SPECIAL GUEST EDITOR SECTION: FOOD ALLERGENS MANAGEMENT

Managing Food Allergens in the U.K. Retail Supply Chain

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The U.K. food and grocery market is highly significant financially and dominated by 10 retailers within a regulated and extremely economically competitive environment. We summarize the approach of U.K. retailers to allergen risk assessment (RA) and risk management (RM) within the U.K. legal framework and explore public visibility of retailers' allergen policies. RA and RM of allergens appear effective in curtailing retail-triggered severe food allergy reactions. However, allergen recalls remain high, precautionary allergen labeling (PAL) remains an area of confusion, and there is no consistent Web-based provision of information for consumers who have allergies. Resolution of PAL awaits an agreed-on threshold framework, but a key challenge is to engage with patients and gain their trust rather than thrust education at them. It would be helpful for retailers to publish their allergen RA and RM policies. A target should be agreed on between government and retailers for a reduction in the proliferation of PAL wording variants by a given date within the next 3 years. A further hurdle is potentially flawed allergen analysis—development of reference methods and reference materials are acknowledged needs. Laboratories should report allergen results in an informative manner, communicating uncertainty and caveats. Ideally a laboratory representative would be included on any incident control team. Efforts must continue to standardize preparedness for protecting and defending food and drink from deliberate attack.

Why do food allergens need to be managed? Because people with food sensitivities, such as allergies, intolerances, and celiac disease need to avoid them—otherwise they may come to actual harm. Risk assessment (RA) and risk management (RM) of food allergy and food allergens involve different stakeholders (Figure 1); the latter, being a special case within general food safety, involves all stakeholders and prominently impacts retailers and caterers and their manufacturing suppliers. The attitudes of these players toward RA and RM influence to a significant degree the safety and quality of life of people who have food allergy. Herein, we (*1*) describe the U.K. legal framework in which retailers' RA and RM of allergens operates, (*2*) describe the structure of the U.K. food retail industry, (*3*) summarize the approach of U.K. retailers' and their manufacturing supply chain to allergen RA and RM, (*4*) discuss management of incidents, (*5*) discuss precautionary allergen labeling (PAL), and (*6*) explore public visibility of retailers' allergen policies and how much practical use they are to food-sensitive consumers in making informed decisions. Finally, we draw some conclusions and recommendations for future action to better support retailers in protecting consumers who have food allergy.

Allergens, Food Law, and Guidance in the United Kingdom

Responsibility for safe and properly labeled food rests with those who make and sell it. The food industry seeking to provide safe products and consumer choice must have policies and procedures in place to label products accurately and minimize allergen cross-contamination in the harvesting, storage, transport, and processing of food and the cleaning of equipment. The development of allergen-free product lines places a particular burden of responsibility on allergen control. There is a public expectation for government oversight; hence, food industry responsibilities are prescribed in law and informed by guidance from trade bodies and government.

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 that mislead consumers. Being misled about what a food contains carries risks for people who have food sensitivities. Article 14 prohibits the sale of unsafe food, such as food injurious to health, including the particular health sensitivities of any specific category of consumers (i.e., including, but not exclusively, people who have food allergy) for whom the food is intended for that category of consumers.

Regulation (EU) No. 1169/2011 on the provision of food information to consumers addresses allergen avoidance risks related to composition, labeling, and food safety and stems from the global food-labeling standard of mandatory disclosure of the presence of allergens on prepacked food labeling, which is found in the Codex Alimentarius General Standard (1). The Codex

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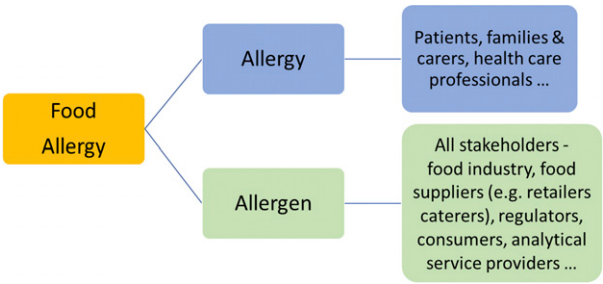

Figure 1. Stakeholders involved in the risk assessment and risk management of food allergy and food allergens.

standard lists eight allergens with international variants (2, 3). The inclusion in prepacked food of any of the 14 allergens defined by Annex II to Regulation No. 1169/2011 triggers, with certain limited exemptions, specific labeling requirements. Any Annex II allergens included in a food as ingredients or processing aids and still present in the finished product, even if in an altered form, must be included in the list of ingredients. The citation must be a clear reference to the name listed in Annex II and emphasized through a typeset that clearly distinguishes it from the rest of the list of ingredients, e.g., by means of the font, style, or background color; Figure 2 illustrates an example. Exceptions are prepacked food exempt from an ingredients list (e.g., single-ingredient foods or alcoholic drinks with more than 1.2% alcohol by volume); these must still disclose any Annex II allergens present under the heading "Contains," followed by the Annex II name. The obligation to declare Annex II allergens was extended on December 13, 2014, to non-prepacked food, whether in or from catering establishments. The means of doing so was left to individual European Union (EU) member states. In the United Kingdom, Annex II allergen information may be provided in writing and also orally, as long as it is accurate, consistent, and verifiable, and signage invites consumers to request it.

The Annex II list includes only one allergen for which a quantitative limit is given, i.e., "sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L in terms of the total SO_2…." This limit is derived from the LOD of the reference method (4) for the determination of sulfites in food. However, for "cereals containing gluten," Commission Implementing Regulation (EU) No. 828/2014, which came into force July 20, 2016, sets out limits for gluten. Food can be described as "gluten-free" if it contains no more than 20 mg/kg gluten and "very low gluten" if it consists of or contains one or more ingredients made from wheat, rye, barley, or oats or their cross-bred varieties, which have been specially processed to reduce the gluten content, and contain no more than 100 $mg \cdot kg^{-1}$ gluten in the food as sold to the final consumer. It should be noted that inclusion in a food of a "cereal containing gluten," albeit one that conforms to the above criteria, still requires declaration in the list of ingredients.

