allergies have 2 – 4 times higher rates of co-morbid conditions including asthma, rhino conjunctivitis and eczema. Interestingly Chan *et al.* (2015b) reported 15.6% of children with food allergies aged 14 years or less are estimated to have a risk of anaphylaxis which is high relative to other countries.

There are over 170 foods known to provoke allergic reactions. Of these, the most common foods responsible for inducing 90% of reported allergic reactions are peanuts, milk, eggs, wheat, nuts (eg, hazelnuts, walnuts, almonds, cashews, pecans, Brazil nuts etc.), soya, fish, crustaceans and molluscs (Boye, 2012). However as indicated above there are differences between regions in the patterns of prevalence. Gendel has helpfully collated the way in which different countries legislate for different allergens, (Gendel, 2012).

A large study by the European Food Safety Authority in 2014 recognised the heterogeneity of prevalence studies but suggested that the most common foods triggering about 75% of allergic reactions among children are from egg, peanut, cow's milk, fish and various nuts. In adults about half of allergic reactions are caused by fruits of the latex group and of the *Rosaceae* family, vegetables of the *Apiaceae* family, and various nuts and peanuts, (EFSA, 2014a).

4.4 Anaphylaxis

Anaphylaxis, a clinical emergency, is an acute, rapid onset, multi-organ systemic allergic reaction with life-threatening airway, breathing or circulatory problems. Anaphylaxis can be caused by any allergic reaction and is relatively common with considerable morbidity (Panesar *et al.*, 2013; Dhami *et al.*, 2014). First-line treatment for anaphylaxis is rapid intramuscular adrenaline (epinephrine) (usually into the thigh) typically, in the community, using the person's own autoinjector. Emergency medical aid must be summoned for a range of second-line interventions (Muraro *et al.*, 2014a). A patient with breathing difficulties should be placed in a sitting position, and if faint or dizzy should lie down with head and heart level and legs elevated. It is crucial that the patient does not stand up as this may result in death from "empty ventricle syndrome".

In children the most common cause of anaphylaxis is food allergy, and deaths from food induced anaphylaxis are particularly shocking. Although fatal food anaphylaxis is rarer than accidental death in the general population, (Umasunthar *et al.*, 2013), hospital admissions from all causes of anaphylaxis increased by 615% between 1992 and 2012 in the UK. Admission and fatality rates for drug- and insect sting-induced anaphylaxis were highest in the age group 60 years and older. In contrast, admissions because of food-triggered anaphylaxis were most common in teenagers and young adults, with a marked

peak in the incidence of fatal food reactions during the second and third decades of life (P19 – 2015 and Gibbison *et al.*, 2012).

It is not possible to predict with precision which allergic individuals are likely to have anaphylactic reactions; however some risk stratification is possible such as coexistent asthma, particularly in children, and a history of previous severe reactions. Adolescents are also at a higher risk of anaphylactic reactions owing to biological and social factors. Other factors such as exercise, presence of infection or alcohol consumption at the time of exposure to the allergen can have an influence and there is also a condition recognised as food-associated, exercise-induced anaphylaxis. Swan *et al.*, (2016) review the prevention and management of anaphylaxis (Swan *et al.*, 2016). The catering sector exhibits particular risks for food related anaphylaxis fatalities, (Leitch *et al.*, 2005).

4.5 Severity of allergic reaction

From the perspective of possible application of thresholds as a risk management option the most important current issue is that of the severity of adverse reactions, including anaphylaxis. Not only does the threshold dose for symptoms vary between individuals and in the same individual over time but many other factors influence the severity of reaction. Timely, effective treatment limits, but does not control, all reactions and Smith *et al.*, (2015) have reviewed the possible risk factors that prompt a mild or a severe reaction. Fatal and severe reactions appear more likely if there is a combination and alignment of risk factors. For a similar dose in patients with equivalent levels of severe food allergy it is possible to envisage different clinical outcomes. A mild reaction would be expected in a patient with less current allergic disease, fewer metabolic factors, fewer contributing medications and early effective use of adrenaline / epinephrine and the converse will amplify a severe allergic reaction. The factors include the following and the paper by Smith *et al.*, should be consulted for further information on the underlying mechanisms:

- asthma – is probably the most significant risk factor for death from food allergy anaphylaxis and pollen season is also implicated;
- allergic disease burden - severe rhinitis and severe eczema appear to be correlated with increased risk of more serious symptoms in anaphylaxis events;
- intercurrent illness –there is evidence of immunological vulnerability with infective illness;

- comprehension and education – will enhance the prevention, recognition and appropriate and timely treatment of anaphylaxis;
- late or absent treatment – failure or delay in administering adrenaline / epinephrine, is considered to be an important and avoidable factor in fatal reactions;
- medication – Beta-blockers, nonsteroidal anti-inflammatory drugs (NSAID) (eg cox-inhibitors), ACE inhibitors and aspirin have been reported as possible contributors to the severity of all forms of anaphylaxis;
- physiological factors – the expression of multiple allergic mediators (eg histamine, interleukins-2, -6 and -10), and serum angiotensin converting enzyme I (ACE) and other enzymes, menstruation;
- the allergen – peanut has been found to cause more severe reactions than other (hazelnut, egg and milk) foods studied;
- concealment of allergen – delayed recognition of an allergenic food caused by lipid matrices gives rise to increased dose exposure; itch and burning from spices could mimic allergic symptoms and confuse the issue;
- age – youth is a risk factor for fatal reactions for a variety of reasons including social and emotional, while older age has been associated with more severe hypoxemia with anaphylaxis episodes and higher risk of severe cardiovascular symptoms;
- exercise – can cause anaphylaxis directly and is a co-factor for food anaphylaxis, best defined as food dependent exercise induced anaphylaxis (FDEIA), exercise is also a physiological state that increases release of mediators (eg serotonin, bradykinin and endorphins);
- alcohol (ethanol) – brings psychosocial and physiological risk factors.

It was also noted there seem to be important co-factors in the community that influence the severity of food allergic reactions outside the controlled clinical setting of a formal food challenge (Smith *et al.*, 2015). A history of severe allergic events including anaphylaxis has been identified as a risk factor for fatal events but about half of a UK series of food anaphylaxis deaths occurred in patients with a history of mild reactions; thus there can be little reassurance based on a history of previous mild reactions (P4 - 2007).

Publications from the Food Standards Agency funded TRACE Peanut Study should be available later in 2018. This study examined peanut thresholds in adults (18-45 years), symptom severity and the impact of two 'extrinsic' or co-factors, exercise and stress induced through sleeplessness, which are both known to influence allergen thresholds. (Gowland has contributed to this study as a member of the project's Trial Steering Committee.)

4.6 Quality of Life

Food allergy results in well-documented detriments to the quality of life (QoL), for allergic consumers and their families and carers (King *et al.*, 2009, Venter *et al.*, 2015). Teenagers in particular do not feel that their peers appreciate the difficulties they face and a significant number demonstrate risk-taking behaviour in the management of their food allergies (Monks *et al.*, 2010). DunnGalvin *et al.*, (2015) categorised adverse QoL impacts in terms of social, dietary, and psychological factors. For those living with food allergy, social events are experienced differently with feelings of exclusion and difference. Children, teens, and parents need to cope with normal developmental changes as well as with the food allergy, placing them under increased psycho-social stress and leading to adverse effects on QoL and coping. Unsurprisingly parents and carers of food allergic children and teenagers 'live on their nerves' and find planning for and participation in school, activities and social occasions such as eating out challenging.



Figure 5: Wordle – Stress and quality of life with food allergy

To address and attempt to alleviate such causes of stress, both quantitative and qualitative research suggests that targeting uncertainty should be a major goal for health professionals working with children, teens and families with a food allergy. Remarkable similarities in response to food allergy across countries suggest that policies and programmes that address quality of life issues may be relevant to many different populations. An in-depth understanding of the relationship between a diagnosis of food allergy and health-related quality of life, (HRQL), as well as the factors that impact it, will ultimately lead to the promotion of earlier, more effective preventive strategies and interventions that are focused on maximising optimal health development and quality of life (DunnGalvin *et al.*, 2015).

In 2017, both the European Academy of Allergy and Clinical Immunology (EAACI) and British Society of Allergy and Clinical Immunology (BSACI) meetings focused on stress and quality of life challenges for those living with food allergy and their carers. Gowland prepared the *Wordle* (Figure 5) to demonstrate this for a mixed clinical and lay audience.

Individuals with nut allergies adopt strategies to make safer food choices. Three main examples were identified by Barnett *et al.*, (2013) as (a) qualities of product such as the product category or the country of origin, (b) past experience of consuming a food product, and (c) sensory appreciation of risk. Risk reasoning and risk management behaviours were often contingent on the context and other physiological and socio-psychological needs which often competed with risk considerations. Stakeholders could benefit from an understanding of these food choice strategies when designing and implementing allergen risk management policies.

4.7 Is there a cure for food allergy?

For those with food allergies, lifelong avoidance of the eliciting food(s) is required. Possible cures for food allergy remain experimental although promising. Studies suggest that peanut oral immunotherapy (OIT) might be effective in the treatment of peanut allergy. A team at Addenbrooke's Hospital, Cambridge, UK, have established the efficacy of OIT for the desensitisation of children with allergy to peanuts. A randomised controlled crossover trial compared the efficacy of active OIT (using characterised peanut flour; protein doses of 2 – 800 mg/day) with control (peanut avoidance, the present standard of care). OIT successfully induced desensitisation in most children

within the study population with peanut allergy of any severity, with a clinically meaningful increase in peanut threshold. Quality of life improved after intervention and there was a good safety profile. Immunological changes corresponded with clinical desensitisation (Anagnostou *et al.*, 2014). These authors recommended further studies in wider populations and that peanut OIT should not be done in non-specialist settings, but it was effective and well tolerated in the studied age group. For further information see Anagnostou and Clark, (2015). Parallel studies and clinical trials involving characterised peanut flour consumption and induced tolerance to peanut via skin patches are also underway.

4.8 Prevention of food allergy

Prevention of food allergy has been classified as primary, secondary or tertiary. Primary prevention would block the initial IgE sensitisation, secondary prevention would interrupt the development of food allergy in those sensitised and tertiary prevention would reduce the expression of end-organ allergic disease in patients with established food allergy. A large proportion of the allergy burden is probably inherited. However genetic predisposition alone cannot explain the disturbing increase in food allergy over an evolutionary short 20 year timespan. Studies on changes in gene function in relation to environmental influences (epigenetic modifications) are beginning to provide evidence to explain the mechanisms underlying the development of food allergy. (Du Toit *et al.*, 2016a)

Sensitisation can occur early in infancy, and it appears that prevention strategies should ideally commence during these early-life periods of immunologic vulnerability. Families can be provided with evidence-based advice about preventing food allergy, particularly for infants at high risk for development of allergic disease. The advice for all mothers includes a normal diet without restrictions during pregnancy and lactation. For all infants, exclusive breastfeeding is recommended for at least the first 4 – 6 months of life. If breastfeeding is insufficient or not possible, infants at high-risk can be recommended a hypoallergenic formula with a documented preventive effect for the first 4 months. There is no need to avoid introducing complementary foods beyond 4 months. There is no evidence to support the use of prebiotics or probiotics for food allergy prevention. In 2014, the evidence did not justify recommendations about either withholding or encouraging exposure to potentially allergenic foods after 4 months once weaning has commenced, irrespective of atopic heredity, (Muraro *et al.*, 2014c).

However two studies 'LEAP-On' and 'EAT' reported in early 2016 are important and reassuring additions to our knowledge about possible prevention of food allergy. 'LEAP-On' studied infants at high-risk of developing peanut allergy ('high risk' was defined as infants at with suspected egg allergy based on skin prick testing, and /or with severe eczema based on a clinical evaluation that combined the extent, severity and subjective symptoms of the eczema, and the treatment required).

The earlier Learning Early About Peanut Allergy (LEAP) study from 2015 found, somewhat counter-intuitively, that the majority of such high risk infants can be protected from peanut allergy at age 5 years if they eat peanut frequently, starting within the first 11 months of life. The LEAP-On findings were that early peanut introduction protection is sustained even when peanut is no longer consumed for 12 months.

Enquiring about Tolerance (EAT) by contrast looked at breast fed infants from the general population and the early introduction of six major allergenic foods, peanut, cooked egg, cows' milk, sesame, whitefish and wheat. There were very encouraging findings that peanut and cooked egg allergy in particular, and food allergies generally were lower with early introduction. Moreover, although not easy, such introduction was found to be safe.

Taken together these are reassuring findings that may pave the way to stem the epidemic of peanut allergy. These studies were carried out under the close guidance of allergy doctors. Parents should not attempt to replicate what the studies did by themselves but should follow general guidance, for example that encourages mums to breast feed, and common sense attitudes to weaning, introducing a wide variety of foods as appropriate. Parents and carers, especially with infants at high risk, should bring any concerns to their family doctors or other medical advisors for advice (Du Toit *et al.*, 2016b, Perkin *et al.*, 2016).

The findings of EAT, LEAP and LEAP-On are currently being assessed and introduced into official guidance and widespread parental practice.

5 Food allergen management – Discussion

Businesses too have found the emergence of food allergy challenging. New systems of traceability (Millard, 2015), management and segregation (Stein, 2015), cleaning (Nikoleiski, 2015), and communication (Flanagan, 2015) have been required. Key industry standards (eg BRC, 2015) emphasise greater transparency, traceability and integrity in the supply chain. At the same time incidents and recalls have burgeoned with associated management time, costs and reputational damage (Walker, 2012). The EU-funded project developing Integrated approaches to food allergen and allergy management (iFAAM), found over 2000 food allergen recalls recorded in the period 2011-2014 based on publicly available information in Europe, North America, Hong Kong, Australia and New Zealand. The biggest incidence of undeclared allergens was found to be for milk and milk products (16 – 31% of all products with recall or alert), followed by cereals containing gluten (9 – 19%), soya (5 – 45%) and egg and egg products (5 – 17%). Between 42 and 90% of the products with recalls/alerts were explained as being 'Not indicated on the label. However, 0 – 17% of products with recalls/alerts were coded as caused by the unintended presence in production of an allergen as the probable result of cross contamination, (described by some in the food industry as 'cross-contact') (Bucchini *et al.*, 2016).

It is important to distinguish risk assessment and risk management of food allergy from risk assessment and risk management of food allergens. The former involves patients, families and carers and health care professionals. The latter is a task for all stakeholders, particularly the food industry, regulators, analytical service providers, and food suppliers eg caterers, carers and consumers.

The responsibility for safe and properly labelled food rests with those who make and sell it. The Codex Alimentarius General Standard for the Labelling of Prepackaged Foods harmonises globally the concept of mandatory disclosure on prepacked food labelling of the presence of allergens, with a list of eight major allergens. Gendel has helpfully reviewed country-specific implementation of Codex requirements on allergens (Gendel, 2012). The food industry seeking to provide safe products, consumer choice and subject

to the law must label products accurately and minimise cross-contamination in harvesting, storage, transport, processing of food and cleaning of equipment. The development of 'allergen-free' product lines places a particular burden of responsibility on allergen control. For food businesses there are potentially serious financial impacts and reputational risks of increased food recalls. Compensation in civil law for loss or damage caused by an allergic reaction to a food supplied is a foreseeable risk for food businesses. European food law aims for a high level of protection of human health and consumers' interests. Article 8 of Regulation (EC) No 178/2002 prohibits adulteration of food and fraudulent, deceptive or any other practices which mislead consumers. Article 14 (of the same regulation) prohibits the sale of unsafe food such as food injurious to health, including the particular health sensitivities of any specific category of consumers (eg but not exclusively people with food allergy) where the food is intended for that category of consumers. More specifically, Regulation (EU) No 1169/2011 addresses allergen avoidance risks relating to composition, labelling and food safety. The inclusion in prepacked food of any of 14 major allergens defined by Annex II to Regulation 1169/2011 EC (replacing Annex IIIa to Directive 2000/13/EC) triggers, with certain limited exemptions, specific labelling requirements extended on 13 December 2014 to non-prepacked food, including catering establishments. Cross-contamination with allergens may trigger general principles of European and UK food law that make it an offence to sell food that is unsafe for, or not of the nature, substance, or quality demanded by, allergic consumers, particularly if specifically intended for their consumption. Hence the food industry must know whether allergens are present in their products and / or production environment and work out ways of controlling them or alerting consumers to the possible risk of their presence through advisory labelling. Allergens in the 'wrong place' can render food unsafe for people with food allergy. The effect of requiring certain allergens to be labelled / highlighted is to prioritise controlling them in the supply chain.

However there are many other foods that provoke allergic reactions than are legislated for. Thus foods not listed in legislation as priority allergens must still be managed when known to be allergenic for some people. The UK Food Standards Agency (FSA) has published comprehensive best practice guidance on allergen cross-contamination and 'may contain' labelling and innovative online food allergy training that is available via <http://allergytraining.food.gov.uk/english/> . The training includes factory and non-

prepacked food scenarios, including catering, and aims to provide a greater understanding of the issues surrounding enforcing relevant legislation in the area of food allergens for local authority enforcement officers. The online food allergy training course was launched in 2008. FSA guidance was published in August 2014 to help small and medium-sized enterprises (SMEs) comply with new rules on allergen labelling (Gowland and Walker, 2015 **P18 - 2015**). There is an urgent requirement for effective communication between healthcare professionals, patient organisations, food industry representatives and regulators to develop a better approach to protecting consumers with food allergies (Muraro *et al.*, 2014b). A framework for categorisation and prioritisation of allergenic foods according to their public health importance has been proposed (Houben *et al.*, 2016).

5.1 Processing

Food processing has many beneficial effects. However, processing may also alter the allergenic properties of food proteins. It is now well known that roasting increases the allergenicity of peanuts compared to raw. A wide variety of processing methods is available and their use depends largely on the food to be processed. Verhoeckx *et al.*, (2015) reviewed the impact of processing (heat and non-heat treatment) on the allergenic potential of proteins, and on the antigenic (IgG-binding) and allergenic (IgE-binding) properties of proteins. A variety of allergenic foods (peanuts, tree nuts, cows' milk, hens' eggs, soya, wheat and mustard) were reviewed. The overall conclusion was that processing does not completely abolish the allergenic potential of allergens. Currently, only fermentation and hydrolysis may have the potential to reduce allergenicity to such an extent that symptoms will not be elicited, while other methods might be promising but need more data. Literature on the effect of processing on allergenic potential and the ability to induce sensitisation is scarce. This is an important issue since processing may impact on the ability of proteins to cause the acquisition of allergic sensitisation, and the subject should be a focus of future research. Thus, there remains a need to develop robust and integrated methods for the risk assessment of food allergenicity (Verhoeckx *et al.*, 2015). Processing may also have a profound impact on protein structure influencing solubility and hence extractability in an analytical process. (Walker *et al.*, 2016)

5.2 Precautionary Allergen Labelling

A consequence of the absence of an accepted risk assessment and risk management framework for allergens has been the proliferation of precautionary allergen, 'may contain', labelling (PAL). Wide variation persists in PAL wording, with an estimated 25 different variants of PAL in use, see for example, Hirst, (2014). Within the wide variation there are two principal formats for PAL:

- May contain (X) – this is the simplest format, providing information and with fewer words to take up packaging space,
- Not suitable for people avoiding (X) – the food supplier adopting a more directive approach.