In the United Kingdom, the Food Safety Act of 1990 provides the enabling powers under which all food regulations are made and establishes the main criminal offenses. These are rendering food injurious to health (Section 7); selling, to the purchaser's prejudice, food that is not of the nature or substance or quality demanded (Section 14); and falsely or misleadingly describing or presenting food (Section 15). A retailer could find itself in court under any of these for allergen noncompliance, although Section 14 is probably the most frequently applied.

Thus, allergens added as ingredients and "free-from" products are primarily controlled by food labeling, whereas cross-contaminant allergens (i.e., allergens that are not intended in foods, but arise therein during harvesting, transport, storage, or processing, are sometimes referred to as "cross-contact" or "hidden" allergens; we prefer to use the term "cross-contaminant allergens") in all products are subject to general food law (Figure 3). Cross-contamination with allergens may trigger general principles of European and U.K. food law that require the application of Hazard Analysis Critical Control Points and make it an offense 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.

In light of the United Kingdom's intention to leave the EU (i.e., Brexit; 5), the Department for Exiting the EU plans (6) for the conversion of existing EU law into domestic legislation and intends that any question as to the meaning of EU-derived law will be determined in U.K. courts by reference to Court of Justice of the European Union case law as it exists on the day the United Kingdom leaves the EU. Hence, EU law on allergen labeling will continue to apply in the United Kingdom for the medium term, and the Food Safety Act of 1990 is unlikely to be altered significantly. In the longer term, it will be open to the U.K. parliament to make changes to law transposed from the EU. However, the need to trade with the EU and overriding Codex standards render it unlikely that significant change to allergen law will occur.

Hence, the food industry, and retailers in particular, must know whether allergens are present in their products and/or

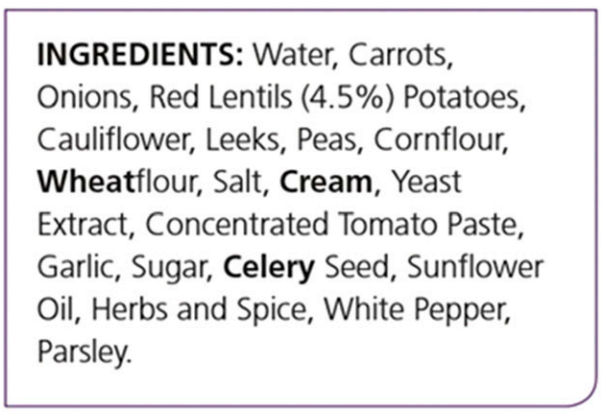

Figure 2. Illustration of allergens highlighted in the ingredients list of a prepacked food (49).

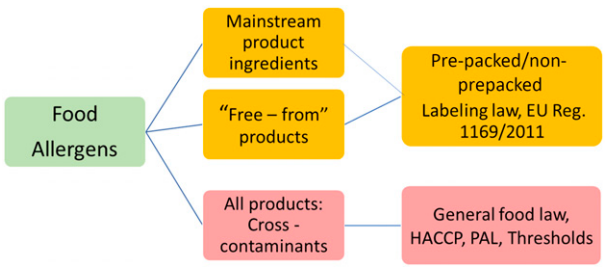

Figure 3. Law applicable to food allergens and food products. HACCP = Hazard Analysis Critical Control Points.

production environment and work out ways of controlling them or alerting consumers to the possible risk of their presence through advisory labeling. Allergens in the "wrong place" can render food unsafe for people with food allergy. The effect of requiring certain allergens to be labeled/highlighted is to prioritize controlling them in the supply chain. However, there are many other foods that provoke allergic reactions that are not specifically legislated for and must be managed. The U.K. Food Standards Agency (FSA) has published comprehensive best practice guidance on allergen cross-contamination and "may contain" labeling. Training first introduced in 2008 (7) includes factory and non-prepacked food scenarios. Guidance aimed at small- and medium-sized food businesses was published in August 2014. Technical guidance on Regulation No. 1169/2011 was provided in April 2015 (8), supplementing FoodDrink Europe, the 2013 guidance on Food Allergen Management for Food Manufacturers (9).

Retailers are subject to the U.K.'s official food control system that must, in turn, comply with Regulation (EU) No. 2017/625 of March 15, 2017 (10) on official controls and other official activities, which recently replaced Regulation (EC) No. 882/2004. Regulation is primarily the activity of the state embodied in the central competent authority, which is a government department that advises Ministers on policy and drafting legislation for approval by Parliament. Regulatory responsibility in the United Kingdom for food allergy rests with the FSA (11), and, separately, Food Standards Scotland (Scotland Food Standards established by the Food Act of 2015 in Scotland as a non-Ministerial Office, which is part of the Scottish administration, alongside, but separate from, the Scottish Government; 12). Enforcement of legislation is mainly a function of local government. Owing to the large number of local authorities, coordination on allergen control can be difficult. However, businesses are encouraged to avail of primary authorities, usually where the business headquarters are located, which aims to ensure consistency of approach for a single retailer across all U.K. outlets and products. Major food businesses may demonstrate earned recognition in their RAs and RM, leading to light-touch regulatory oversight. Against declining food enforcement activity, generally, U.K. local authorities continue as best they can to prioritize allergen safety.

Thus, retailers operate within a heavily regulated environment that may lack consistency in approach and currently features some future legislative uncertainty.

The U.K. Food Retail Industry

The U.K. food and grocery market is highly significant financially, estimated to be £206 billion (U.S. $264 billion) by 2018 (13) and dominated by 10 retail multiples, which, by descending market share in 2015 (latest available data), are Tesco, Asda, Sainsbury's, Morrisons, ALDI, Waitrose, Lidl, The Co-Operative (Co-Op), Marks and Spencer (M&S), and Iceland Foods (Figure 4). The combined market share of food and nonalcoholic drinks of the largest four food and drink retailers was 54% in 2015, down from 61% in 2014. The three largest discounters (ALDI, Iceland Foods, and Lidl) had a combined market share of 13%, up from 12% in 2014 (14).

The United Kingdom is unusual in that the dominant retail multiples have a strong own-label history. The proportion of own-label food products varies, but is typically around 50% for the "big 4" (Tesco, Asda, Sainsbury's, and Morrisons), with ALDI and M&S being almost entirely own-label. Retailers have a high degree of control over the manufacture of own-label products, but rarely any transparency or control over the manufacture of the branded products that they sell. Manufacture of own-label foods is under contract, either by manufacturers who also produce their own equivalent branded products or by companies that specialize in own-label and may produce similar products for different retailers' own-label. There has been significant industry consolidation over recent years, and relatively few manufacturing multiples now account for the majority of U.K. own-label production.

Post-horse meat scandal, and in an extremely economically competitive environment, there have been significant moves by own-label retailers to simplify and consolidate their supply chains for the raw materials they use. It is increasingly the case that one retailer will use the same source of an ingredient across as many of their own-label lines as possible, irrespective of which manufacturer produces them. Thus, an allergen incident relating to a single ingredient will impact a wide range of a retailer's own-label portfolio, impact own-label

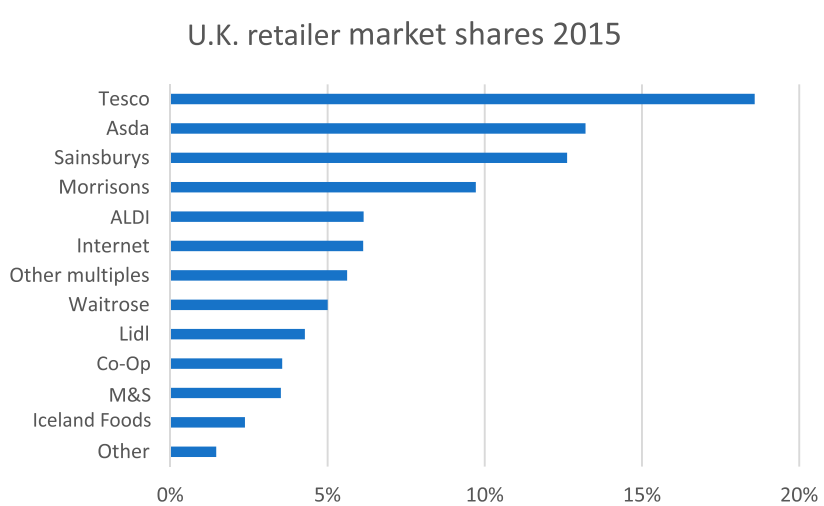

Figure 4. U.K. retailer market shares (14).

products from many different retailers, and also impact branded products manufactured at the same site(s).

Allergen Risks in the Retail Supply Chain

Allergen risks to consumers from manufactured foods can be categorized as arising from the following:

(*1*) mispacks, i.e., putting a product in the wrong packaging
(*2*) inadequate labeling of an allergenic ingredient
(*3*) cross-contamination

In our experience, mispacks and inadequate allergen labeling are the predominant reasons for recalls. Cross-contamination can arise at any point in the supply chain: primary production of an ingredient, transport, storage, or manufacture of allergenic foods in proximity to nonallergenic foods. A rare, but disturbing, risk that must also be managed is the malicious adulteration of foods with an unlabeled allergen by someone with access in the supply chain (15).

Allergen RM to secure consumer safety and to attempt to avoid incidents involves traceability (16), active management and segregation (17), cleaning and its validation, verification and monitoring (18), and communication (19).

Retailers' Approach to Own-Label Risk Management

The traditional U.K. supermarket model is for a central technical team to manage all aspects of own-label product quality, with specialists within the team responsible for different categories of foods. This is underpinned by a set of documented quality and RM policies that are written into their trading terms with the contract manufacturers. The retailer's technical team visits manufacturing sites to audit these policies. Some retailers may also have their own central audit team or use third-party auditors.

The larger retailers often mandate that their larger suppliers be certified to the British Retail Consortium (BRC) Global Standard (i.e., BRC7; 20) as a minimum. BRC7 imposes allergen RA and RM, including the following:

- RAs of all raw materials and an inventory and the labeling of all allergenic materials handled on-site;
- risk-assessed documentation of potential contamination routes;
- zoned (segregated areas and dedicated equipment) for storing and handling allergenic ingredients;
- production scheduling to minimize cross-contamination risk;
- validation of production processes to support any free-from claim; and
- validation of the effectiveness of factory cleaning procedures used to remove allergens.

Some retailers have their own policies on allergen management based on BRC7 and may have more stringent policies if they produce free-from foods. For example, some retailers may specify that no wheat flour may be handled at all on a site that produces gluten-free products, whereas others may permit it in separate buildings or on the condition of rigorous deep-cleaning between factory production runs. Some retailers may require positive-release testing of ingredients for certain high-risk products. Guidance on making a free-from claim has been produced by the BRC and Food and Drink Federation (FDF) and endorsed by the FSA. Figure 5 outlines the principles involved, and the open-access guidance itself elaborates on these (21).

The traditional U.K. supermarket model has been challenged by the successful inroads that supermarkets operating a discounter model have made into the market. They have a much smaller range of lines and smaller central technical teams. They rely more on technical and QA teams within their manufacturing suppliers and on third-party certification and auditing.

Manufacturers' Approach to Risk Management

The bigger manufacturing groups also have their own central technical teams, QA policies, and internal audit teams.