A qualitative study (Barnett *et al.*, 2011 **P9 – 2011**) indicated consumers with peanut and/or tree nut allergies adopt a complex range of responses and strategies to interpret PAL. They take into account not only the detail of the labelling but also external factors such as the nature of the product, the perceived trustworthiness of the producer and the previous experience of the person affected.

Analytical methods for the presence of allergens in food have been used to assess foods on sale carrying PAL to determine the actual presence of unintended allergens. Hirst, (2014), indicated that of foods carrying PAL the total percentage of samples tested in which no allergen was detected was 19% for gluten, 18% for milk, 44% for hazelnut and 45% for peanut. It is therefore understandable that some consumers, basing their decision-making on previous experience may choose to ignore PAL warnings. Thus the prevalence and variation of precautionary labelling, although intended to assist the consumer in their food choices, is increasingly considered as problematic for food allergic consumers. It is vital that food producers continue to undertake risk assessment for allergen contamination and seek to use clear 'contains' or 'does not contain' labelling wherever possible, using the advice available (Health Canada, 2012, Boye and Godefroy, 2010, FSA, 2006, FSA 2016). It is also clear we need to take into account the rich range of reasoning that consumers draw on to make and justify their decisions to consume products bearing PAL (Barnett *et al.*, 2013).

It is not surprising therefore that recent global stakeholder reviews view PAL in its current form as counter-productive for consumers with food allergies and call for

standardisation of PAL, (DunnGalvin *et al.*, 2015, Zurzolo *et al.*, 2016, Turner and Gowland, 2016 **P2 - 2016**). Stakeholders agree that the lack of agreed reference doses has resulted in inconsistent application of PAL and withdrawal action by enforcement authorities. This has led to a loss of trust in PAL, reducing the ability of consumers with food allergies to make informed choices. The result has been reduced avoidance, reduced quality of life and increased risk-taking by consumers who often ignore PAL. All contributing stakeholders agree that PAL must reflect actual risk. PAL should be transparent and consistent with rules underpinning decision-making process being communicated clearly to all stakeholders. The use of PAL should indicate the possible, unintended presence of an allergen in a consumed portion of a food product at or above any proposed action level. This will require combined work by all stakeholders to ensure everyone understands the approach, and its limitations. Marchisotto *et al.*, (2016) in a study of global perceptions of food allergy thresholds in 16 countries found that understanding of food allergen thresholds and precautionary allergen labelling is limited and consumers may develop their own risk assessment strategies based on interpreting labels, which are not based on clinical validation. Improved awareness of thresholds, standardisation of PAL, and clinical validation are needed globally. Consumers with food allergy will then need to be advised and empowered to undertake individualised risk assessments in relation to any PAL present.

Before looking at reference doses, action limits and thresholds, we should consider some traditional toxicology.

5.3 Basic Toxicology

Although for the majority of the population food allergens are not hazards for those with food allergy the allergen to which they are sensitised acts as a toxin when ingested. The assessment and management of the risks that potentially hazardous compounds may pose if present in food are dealt with by the science of toxicology. Examples include food additives, and contaminants including metals, pesticides, veterinary residues and naturally occurring toxins such as mycotoxins (Walker and Wong, 2014). International and national bodies that deal with food and consumer safety include the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization (FAO), the World Health Organization (WHO), the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA). Although the toxicology paradigm has not always been viewed as suitable to deal with allergy various authors have investigated its

application to attempt risk assessment and risk management of food allergens (Crevel, 2015). A full treatment of toxicology is beyond the scope of this section. However some discussion of basic concepts may be helpful.

The process of risk assessment is shown in Figure 6 which shows the inter-relationship with risk management and risk communication.

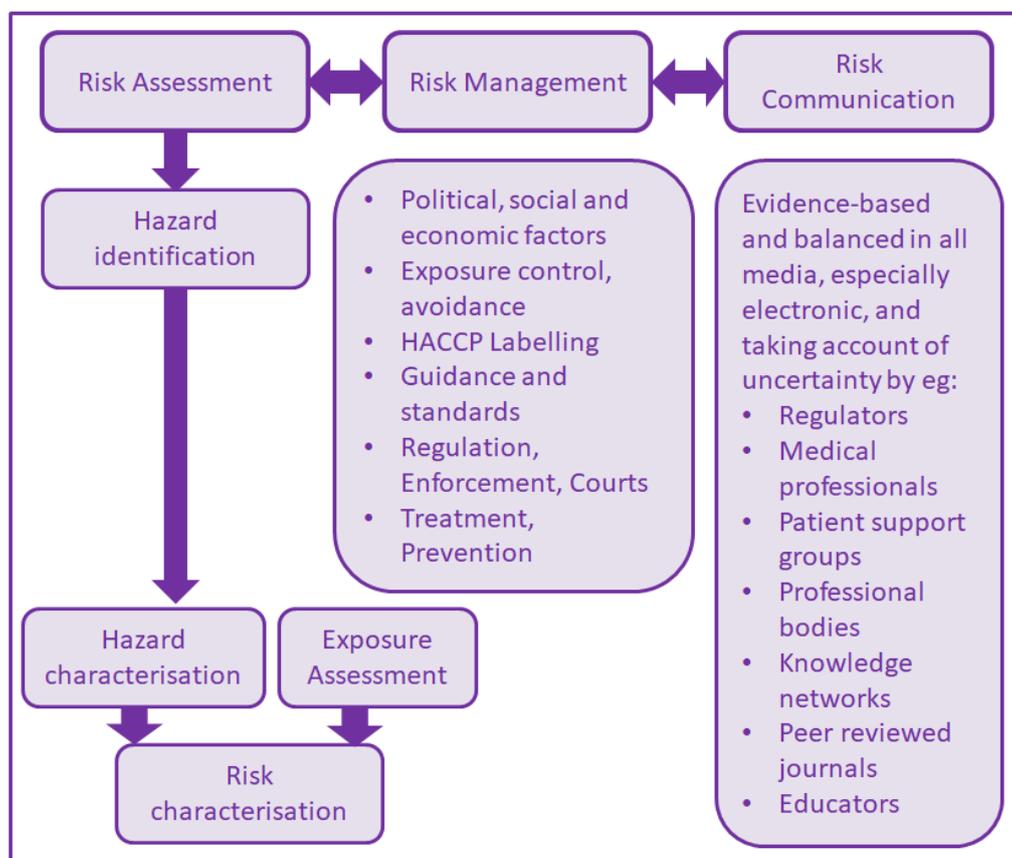


Figure 6: Risk assessment, management and communication

Toxicological risk assessment begins with the identification of the hazard – “the identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system or (sub)-population” (EFSA, 2014b) – usually through epidemiological or animal studies. Food allergy differs in the availability of human clinical data. Recognition of a clinical allergy hazard occurred over 100 years ago (Igea, 2013) but only since the mid-1990s has food allergy been widely regarded as a public health issue (Crevel, 2015). The *Codex Alimentarius* General Standard for the Labelling of allergens lists eight major allergens of global significance (Codex Alimentarius, 2010) while country-specific variations exist, (Gendel, 2012). The

European Union lists the largest number of allergens that are considered sufficiently serious to warrant legislative attention (Table 4). Traditional toxicological exposure assessment attempts to identify potential or completed exposure pathways resulting in contact between the toxin and at-risk populations. It also includes demographic analysis describing the properties and characteristics of at-risk populations that potentiate or mitigate concern and description of the magnitude, duration, and frequency of exposure (Baynes, 2010). Thus, although cumulative exposure appears not to be an issue, many aspects of exposure assessment are problematic for food allergy, such as prevalence, severity, actual cross-contamination concentrations and unbiased analysis.

Table 4: Food Allergens

| Codex Alimentarius¹ | European Union² |
|--|--|
| Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these | Cereals containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof |
| Crustacea and products of these | Crustaceans and products thereof |
| Eggs and egg products | Eggs and products thereof |
| Fish and fish products | Fish and products thereof |
| Peanuts, soybeans and products of these | Peanuts and products thereof |
| Milk and milk products (lactose included) | Soybeans and products thereof |

Tree nuts and nut products

Milk and products thereof (including lactose)

Sulphite in concentrations of 10 mg/kg or more

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

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

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

Lupin and products thereof

1. CODEX STAN 1-1985, General Standard for the Labelling of Pre-packaged Foods

2. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011, Annex II. Please see Annex II for certain exemptions to some of the entries.

These are subject to change and the latest versions should be examined in Codex Alimentarius and Eur Lex respectively

NB – At the time of writing, there is a proposal being addressed by the Codex Committee on Food Hygiene (CCFH) to develop a code of practice to provide guidance to governments and food businesses to manage allergens in food production (Codex Alimentarius 2018)

Hazard characterisation is “the qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects” (EFSA, 2014b). Hazard characterisation should, where possible, include an assessment of dose-response and an evaluation of uncertainties (WHO, 2009). Dose-response is one of the fundamental concepts in toxicology “...the dose makes the poison...” attributed to Paracelsus (1493 – 1541), (Borzelleca, 2000).

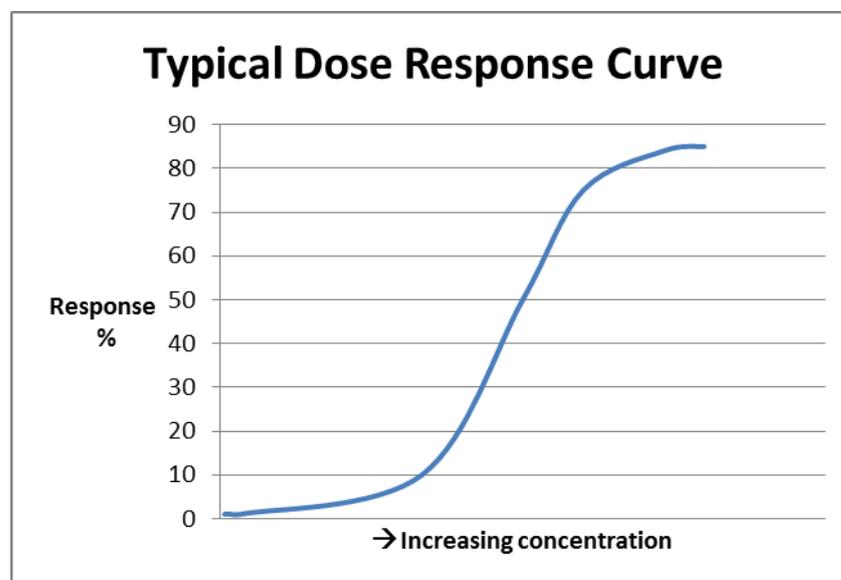


Figure 7: Typical Dose response curve

A typical dose-response curve is illustrated in Figure 7 in which the percentage of responding organisms is plotted against the dose or concentration of the compound. The focus of risk assessment is generally on the lower regions of the dose response curve where it is expected that people are realistically exposed. This is often below the experimentally observable range. Chemicals that pose a cancer risk are dealt with differently, but for many chemicals which do not pose a cancer risk there are concentrations below which no response is observed. This is because protective mechanisms are believed to exist that must be overcome before an adverse effect is manifested. The extent to which this is the case for food allergy and the mechanism(s) that underlie any such tolerance are interesting questions.

The aim in risk assessment is to identify the upper bound of this tolerance range to obtain a no observable adverse effect level (NOAEL). The NOAEL is the highest dose level that does not produce a significant elevated increase in an adverse response. Significance refers to biological and statistical criteria and depends on factors such as dose levels tested, number of animals exposed in animal studies, and background incidence in the non-exposed control groups. Sometimes, there are insufficient data to arrive at a NOAEL, and a LOAEL (lowest observed adverse effect level) is derived. The NOAEL is the key datum obtained from the study of the dose – response relationship and is known as the threshold dose. This concept is of significance because it implies that a NOAEL can be used to determine intakes for food additives and contaminants that should be protective of the majority of consumers.

In mainstream toxicology the NOAEL is used to calculate a reference dose (RfD) for chronic oral exposures and, divided by a 'safety factor' or 'uncertainty factor' to calculate acceptable daily intakes, (ADI), for food and feed additives and pesticides and the Tolerable Daily Intake, TDI, for contaminants and chemicals in food contact materials. For acute effects, the Acute Reference Dose (ARfD) can also be calculated. The safety / uncertainty factor is often 100 to allow for inter-species and inter-individual variability in toxicokinetics and toxicodynamics.

The RfD is an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily exposure to the human population, including sensitive subgroups that is likely to be without appreciable deleterious effects during a lifetime. The calculated RfD is based on the selected critical study and selected critical end point. The risk assessor may obtain numerous studies where the toxicant may have more than one toxic end point and thus

there may be many NOAELs to choose from in the literature. In some instances, even poor data quality may be used to exclude some end points from consideration. Also at issue is determining what is considered an adverse effect, ranging from reversible cellular changes to death. In effect, the RfD is based on the less serious effects rather than serious effects.

Chemicals that are difficult to deal with by traditional toxicology are those that are both genotoxic and carcinogenic where in theory one molecule may initiate a tumour. This tumour initiation may not in practice happen, it is thought, owing to DNA repair and other protective mechanisms. To address these compounds a 'Margin of Exposure' (MOE) approach has been developed. MOE can be used to support prioritisation of risk management action and, if the MOE is very large, communication of a low level of human health concern. However it is essential that the selection of the cancer endpoint and mathematical treatment of the data are clearly described and justified if the results of the MOE approach are to be trusted and of value to risk managers.

5.4 Allergen Reference Doses, Action Limits and Thresholds

There is a general duty of care on the food industry and obligations in global legislation to reduce and manage the presence of allergens alongside other food hazards. Current evidence appears to enable the establishment of allergen reference doses which might be translated into action limits or population thresholds to underpin reliable food safety management plans for some foods. However, further work is required to include a wider variety of foods and to understand the impact of the food matrix as well as additional factors which affect the progression and severity of symptoms as a function of dose. There is an urgent requirement for effective communication between healthcare professionals, patient organisations, food industry representatives and regulators to develop a better approach to protecting consumers with food allergies (Muraro *et al.*, 2014b). Below we examine the development of ‘thresholds’ and speculate on their future development.

A reminder or introduction of some definitions may assist at this point.

- Threshold – “dose or exposure concentration of an agent below which a stated effect is not observed or expected to occur. It lies in an interval bounded by the LOAEL (upper) and NOAEL (lower)”. Taylor *et al.* (2002) defined the threshold dose as “ ... the lowest amount of the offending food that would elicit mild, objective symptoms (eg, mild urticaria, erythema, and oral angioedema) in the most sensitive individuals.” Thus it is important to note that we are discussing thresholds of elicitation rather than thresholds of sensitisation (Crevel *et al.*, 2014a). The latter topic is one which is important but much more difficult and outside the scope of this work.
- Reference dose – an estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. In the case of allergens, since acute exposure defines risk for adverse deleterious effect, the exposure estimate is derived from amount per eating occasion.
- Dose distribution – A plot of the cumulative proportion of (allergic) individuals reacting as a function of dose, based on their minimum eliciting doses.
- Eliciting dose – the dose (in a dose distribution) which is predicted to provoke reactions in a defined proportion of allergic individuals, commonly stated as the eliciting dose (ED_p) for a percentage of the allergic population p . Thus ED_{50} is the dose of an allergen that will cause a reaction in 50% of the population. ED_5 and

ED₁ are the respective eliciting doses that would be expected to be protective of 95 % and 99 % of the allergic population. A 'minimum eliciting dose' is the minimum dose that elicits an effect in an individual in a challenge study – equivalent to an individual's LOAEL.

- Action level – the concentration of an allergen in a product above which some risk management must be carried out, eg further efforts to eliminate cross contamination and below which a precautionary label is deemed unnecessary.

In a series of studies Crevel and colleagues have developed the concepts of risk assessment for food allergens that are not used as ingredients in food but arise through cross contamination at harvest, transport, storage or processing. This is also known as 'cross contact' or 'adventitious presence' but the term 'cross contamination' suggests the unwanted nature of the allergen, although the concepts developed to deal with these issues are also applicable to low concentrations of deliberately added ingredients.

Towards the latter part of the 20th century it was questioned whether the nature of food allergens precluded risk assessment by classical toxicology such as dose-response relationships. This was challenged by studies by Hourihane and colleagues working initially on highly refined peanut oil (Hourihane *et al.*, 1997a). This was followed by the first study of peanut allergic subjects deliberately to attempt to determine a threshold dose, (Hourihane *et al.*, 1997b) and a paper on the threshold concept in food safety and its applicability to food allergy (Hourihane, 2001). Hourihane *et al.* administered peanut to 14 subjects in doses from 10 µg to 50 mg, in the form of a commercially available peanut flour. The highest dose of peanut, 50 mg was well below previous published levels of reactivity (Hourihane *et al.*, 1997b). The other innovation was the interspersing of placebo doses between the active doses so that in total 12 active and 12 placebo doses were given in random sequence. This contrasted with previous routine challenge practice of two separate active and placebo challenge series. These authors concluded that even in a group of well-characterised, highly sensitive subjects with peanut allergy, the threshold dose of peanut protein varies. As little as 100 µg of peanut protein provoked symptoms in some subjects with peanut allergy.

A review of the introduction to toxicology indicates that the 'toxicology' of allergens may be described in similar terms. Thus hazard identification occurs retrospectively because

individuals are reported to react to a food in a manner consistent with an allergic reaction mediated by IgE. Hazard identification may then be undertaken through demonstrating IgE binding to individual proteins in the food and confirmatory tests including clinical controlled oral challenges in affected individuals. In this respect allergen hazard identification resembles microbiological hazard identification, which relies principally on epidemiological and surveillance data rather than prospective studies in animals. Hazard characterisation for food allergens thus relies on human data, obviating the uncertainties of animal to human extrapolation of toxicological studies. However, human data also brings ethical and practical constraints in conducting studies that rely on volunteer participants which limits both the amount and type of data that can be generated. Exposure assessment to allergens differs from chemical risk assessment in that it relates to the amount consumed on a single eating occasion, or within a relatively short period of time, rather than long-term exposure; again this resembles microbiological risk assessment.

Nevertheless, the work of Hourihane and colleagues described above paved the way for Taylor and colleagues to ask the question “How much is too much?” Taylor *et al.* (2002) described a 1999 roundtable discussion among clinical allergists and other interested parties to share data on threshold doses and to discuss clinical approaches for the acquisition of such data (Taylor *et al.*, 2002). It is worth discussing this work in detail because several key concepts were articulated that merit consideration now and in the future.

Although Taylor *et al.* identified considerable clinical data on threshold doses for peanut, cows’ milk, and egg, with limited data for other foods, such as fish and mustard, these data were often obtained by means of different protocols. Hence the estimation of a threshold dose proved difficult and development of a standardised protocol for clinical experiments to allow determination of the threshold dose was recommended. This subsequently was developed (Bindslev-Jensen *et al.*, 2004).