The risk of inadequate labeling of an allergenic ingredient is managed by the BRC7 requirement, also adopted by many

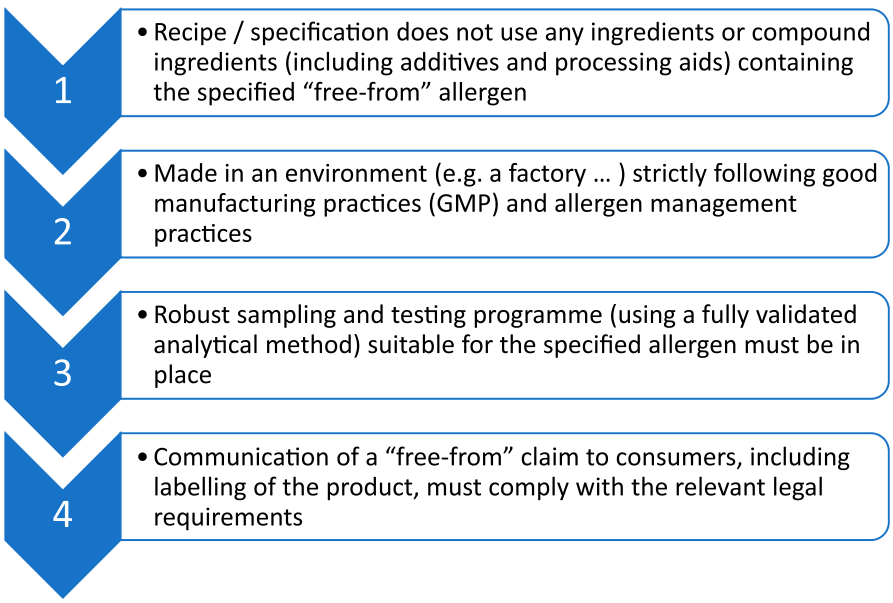

Figure 5. BRC/FDF guidance principles on the production and sale of free-from foods.

non-BRC-certified manufacturers as a best practice to risk-assess all ingredients and raw materials for their allergenicity and to keep an inventory of ingredients that are allergens. This guards against, e.g., a lack of awareness that tahini is made from sesame. Most residual risk arises when this assessment is passed down the supply chain and taken on trust; e.g., in the case of commercial seasoning mixes in which the composition of the ingredient is the closely guarded intellectual property of the ingredient supplier.

Most of the RM effort of manufacturers goes into the prevention of cross-contamination. Practical measures include segregated storage areas (ideally, but regrettably, not always, for each allergen), storing allergenic ingredients at ground level to help contain any spills; control of people- and forklift-movement around the site; and color-coding equipment, workwear, and cleaning tools. It can be challenging to keep color-coding simple and obvious on more complex sites. Sites are already segregated and color-coded into microbiological high- and low-care areas. Layering on a system for color-coding four or five different allergens handled on-site can result in 10+ color schemes and workwear changes.

It is not always possible to manufacture allergenic and nonallergenic products on different lines, and so there is an emphasis on cleaning validation and verification. Deep cleaning can be complex and expensive, particularly with sticky ingredients, such as chocolate or egg. Deep cleaning can be impractical within an economic timescale in dry factories (bakeries), which are much more likely to maintain segregated manufacturing lines. The ideal is for a deep-clean to be able to be conducted by an overnight hygiene team, to be verified by testing of swab samples, and for production to be ready to restart the next morning. This has driven the use of point-of-use allergen immunoassay lateral-flow devices (LFDs) rather than sending swab samples to laboratories. Food manufacturers are familiar with such LFDs, having used ATP test kits for many years for cleaning validation. However, they are semiquantitative at best, with significant uncertainty driven by the choice of swabbing sites, the effectiveness and consistency of the swabbing, and the response of the LFD (22).

Manufacturers who have strong allergen management policies should also have enhanced controls on rework (the reuse of ingredients or intermediates that failed to make a final product), specifically risk-assessed from a view of allergen cross-contamination.

Although many manufacturers consider and manage the risk of malicious sabotage (within Threat Analysis and Critical Control Points), this is a recent development, and, although open-access guidance is available (23), which recognizes allergens as a potential threat, the guidance is perforce widely drafted and industry approaches are not yet standardized. Typical threat assessment considerations include (*1*) whether there have been significant cost increases that have affected any products or raw materials; (*2*) whether new recruits, especially agency and seasonal staff, have been appropriately screened; (*3*) whether any employees have reason to feel disgruntled or show signs of dissatisfaction; and (*4*) whether there is anything potentially controversial about the company ownership, leadership, global locations, or brands. Responses to these questions include banning nut products from site, putting physical barriers between non-nut lines and employee access to nut ingredients, or escorting from site employees under threat of dismissal or disciplinary action. The investigation of an allergen sabotage incident requires assessing and seizing evidence to criminal DNA standards (15).

The risk of mispacks is managed by mandatory policies to clear all unused packaging from the line before starting production of another product, strict stock-control and segregation of packaging for similar-looking products, and regular QC checks of packaging and labeling as the food is produced. Mispacks may create a far higher potential risk to food-sensitive consumers than cross-contamination, owing to ingredient-level allergen presence often well above putative threshold levels.

Management of Incidents

Incidents and recalls have burgeoned with associated management time, costs (15), and reputational damage. The number of U.K. allergen incidents reported to the FSA increased from 89 in 2013 to 206 in 2015, and at 14% of incidents recorded were second only to pathogens (18%; 24). In the period 2011–2014, based on publicly available information in Europe, North America, Hong Kong, Australia, and New Zealand, significant numbers of recalls/alerts were due to allergens not indicated on the label or by the probable result of cross-contamination (25). Different countries that might be expected to have a similar allergy risk profile (e.g., United States and Canada, United Kingdom and the Republic of Ireland, Sweden and Norway, Australia and New Zealand, and Germany and France) have a different bias of allergy-related incidents as a proportion of total food safety incidents (Figure 6), suggesting that the industry and regulators in similar countries give it different relative focus. Incidents are identified by various means, including by the companies' own checks, consumer reports, and enforcement surveillance. Compensation in civil law for loss or damage caused by an allergic reaction to a food supplied is a foreseeable risk for food businesses (26).