Taylor *et al.* noted for all practical purposes, allergists had always assumed that the threshold dose for the food to which a patient was allergic was zero and prudently advised patients to adhere to specific avoidance diets. Clinicians thus needed thresholds

adequately to advise their patients. Equally, such zero tolerance created enormous practical problems for the food industry, eg shared equipment necessitates clean down to prevent cross contamination. This led Taylor and colleagues to a second question: “ ... how clean is clean enough?”

Taylor *et al.* defined the threshold dose as “ ... the lowest amount of the offending food that would elicit mild, objective symptoms (eg, mild urticaria, erythema, and oral angioedema) in the most sensitive individuals” (Taylor *et al.*, 2002). They also noted the threshold as variable, possibly over an order of magnitude or more between different individuals with the same type of food allergy. Factors contributing to this variability were considered to include exercise, alcohol, and acetylsalicylic acid and the threshold doses for different allergenic foods were recognised as not necessarily equal. Anecdotally, threshold doses were recognised as very small but little or no quantitative information was available. Presciently Taylor *et al.* attributed paucity of quantitative data to the lack of simple methods for the analysis of the implicated food product for residues of commonly allergenic foods and absence of validated, collaboratively studied, standard methods. The best estimates of the threshold dose for various allergenic foods can be obtained from controlled clinical challenge trials. In only a few cases were such trials intended specifically to determine the threshold dose. More frequently, challenges have been conducted for diagnostic purposes rather than for determining the lowest provoking dose.

Taylor *et al.* listed the lowest provoking doses they had found from the clinical data gathered from DBPCFCs, some single-blind, placebo controlled food challenges (SBPCFCs) and open challenges used for diagnostic purposes. The data were cited as the whole food and in terms of protein. For peanut protein lowest provoking doses ranged from 0.25 mg to 100 mg peanut protein, data for egg protein ranged from 0.13 mg to 200 mg and data for milk spanned 0.6 mg milk protein to 180 mg milk protein. Interestingly data for fish were cited only as the food itself, no conversion to protein having proved possible owing to lack of data on the protein content of the fish used. Taylor *et al.* concluded that threshold doses for commonly allergenic foods are finite, measurable, and above zero, however, no attempt to reach consensus on the threshold

doses was made at that time. This was owing to the different protocols used to obtain the data but largely because data were mainly LOAELs rather than the more useful NOAELs, the highest dose in the DBPCFCs that did *not* elicit an adverse reaction. The most sensitive patients involved in these challenge trials reacted to the first and lowest dose used. These authors questioned if the acknowledged exclusion of some of the most seriously affected patients (i.e., those with histories of anaphylaxis) from the trials implied that the patients selected for DBPCFC may not be representative of the entire population of individuals with allergies. They speculated if uncertainty factors might need to be applied to NOAELs to determine threshold doses to account for this. The age and body weight of the patients and the nature of the challenge materials were other factors to be considered - standardisation of challenge materials and the vehicles in which they were presented were recommended. Importantly Taylor *et al.* listed the typical amounts of protein in challenge materials noting conversion between doses expressed as the food and as allergen protein required some important assumptions regarding appropriate conversion factors. For example, the proportion of the major egg allergens Gal d 1 and Gal d 2 as a function of total protein would be higher in egg white than in whole egg. More reassuringly for peanut, little difference appeared to occur in the specific allergen content as a function of variety or agronomic conditions. The conversion data used by Taylor *et al.* included:

- Peanut flour is assumed to contain 50% protein unless the value is specifically known;
- Liquid egg white has an average protein content of 10%;
- Dried egg white has an average protein content of 90%;
- Whole egg has an average of 13% protein on a liquid basis and 50% protein on a dry basis;
- Cows' milk formula is estimated to contain 15 g of milk protein per litre.

The fullest possible reporting of such data and trial conditions (eg single or double blind, or open) remain essential to current and future derivation of useful threshold data. Taylor *et al.* concluded that the threshold doses for peanut, egg, and cows' milk appeared to be in the low milligram range or higher for most individuals with allergies to those particular foods. Thus these individuals can (and probably do) ingest foods, on occasion, containing lower amounts of their offending food without any untoward reactions. They recommended international efforts to establish threshold doses for

commonly allergenic foods using standardised clinical challenge protocols and as wide a range of affected patients as possible.

Much work has been done since the initial investigations of Hourihane, Taylor and colleagues culminating in a series of papers in the first two decades of the 21st century that appear to point the way forward in risk assessment for food allergens.

In a 2007 workshop organised by EuroPrevall, the U.K. Food Standards Agency, and International Life Sciences Institute (ILSI)-Europe, three main, non-mutually exclusive risk assessment approaches were identified (Madsen *et al.*, 2009):

- (1) Use of the NOAEL and/or the LOAEL with application of uncertainty factors,
- (2) the Benchmark dose and margin of exposure (MOE) approach, and
- (3) the use of probabilistic models

In the U.S. in 2008, the Threshold Working Group of the FDA also considered multiple approaches:

- (1) defining a limit by statute,
- (2) applying analytical limits of detection (as was done for the sulphites group in the European list of legislated allergens)
- (3) a deterministic approach with uncertainty factors, and
- (4) quantitative approaches including probabilistic modelling.

It is clear that quantitative probabilistic risk assessment provides the strongest scientific approach but is the most data-intensive, with current lack of sufficient data for many allergens and the least transparent to all stakeholders, particularly non-scientists.

Hattersley *et al.*, (2014) reviewed developments in allergen risk assessment. The first author was at the time head of the Food Allergy and Food Intolerance team at the UK Food Standards Agency and widely trusted for as a transparent precautionary member of the regulatory community. FSA has maintained a position at the forefront of food allergy research and regulation. Hattersley *et al.* concluded that all stakeholder groups now recognise that zero risk is unrealistic. It is to be noted that not all those with food allergy, or their parents or carers are prepared to accept that zero risk is unrealistic. However Hattersley *et al.* felt it was accepted that classical toxicological assessment and

management principles of risks from chemicals or microorganisms in food could be applied to allergens in foods. Crevel and colleagues (Crevel *et al.*, 2014) have described two approaches – ‘deterministic’ and ‘probabilistic’. In the deterministic approach action levels are derived from reference doses, food intake and contamination data by a simple arithmetical method explained below. In the probabilistic approach modelling is used to derive action levels using food intake and minimum eliciting dose distributions, as well as a certain accepted residual risk level as a starting point.

5.5 Deterministic allergen risk assessment

This approach can be used when no or limited data are available on the consumption of the food of interest or its distribution. It is also more practical for the food industry. Action levels can be calculated from an ED value derived from a reference dose and an assumed intake (portion size). This is the approach used by the Allergen Bureau, established on a membership basis in 2005 by the Australian Food and Grocery Council. The Allergen Bureau Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Programme is a standardised allergen risk assessment process for food industry (Taylor *et al.*, 2014, Allen *et al.*, 2014, <http://allergenbureau.net/about-us/>). It is used in Australia and New Zealand but has yet to gain widespread acceptance globally. The VITAL system is free to download and should be consulted in full. It operates under the following broad principles:

- Intentionally added allergens must be declared on the product label (eg in the List of Ingredients according to local law).
- Action Levels are the concentrations which define the labelling outcomes for each concentration of cross contact allergen. They are determined using the Reference Dose and the Reference Amount / Serving Size.
- Cross contact must be reviewed for opportunities to reduce or eliminate cross contaminant allergens from the product.
- Where cross contaminant allergens cannot be eliminated, they should be labelled as specified by the appropriate Action Level:
- Action Level 1 – precautionary cross contact statement is not required for the relevant allergen under evaluation

- Action Level 2 – precautionary cross contact labelling statement is required for the relevant allergen using the standard VITAL statement.
- Precautionary labelling should only be used after a thorough assessment of the risk. Precautionary cross contact statements must NEVER be used as a substitute for good manufacturing practice (GMP) or as a generic disclaimer. Every attempt must be made to eliminate or minimise cross contact by adhering to GMP
- The ONLY precautionary statement to be used in conjunction with VITAL is: “May be present: name of allergen”

The calculation of action levels is as follows.

$$La = 1000 \times \frac{Rd}{Ar}$$

where

La is the Action Limit above which risk management must take place and below which risk management is less likely to be required; Rd is the reference dose, in milligrams, mg, i.e. the milligram protein level (total protein from an allergenic food) below which according to current data only the most sensitive individuals (between 1% and 5% depending on the quality of the data set available) in the allergic population are likely to experience an adverse reaction, and Ar is the reference amount (in grams, g) – usually defined by manufacturer and the maximum amount of a food eaten in a typical eating occasion. This may be the same as the “serving size”.

A table of reference doses for 12 major allergens can be found in Muraro *et al.* (2014b).

As a worked example let us estimate an action level for peanut in a 400 g meal containing meat and 100 g of sauce. Let us suppose there is a risk of peanut flour gaining access to the sauce in the supply chain of the ingredients. How can we use an action level to appraise the results of analytical testing of the product? The data need to use the above equation are:

Rd for peanut is ED₀₁ for peanut protein of 0.2 mg; Ar is 100 g

$$\text{Thus } La = 1000 \times \frac{0.2}{100} = 2 \text{ mg kg}^{-1} \text{ peanut protein.}$$

That is to say, a concentration of more than 2 mg kg⁻¹ (ppm) peanut protein in the sauce is a risk for at least 1 % of the peanut allergic population and risk management measures are required. The 'dilution' of the sauce by the meat, which could be separately tested and assessed may give a margin of error but bear in mind the uncertainty in the ability to measure peanut protein in the sauce may approach ± 50%.

Does this mean that if we find less than 2 mg kg⁻¹ (ppm) peanut protein in the sauce the meal is safe for peanut allergic consumers? This is not so easy a question to answer, especially if the inadvertent presence of peanut is not homogenous – particulate peanut fragments rather than peanut flour.

In practice, the food industry may be nervous of the deterministic approach. An ED₀₁ has an underlying risk that 1 in 100 allergic individuals will have a reaction; Is this an acceptable balance of risk? It may be acceptable to a food business selling 1,000 units a week, but not to a food business selling 100,000 units a week. Food retailers may be tempted to, and probably do, opt for the analytical limit of detection as a default action limit, which may not bear any relation to true risk. Thus we need to factor in sales and consumption as a measure of exposure, and the percentage of the population who have the allergy.

5.6 Probabilistic allergen risk assessment

Some of the above questions may be addressed by the probabilistic approach. Spanjersberg *et al.* (2007) developed a quantitative risk assessment model for allergens based on probabilistic techniques and presented a case study, hazelnut proteins in chocolate spread.

Kruizinga, *et al.* (2008) performed a sensitivity analysis on a previously developed probabilistic model to predict the likelihood of an allergic reaction due to unintended exposure to food allergens to identify which parts of the model most influence the output (Kruizinga, *et al.*, 2008). The model included the proportion of the population which is allergic, the proportion consuming the food and the amount consumed, the likelihood of the food containing an unintended allergen and its concentration, and the minimum eliciting dose distribution for the allergen. A shift in the distribution of the minimum eliciting dose reflecting a more potent allergen, and an increase in the

proportion of the population consuming a food, increased the number of estimated allergic reactions considerably. In contrast, the number of estimated allergic reactions hardly changed when the minimum eliciting doses were based on a more severe response, or when the amount of food consumed was increased.

Spanjersberg *et al.* (2010) prompted by a severe allergic reaction in a cow's milk protein allergic patient to a dark chocolate product containing undeclared milk protein applied probabilistic modelling to investigate to what extent allergen concentrations of unlabelled products reach levels that are of public health relevance. The concentrations of milk proteins in the complaint sample and a collection of products of other batches and brands purchased from different stores were determined. Together with appropriate threshold and food consumption data, the risks of allergic reactions and the severity of these reactions within the adult milk-allergic population were determined using probabilistic risk assessment techniques. The results showed that milk protein concentrations in unlabelled products reach levels that may elicit allergic reactions in up to 68% of the adult milk allergic consumers.

Rimbaud *et al.* (2010) reported a quantified risk assessment of the consumption of peanut in chocolate products. The occurrence of unintended peanut protein in chocolate and the dose-response relationship were estimated with a Bayesian approach using available published data. The consumption pattern was described by a French individual consumption survey. Risk simulations were performed using second-order Monte Carlo simulations, which separately propagated variability and uncertainty of the model input variables. Peanut allergens were found to occur in approximately 36% of the chocolates, leading to a mean exposure level of 0.2 mg of peanut protein per eating occasion. The estimated risk of reaction averaged 0.57% per eating occasion for peanut-allergic adults. The 95% values of the risk were between 0 and 3.61%, which illustrates the risk variability. The conclusion was that unintended peanut allergens induce a risk of reaction for a part of the French peanut-allergic population. The method was considered to be capable of generalised development to assess the risk due to the consumption of every foodstuff potentially contaminated by allergens.

Rimbaud *et al.* (2013) revisited this topic. Food products analysed for the possible presence of peanut traces in scientific literature were selected. For each foodstuff, the allergic risk associated with their consumption was estimated using the French

individual food consumption survey, representative of the general French population. An internet survey on the attitudes of peanut-allergic individuals toward food precautionary labelling was conducted. For three foodstuffs, the allergic risk was then refined integrating the information on specific food behaviours of French allergic individuals. Considering the mean probability, inadvertent presence of peanuts was identified in 20% to 37% of products. Adults were exposed to up to 12.5 mg of peanut protein on 97.5% of their eating occasions. The mean risk of reaction ranged from 0.2 % to 2.4%. Considering eating occasions for all the products, 1.5% of the peanut-allergic adults would have at least one allergic reaction in a week. This demonstrated the benefits of integrating all available information to underpin decision making in the area of food allergen cross-contamination and highlighted the need to generate more data to further refine the risk assessment for the benefit of allergic consumers.

Crevel *et al.* (2014a) reviewing the development of risk assessment for food allergens noted dose distribution modelling of minimum eliciting doses permitted the quantification of the risk of reaction at the population level and has been readily integrated with consumption and contamination data through probabilistic risk assessment approaches to generate quantitative risk predictions. These authors discuss the strengths and limitations of this approach and identify important data gaps, which affect the outcomes of these predictions. These include consumption patterns among allergic individuals, analytical techniques and their application, severity-dose relationships, and the impact of extraneous factors which alter an individual's physiology, such as infection or exercise. Nevertheless, Crevel *et al.* conclude application of these models has provided valuable insights, leading to further refinements and generating testable hypotheses.

Crevel *et al.* (2014b) also identified challenges relevant to each component of the risk analysis: risk assessment (data gaps and output interpretation); risk management (clear and realistic objectives); and risk communication (clear articulation of risk and benefit) (Crevel *et al.* 2014b). It was noted that translation of the outputs from risk assessment models into risk management measures must be informed by a clear understanding of the model outputs and their limitations. Crevel *et al.* (2014b) considered this would lead to feasible and achievable risk management objectives, grounded in a level of risk accepted by the different stakeholders, thereby avoiding potential unintended detrimental consequences. Clear, consistent and trustworthy communications actively

involving all stakeholders were recognised as necessary to underpin these objectives. The conclusions, integrating the perspectives of different stakeholders, offer a vision where clear, science-based benchmarks form the basis of allergen management and labelling, cutting through the current confusion and uncertainty. Finally, these authors recognised that the proposed framework must be adaptable to new and emerging evidence.

Crevel *et al.* (2014a) have given a comprehensive analysis of the research and knowledge gaps of both the deterministic and probabilistic approaches to quantitative allergen risk assessment (Crevel *et al.* 2014a). Deterministic allergen risk assessment is already carried out however given the considerable resource implications it is unlikely that the food industry will routinely adopt probabilistic allergen risk assessment in the near future.

However, if, as is currently the case, different measurement approaches give different results, sometimes markedly so, for the same sample, and results cannot be anchored by reference materials, it will be impossible to make use of thresholds properly. Moreover, progress towards using thresholds in practice, voluntarily or through regulation will depend on consumer understanding, confidence and trust. Food allergen thresholds are complex and difficult to explain, particularly for those making risk decisions about their own food, or food for those in their care.

6 The early days - advocacy and the foundation of the Anaphylaxis Campaign – Discussion

In 1993, seven young British adults (aged 16-26) died from food allergy. Their deaths were reported in the media (newspapers) and came to wider public attention. One was Sarah Reading (17) whose father David was a journalist on a local newspaper in Hampshire. He became the focal point for media attention, writing news articles and eventually receiving substantial daily correspondence from people living with the risk of severe allergy, as well as other families of people who had died.

This coincided with interest in, and wider recognition of food allergies and intolerances in the UK (Young *et al.*, 1994).

Early in 1994, David and others living with family members at risk from severe allergy set up the Anaphylaxis Campaign as a voluntary charitable organisation. Its earliest slogan was “fighting for those with potentially fatal allergies.” Resources were limited and the small committee met at David’s house. The Campaign became more widely known, primarily through written media – local and national newspapers.

David and Erik Brown, another parent member who was also a journalist and public relations expert compiled the first newsletter in spring 1994. It was a professionally produced 8-page glossy document. Contact had already been made and meetings held with the Chief Medical Officer, the Food Minister and leading clinicians. Advocacy was underway at the highest level. Letters from subscribers described people’s experiences getting support for their children, and also called for subjects to participate in clinical research. There were contact details for 25 volunteers throughout the UK who were willing to provide support in their local areas. Importantly, there was also guidance on managing allergic emergencies and how to get hold of adrenaline devices.

Hazel Gowland joined the Anaphylaxis Campaign as a subscription member in April 1994. It was clear that although a small voluntary charitable organisation, it was already a recognised, influential and effective advocate for people living with potentially fatal allergies. The primary focus was on food allergy, which affected the majority of member families, but support was also available for people with allergy to insect stings and medication.

At this point Gowland was still a secondary school teacher. Her early work with David Reading and others shaped the Campaign's policies to support food allergic children in schools. She also realised that although (like her) many Campaign members were parents of young children, there were fewer allergic adult members. She was able to provide reassurance and practical advice about growing up with, and living with a severe allergy.

By 1995, volunteers at the heart of the Campaign were taking responsibility for different priority areas. With family members in the food industry, Gowland started to develop expertise in food allergen labelling and allergen controls throughout the food supply chain, and became the Campaign's Food Adviser. She took a secondary role on the Campaign's management committee and later National Executive, representing the patient / consumer / member perspective and shaping strategy and policies.

In retrospect, the need for advocacy for people living at risk of anaphylaxis and / or with food allergies had become increasingly apparent in the early 1990s. Establishing a specialist organisation to support growing numbers of children and champion severe allergy would begin to meet this need. There were two main priorities: a) improved food description and allergen controls in food production, and b) improved access to specialist allergy health care and patient allergy management. In its earliest days, the Campaign had made significant progress in both of these.

6.1 Developing skills and knowledge

When she started working in allergy, Gowland was a trained secondary teacher and qualified youth worker. She had some experience of working with local news journalists and writing press releases and copy for school and musical events. In addition to teaching French and German, she was also delivering a Business Studies NVQ. She had worked in food retail and catering in the UK, France and Germany. Her sister (C J Derby – see [P3 - 2005 Sesame allergy paper](#) above) was then a food scientist with insight into food production. Other family members worked in quality and safety, and for a major food manufacturer.

By 1995, and perhaps as a result of the fatal reactions in 1993, and the public profile of the Anaphylaxis Campaign, the Women's Institute (WI) made food allergies one of the priority topics for wider discussion, which would eventually be brought to government

attention. Gowland was asked to deliver a presentation to the leaders of WI branches throughout Hertfordshire and Bedfordshire. This was her first speaking engagement, for which she developed a set of acetate overhead projector slides. It was followed by a lengthy question and answer session, and individual audience members had personal questions and comments after the meeting.

Most work for the Anaphylaxis Campaign at this time was by telephone, usually during evenings and weekends, or by letter and sometimes fax. Contact was established with the British Allergy Foundation (later Allergy UK) and Gowland worked with them on a set format for translations to help people travelling abroad with food allergies.

All those involved in the Campaign at this time were volunteers. Gowland was invited to attend food industry, clinical and regulatory conferences, exhibitions and meetings (with expenses paid), making notes, providing feedback to David Reading and colleagues and developing strategy.

As Food Adviser, and with a teaching background, Gowland started to work out how to get food allergies onto the standard training curriculum for food handlers, and particularly chefs and front of house staff. She established contact with the Hotel and Catering Industry Management Association (HCIMA) now the Institute of Hospitality, and the Hotel and Catering Training Company (HCTC) later the Hospitality Training Foundation (HTF), the Sector Skills training council. Following a meeting with their training committee, agreed text was inserted into relevant training modules to ensure that all professionally trained chefs and foodservice personnel were aware of food allergies and would know how to respond to customer enquiries and control allergen risks. Further relationships were established with leading chefs and hospitality organisations.

In 1996 Gowland was the guest speaker for the Académie Culinaire's update meeting in London attended by leading chefs. She spoke from notes, followed once again by a lengthy question and answer session. A pattern emerged that there would be people in any audience who, having listened to the talk would begin to realise that they or a family member had a food allergy or associated condition, so that such events became life-changing for them and those around them. Even with improved allergy awareness and public information, in 2018, this still happens after training courses, presentations and

lectures. Those delivering talks and training need to be ready to give time and on-going support if necessary in such situations.

6.2 Early research

As described above, the first Anaphylaxis Campaign newsletter produced in its earliest days in 1994 included a call for subjects for a research study. At this time, Gowland had no academic or clinical research experience.

The growing membership of food allergic individuals and families began to be considered as a useful research resource. Research questions to assess the impact of allergy and related atopic conditions were also discussed by the Campaign's management committee and others. The Ministry of Agriculture, Fisheries and Food (MAFF) government scientists were engaged with the international Codex Committee on Food Labelling (CCFL) on improving food labelling for the benefit of people with allergies, intolerances and coeliac disease. They asked the Campaign to obtain member data about allergies to milk and egg which could be used to shape CCFL policy and eventually regulation.

Unfortunately at this time, the Campaign had no experience of research methodology. A note in the Campaign's newsletter invited members to send in their experiences of milk and egg allergy. Over 300 letters were received representing 330 people, some extending to 8 pages of handwritten text. These were forwarded to Gowland who highlighted key points and did her best to collate and report the results. Many lessons were learned, not least that such surveys would benefit from a proper questionnaire and systematic data capture!

However, it was also established that:

- Anaphylaxis Campaign members were more than willing to participate in such research
- Living with food allergy and related chronic conditions provides a longitudinal perspective
- People are ready to provide prolific amounts of information in the hope of helping their own family members and others
- In the absence of wider scientific, clinical or consumer research, such data may be the best available evidence to influence policy and regulatory decision-making

- It would be likely that members of patient / consumer support organisations such as the Anaphylaxis Campaign might be informed through their Campaign membership to the extent that their perspective on some issues may be different from that of the wider population.

A further survey followed in 1997 – this time using a standardised questionnaire. Allergy specialist clinician, Dr (now Professor) Jonathan Hourihane helped to shape the questionnaire and provided guidance on reporting the data for a survey on sesame allergy. Early results were shared with MAFF for the Codex Committee on Food Labelling (CCFL), and also with leading retailers including Marks and Spencer who funded a further study leading to the eventual publication of **P3** above in 2005.

6.3 Work with the media

In the early days of the Campaign, as well as attending key meetings with parliamentarians, government officials, allergy clinicians, scientists, industry representatives and others, and writing articles and correspondence, David Reading became the Campaign's figurehead. His name and face were well-known and he would undertake television or radio interviews as required. In 1996, Gowland started to share this role. Interviewers would often want details of symptoms and 'what it feels like' to have an allergic reaction. Interviews followed - by phone and in person for the BBC consumer programmes 'You and Yours', 'Watchdog', local radio stations and television. She and Reading would also brief journalists and others writing specialist articles on allergy-related issues.

Reading and Gowland were invited to contribute to publicity surrounding a key study into peanut oil allergenicity undertaken by Dr Jonathan Hourihane and the team at Southampton University. It was recognised that industry processing methods (Neutralising, Bleaching and Deodorising - NBD) would remove or denature allergenic proteins. This study also involved the industry body, the Seed Crushers and Oil Producers Association (SCOPA).

(See: Hourihane et al., 1997a).

6.4 Developing as a researcher and consumer / patient advocate

From 1995, Gowland took an active role in the Campaign's food industry related initiatives, and acted as the point of contact for food queries from consumers as well as

manufacturers, retailers and caterers. A permanent staffed office was established in 1997, and Moira Austin became the full time helpline manager. Gowland would receive requests to make contact with families reporting an allergic reaction and would work with Austin to identify the relevant product, and then contact the retailer or manufacturer. At that time, calls from the Campaign would often be put through directly to a food technologist or member of staff working on the factory production line, and together an investigation would follow. The results of such investigations would be explained to the family reporting the problem, and if necessary, the product might be withdrawn from sale. The Campaign began to send out postal alerts to members who had listed the relevant food allergies on their membership renewal forms.

There were four important outcomes of this investigative work:

- The person or family making the complaint would be fully informed by a trusted support organisation about what had happened
- Gowland and colleagues became very well informed about food production throughout the supply chain from field, to factory, retail and catering
- They would negotiate for better practice in the medium and longer term on behalf of those at risk so that the wider public would be protected from consuming products containing unlabelled allergens
- The practice of targeting food allergy alerts at high risk food allergic consumers was established.

6.5 The Anaphylaxis Campaign member database and allergy product alerts

From 1999, Campaign members who had declared particular food allergies on their membership forms would be notified by post if there was a relevant allergy product alert. In the absence of more formal prevalence data, summary information about the number of members avoiding particular allergens, as well as the frequency of alerts concerning those allergens supported other impact assessment initiatives. There was a steady increase in both the number of times allergy product letters were sent, and the number of members receiving them for different foods from 1999 – 2003. See Figure 8. Gowland continues to review Campaign member data as one indicator of UK allergy prevalence for different foods.

Number of times product alert letters sent

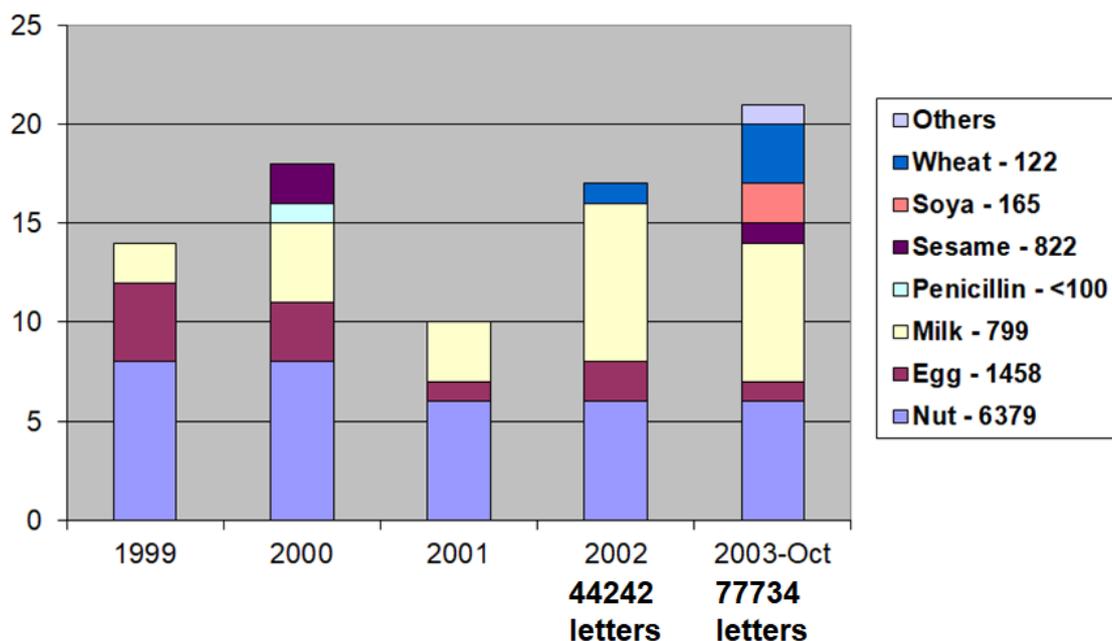


Figure 8: Anaphylaxis Campaign product alert letters sent 1999 - 2003

The Campaign also funded subscriptions to industry journals, for example *Caterer and Hotelkeeper*, *the Grocer* and *Tolley's Food Safety* which were read by Gowland who reported back to the Campaign's National Executive. At first, this was primarily a fact-finding activity, but Gowland started to enter into correspondence to raise food allergy issues, and was soon recognised as an expert in this field and asked to write for these and other publications. Such widely-read publications brought food allergies, the Campaign and Gowland's role into a more public arena and led to invitations to attend and then to speak at food industry and research events.

Further invitations were extended to visit sites, review and advise on allergen controls and to deliver training. An early client was the National Exhibition Centre in Birmingham. Gowland and the technical manager visited the on-site production unit, as well as fine dining, counters, vending and events management, examining the information available for people with food allergies, intolerances and coeliac disease, as well as ways to reduce cross contamination and implement best practice. Staff at all levels were included in an advisory and consultation activity leading to a bespoke allergy training programme delivered by Gowland in support of the organisation's new allergy policy and practice.

In 1997, following dialogue with Sir Cranley Onslow MP (who became the Campaign's chairman) and Jeff (now Lord) Rooker, the government food allergy team at MAFF supported by the Anaphylaxis Campaign (Reading and Gowland) and foodservice industry led a national campaign for the catering industry to raise awareness of the needs of people with food allergies, intolerances and coeliac disease, and to provide best practice guidance, window and counter stickers (W1 – 1997). Gowland was interviewed on television and radio as a food allergic consumer and as a project adviser. This was a pioneering initiative. Packs of materials were addressed to catering businesses using the Yellow Pages database. Unfortunately, the turnover of small food businesses can be quite high and the database was not up to date so many packs were not used. A review was undertaken and lessons learned about optimising information distribution for future campaigns.

Following complaints from families with food allergic children about the letterbox distribution of cereal packets and sweets given to children in supermarkets, Gowland worked with the Direct Marketing Association and the Advertising Association to communicate allergy risks and to develop policies and best practice for sampling through letterboxes, and also in shops and other situations where people are offered food and drink samples to try.

Gowland established working relationships with people who would become useful allies and introduce her to others. These included (now Professor) Dr Lisa Ackerley, leading Environmental Health consultant whose local food safety and health and safety consultancy Hygiene Audit Systems supported a number of leading restaurant, leisure and hospitality clients for 25 years. Networking became increasingly significant, as did establishing a reputation as the leading UK allergy expert adviser in catering and hospitality. Long-standing relationships were also established with key individuals at Sainsbury's and Whitbread as well as with professional bodies such as the Institute of Food Science and Technology and the industry research organisations; Leatherhead Food Research Association, Campden and Chorleywood Food Research Association and the Institute of Food Research. The Institute of Grocery Distribution working group (including Gowland) produced an early guide; *This product may contain nuts – Voluntary labelling guidelines for food allergens and gluten* in May 2000.

She was approached by a food technologist master's student for help with his thesis on allergen management in the commercial bakery sector – the first of many master's students to receive her encouragement and guidance.

By mid-1996, Gowland was no longer teaching. Allergy work became her main occupation, and she started to accept fees for consultancy. This led to the establishment of Allergy Action, her sole trader organisation in 2000, with its associated website www.allergyaction.org.

Working with Ackerley and with other local authority and private sector environmental health and trading standards officers initiated a campaigning and research interest in the regulatory protection available for people with food allergies, intolerances and coeliac disease. A landmark prosecution in 2000 following the hospitalisation of a student in Hull (who had eaten a curry containing peanut, having asked for it to be peanut free) led to close working partnerships with a number of local authorities and Public Analysts who undertook sampling projects, advised businesses including many takeaways, and supported consumers making food allergy complaints.

One high profile sampling project looking at undeclared peanut in curry was led by Dr Ian Leitch in Northern Ireland, assisted by (now Dr) Michael Walker, Public Analyst in Belfast. This work received considerable media attention including an episode of the BBC consumer programme, *The Food Police* (Leitch *et al.*, 2005). Undeclared or unrecognised peanut in curries and similar dishes has caused a number of fatal and many more 'near miss' reactions and remains a focus of regulatory attention in 2018.

From 1998 Gowland started to make contact with professional bodies involved in food safety and standards, health and safety and public health starting with the Chartered Institute of Environmental Health (CIEH), the Society of Food Hygiene and Technology, the Royal Institute of Public Health and Hygiene (RIPHH), the Association of Public Analysts (APA) and the Royal Environmental Health Institute in Scotland (REHIS).

6.6 Understanding fatal and 'near miss' allergic reactions to food

From 1994 – 1998 Gowland's work focused on reducing risks from food. Other volunteers and paid staff (Reading and Austin) focused more closely on work with allergy clinicians and researchers. The Campaign had a news subscription service for allergy and anaphylaxis stories in newspapers and magazines. Gowland had collected cuttings and notes from fatal allergic reactions since 1988. Reading attended early inquests, maintained contact with bereaved families and acted as spokesman when necessary. Calls and letters to the Campaign helpline reporting reactions were reviewed by Austin who passed cases onto Gowland. Phone calls, letters and eventually emails with families and friends provided information and support. Austin and Gowland both became very experienced in recording full details of reactions reported, and worked in partnership to establish ethical standards and working methods to obtain consent to share some details with clinicians for research purposes.

In February 1998, Gowland became closely involved with one particular family whose daughter, Katherine Baker had died in her home town. Gowland attended the funeral and provided family support at the inquest and afterwards. Money raised for the Anaphylaxis Campaign at Katherine's funeral was used to print leaflets (W2 – 1998) which were distributed through the Bradford and Bingley Building Society where her mother worked. These provided information about potentially fatal allergies and were used to raise further funding (c £7000) to buy and distribute the Anaphylaxis Campaign's information video to schools in Hertfordshire, Bedfordshire, north London and the surrounding areas where funds had been raised. Further copies were given to nurseries and to local authority under eights officers for people to view and pass on. Gowland also supported the family in a number of media initiatives including newspaper and magazine articles and television.

An issue arising from this fatal case was the likelihood that people experiencing a severe allergic reaction might walk into a community pharmacy for help. It was therefore important for community pharmacists to be trained and ready to recognise symptoms and source and deliver injectible adrenaline as the first line community treatment. The family worked with Gowland, Boots the Chemist and Dr Pamela Ewan (consultant allergist) to draft an information leaflet (W2 – 1998) for distribution in Boots stores. This team also worked with the Royal Pharmaceutical Society of Great Britain (professional body for pharmacists) on text for the Red Book – a handbook on managing a number of

key medical emergencies, including anaphylaxis and severe asthma, for which people may seek help in a community pharmacy.

Following the Baker case, Gowland began to work more closely with Dr Richard Pumphrey on investigating, reviewing and attributing fatal reactions supposedly caused by or exacerbated by food allergy. Dr Pumphrey was a consultant immunologist at St Mary's Hospital, Manchester with a long-standing interest in collecting data about severe and fatal allergic reactions to foods, drugs and insect stings. He had maintained a confidential clinical database since the 1980s and was often called by coroners to support investigations and give expert evidence at inquests. He published a series of fatal anaphylaxis cases (Pumphrey, 2000) and further work with Gowland (who was able to provide background information from inquests, news reports and family members) led to improved understanding of circumstances and risk factors. Over time, Gowland has maintained contact with many of these families. Lessons learned have been shared to protect others and reduce risks.

6.7 Media recognition – further awareness

In 2000, the BBC called for nominations for the first Radio 4 Food Programme Awards. Gowland was nominated in the *Campaigner / Educator* category, and as a Finalist was invited to St James Palace where she met H R H Prince Charles. It was significant at this time that food allergies and associated conditions were recognised in the wider context of best practice in food production (W3 – 2000).

6.8 Expert patient – early journal papers

Gowland's early research partnerships with Pumphrey and Hourihane led to an invitation to speak at the European Academy of Allergy and Clinical Immunology (EAACI) Symposium on Immunological, Chemical and Clinical Problems of Food Allergy in Venice in March 2001. Although Gowland was used to preparing lecture and training slides (still on acetate), she needed guidance from academic clinical colleagues to draft the necessary abstract and research paper. The proceedings were published (P1 – 2001) in *Allergy*, the Academy journal. Gowland's contribution as an atopic and food allergic patient and consumer was written from a life-long personal perspective. It has been widely cited, and set the scene for expert patient involvement in allergy advocacy, and improved clinician understanding of quality of life and everyday management and quality of life issues for food allergic individuals.

In 2001, Gowland was also invited to present at the (UK and Ireland) Nutrition Society meeting in Coleraine. The audience were primarily academic and clinical practitioners in nutrition and dietetics. Once again, the audience were interested in Gowland's personal perspective of living with food allergy for over 40 years. In addition, Gowland, Reading, Pumphrey and others had now established a *modus operandi* for collecting and analysing reaction data. This paper examined some recent fatal and 'near miss' reactions and also called for improved food control by local authority officers to support consumers and reduce risks (P2 – 2002).

7 Allergy Action – Discussion

By 2000, Gowland had established a reputation as an expert consultant to the food industry. She worked regularly with Dr Lisa Ackerley at Hygiene Audit Systems for high profile clients including the BBC, John Lewis Partnership and Mitchells and Butlers and independently for many others. At the same time, the Anaphylaxis Campaign offered her a regular consultancy arrangement, focusing on two key areas:

- Representing the Campaign with the Food Standards Agency, and on matters relating to food labelling, food safety, manufacturing, retail and catering including investigating complaints following reactions or poor allergen controls
- Continuing to support families and friends of people who have died from possible food allergy, and to investigate, collect, collate and communicate information about the circumstances surrounding fatal and 'near miss' reactions

These parallel roles led to Gowland setting up Allergy Action as a sole trader organisation, registering the business name and acquiring associated domain names and a website.