Despite RM procedures, unlabeled allergenic foods still make it to market. The most common causes are mispacks (either of the food itself or of an ingredient further up the supply chain) or cross-contamination of an ingredient (again, usually further up the supply chain). The latter is typically detected as a result of retailers' testing programs and so may be assumed to have been occurring undetected for an unknown period beforehand.

Once an incident is known, retailers must make a rapid RA before deciding on action. Depending on the risk, action could range from a full public recall to the unpublicized withdrawal of stock or leaving stock on sale, but taking preventative measures in future. Large retailers have well-rehearsed incident control procedures that enable decisions and actions within hours and systems that enable actions to be simultaneous and consistent throughout their estate of stores. It is imperative to preplan for incidents, and useful advice, including a planning checklist, is available (27).

In the case of mispacks, the decision is usually clear-cut. The hazard is high, and a public recall is needed.

In the case of contamination, however, retailers may have to make a very difficult risk-based decision. It would be impractical, and even counterproductive in terms of diluting the allergen risk message, to publicly recall every case of known or suspected contamination in which the risk to food-sensitive consumers is negligible. Factors to be considered include the following:

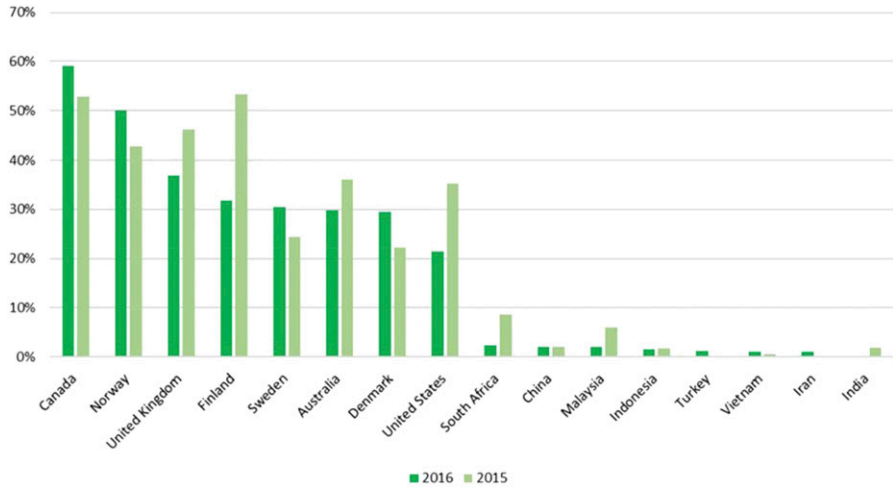

Figure 6. Allergen incidents in the HorizonScan database, reported as a proportion of total food safety incidents. The highest and lowest eight incident-producing countries are listed.

- severity of the allergenic effect
- likely portion size and resulting dose
- deterministic assessment of the effect at that dose [e.g., using Voluntary Incidental Trace Allergen Labeling (VITAL 2.0)]
- probabilistic assessment, including the concentration distribution of the allergen in the product, the number of customers buying the product, or typical population consumption patterns from diet and nutrition surveys and the prevalence of the allergy
- whether food-sensitive customers would buy it in the expectation that it contained no allergen (i.e., does it have PAL?)
- whether it will have been consumed on the day of purchase or may still be in customers' store cupboards
- whether the contamination is likely to have been ongoing for some time, with no reported effects

VITAL 2.0 is a deterministic approach to RA pioneered by the Allergen Bureau, established on a membership basis in 2005 by the Australian Food and Grocery Council. Action levels, calculated from reference doses from dose–response studies and an assumed intake (e.g., portion size, dictate whether or not RM must take place (28–30).

Retailers' incident control teams are generally appreciative that there are uncertainties in the VITAL 2.0 reference doses and portion-size estimates and that there are large data gaps (31), but may be less familiar with the concept of uncertainty in an analytical result and unaware of nuances, such as different tests measuring different proteins or the effect of processing and cooking on the response of certain tests (32). Retailers tend to take the concentration as-reported by the laboratory, even at levels approaching the detection limit of the test and so may not appreciate the sensitivity of their assessment to uncertainty in the analytical result. Laboratories can help by clearly reporting the method of analysis, the units reported (allergen protein or allergenic food), and any associated method uncertainty or method cross-reactivity.

Within this gray area, different retailers have different approaches to deciding between an unpublicized stock withdrawal and a public recall. Brand protection considerations can come into play, particularly if the retailer feels that a recall would damage their own-label reputation for allergen control. It is sometimes the case that there is a cascade of recalls; once one retailer or brand has recalled its product, then other retailers reconsider whether to recall their own equivalent products, which risks undermining consumer confidence; hence, supermarkets will try to co-ordinate their recalls, when possible, to give a clear and consistent consumer message (33).

If there is a significant risk to food-sensitive consumers, as in the case of a mispack, then retailers attempt to get the message quickly as possible to those who are most at risk. It is recognized that traditional recall methods, such as notices in stores and in newspapers, are slow, untargeted, and result in relatively few returns. Some retailers now supplement these and notification to the FSA by more innovative means, such as using loyalty card data to e-mail people who have purchased the specific product or by notifying allergy associations or consumer groups.

The U.K. patient support group, Anaphylaxis Campaign, from the mid-1990s, has been involved in notifying the FSA of reactions and assisting in RAs, sending out alerts to members by mail before the FSA started its own alert scheme. Technology has moved on and alerts from the FSA and from consumer/patient groups are now delivered by e-mail and text, as well as via social media, such as Twitter. In addition, commercial and patient benefit digital platforms (such as Food Maestro; 34) are now used, which can access manufacturer and retailer databases. This enables clinicians, including dietitians, to train food-sensitive patients to access information about a wide range of allergens and other ingredients that they seek to avoid or need to include in their diets.