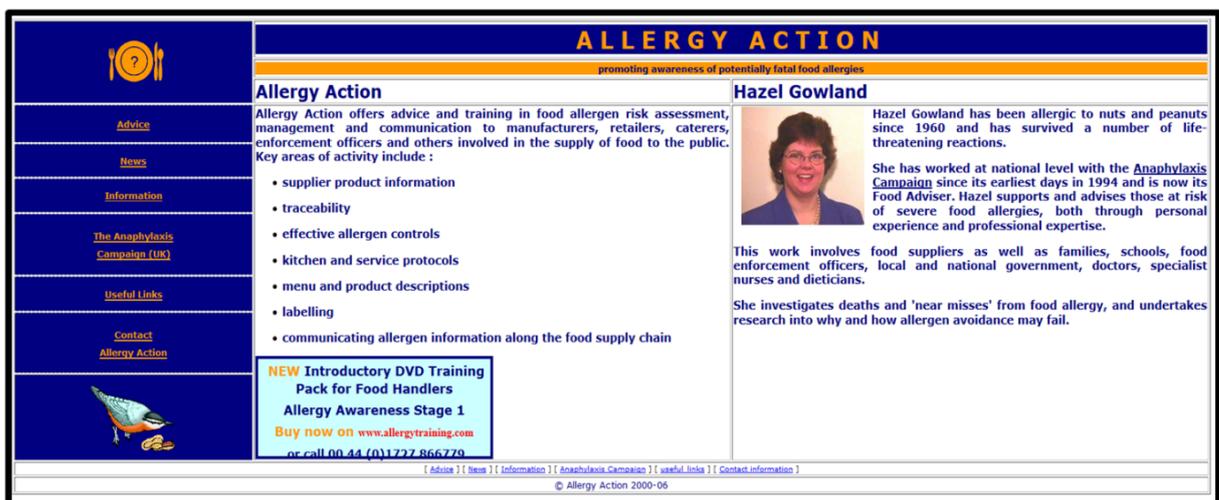


Figure 9: Allergy Action website from 2000

As a starting point, Gowland made translations available for people travelling with food allergies. They were supplied free of charge by friends and contacts who are native speakers of the relevant languages.

The translation format could be printed onto paper or card. In recent years, they are more likely to be downloaded on mobile phones.



Figure 10: Allergy Action website - Translations page: 2018

7.1 'May contain' labelling – assessing the impact of nut and peanut warnings on prepacked foods

The MAFF programme to commission and fund food allergy research continued towards the end of the 1990s under the Joint Food Standards and Safety Group which included officials from MAFF and the Department of Health who together formed the Food Standards Agency (FSA) in April 2000. Gowland was invited to attend the annual food allergy and intolerance research review meeting in autumn 2000 and has attended all meetings since to date as a patient / consumer representative, an expert in food allergy risks and a contractor.

One key research question which remained unanswered was to find out how people with nut and peanut allergies (the most common allergies reported to the Anaphylaxis Campaign then and still in 2018) managed when buying everyday prepacked foods in

supermarkets. There was a perception among food allergic people that certain food items (cereals, biscuits, confectionery, bakery items) were increasingly likely to have 'may contain' precautionary allergen labelling (PAL) for nuts and peanuts, possibly due to shared production environments and processes.

Gowland and FSA officials devised a novel methodology to undertake a shopping survey to assess the impact of such labelling. 16 everyday prepacked food items were chosen and a shopper went into 8 UK supermarkets to try to buy their 'own brand' versions. The selection time and price paid were noted. The shopper then returned to the store and tried to buy the same items for a person with a nut / peanut allergy. A similar exercise compared the leading brands for the 16 items. It was found to take 39% longer to choose the items for the nut / peanut allergic person, and cost 11% more. In some cases the allergic consumer's item was plainer or cheaper. Further work was undertaken to examine the presentation of ingredients and 'may contain' precautionary allergen labelling for nuts and peanuts – colour, text size and style, shiny packaging, colour contrast, and proportion of the packaging surface. Lastly packets were examined by a number of individuals who had to decide whether or not the product would be suitable for a person with a nut / peanut allergy. One in ten 'may contain' precautionary allergen labels was missed (W4 – 2001). The study report was published by the Food Standards Agency and attracted national and international interest. It set a standard for accessible quantitative and qualitative food allergy consumer research. Gowland presented this study at the FSA Food Allergy and Intolerance research meeting in November 2002.



7.2 Consumer advocacy

From its earliest days, the Anaphylaxis Campaign (Reading, Austin and Gowland) was invited to participate in Food Standards Agency consultations, for example advising on the Agency's Strategic Plans for the 5 years ahead and commenting on food labelling, food safety and food enforcement proposals. Gowland also contributed to a 360 degree appraisal of board members and participated in tender evaluation for food allergy research projects (when she wasn't a possible contractor herself.) The Campaign, (usually represented by Gowland) was trusted by other consumer and

patient advocacy organisations on food allergy issues, and worked closely with associated charities eg Coeliac UK and Allergy UK on FSA Consumer committees and panels, and drafting consumer information.

7.3 Improving access to allergy health care

From 1998, Gowland worked with consultant allergist Dr Pamela Ewan to understand and map allergy patient care pathways for policy makers, health care commissioners and patients. Together with Keith Gowland, they mapped out the model (W5 – 2003 and W6 – 2004). A version of this diagram was first prepared for a meeting with Tessa Jowell MP, Minister for Public Health in 1998, and used by Dr Ewan in her paper *The Provision of allergy care for optimal outcome* (Ewan, 2000). It was reused in two further reports lobbying for improved allergy patient care by the Royal College of Physicians in 2003, and the House of Commons Select Committee on Health report; *The provision of allergy services* in 2004.

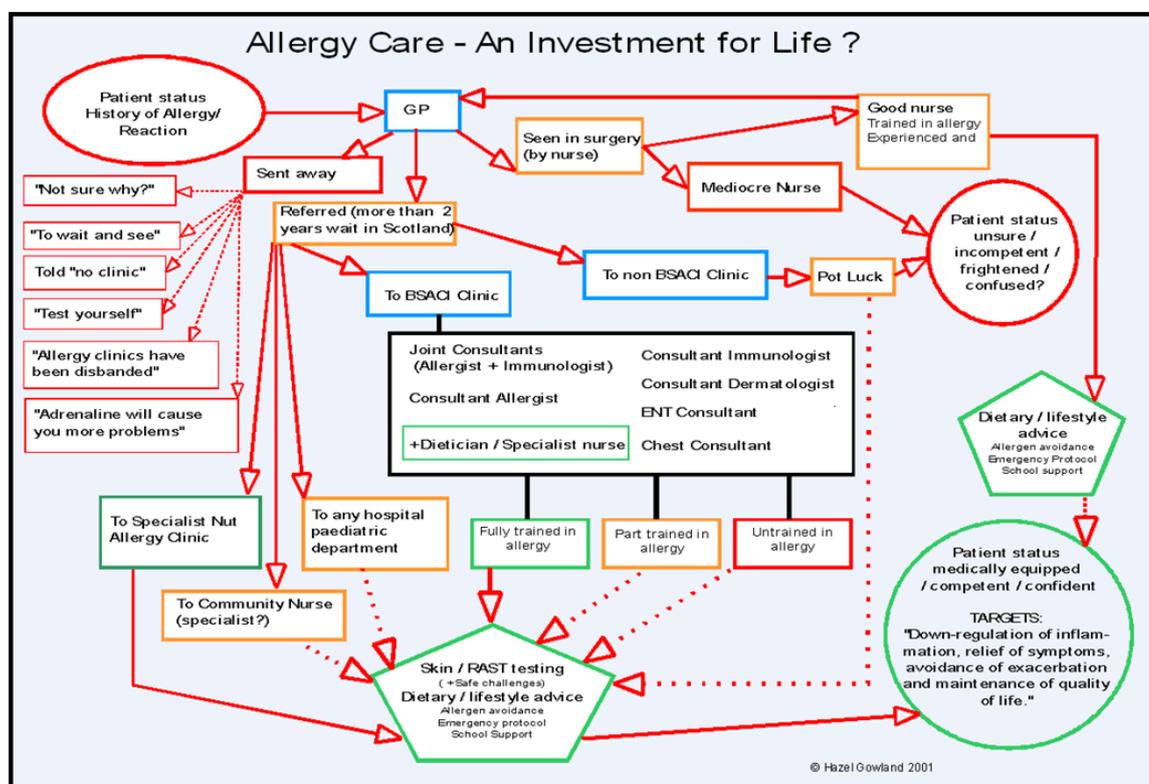


Figure 11: Mapping care pathways for allergic disease

From its earliest days, the Anaphylaxis Campaign participated in government and industry food allergy initiatives. David Reading reviewed the MAFF booklet (*Food Allergy and other unpleasant reactions to Food* (Foodsense 1994). In 1998 the Institute of Food

Science and Technology (IFST) invited Gowland to review a new chapter *Dealing with allergens in Good Manufacturing Practice – A guide to its responsible management* in 1998. This is a widely used industry guide and the inclusion of this chapter reflected work underway across all sectors of food supply to develop and adopt best practice for effective allergen control. (Gowland was invited to address the IFST conference in 2002, and worked with David Reading to prepare an article for the IFST journal in 2004.)

In 2002, Gowland was invited to speak at an international food industry conference organised by the Leatherhead Food Research Association. By this time, working partnerships had been established between leading allergy clinical researchers, food scientists and technologists, regulators, particularly the Food Standards Agency and consumer / patient support organisations. Victoria Emerton and the Leatherhead team organised the conference and then commissioned the speakers to write chapters for *Food Allergy and Intolerance Current Issues and Concerns (B1 – 2002)*. Gowland's role now extended beyond representing the expert patient and consumer interest. She had recognised expertise in collecting, managing and reporting data about severe allergic reactions, consumer research into shopping with an allergy and strategies to control and communicate the presence of food allergens throughout the food supply chain.

Another partnership was established with the Coroners' Society of England and Wales following a number of fatal reactions in 2003. Pumphrey and Gowland had contributed to coroner's investigations including giving expert evidence. One of the coroners with whom they had worked edited the Society's annual report in 2004 and invited them to submit an article, *Investigating deaths from allergen-induced anaphylaxis and asthma (W7 – 2004)*.

7.4 Sesame allergy

Data from early surveys undertaken by Gowland for the Anaphylaxis Campaign into sesame allergy remained unpublished. Following the 'May contain' study into shopping with a nut / peanut allergy (*W4 – 2001*), there was interest in assessing the impact of other food allergies. Sesame was chosen a) because some people with nut and peanut allergies reported being allergic to it b) because reactions to sesame were being reported and c) because food industry representatives needed a clearer understanding of the controls they needed to implement to protect those at risk.

Industry funding was made available to revise the previous questionnaire, to send it out to Campaign members reporting sesame allergy, and for Gowland, Derby and Hourihane to collect, collate, review and report the findings. It also provided an opportunity to phone subjects to obtain more details of the foods thought to have triggered symptoms and the timing and progression of those symptoms (P3 – 2005).

Collecting and recording details of allergic reactions was increasingly standardised. Gowland contributed to developing the Anaphylaxis Campaign *Reaction Record* form which was used in further studies including Uguz *et al.* (2005).

It was also recognised that improved understanding of the quality of life aspects of life with food allergy could be useful in patient and consumer advocacy. One innovative early study undertaken by a Southampton medical student was Avery *et al.* (2003), which used diaries and disposable cameras to record food allergy-influenced events in the lives of primary aged children.

7.5 Developing resources and training tools

The Anaphylaxis Campaign had produced a general information video about anaphylaxis in 1997 and its printed catering guidance was available by post, and online, but a need was identified for a video and linked training resources for use in food businesses and



particularly for caterers and those selling non-prepacked foods. In 2006, Gowland, Dr Lisa Ackerley and colleagues at Hygiene Audit Systems developed and produced a DVD Training Pack for Food Handlers. Environmental Health Officer, Dr Ian Leitch was the script editor for this project.

Filming began in January 2006. Ackerley's contacts at the John Lewis Partnership catering department provided a working kitchen and workplace dining area. Other locations included the local market, restaurants and takeaways. The actors included the kitchen staff, drama students and family members. A professional actor (who had lost a family member from severe food allergy) narrated the film.

Accessible learning was made possible through a 17 minute mini drama featuring a range of food preparation and catering scenarios and a severe allergic reaction, followed by a 6 minute review, and then tutor's notes and a short multiple choice assessment with an aide-mémoire for students to keep. Recognising that people providing food

training come from a range of backgrounds and experience, the pack allowed more experienced trainers to use it flexibly, whilst less confident trainers could adhere more closely to the suggested lesson plan.

The Allergytraining DVD Training Pack *Allergy awareness: an introductory pack for food handlers* won the Society of Food Hygiene and Technology 'Best new product' award in 2006 and was also accredited as a training tool by the Royal Institute of Public Health (W9 – 2006).

7.6 Work to ensure food law protection for consumers with food allergies, intolerances and coeliac disease

Early surveys on milk and egg allergies and sesame allergy (as described above) provided UK officials at MAFF with evidence to support initiatives undertaken by the international Codex Committee on Food Labelling (CCFL) from mid-1990s to improve food allergen information and to prioritise the needs of consumers at risk. One particular issue was the 25% rule. If a product (eg a biscuit) contained toffee pieces which made up less than 25% of the biscuit, it was not necessary to list the ingredients of the toffee pieces, even if they included key allergen ingredients eg milk or nuts. This presented significant challenges to allergen avoiding consumers, as did the absence of ingredient and allergen information for catered and non-prepacked foods, and the growing presence of precautionary allergen labelling (PAL) also described as 'may contain' labelling

EU Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs established principles which began to benefit these consumers, but were far from adequate. For the first time businesses supplying 'mass caterers' needed to provide ingredients information, but as yet, there was no specific requirement to label allergens.

Whilst work was underway to develop legislation at EU level to protect these consumers, the Anaphylaxis Campaign (Gowland) and the Food Standards Agency worked together and independently to develop consumer and business guidance to improve understanding and reduce risks. The FSA produced a catering booklet, *Be allergy aware*, and associated posters in English and other community languages in 2001.



Gowland attended stakeholder meetings to develop and review these resources. She also established working relationships with two Food Standards Agency board members, chef and restaurateur, Robert Rees and Public Analyst, (now Dr) Michael Walker who became a collaborator and co-researcher (see above). In 2003, Gowland and EHO, Dr Ian Leitch gave evidence on food allergens and controls to the FSA Board. This was an important period in the development of principles and practice leading to improvements in both food standards and food safety for food allergic and intolerant consumers.

Food allergies were now more widely recognised. The deaths of young adults from food (usually peanut / nut) allergy received national media attention, more often on television and radio at this time. Parallel initiatives were underway to improve access to expert patient care, and to support children and young adults in childcare, school and leaving home. Gowland and Reading were often called to give interviews and support journalists writing comment articles. A Mintel survey in 2003 looking into food safety identified food allergies as the most important food safety concern for young people aged 15-24 (Daily Research News Online (UK) *High concerns over food safety in UK* 2003).

7.7 Evidence to the House of Lords enquiry into Allergy

By 2006, the framework of food allergy stakeholders and advocates was well-established and many were working collaboratively. Work (with which Gowland was not directly involved) had been underway since 1994 to improve access to specialist allergy healthcare and better management of all allergy-related symptoms. David Reading, and the Anaphylaxis Campaign National Coordinator, Mandy East (who also worked for the National Allergy Strategy Group parliamentary organisation) worked closely with Dr Pamela Ewan and leading clinicians, regulators, officials and others at parliamentary level. The House of Lords Science Committee called for evidence in 2006, and held face to face sessions in 2007. Gowland was called to give evidence with Dr Richard Pumphrey with whom she worked on understanding and reporting fatal allergic reactions, and Dr Ian Leitch with whom she was working on the role of local authority officers and measures to improve training and understanding for food businesses (**W11 – 2007**). The House of Lords Evidence and Report helped to shape policy in public health, NHS specialist provision and FSA and local authority activity.

7.8 Further work to ensure food law protection for consumers with food allergies, intolerances and coeliac disease

Feedback from Campaign members and others also indicated that EU Directive 2000/13/EC was not meeting the information needs of consumers at risk of reactions to foods. It was recognised that they depended not only on accurate food information (ie labelling or 'standards') but also on food safety, for example that food should be prepared safely and protected from cross contamination.

Food law - national and EU regulation and much local authority food control activity separated these two key areas, not least in parts of the UK where food composition (labelling or standards) was (and is still) controlled by Trading Standards Officers (TSOs), usually operating at county level, whilst food safety (managing risks) was (is) controlled by Environmental Health Officers (EHOs) working at city or district level. In other areas EHOs also controlled food standards (Scotland, Northern Ireland, London Boroughs and some unitary authorities). Early food allergy-related prosecutions (eg in Hull in 2000 – see above) had been taken by TSOs using the Food Safety Act 1990, which includes an offence of 'selling food not of the substance demanded' and another one of 'misleading consumers'.

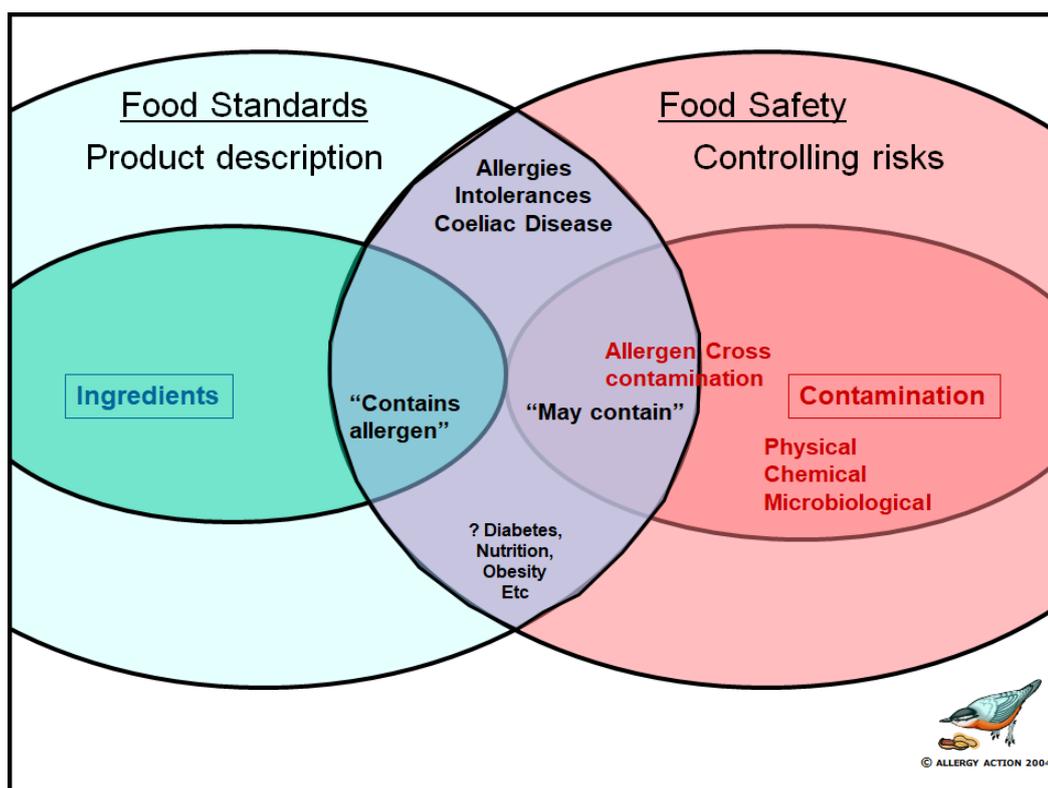


Figure 12: Food Allergy involves both Food Standards and Food Safety

Both TSOs and EHOs had undertaken sampling and awareness projects, often working closely with Gowland to target areas with high risk populations (eg students and young adults) and foods (eg takeaways) and raise awareness of the findings. It was obvious that the protection of food allergic / intolerant consumers crossed both food labelling and safety. Gowland prepared the diagram above to demonstrate this. However, there was resistance to including food allergen control with other food hygiene / food safety controls. TSOs were not usually trained in food safety, and some were reluctant to advise on allergen controls, whilst EHOs had traditionally focused their attention on microbiological foodborne disease.