Public Visibility and Utility of Retailer Allergen Information

In order to assess the public visibility and utility of retailer policies on food allergy, the official Web sites of the 10 major U.K. food retailers (mentioned earlier) were investigated. The Web sites were accessed between May 27 and 29, 2017 and, when a search option was provided, the search terms "food allergy," "allergy," "allergen," "allergy policy," and "allergy info" were applied. When no results were evident from these search terms, other sections of the Web site were investigated, such as About Us, Frequently Asked Questions, Corporate, Customer Services, Good to Know, or Lifestyle. The results

are presented in Tables 1–3. Of the 10 Web sites examined, only one exhibited information on food allergy (and cognate conditions) and food allergens when a user enters an appropriate term in the search function of the Web site home page. From two other retailer Web sites, food allergy and allergen information was available from other sections of the Web sites. Information on free-from products, mainly gluten-free, was available from an additional three Web sites, and no allergy/allergen information was provided on two Web sites, whereas an additional two Web sites had no search function and provided no allergy/allergen information on any section of the sites (Figure 7). When allergy or free-from advice was provided on the Web site, the importance of referring to the purchased product rather than the Web site for definitive allergen information was noted. *See* also Watson's discussion (35) of Sainsbury's commitment to remove unnecessary and unexpected allergens from own-brand food and unnecessary PAL.

PAL: The Attitude of the Retailers

A significant, if flawed, mechanism for retailers communicating allergen risk to customers is PAL, otherwise known as "may contain" labeling. PAL is estimated to occur in around 25 different variants (36), with two main forms: (*1*) "may contain *x*," which is the simplest format, providing information and with fewer words to take up packaging space; or (*2*) "not suitable for people avoiding *x*," with the food supplier adopting a more directive approach. Inconsistent application of PAL has resulted in loss of trust, reducing consumers' ability to make informed choices, with reduced allergen avoidance, reduced quality of life, and increased risk-taking by consumers who often ignore PAL (37). Enhanced risk taking is perhaps driven partly by the percentage of PAL foods that do not contain detectable allergens; hence, it is understandable that some consumers base their decision making on previous experience. U.K. retailers have recognized this, and some have relaunched their PAL in a much more targeted and risk-based manner, based on their allergen management policies. Unfortunately, consumers have no indication as to which brands' PALs are risk-based and which are not (38).

Discussion

U.K. major retailers apply variants of standard industry guidance in compliance with U.K. and EU food law for the RA and RM of food allergens. They are supported with excellent guidance from the FSA, which has consistently funded world-class research into food allergy (39). When RM is required in the form of incident response, this must, by law, be communicated to the central competent authority, the FSA, which disseminates the information widely, as do the retailers themselves, using a variety of digital platforms.

There are several factors that have established the United Kingdom as a leader in communicating allergen risks to consumers. The Institute of Food Science and Technology provided early industry guidance on dealing with allergens in 1998 (40). Close-working partnerships between consumer/patient organizations, such as the Anaphylaxis Campaign and Celiac UK, BRC and FDF, local authority enforcement teams, and the FSA (and its predecessor department) have been in place for over two decades. The FSA's culture of openness, consultation (FSA, London, United Kingdom, Andrew Stephenson, December 9, 2003; on alternative wording to may-contain statements alerting consumers to possible contamination with peanuts, nuts, and sesame), innovative consumer research to shape policy (41), commitment to transparent RA and RM, and engagement in developing and circulating food business best practice and consumer guidance continue to support the control and communication of allergens in food throughout the supply chain.

Another key factor is the proportion of U.K. food products sold under retailers' private or own labels—nearly 50% in recent years (42). Retailer technical and regulatory oversight of third-party suppliers has ensured, within the current scientific limitations, consistency and effectiveness of allergen RA, RM, and labeling within and across categories, influencing innovation and leading to improved product choices for consumers who avoid particular allergens. Since the mid-1990s, leading retailers have been producing lists of products suitable for those consumers avoiding nuts and peanuts and continue to do so for a wide range of food allergens (43). Allergen controls implemented for mainstream products have been enhanced further (e.g., by the positive release of ingredient batches into production after testing) for the free-from market, particularly for those avoiding milk and cereals containing gluten.

Clearly, the major retailers have differing Web strategies; on the one hand, Lidl and Iceland Foods adopt a minimalist stance, with quite basic Web information in general and nothing on allergy/allergen policy. At the other end of the spectrum, Waitrose has a sophisticated and informative Web platform in which allergy/allergen information and policy is both extensive and accessible by a simple search of the site home page. Sainsbury's and M&S provide good allergy/allergen information and policy on what might be considered the appropriate areas of their Web sites. Free-from gluten information is featured on the Web sites of the Co-Op, Morrisons (where some explanatory detail is also available), and Tesco (where milk and egg allergens are also featured). The gluten-free industry is generally recognized as an area of growth, experiencing a 136% growth between 2013 and 2015, reaching estimated sales of $11.6 billion in the United States in 2015 (44). In the United Kingdom, a study in Sheffield found good availability of gluten-free food in regular and quality supermarkets, as well as online, but none, in 2014, in budget supermarkets (45). However, these gluten-free availability data are likely outdated, as this area is seen as one of considerable commercial growth, even for budget supermarkets (e.g., in mid-2017, ALDI launched a range of free-from foods); the availability of egg-free or lactose-free appears to remain relatively rare.

Table 1. Retailers studied and their Web site addresses

Retailer	Web site
Tesco	https://www.tesco.com
Sainsbury's	http://www.sainsburys.co.uk
Asda	http://www.asda.com
Morrisons	https://groceries.morrisons.com/webshop/startWebshop.do
ALDI	https://www.aldi.co.uk
Co-Operative	https://www.co-operative.coop
M&S	http://www.marksandspencer.com/c/food-and-wine
Waitrose	http://www.waitrose.com
Lidl	https://www.info.lidl/en-gb/index.html
Iceland Foods	http://www.iceland.co.uk

Table 2. Summary of Web site retailer allergen information

Retailer	Search results			Other information
	Search term	Results	Information	
Tesco	"food allergy"	0		In-store frequently asked questions signposted to free-from sections
	"allergy"	61	Products listed	
	"allergen"	0		
	"allergy policy"	0		
	"allergy info"	0		
Sainsbury's	"food allergy"	0		How Can We Help? section is searchable; querying "allergy" yielded information, including information on allergens and intolerances
	"allergy"	17	Products listed	
	"allergen"	1	Product	
	"allergy policy"	0		
	"allergy info"	0		
Asda	"food allergy"	0		No further information readily available on allergies or allergens
	"allergy"	141	Products listed	
	"allergen"	0		
	"allergy policy"	0		
	"allergy info"	0		
Morrisons	"food allergy"	1	Product	In the Good to Know section in the Lifestyle category, gluten-free information was provided
	"allergy"	30	Products listed	
	"allergen"	2	Products listed	
	"allergy policy"	0		
	"allergy info"	0		
ALDI	"food allergy"	55	Products listed	No further information readily available on allergies or allergens
	"allergy"	0		
	"allergen"	0		
	"allergy policy"	0		
	"allergy info"	0		
Co-Operative	"food allergy"	0		List of gluten-free products available
	"allergy"	11	Products listed	
	"allergen"	11	Products listed	
	"allergy policy"	0		
	"allergy info"	0		
M&S	"food allergy"	0		In the Help and Contact Us sections, information was provided on allergies and allergen labeling, celiac disease, and gluten and gluten-free
	"allergy"	0		
	"allergen"	0		
	"allergy policy"	0		
	"allergy info"	0		
Waitrose	"food allergy"	118	Mainly information	References to information in all search results (n = 7 to 120 items listed)
	"allergy"	25	Products	
	"allergen"	1	Product	
	"allergy policy"	24	Products	
	"allergy info"	0		
Lidl	No search function	N.A.[a]	N.A.	No allergy/allergen information found
Iceland Foods	No search function	N.A.	N.A.	No allergy/allergen information found

[a] N.A. = Not Applicable.

Prior to Regulation (EU) No. 1169/2011 on the provision of information to consumers, both retailers and consumers found the separate on-label allergy box useful, wherein the presence of allergens is emphasized and the PAL articulated. To preserve the primacy of the ingredients list as a focus for information, this approach was no longer allowed under Regulation No. 1169/2011 for reasons of harmonization and because the format of the ingredients list is under legal control. Guidance produced by the BRC (46), with support from the FDF and endorsed by the FSA, recommended the continuance of voluntary labeling that both intentionally added Annex II allergens and included PAL be signposted to the ingredients list.

RA and RM to minimize PAL, and generally to deal with incidents, hinge on two approaches: deterministic and probabilistic (47). In the deterministic approach, action levels are derived from reference doses, food intake, and contamination data by a simple arithmetical method (VITAL 2.0). In the

Table 3. Details and retailer Web site allergen information, if available

Retailer	Nature of detailed Web site allergen information
Tesco	Questions on gluten intolerance, milk, milk by-products, eggs, and egg by-products are directed to the free-from section at Tesco.com, which lists all current products free from the ingredients in question.
Sainsbury's	The Health Advice section on this Web site provided advice on what food allergy and food intolerance are; provided the importance, if suspected, of a medical diagnosis, signposted to free-from products; and provided advice on making or preparing food for a family member or guest who has a food intolerance or allergy. The advice included avoiding cross-contamination by appropriate storage; hand-washing; avoidance of touching other foods; washing equipment, work tops, and chopping boards; and not reusing cooking oil. Also available was a group of allergen-specific lists updated monthly of own-brand products suitable for specific diets, including avoiding Annex II allergens; the listed items did not contain the specific allergens, and the risk of cross-contamination has been avoided. Products prepared in-store may carry a cross-contamination risk due to products being prepared in an open environment; proper labeling and signage was said to be available. Allergen labeling was explained.
Morrisons	A video featuring a dietician from Dr. Shär gave information about going gluten-free, which foods are safe for a gluten-free diet, and how to find gluten-free information when shopping for gluten-free products.
M&S	Allergen labeling was explained, with lists of products not containing gluten, dairy, nuts, soya. An "Allergies and Intolerances" Web page explained food allergy, food intolerance, and the importance of medical diagnosis and provided dietician advice to avoid the inappropriate foods. Links to Allergy UK, Celiac UK, and Anaphylaxis Campaign Web sites was provided. Celiac disease and gluten were explained on a separate Web page. It was noted that when the company develops new foods, wherever possible, M&S avoids the use of ingredients commonly known to cause allergies, particularly in foods in which one would not expect to find them, e.g., milk protein in sliced meat. Within-store-made and -baked products were not guaranteed to be free from allergens due to potential cross-contamination. More information is available on each product in stores.
Waitrose	The applied search terms elicited four categories from the Web site home page: Groceries, Entertaining, Recipes, and Inspirations and TV. Product names were retrieved from Groceries section, two recipes were found, and all search terms elicited citations to information more general than simply product names in the Inspirations and TV section, with the maximum number (120) attributed to "food allergy." Many of these may have been repetitious or trivial and were not explored; however, the main items led to good explanations of the nature of food allergy, food intolerance (e.g., lactose intolerance and how it is different from milk allergy), and celiac disease and gluten. The advice of a doctor or a state-registered dietician was recommended if there are concerns. Allergen labeling was explained, and cross-contamination was acknowledged with "we work with our suppliers to reduce the risk of cross-contamination through good manufacturing practice … and if there is real risk, an additional statement is given on the packaging at the bottom of the ingredients list." Lists of products suitable for those who are avoiding common allergens are available. Links were provided to the Web sites of Celiac UK and Anaphylaxis Campaign.

probabilistic approach, modeling 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 (48).

The relatively straightforward deterministic approach is available to all retailers, but, even so, has drawbacks. These include that only a limited number of reference doses have been published and, e.g., in the RA of nuts other than hazelnut, reference doses must be inferred. A classification of ED01 indicates the eliciting dose is the 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 1000 units per week, but not to a food business selling 100 000 units per week. Food retailers may be tempted to opt for the analytical LOD as a default action limit, which may not bear any relation to true risk. There is also, of course, the deficit in analytical systems (22).