New food safety legislation (Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002), placed emphasis on food safety being dependent on the accuracy of information supplied with the food. For the first time, businesses selling food were required to take into account the needs of people with food avoidance needs who might consume it. *In determining whether any food is injurious to health, regard shall be had: ... (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers* (Article 14). This law has been used to prosecute food business operators who served food containing an allergen to which the consumer was allergic / intolerant, in cases where the avoidance need had been explained in advance.

From 2001 the principle of identifying priority allergens was established. Gowland worked closely with a group of stakeholders representing the UK and wider EU food industry, allergy clinicians, other consumer advocates, scientists, regulators including EHOs and TSOs, the Food Standards Agency Allergy and Labelling teams and the Directorate General for Health and Consumer Protection (DG SANCO) in Brussels in shaping the new food labelling regulation. Directive 2003/89 EC (published in November 2003 and in force from November 2005) amended Directive 2000/13 EC so that key food allergens (listed in Annex IIIa) would need to be declared on prepacked foods. Eight tree nuts were listed by name.

'ANNEX IIIa

Ingredients referred to in Article 6(3a), (10) and (11)

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof

Crustaceans and products thereof

Eggs and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk and products thereof (including lactose)

Nuts i. e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.'

(This list was extended to include molluscs and lupin in Directive 2006/142 EC in 2006.)

In addition the principle was established that certain processing methods, not least the oil processing method (Neutralising, Bleaching and Deodorising - NBD) would eliminate the risk of allergic reactions by denaturing or removing the allergenic proteins, and that labelling the allergen as present when it was no longer present in active form was not only misleading, but may also lead to people believing falsely that their allergy had resolved. An expert panel at the European Food Safety Authority (EFSA) was able to review portfolios of evidence and supply opinions on whether a particular food allergen (in a particular form) should be added to or removed from the Annex IIIa. During the drafting period, Gowland (as a consumer representative) was asked by industry and regulatory colleagues to make contact with DG SANCO officials to ensure that the regulation would ensure this flexibility.

Although Directive 2003/89 EC enabled consumers and caterers to identify allergen ingredients in foods they had bought, there were a number of key areas where food allergic, intolerant and coeliac consumers were still at risk.

- The Directive did not enable consumers to obtain allergen or other ingredients information when eating out or buying non-prepacked foods

- The possibility of unintended allergen presence and associated precautionary allergen labelling - PAL) were not regulated for prepacked or non-prepacked foods.
- Food Safety Regulation (EC) No 178/2002 was useful but usually depended on a consumer having declared their allergy or intolerance before ordering their food
- Other legislation (eg 852/2004 EC) requiring food businesses to undertake hazard analysis to assess and control risks *to ensure a high level of consumer protection with regard to food safety* did not specifically include allergen risks

In practice, like manufacturers and major retailers, many larger foodservice businesses were already managing food allergens within their Hazard Analysis and Critical Control Points (HACCP) systems, or in a parallel but separate allergen management system. Gowland wrote to David Byrne, EU Commissioner for DG SANCO, in September 2004 to ask for allergen risk assessment to be included in hazard analysis (HACCP). The practicalities of implementing even simple hazard analysis and risk management in smaller food businesses proved a challenge. Allergen information and controls were addressed inconsistently in food safety policies and inspection reports.

8 Implementing an action plan - Discussion

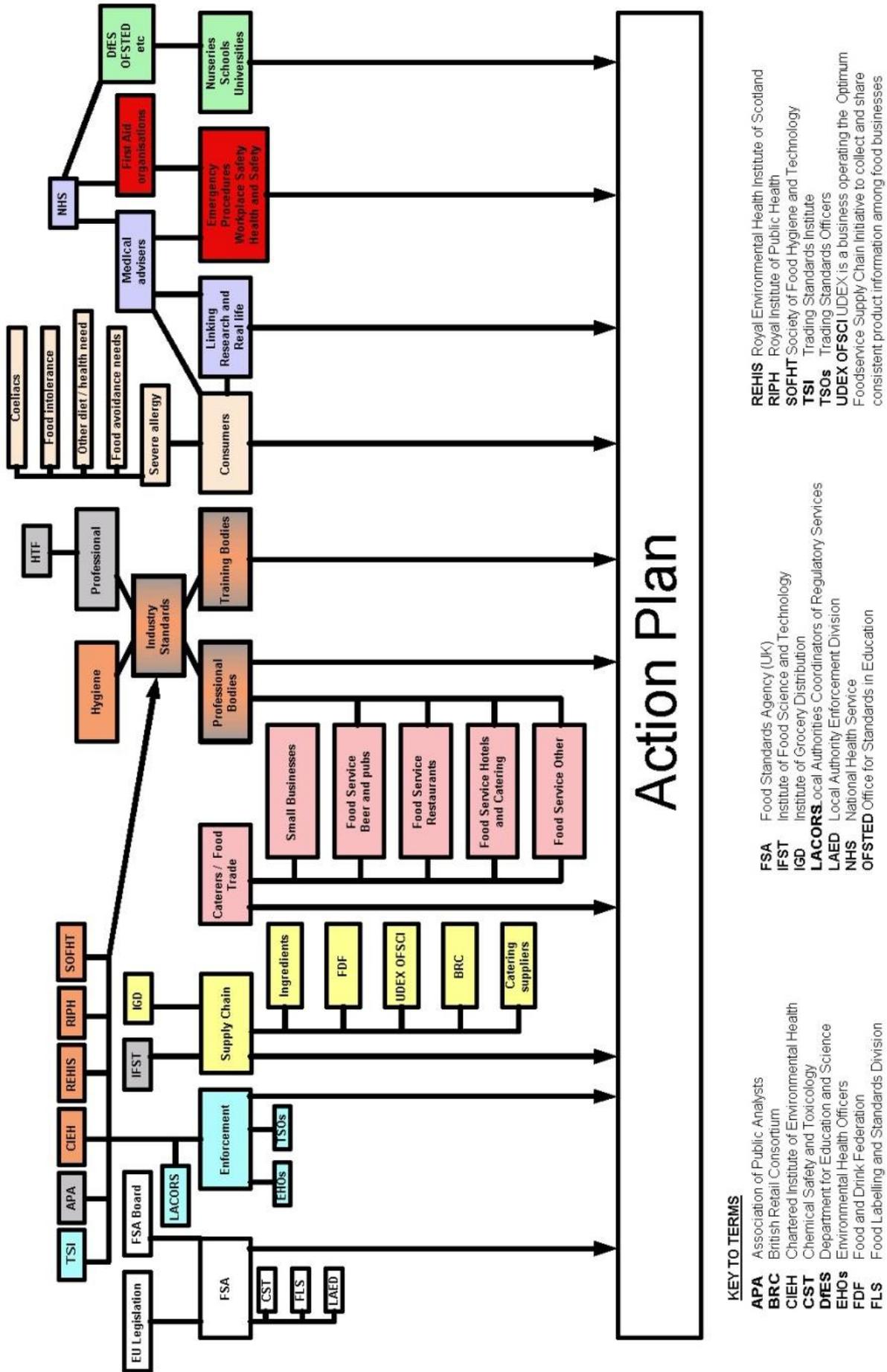
In 2003, Gowland undertook a strategic review of progress to date on reducing allergy risks, for the Anaphylaxis Campaign. Recent fatal reactions from takeaways and at weddings and parties led to a focus on catering and foods consumed away from the home, as well as the need for improved education and training in nurseries, schools and universities. This involved recognising all current partners, and also identifying others with whom we might work. The partners were classified under these headings:

Gowland then prepared the Action Plan below, using this colour coding

| | | | | | | | | |
|-------------|---------|--------------|----------|----------------------------|----------------------|-----------|-----------|---------------------------------|
| ENFORCEMENT | HYGIENE | SUPPLY CHAIN | CATERING | FOODSERVICE - PROFESSIONAL | MANAGING EMERGENCIES | EDUCATION | CONSUMERS | LINKING RESEARCH WITH REAL LIFE |
|-------------|---------|--------------|----------|----------------------------|----------------------|-----------|-----------|---------------------------------|

An action plan with aims and objectives under these headings was drawn up and agreed with Campaign colleagues. It was also shared with the Allergy team at the Food Standards Agency, and other key partners, and became the focus for Gowland's Campaign and independent work from 2003 until 2008.

Figure 13: Gowland's Action Plan identifying partners 2003



8.1 Work with local authority environmental health and trading standards officers

It was recognised that local authority food officers (EHOs and TSOs) had a key role in supporting consumers with food allergies, intolerances and coeliac disease, and Gowland and Campaign colleagues had worked closely with some key individual officers and teams around the UK since the mid-1990s.

Gowland had given presentations at EHO and TSO Continuing Professional Development (CPD) and FSA update programmes and other events in England, Scotland, Wales and Northern Ireland. She spoke at Chartered Institute of Environmental Health (CIEH) and Trading Standards Institute (TSI) conferences and contributed articles to professional journals including that of the Royal Environmental Health Institute in Scotland (REHIS). In all, it was likely that over 750 of the estimated 1400 UK food enforcement officers may have attended an event which included a presentation on food allergies and supporting those at risk, either delivered by or with content produced by Gowland during this period.

Some officers had been involved in investigating fatal and other reactions or undertaking follow-up projects to identify undeclared allergens, particularly in takeaway meals. Others were developing materials to raise awareness among food businesses through cascaded training events and publicity campaigns. It became increasingly clear that there were differences in policy and practice between local authority teams.

Gowland's strategic review had identified these officers as critical to supporting consumers and food businesses so in September 2004, a questionnaire was circulated by email to find out what UK Local Authority food enforcement officers were doing to protect allergic consumers, what training they had received and what resources they were using. This followed the first survey undertaken by Dr Ian Leitch in 1999 which established that only 6 of 37 of Northern Ireland officers surveyed were engaged in any activities to protect allergic people, and that only one officer had received previous training in food allergen controls (Leitch *et al.*, 2001).

Although the survey was not formally published, the results were shared with the FSA Allergy Branch and shaped a number of key initiatives to train local authority officers throughout the UK in 2007-08, and to provide printed and online materials for

consumers, businesses and EHOs and TSOs. Gowland then repeated the survey in 2008 to assess the impact of the FSA initiatives.

8.2 Work with food manufacturers – establishing best practice for allergen controls and information for prepacked foods

David Reading and Hazel Gowland had both worked closely with leading food manufacturers since the mid-1990s. This included visits to production sites around the UK, learning about the practicalities and constraints of food production, gaining an understanding of food science, food safety and food allergen controls throughout the supply chain and establishing working relationships with staff and particularly food technologists and quality assurance teams. Sites visited were producing a range of products including breakfast cereals, biscuits, confectionery, Christmas cakes and puddings, cream crackers, raw meat products, cooked meat products and pies, party cakes, fruit and vegetable washing and packaging, chilled desserts, ready meals and ambient sauces. Gowland was invited to review pilot projects to redesign production facilities and equipment, and verification and validation of cleaning and allergen management processes and staff training.

This 'hands on' experience for a wide range of food types and production environments was useful for the FSA's next project – voluntary best practice guidance for food manufacturers. (*Guidance on Allergen Management and Consumer Information* FSA 2006 (W8 – 2006).

The FSA Allergy branch brought together a working group of key stakeholders including the Food and Drink Federation (representing manufacturers), the British Retail Consortium (representing supermarkets and other retailers), EHOs and TSOs representing the Local Authority Coordinators of Regulatory Services (LACORS) and Gowland representing the Anaphylaxis Campaign. They collected examples of best practice for allergen risk assessment, management and communication and produced a definitive 58 page practical guide which included worked examples and useful contacts and resources. This guide was widely adopted and set standards for improved allergen management in food manufacturing. A simplified version of the guidance was made available for smaller scale food producers (A5 Leaflet for small businesses - *Allergy: What to consider when labelling food: A guide for small businesses that make or sell pre-packed food 2006 and the Welsh version Allergedd*).

8.3 Work with caterers and businesses selling ready to eat foods – establishing best practice for allergen controls and information for non-prepacked foods

Attention now focused on non-prepacked and catered foods. Between 2006 and 2008, the FSA undertook a number of projects to identify food allergy risks, and develop best practice for catering and open food suppliers. At the same time it was recognised that EHOs and TSOs would be better able to provide advice and protect food sensitive consumers if they had appropriate training and resources available.

Another FSA working group was established, with similar representative stakeholders to the previous group, and additional representation from catering suppliers and the hospitality sector. Gowland provided expertise in consumer behaviour and expectations and also from consultancy projects developing codes of practice and training with a wide range of caterers and other food businesses. The FSA published the second guide; *Voluntary food industry guidance The Provision of Allergen Information for Non-Prepacked Foods* in 2008 (W13 – 2008).

8.4 Developing materials and training for Environmental Health and Trading Standards Officers throughout the UK

The FSA commissioned Dr Ian Leitch to research and tailor the core knowledge and skills required by EHOs and TSOs in supporting food businesses. Key FSA staff from the Allergy branch and the Enforcement team reviewed the practicalities of including food allergen controls in the everyday activities of local authority food officers.

In autumn 2006, the FSA put out a tender for a training project to develop and deliver a pilot workshop with online pre-course learning for Food Environmental Health and Trading Standards Officers in England. The contractor appointed was Hygiene Audit Systems in partnership with Allergy Action.

Gowland worked closely with Dr Lisa Ackerley and experienced EHO and interactive trainer Karen Martin to develop the online learning and administer and deliver the courses. A pilot one day workshop was delivered successfully in London in December 2006 and was followed by a programme of 10 further workshops in January – March 2007 delivered by Gowland and Martin. The programme was then extended to include workshops for officers in Scotland, Wales and Northern Ireland. In total 1043 officers, Public Analysts and FSA staff participated and 49 courses were delivered, finishing in

spring 2008. An FSA representative said that the workshop programme was ‘a phenomenal success’ (W10 – 2006).

The new FSA industry guides and associated posters and leaflets were distributed to all delegates (A5 Leaflet for restaurants, takeaways and other businesses preparing and selling non-prepacked foods *Food Allergy: What you need to know* and A3 laminated poster for caterers selling non-prepacked foods *Think Allergy*).

The course content was then developed into free online learning for food handlers, still available in updated form on the FSA website (<http://allergytraining.food.gov.uk/english/>).

8.5 Developing and delivering a cross-border training programme and conferences in Ireland

During this period a separate project was underway across the border of Northern Ireland and the Republic of Ireland funded by the CAWT and safefood organisations. Allergy Action (Gowland), Hygiene Audit Systems (Ackerley) and Allergy Audit (Dr Ian Leitch) had successfully tendered to deliver a programme of one day programmes with online learning and conferences. 45 Northern Ireland and 50 Republic of Ireland EHOs, and Public Analysts participated and cascaded key messages and best practice to their colleagues. This project also provided officers with extensive supplies of additional resources for distribution to food businesses including dialogue posters, aide-mémoires, key messages and manager’s checklists (W12 – 2008).

8.6 Update research study on current allergy-related activities undertaken by UK Local Authority Food Safety and Standards Enforcement Officers 2008

The study followed a similar protocol to that used in 2004, and used the same questionnaire with tick boxes for the majority of replies, and additional boxes for comments about training and resources. In order to provide some indication of the impact of the FSA workshop programme, a new question (11a) was added:

I attended an FSA funded one day workshop on allergens.

(38% of respondents had done so.)

This questionnaire was emailed in April 2008 to the 92 food enforcement officers who had submitted a completed questionnaire in 2004. Officers were requested to forward

the email questionnaire to colleagues working on food standards / safety issues if they were no longer working in this area.

37 officers replied; 27 who had submitted questionnaires in 2004 and 10 who had since taken over the work of a respondent in 2004.

Respondents to the survey included 19/37 (51%) responsible for food standards and 26/37 (70%) responsible for food safety. Some officers enforce both.

Respondents reported an increase in work to control and communicate the presence of allergens in food businesses in considering legal action relating to food allergens and in sampling programmes to assess allergy risks.

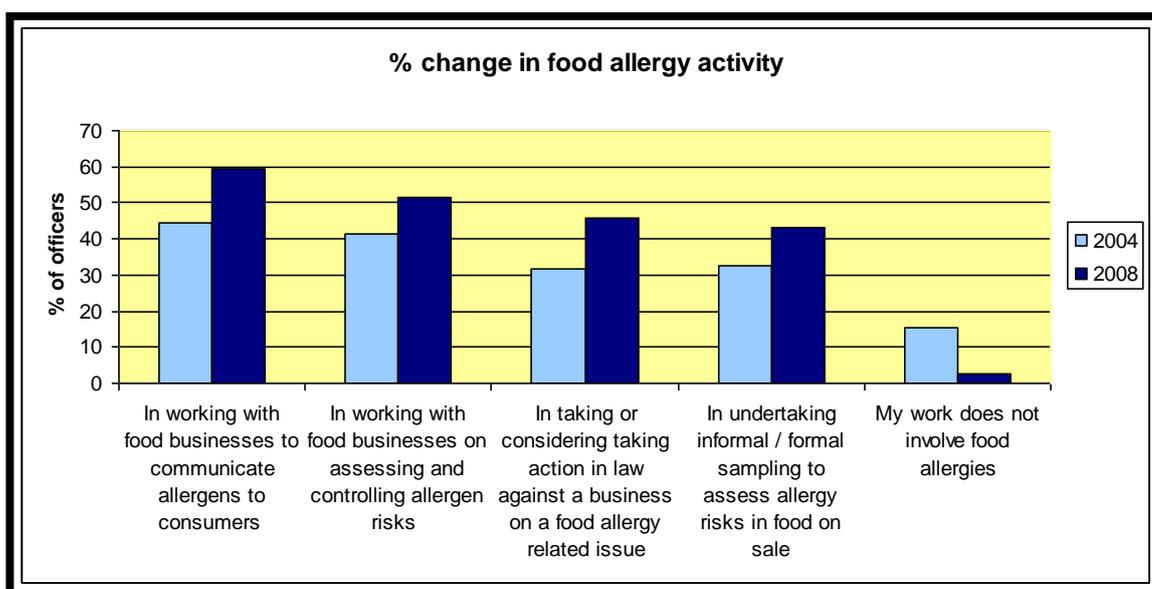


Figure 14: Local authority EHO and TSO food allergy activity: comparison 2004 and 2008

Comments were collected on guidance now available for food businesses, training for officers, national guidance and support on enforcement for allergen issues, and the availability of materials and resources. It was recognised that further training and resources both for businesses and officers were still required, as well as time during their inspection visits to discuss and then review allergen controls. Specialist expertise would also be valuable for managing and controlling allergy risks (integrated with health and safety) in other environments eg childcare, schools, care homes, hairdressers, beauty salons but in some cases fell beyond the remit of the Food Standards Agency.