The probabilistic approach that factors in sales and consumption as a measure of exposure and the percentage of the population who have the allergy is as yet probably beyond the reach of retailers and their manufacturer suppliers to whom retailers pass on responsibilities for allergen RA.

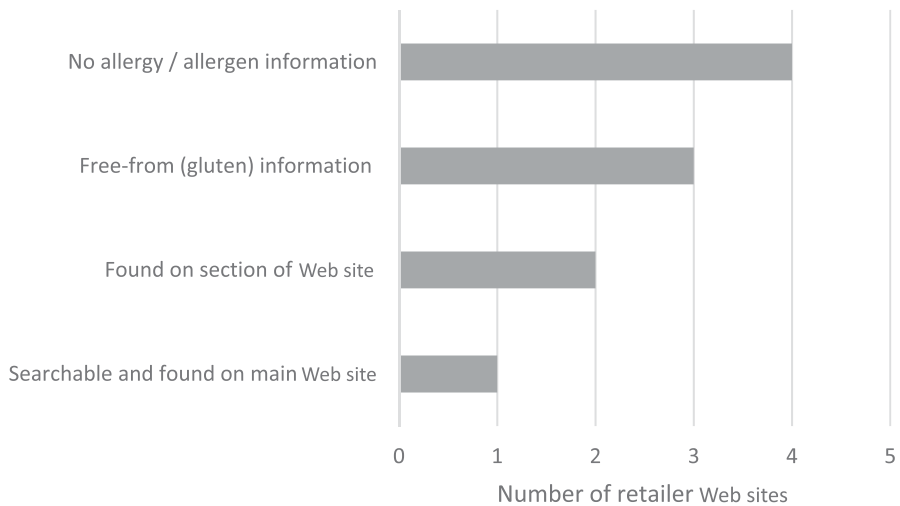

Figure 7. Retailer Web site food allergy/allergen information.

The majority of serious U.K. food allergy incidents occur in the catering sector, which deploys 2.4 times as many enterprises over 5.8 times as many sites as the U.K. retail sector (131 380 U.K. caterer enterprises with over 448 950 sites versus 54 000 U.K. retailer enterprises with over 77 475 sites; (14)). Deterministic or probabilistic allergen RA and RM are much further from effective implementation in the catering than retail sector. However, their adoption in the latter could pave the way for uptake in the former.

Conclusions

To our knowledge, ours is the only study in the open literature that attempts to survey U.K. retailers' allergen management practices, which is largely a matter of commercial confidentiality. BRC guidance, in which all the major retailers are represented, gives a window into retailer attitudes.

Overall, U.K. retailer risk analysis and management of allergens appear to be effective in curtailing severe food allergy reactions triggered by retail foods. However, allergen-prompted recalls remain high, PAL remains an area of confusion for people who have allergies, and there is no consistent retailer Web-based approach to providing information for consumers who have allergies.

Resolution of PAL awaits an agreed-on RA and RM framework. Although this seems to be moving in the direction of accepted deterministic screening (i.e., thresholds), followed, if necessary, by probabilistic RA, there remain hurdles in its acceptance. Food-allergic consumers and those buying their food are a very diverse group with very different experiences of managing their condition and attitudes to risk. Many claim to insist on zero risk, particularly when purchasing food for children in their care. It is considered by those working toward the application of allergen thresholds that considerable education of consumers, patients, and clinicians in the complexities of food production and testing is desirable, as well as instilling a much deeper understanding of severity. The latter is being addressed by current research, but one of the key challenges to the adoption of thresholds for allergen management is to engage with patients and gain their trust rather than thrust education at them.

Dialogue between all stakeholders based on the model established by the FSA when dealing with bovine spongiform encephalopathy would facilitate an optimum outcome. In brief, this consisted of informative, well-drafted opinions with minimal technical jargon that were widely circulated for consultation and independently chaired open meetings involving all stakeholders moving toward transparent consensus. Such activity is expensive, but with incidents and recalls costing the industry, on average, £1 million for each incident or recall, it would be cost-effective in the long run.

It would also be helpful for retailers to acknowledge on their Web sites whether they have adopted allergen RA and RM policies and, if so, that they publish them. For example, a link listed in the PAL could direct the consumer to a Web site definition that explains that allergens are handled on-site, detailing the measures taken to prevent mislabeling or cross-contamination. All the retailer Web sites we examined exhibited stances on issues, such as corporate responsibility, with most addressing microbiological risks and environmental, animal welfare, and other salient issues—food allergy should also be featured.

An agreed-on target between government and retailers for reduction in the proliferation of PAL variants would focus discussions between retailers and their manufacturers, e.g., a target for all retailers to adopt either of the two BRC/FSA-recommended formats by 2020.

A further hurdle in the path of allergen RA and RM lies in potentially flawed allergen analysis and the development of reference methods and reference materials, which is a frequently acknowledged need. There is also an onus on laboratories and test-kit manufacturers to report allergen results in an informative manner, being clear about the units (allergen as food or allergen protein) and the method of analysis. Communicating the uncertainty, nuances, and caveats in allergen test results to retailers and food manufacturers will enable more informed decision making, both on cleaning validation and on incident control. In an ideal world, a laboratory representative would be included on the incident control team.

Lastly, efforts must continue in the current geopolitical climate to standardize retailer preparedness for protecting and defending food and drink from deliberate attack.

Further consolidation within the U.K. food and grocery market, including in the supply chain, will increasingly prompt recall cascades if an error in allergen management occurs. This, coupled with lack of a consistent enforcement approach within the United Kingdom and legislative uncertainty stemming from the U.K.'s exit from the EU, hampers progress in alleviating the burdens of poor quality of life for allergic consumers. Now is the time for transparent communication and dialogue among all stakeholders.

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