Gowland collated the replies, and submitted the report to the FSA on behalf of the Anaphylaxis Campaign.

8.7 European research collaborations - Informall and Europrevall

David Reading had contributed to an early EU-funded network, Protall, looking at food allergenicity and the science behind allergy diagnosis and allergen analysis on behalf of the Anaphylaxis Campaign. He and Gowland were then invited to participate more formally in the Informall project which followed. In addition to establishing an allergen database, consideration began to be given to the needs of consumers and allergy patients, and also for the first time, assessment of the economic and social impact of living with food allergies.

From 2004 to 2009, Gowland was one of the consumer / patient representatives on the Europrevall Integrated Project. Her main contributions were to work packages looking into the quality of life and cost of living with food allergy, and the dissemination of findings to appropriate audiences. The development of questionnaires or 'tools' to assess the impact of quality of life for people with food allergies (and then intolerances) led by Dr Audrey DunnGalvin at the University of Cork led to further projects to understand key issues and develop policies to reduce risks and improve their lives and the lives of people caring for them.

The project also examined progress towards agreed allergen thresholds to control allergens in food production sufficiently to protect consumers at risk, and published a number of position papers including (P6 – 2010). Gowland also contributed to a study into school preparedness for managing food allergic children in their care in different countries. She provided expert patient / consumer insight, and experience as a schoolteacher in designing the questionnaire, reviewing the analysed data, and contributed to writing and editing the paper (P16 – 2014).

8.8 Teenagers and young adults

On-going research into fatal and 'near miss' allergic reactions had identified teenagers and young adults as a high risk group. Social and physical characteristics of adolescence were thought to be responsible – perhaps not having experienced a severe reaction ever, or at least not in recent memory, being away from parental supervision, eating out and travelling with friends, and co-factors such as poor asthma control and the impact of hormonal changes. The need for age-appropriate allergy care and support, possibly through transition clinics was discussed. (Now Dr) Hannah Monks, a medical student at Southampton University led a study to interview teenagers and young adults in clinic and learn more about allergy self-management and attitudes to risk (P7 – 2010).

Personalised strategies to undertake risk assessment, make food choices, carry and use emergency medication depended on parental, school and social support leading towards competent and confident self-management.

8.9 Modelling the outcome of allergic reactions

Together with Anaphylaxis Campaign colleagues, Gowland had been collecting details of allergic reactions since 1994. As discussed, the Campaign's *Reaction Record* addressed symptoms, timing, treatment and some details of how the allergen might have been encountered – eaten, touched, inhaled etc. Data collected had been published formally and presented informally.

Gowland developed the diagram below (Figure 15) to illustrate the routes which might be followed by a consumer, parent or carer following an allergic reaction. It was published in a book chapter (B3 – 2014) and has been used to model reactions, outcomes and complaints.

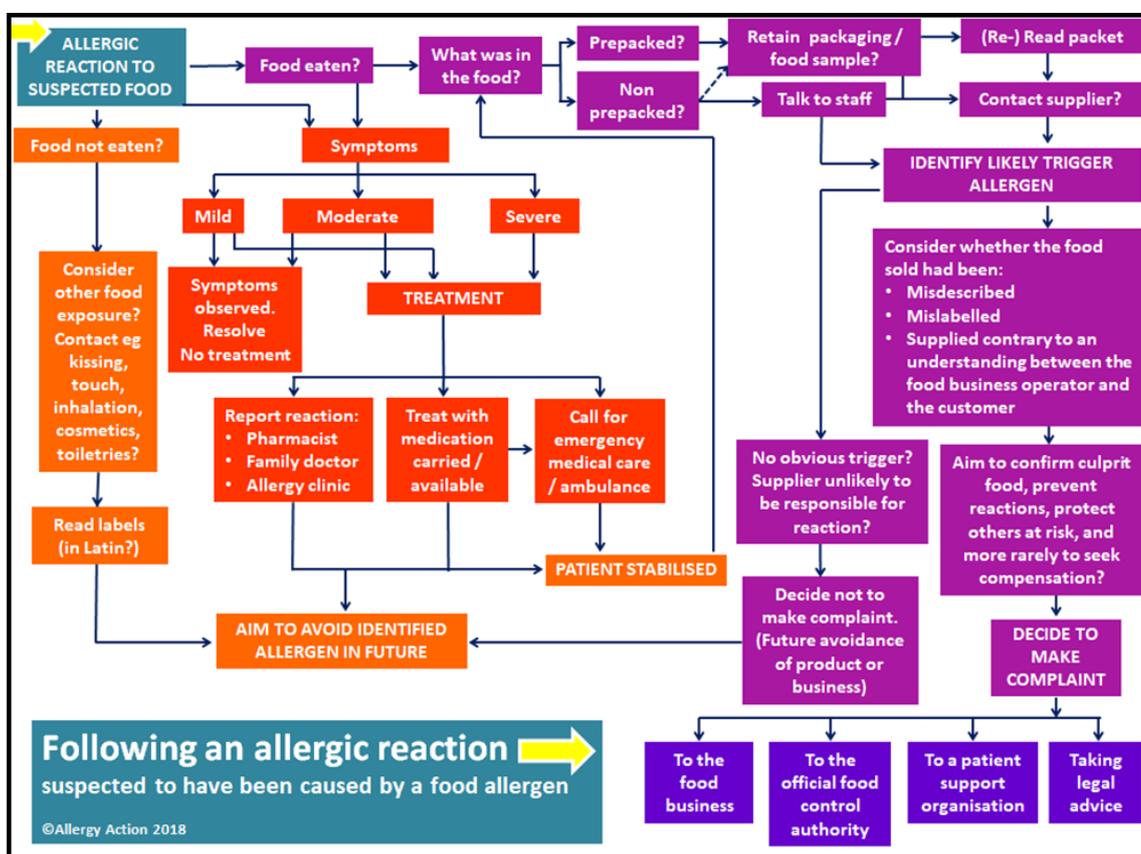


Figure 15: Possible routes of treatment and investigation following an allergic reaction to a suspected food from B3 – 2014

8.10 Review of progress to date - 2008

By 2008, Gowland was recognised as an authoritative partner in advocacy and training projects and experienced research collaborator. Through the Anaphylaxis Campaign and independently, she had become a 'hub', linking a wide range of individuals and organisations and helping to identify common ground. On the regulatory front, key allergens were now identified on prepacked foods and foods delivered to caterers. Early discussions were underway to require the provision of allergen information when eating out or buying non-prepacked foods as part of a major EU review of all food labelling (which led to Regulation 1169/2011 EC.) The possible unintentional presence of allergens (precautionary allergen labelling – PAL see 5.2 above) was not regulated for prepacked or non-prepacked foods. (It is still voluntary in 2018). Debate was still ongoing as to whether a food safety inspection should include the control of allergens as well as the traditionally policed risks (chemical, physical and microbiological.) The Food Standards Agency introduced the Food Hygiene Ratings Scheme, but food allergen controls were not necessarily included in the associated food safety risk assessment or scoring. This was (is) considered misleading by consumers with food allergies and intolerances.

Gowland and Dr Michael Walker continued their research into food allergy-related court cases. This led to the poster **(A3 – 2011)** which was presented at UK (BSACI) and EU (EAACI) allergy research meetings.

8.11 Research into living with a nut and / or peanut allergy

Anaphylaxis Campaign member data, and reports of fatal and other severe food allergic reactions suggested that allergies to peanuts and tree nuts were those most commonly reported in the UK population. The Food Standards Agency commissioned a consortium led by (now Professor) Julie Barnett at Surrey, then Brunel and now Bath University. Gowland acted as expert project adviser with a team of experienced research psychologists and Professor Jane Lucas from Southampton University. The study included an accompanied shop using a novel 'thinking out loud' methodology to collect data about consumer decision-making in-store, as well as an in-depth interview and a shopping basket activity. Gowland brought experience from her own study in **(W4 – 2002)** and as a peanut / nut allergic consumer, as well as her presentation and training skills to prepare the researchers and to analyse the data.

The output from the project was significant. In addition to the project report to the Food Standards Agency (Final Technical Report T07058 Understanding the food choice reasoning of nut allergic consumers), Gowland gave an oral presentation at the EAACI Food Allergy and Anaphylaxis Meeting in Venice (A2 – 2011). Papers were published on eating out with a nut / peanut allergy (P8 – 2011), interpreting labelling and packaging (P9 – 2011) and using 'May contain' labelling (P10 – 2011). Additional data analysis led to a poster (A6 – 2012) and papers (P11 – 2012) on travelling with a nut / peanut allergy and on other strategies used by consumers and those choosing their food (P12 – 2013). Gowland also gave oral presentations on eating out in a restaurant and managing food allergies in school at the EAACI Paediatric Allergy meeting in Barcelona (A4 – 2011 and A5 – 2011).

8.12 MSc courses in Allergy

Gowland had worked with the allergy clinicians at Southampton University School of Medicine / Southampton General Hospital since 1996. The part time modular MSc course in Allergy attracts students from around the world and from a range of backgrounds including general practice, paediatrics, dietetics and immunology. From 2009, Gowland was invited to give an annual lecture on this programme - *Living with Allergy* (W15 – 2009). This has also involved supporting some student projects.

From 2016, Gowland was also invited to deliver an annual lecture on the MSc in Allergy at Imperial College Medical School, London - *Risk Management in Food Allergy* (W23 – 2016).

8.13 Training partnership in Scotland

From 2009 Gowland worked with Graeme Kerr of Allergy and Hygiene Systems Ltd on developing and delivering a three hour training programme on Allergy Awareness. Initially this course was supported and accredited by James Watt College (now West College, Scotland) where Kerr was a lecturer. The interactive learning programme was shaped for a range of audiences (schools, nurseries, manufacturing, prisons, hospitals, hotels and restaurants), and includes a multiple choice assessment (W14 – 2009).

In 2011, Gowland and Kerr entered into partnership with the Royal Environmental Health Institute in Scotland (REHIS) to establish the Joint Award in Allergy Awareness (W16 – 2011).

They now provide materials, training and support for this accredited award to over 30 trainers delivering the award in Scotland and two in England.

8.14 Support for the London 2012 Olympics

Gowland was invited to produce food allergy guidance for caterers by Sustain - the alliance for better food and farming for the London 2012 Olympics ([W17 – 2012](#)).

8.15 Investigating Anaphylaxis Campaign member data and market research

Gowland and colleagues continued to collect data about Anaphylaxis Campaign members avoiding different food allergens. From 2008, these data were presented in Campaign talks, and shared with food industry and regulatory representatives.

It was noted that the list of food allergens on Annex IIIa (see Directive 2003/89/EC) did not include some foods to which members were commonly allergic. It was, and continues to be important to alert food suppliers to allergies which are 'on the horizon' or growing in prevalence. Gowland prepared and presented this poster at BSACI ([A7 – 2012](#)).

Further data on allergens avoided were made available by the study initiated by Dr Stella Cochrane and René Crevel of Unilever and undertaken by Mintel. This population survey provided data about consumers with food allergies from different areas of Great Britain and subjects from different economic and social backgrounds. Poster ([A1 - 2010](#)) and journal paper ([P13 – 2013](#)) were key outputs from this study.

8.16 The Food Information to Consumers Regulation

Regulation (EU) No 1169/2011 EC was developed from 2008 onwards, published in November 2011 and enforceable from December 13th, 2014 throughout the European Union. One key intention was to ensure that information on key allergens present as ingredients should be available for catered and non-prepacked foods. Another was to regulate the size of text on packaging to make it more legible. The practice of repeating key allergen ingredients in a *Contains* box was no longer permitted; instead they needed to be highlighted (eg **bolded**) in the ingredients list on packaging.

Individual member states were required to develop schemes to provide allergen information for loose foods, but allowed the flexibility to decide how best this should be done. Gowland worked closely with the leading catering organisations, the Food Standards Agency and Anaphylaxis Campaign colleagues to establish practical and

flexible ways to enable businesses to provide oral information, provided that they encourage consumers to make enquiries (by signage on counters, menus and websites) and the information is 'accurate, consistent and verifiable.'

In order to shape policy and ensure the needs of consumers with allergies, intolerances and coeliac disease were best met, the Food Standards Agency put out a research call. The core team led by Professor Julie Barnett at Bath University were contracted to carry out a questionnaire survey and in-depth interviews with representative consumers throughout the UK. The study report, *The preferences of those with food allergies and/or intolerances when eating out* (FS305013) <https://www.food.gov.uk/sites/default/files/fs305013-final-report.pdf> was followed by papers on consumer preferences for information, (P23 – 2016), experiences and behaviour when eating out with children with a food hypersensitivity, and a summary paper reviewing changes in eating out practices with the new law in place (P26 – 2018). At the time of writing, a final manuscript from this study is under review, examining the behaviour and expectations of consumers avoiding different food allergens (P29 – 2018).

8.17 Bringing the new regulation into practice

The requirement for all food businesses of any size to provide allergen information represented a major change in everyday practice. By comparison with food regulators in other EU member states, the Allergy and Labelling teams at the UK Food Standards Agency were well prepared. Working closely with stakeholders at all levels (including Gowland and the Anaphylaxis Campaign), they developed support materials, from the simplest information poster to more complex and detailed sector specific guidance with helpful visuals and content in community languages. Nevertheless there was a lot of work to do.

Gowland undertook consultancy work for many more clients in 2013-2014 than in previous years. She and Dr Chun-Han Chan of the FSA Allergy branch worked in a small team to deliver workshops and briefing sessions around the UK for the University Caterers Organisation (TUCO) and many others. She also wrote articles on the new regulation for different audiences - for example (P14 – 2013) for the Royal Society of Public Health (RSPH) and (W21 – 2014) for The Guardian.

Stocks of the Allergytraining DVD Training Pack first developed in 2006 were running low, and the content needed to be updated to meet the new regulatory requirements. Gowland revised the script and included some new film, marketing it through a new website www.allergytraining.com .

The regulation came into force just before Christmas which was not particularly helpful for restaurants and hotels at their busiest time of year. Gowland made a comic video **(W22 – 2014)** about all the resources now available to help meet the new requirements. She wrote the words, designed the graphics and persuaded musical friends to record the soundtrack.

Parallel work was underway to update the 'Catering Industry Guide' for the first time in two decades. Gowland was invited to add a chapter on how to meet legal requirements to manage and control food allergens **(W24 – 2016)**.

8.18 Food fraud: allergen substitution in the food supply chain

In response to a number of fatal reactions and many more 'near miss' reactions following inaccurate food description, and possibly deliberate mislabelling (for example cheaper peanut substituted for more expensive almond in curries), Gowland and collaborator, Dr Michael Walker were particularly aware of the potential risks to people with food allergies from deliberate and inadvertent ingredient substitution. Following the 'horsemeat' mislabelling episode, Walker worked closely with Professor Chris Elliott to examine, understand and report on UK food supply networks, and arranged for Gowland to give formal evidence of food allergy cases with which she had been involved where mislabelling and food fraud might have been involved (W18 – 2013). They also presented a poster at the EAACI Food Allergy and Anaphylaxis meeting in Dublin (A9 – 2015).

Walker's work as Consultant Referee Analyst for the Government Chemist Programme and on-going partnership with Gowland looking into methods for allergen analysis and the forensic aspects of evidence to support regulation continued. Walker coordinates the Masters in Chemical Analysis (MChemA) training programme in food examination for Public Analysts, and invited Gowland to deliver the key food allergen content with him in 2015 and 2017. Both are members of the Scientific Committee of the Institute of Food Science and Technology (IFST) who published their article *Food allergy - A forensic perspective* (P17 – 2014).

They also wrote an article for The Guardian (W20 – 2014).

8.19 R v Zaman – a landmark case

On January 30th, 2014, a chef and bar manager, Paul Wilson (38) bought a takeaway curry from an Indian restaurant in North Yorkshire. He had had a peanut allergy since the age of 7, and asked for his meal to be made without peanuts. This was documented on the order docket and on the lid of the meal. Hours later, he was found dead in the bathroom of his flat. He had suffered a severe allergic reaction. The remains of his meal were on the kitchen table. Analysis of post mortem samples and the curry meal indicated the presence of peanut protein.

The owner of the restaurant, Mohammed Khaliq Zaman, had a number of other restaurants. One of these had sold a curry meal to a 17 year old girl on January 3rd 2014. She had also declared a peanut allergy, and had a severe allergic reaction. She had

recovered after emergency treatment in hospital. The local Trading Standards team were notified and investigated the restaurant in question. Formal food samples were collected and analysed. A meal sold as suitable for a person with a peanut allergy was found to contain peanut protein. In addition, menus indicated that dishes were made with almonds when in fact they were made with peanut powder. Staff at that restaurant were advised not to sell meals to people declaring a peanut allergy.

Mr Wilson's death led to a combined North Yorkshire police and local authority trading standards investigation supported by the West Yorkshire Public Analyst and the Food Standards Agency. Gowland supported the investigation and provided background information about other fatal cases, particularly involving peanut in curries. A supply chain investigation indicated that the owner of the restaurants had changed from using ground almond to cheaper peanut powder the previous summer. A representative from one of his wholesale suppliers gave evidence that Mr Zaman had been advised that the new peanut ingredient was not the same as ground almond and might represent a risk for some people. He was also advised to update and correct his menus to reflect this change which he did not do.

In May 2016, Zaman was convicted of gross negligence manslaughter. It was considered that if he had acted to alert all his restaurants using the peanut powder ingredient instead of ground almond, and taken his responsibilities as a food business operator more seriously, Mr Wilson might not have died. He was also convicted of a number of food offences: *Placing food on the market that was unsafe and injurious to health* (Regulation (EC) No 178/2002 and Food Hygiene (England) Regulations 2013), *Selling food not of the substance demanded* and *Falsely describing food* as containing almonds when it contained peanuts (Food Safety Act 1990). Mr Zaman was sentenced to 6 years in jail. Appeals against his conviction and sentence in October 2017 were both dismissed.

Gowland and Walker continue to examine and review cases involving food allergy and the evidence required for a criminal conviction or civil claim. They presented a summary poster (A12 – 2016) at the BSACI (UK allergy clinicians) meeting and also at the annual meeting of the Association of Public Analysts, and published the paper (P18 – 2015) and article (P20 – 2015).

Their long-standing collaboration with leading professors in chemical and biological analysis led to the publication of the critical review paper (P21 – 2016) targeted primarily

at the analytical community, but also at regulators and people managing food allergens throughout the supply chain.

The analytical community led by AOAC International (previously the Association of Official Analytical Chemists) published an open access special edition of their journal looking into many aspects of food allergy and food allergen control and analysis (P27 – 2018).

Walker, Gowland and fellow IFST scientific committee member, John Points contributed the chapter *Managing Food Allergens in the U.K. Retail Supply Chain*. The influence of UK retailers (primarily supermarkets) in supervising and controlling allergens in the supply chain for their own brand products, and also in managing relationships with food-sensitive consumers, understanding consumer information needs and expectations continues to shape best practice, enhance consumer choice and reduce risks for people with food sensitivities.

8.20 Following the EU Food Information to Consumers Regulation

This regulation, and its requirement that all businesses preparing and selling food should provide information about key allergen ingredients on request were widely publicised throughout the European Union. In many cases this was the first time that clinicians providing patient advice to people with food intolerances and coeliac disease were as well-informed about food regulation to help those in their care. The Food Standards Agency produced guidance for consumers from November 2013 *Advice on food allergen labelling – How to buy food safely when you have a food allergy or intolerance*.

Leading allergy physicians and researchers, Professor Nikos Papadopoulos, President of the European Academy of Allergy and Clinical Immunology (EAACI) at this time and Professor Antonella Muraro, his successor from 2016 were both closely engaged in food allergy patient advocacy. It was significant at this time that EAACI prioritised food allergy and patient / consumer support. This was achieved a) by influencing the practical implementation of food information provision at EU level, b) by setting up the EAACI Food Allergy and Anaphylaxis Guidelines Group and c) by ensuring participation from a range of clinical stakeholders with close working relationships with patient representatives, food allergen scientists and regulators. The resulting EAACI Food Allergy and Anaphylaxis Guidelines and paper (P15 – 2014) continue to provide

authoritative guidance for clinicians and shape policy at EU level. Gowland contributed background information as a food allergic consumer, but also from experience advising a wide range of food businesses and shaping regulation and best practice. It became important at this time for allergy clinicians advising patients on allergen avoidance to understand food labelling, and also the issue of Precautionary Allergen Labelling (PAL) also known as 'May contain' labelling. One leading UK clinician with an informed interest in this area is Dr Paul Turner at Imperial College, London with whom Gowland wrote the letter to Allergy (the EAACI journal) (P24 – 2016).

8.21 Understanding the severity of allergic reactions

The food allergy community had long recognised that allergic reactions to foods were very rarely fatal, and that in many cases, even severe symptoms seemed to wane without treatment (Simons, 2008 and P22 – 2016). Living with the risk of severe allergy is unpredictable. It was also recognised that various factors may affect the progression of symptoms including the amount of allergen consumed (eliciting dose) for the weight of the person, and the form (matrix) in which the food is served, as well as co-factors (such as infection, asthma, age, exertion, alcohol, stress, medication). Using data supplied by researchers in Australia and the UK (including Gowland's fatal allergy data supplied to the UK Fatal Anaphylaxis Registry), Turner presented a poster at the international American Academy of Allergy, Asthma and Immunology (AAAAI) meeting in the USA in 2014 (A8 – 2014).

As described in sections 4.5 and 5 above, it is increasingly recognised that on-going work from clinical challenges to establish (minimum eliciting dose) threshold amounts of proteins from different foods known to cause allergic symptoms represented only one possible component in managing allergens and reducing risks.

Another component in allergy risk assessment is the likelihood of a food allergic person encountering a food to which he or she is allergic. The food industry and others recognise that food allergies differ across different populations (Nwaru *et al.*, 2014) and are influenced by external factors such as age of moving to a different country (Tang *et al.*, 2017).

Yet another component is the likelihood of a reaction becoming life-threatening. Following Pumphrey's work investigating and reporting fatal anaphylaxis (Pumphrey,

2000, and **P4 – 2007**), Turner, Gowland and colleagues involved in the EU-funded iFAAM (Integrated Approaches to Food Allergen and Allergy Risk Management) collaboration examined the perception of reaction severity. It was increasingly recognised that symptoms which may look dramatic (eg facial swelling, rash) may not be as severe as others which are less obvious such as respiratory or circulatory collapse. Some individuals who have experienced anaphylaxis may not have a lower eliciting dose of a food allergen compared with others whose symptoms are less severe (**P22 – 2016**).

As described above, a perennial challenge for food sensitive consumers and for food suppliers is the use of precautionary allergen labelling (PAL) or 'May contain' warnings to indicate the possibility of an allergen being present, not as an ingredient but from the production environment. Gowland contributed to best practice guidance eg *The IFST Dealing with allergens in Good Manufacturing Practice – A guide to its responsible management* in 1998 and recognised industry standards since (including the British Retail Consortium (BRC) Global Standard 2015) which aim to optimise allergen segregation and control to minimise the need for PAL.

Some recent work in this area comes from a consortium which includes experienced allergy physicians, many of whom have contributed data from clinical and research food challenges which have helped to establish thresholds for different food allergens, and understand more about allergy symptoms severity. The consortium which was supported by ILSI, an international industry sponsored research organisation also included the industry regulatory and scientific community, the regulatory perspective, patient and consumer representatives and experts in allergen controls and allergen management (**P28 – 2018**).

It is now recognised that although quantitative risk assessment (QRA) for food allergens has made considerable progress in recent years, its use in practice is limited due to the feasibility of including the additional variable of reaction severity. This depends on multiple factors, related both to the food and the allergen, and also to the person experiencing symptoms, as well as any treatment they may receive. Even when food challenges are administered under highly controlled conditions, the relationship between dose and severity is complex and not clear. Epidemiological studies collecting reaction data have limited benefit. One answer might be to undertake a single-dose challenge – giving everybody the same dose of allergenic protein in the same food item

to reliably identify the effect of dose on severity for use in QRA. This might reduce uncertainty among people at risk and those who care for them, thereby improving their food choice.

8.22 On the horizon

The first paper from the TRACE study looking into the relationship between allergen dose, severity and associated co-factors has recently been published online (Dua S, *et al.*, 2018).

Further publications and the full study report for the Food Standards Agency will follow. They will describe valuable minute by minute details of symptoms development at different challenge doses of peanut protein and under any influence of a) exercise and b) lack of sleep.

Gowland continues her involvement in other horizon-scanning activities. One such is monitoring foods which are more frequently mentioned as causing more reactions (for example peas, beans and other legumes, particularly when used in unexpected foods eg bakery items.) This is made easier, not just through monitoring Anaphylaxis Campaign member data, but also through social media and particularly Twitter – using hashtags such as #foodallergy, #stupidpeas, #stupidsoy, #14allergens #freefrom #hivessuck etc. (See Hamshaw *et al.*, 2018).

Another activity with which Gowland is involved is providing expert insight for individuals and organisations working on technological innovations. Dr Lauri-Ann van der Poel, consultant allergy physician also has an interest in the FoodMaestro digital platform in partnership with the Kings College and Guy's & St Thomas' NHS Trust (<http://www.foodmaestro.me/home.html>). It offers mobile apps combined with clinically verified data (ie following diagnosis by a health professional), enabling users to find products they can eat when living with allergies, intolerances and other food avoidance needs. Gowland worked with the dietetics and allergy team on this poster **(A10 – 2016)**.

Twenty four years after Gowland joined the Anaphylaxis Campaign and started her allergy work, colleagues continue to monitor and record enquiries from members, journalists and many others. These remain one key method of assessing the daily impact of severe allergy, and the challenges still faced by those at risk **(A11 – 2016)**.

9 Conclusion

When she joined a small team of Anaphylaxis Campaign volunteers in 1994, Gowland never anticipated that this would become her main occupation or continue over two decades. The time was definitely right for both advocacy and research, and Gowland had the opportunity, skills, experience and support from those around her to make a viable contribution in this field. One early role of the Campaign was to become a recognised and authoritative hub, joining people and organisations who might not otherwise encounter one another. Gowland too has become a hub – helping different stakeholders connected with allergy to identify and work with others. This is shown in the wide variety of publications – journals, newspapers, magazines and other media in which Gowland’s work has been disseminated.

In 2003, Gowland was invited to chair a Food Allergy conference organised by a leading food law publication. At first this was a daunting prospect, but it soon became clear that she was the only person who knew nearly everybody in the room, and as such was able to ensure that all voices were heard, all questions answered and the event was considered a great success.

In a cross-disciplinary role for which there were no formal professional or academic qualifications, Gowland has adapted to understand and find common ground with many other organisations and individuals. This would not have been possible without the support of key colleagues, and particularly David Reading and Moira Austin. Their partnership has been innovative, effective, fruitful and enduring.

It was useful in the very early days that there were enough capable individuals at the heart of the Campaign for people to specialise. Gowland had primary involvement with issues relating to food – the food industry, regulation, guidance and standards, whilst having secondary involvement with issues affecting schools and child care, and also contributing to managing a fast-growing national voluntary organisation.

9.1 Skills development

Gowland has developed skills in four key areas:

- Advocacy including media
- Research methodology

- Training
- Administrative and business skills

9.1.1 Advocacy skills

- Political – House of Commons, House of Lords, European Union and Codex
- Bereavement support
- Pastoral support
- Listening to and representing the interests of families and individuals
- Taking complaints on behalf of individuals
- Taking histories
- Completing reaction records
- Giving evidence – written and oral
- Recognised point of contact for the BBC and other journalists
- TV and radio interviews and also shaping documentaries
- Writing news articles and press releases
- Networking

9.1.2 Research methodology

- Submitting and developing applications for funding and support
- Building collaborative teams
- Contributing to project ethics
- Literature review
- Setting up and managing databases
- Modelling – presenting ideas
- Preparing abstracts
- Preparing and producing posters
- Presenting posters at meetings
- Giving workshop conference presentations
- Writing papers
- Collaborative writing and editing
- Developing graphics for publications and posters
- Responding to reviewer comments
- Explaining science and technology
- Explaining consumer and patient behaviour

9.1.3 Training skills

- Materials development
- Session planning
- Creating a learning environment
- Developing interactive learning
- Preparing slides
- Devising and developing online learning for different audiences
- Creative learning methods
- Developing and marketing packs
- Accredited learning – HCTC / HTF, RSPH, REHIS standards
- Making learning accessible for students and exam candidates
- Adapting content and materials for care homes, nurseries, schools, colleges, university caterers, factories etc
- Logistics
- Setting learning aims, objectives and assessments
- Setting learning standards to reduce risks

9.1.4 Administrative and business skills

- Communications – responding quickly and flexibly
- Writing press releases, giving interviews
- Public speaking to a wide range of audiences
- Consultancy – being a trusted and respected authority
- Supporting business decision-making at all levels from café and factory floor to board level
- Setting up and managing a small business and brand
- Project tendering and contracts
- Conference and events management and logistics
- Film making – script writing, editing, production, managing and directing actors, scene-setting, props, sourcing music, artwork, locations, marketing, online sales and ethics.
- Websites – building, designing, managing, retail
- Collecting and designing content for slide presentations

9.2 The Impact of innovation

In the early days, all communication between Campaign colleagues and others was undertaken by telephone, letter and occasionally fax. Most committee members were employed elsewhere in the day time, and undertook their Campaign roles in the evenings and at weekends. Contact with members was primarily through the printed and posted newsletter. The first office was opened and staffed during normal office hours in 1997, and Gowland's earliest emails with the Campaign date from the late 1990s. The Campaign was involved in making educational films from 1996 and had a website from about 2000 when Gowland also set up her first website as Allergy Action. Food allergy product alerts were sent out from 1999, initially by letter from the office, then using an external company to print and post out letters, and eventually using texts and emails. From about 2000, the Food Standards Agency was also involved in allergy alerts and people could subscribe directly to receive them by text and email.

In more recent years, contact by email and via social media (eg Facebook and Twitter) or the Campaign's website has become more common than by phone or letter. Figure 16 is taken from poster (A11 – 2016).

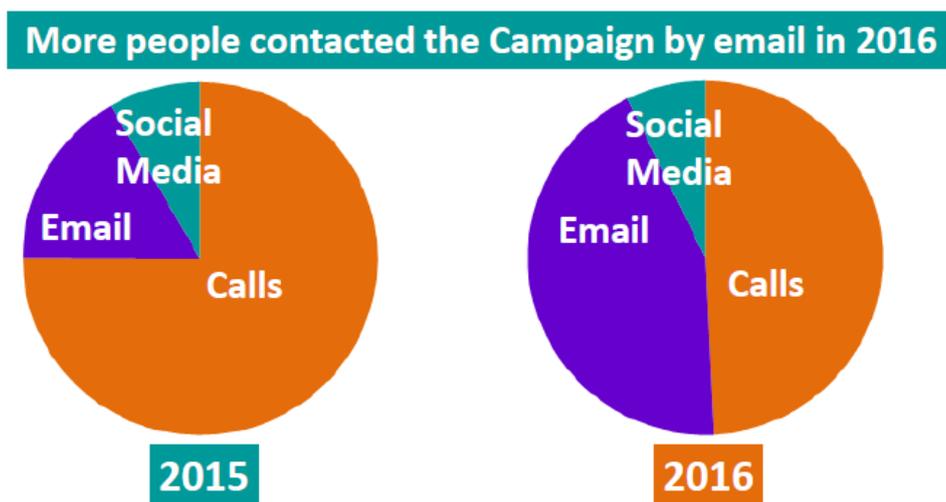


Figure 16: Routes of contact with the Anaphylaxis Campaign 2015 and 2016

In addition, advocacy may involve social media. People who have suffered an allergic reaction may raise this with the food business and / or regulatory authority publicly on Twitter or Facebook. Reputational damage may be mitigated by a swift response, apology if relevant and a thorough explanation of how the incident occurred.

Consumers may expect such replies late into the evening; for example, one leading UK retailer has staff monitoring and responding to Twitter until 11pm.

Technological developments have also had an impact on research methodology. Subjects (eg for the TRACE Study) were recruited online and via social media. Microsoft packages such as Excel (for the hospital admissions and fatal anaphylaxis databases, and also for data collection for the milk, egg, sesame and 'May contain' studies, and for managing student data for training) and Powerpoint (used for lectures and presentations and much training) had been available from the late 1990s. Online journal access and shared editing using 'tracked changes' were more widely used from about 2006. This enabled international collaborators in different time zones to add timely comments and edits, and respond to reviewer comments promptly. Being able to email and share larger files means that working groups can fine-tune amendments without the need for face to face meetings.

Early surveys were undertaken on paper, and data was collected by post. As described above, the very first survey on milk and egg allergy involved a short note in the Campaign's newsletter and 300 lengthy letters in reply. The sesame surveys which followed involved posting out paper forms and stamped addressed envelopes. A few subjects emailed their responses.

More recently, researchers including many masters' students use applications such as Survey Monkey to collect data. Links to the studies are posted on social media. Some studies (eg the FSA funded study looking at consumer behaviour before and after the introduction of the Food Information to Consumers Regulation (EU) No 1169/2011) have relied on consent being obtained in the early stage for subjects to be contacted again to participate in the later stage. It has to be recognised that online surveys and other innovations have some limitations and may exclude some people whose views may not be represented.

The internet has also had a major impact on research into severe and fatal reactions. News media and social media may pick up a news story involving allergy within days or sometimes even hours. Inquests and other court cases may be reported in real time via local and national news sites and then circulated via Twitter and Facebook. When supporting bereaved and other families, Gowland now has to brief them about the

immediate and longer term impacts of media coverage on all family members and friends.

At the same time, it is now possible to watch Twitter feeds and to review and manage allergy misinformation promptly. Posting a link to a reputable evidence-based publication or adding a corrected précis of a journal paper or news story can often limit anxiety and prevent further circulation of inaccuracies. Helping people to find trusted information sources is an on-going challenge – see Hamshaw *et al.*, 2018.

From 2001, Gowland travelled widely within Europe to participate in research workshops and European Union funded projects including Informall, Europrevall and ILSI initiatives. These, whilst enabling face to face collaboration and the establishment of effective working relationships, are expensive in time and travel. More recent collaborations have involved partners meeting for a one day workshop at a hub location, or more commonly in 2018, a teleconference or online meeting with shared screen access.

9.3 The changing role of patient and consumer support organisations

The Campaign began because particular needs were identified. These included:

- Wider recognition of the risks from severe allergies
- Support in accessing medical care – both for emergencies, and on-going specialist care for allergy and related conditions
- Impact assessment to really understand how many people are living with allergy, what people are allergic to and what impact it has on their lives
- Engaging in dialogue to improve food information and reduce risks in food supply to protect those at risk
- Ensuring regulatory and best practice guidance in a number of areas to protect those at risk
- Support for individuals at risk in different scenarios – school, child care, university, workplace, travel etc

Individual, (health care) professional and corporate food and pharmaceutical industry members joined the Campaign to support its aims and to access up to date news and information. This is still the case, but subscription membership of voluntary organisations has been in decline for the last decade. Fundraising through sponsored

events (eg marathon running) and to some extent through 'in memoriam' funding continues. External fundraising through charitable trusts is not as accessible as it used to be and far more competitive. Economic constraints, attitudes to charitable activity and alternative routes of advocacy all have their impact.

Technological innovations described above have changed the role of patient and consumer support organisations, not least the internet. Information is available free from a wide range of sources at anytime and anywhere. Training and education can be delivered using online webinars and videos eg YouTube. Identifying with, promoting and supporting a cause or an organisation can be undertaken for free via social media. Tweets, emails, Facebook messages and Mumsnet threads may lead to instant comments or replies. Conferences and other events are transmitted in real time and posters and key slides shared online.

9.4 Protecting people with food allergies

Through this commentary, Gowland has described work to protect consumers with food allergies, and her contribution to this since 1994.

Key research studies which she has undertaken, and with which she has been associated have contributed significantly to understanding the impact of food allergy from many different perspectives.

She has established and built on relationships with many different organisations and individuals, learning from them, and encouraging and helping them to develop strategies, materials, knowledge and skills to reduce risks to people with food allergies.

Her work with local, national and international regulatory bodies and with those developing policies, protocols and guidance across many different sectors has shaped both regulation and voluntary best practice.

Her legacy also includes the establishment of ethical standards and working practices for advocacy, research and training to represent the interests of those at risk from allergy and those who care for them.

Whilst her career has often been more reactive than proactive, she continues to adapt to new circumstances, remaining focused on understanding and representing the needs of those at risk from allergy. This has involved the development of novel and

creative methods for advocacy, research and training, and the establishment of lasting and successful working partnerships.

10 Future considerations

At the viva examination on October 15th, 2018, Gowland was asked by her examiners to comment on the underlying principles of her work, and how they would influence future work in advocacy, research and training to support and protect those at risk from food allergy.

10.1 Commitment to enabling and empowering

The key principle of advocacy is that living with food allergy is manageable. With appropriate diagnosis, guidance on allergen avoidance, and support in recognising and managing symptoms, those at risk and those who care for them should be able to lead as full lives as possible.

10.2 Commitment to building relationships

Future work to support and protect those at risk should continue to involve identifying partners and potential allies, finding common ground and creating alliances with individuals and organisations who may be able to raise awareness of allergy risks, understand them more fully, and adapt policies and practice to improve lives.

10.3 Commitment to listening to those at risk

The final commitment is to recognise that effective advocacy and support depend entirely on continuing to listen closely to those living with food allergy, respecting their (sometimes conflicting) perspectives and including them and those who care for them in food and healthcare policy decision-making for the improved management of allergens and allergy.

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