Appendix A - Understanding international provision of allergen information

Below is the original search protocol co-produced with the advisors and FSA expert panel.

Review of evidence base for priority research questions on the international provision of allergen information in the non-prepacked sector

Evidence review protocol overview

Research aims

Our focus in this research will be on literature gathered from a number of sources including academic publications as well as grey literature, such as policy/legislation, opinion pieces, government guidance, evaluations and media/news articles which provide evidence on the provision of allergen information in the non-prepacked food sector. We will cover 18 countries and synthesise the evidence from these sources to answer the priority research questions across the five themes as elaborated below, with the aim of supporting the FSA's understanding and decision-making.

Priority research questions

Themes	Primary research questions	Secondary research questions
1. Non-prepacked sector legislation	1.1. What is the current provision of allergen information in the non-prepacked sector per country included in our scope in terms of: a) Legislation b) Guidance (if no relevant legislation available for the country) 1.2. What is the scope of the legislation? For example, in terms of: a) The foods included/excluded? b) Any other points the legislation does/does not cover? 1.3 Is the legislation based on specific evidence, and if so what is the underpinning evidence?	1.4 What are the aims of the legislation? 1.5 How and why has this developed since 2014 in each country? 1.6 How many other countries adopt the same model as the UK?
2. Trends in related deaths or incidents	2.1. What are the statistics on food-allergen-related deaths/incidents in each country? 2.2. Are there any relationships between these data and the development or implementation of the legislation?	2.3 How do the deaths/incidents statistics compare across the countries? 2.4. Which food businesses (types of food and size) have the greatest frequency of incidents?
3. Enforcement process and capabilities	3.1. How is non-prepacked food law enforced in each of the different countries in terms the process, frequency and accuracy of validation/verification approaches?	3.2. What is the ratio of FTE enforcement officers to businesses in each country? 3.3. What training do enforcement officers receive in each country? 3.4. What qualification requirements do enforcement officers need in each country?

Themes	Primary research questions	Secondary research questions
4. Consequences of non-compliance	4.1 What are the consequences (e.g. fines, sanctions or penalties) for non-compliance across countries?	4.2 Are these consequences (e.g. fines, sanctions or penalties) sufficient to discourage fraud or evasion? Why/ why not? Which consequence works best to ensure compliance (in terms of e.g. type, intensity of consequence etc.? 4.3 What other actions (positive or negative), aside from fines, sanctions and penalties, could be put in place to improve compliance? 4.4 How many businesses are investigated, fined, penalised or face sanctions as a percentage of those reported?
5. What works (or may work), for whom and why	5.1 How effective are different approaches in providing allergen information in the non-prepacked food sector? 5.2 Who are they effective for? For example, Enforcement authorities, Businesses, Consumers with food allergy/hypersensitivity 5.3 What are the challenges to using different approaches?	5.4 What factors contribute to the legislation/ compliance success from the perspective of the following? a) Enforcement authorities b) Businesses c) Consumers/ campaigners 5.5 Have there been any unintended consequences for the different stakeholders?

Protocol for searching, screening and reviewing the literature

Stage 1. Database searches

We will be reviewing relevant literature from two types of sources: published studies in scientific journals and grey literature from government and other public agency sources. Dr Audrey Dunn-Galvin will conduct the search for published/academic literature via the University Collage Cork Library Services based on agreed search terms, RSM will search the grey literature and co-ordinate the call for evidence. To structure our search strategy and optimise the time available, we will use the PRESS checklist. (footnote 1)

Alongside the formal search strategy, our advisors, Dr Audrey Dunn-Galvin (University College Cork) and Cherry Hagger (Allergy UK) will be asked to contribute any key sources, including those not yet published, based on their own knowledge and networks. RSM will also issue a call for evidence and ask the FSA specialist advisors, and our advisors to disseminate this call for evidence.

We propose to use the following search criteria and databases, but these may need to be further refined depending on the number of ‘hits’ returned from the database searches.

Search terms and inclusion criteria

Language	English or accredited translations
Time period	January 2014- Present If this search does not result in maximum 2000 results, we will use an iterative process going back one year at a time until we reach 2000 titles.
Food sector specifics	Food allergens Non-prepacked food sector only

Search strings	**1. For allergy-related information provision** (Food) AND [Terms for non-prepacked food sector:] (Non-pack*) OR (Non pre-pack*) OR (Restaurant) OR (Distance selling) OR (delivery) OR (Loose) OR (Outlet) OR (Stall) OR (market) OR (Supermarket) OR (Cafe) OR (Cater*) OR (Food service) AND (Allerg*) OR (Coeliac) OR (hypersensitivit*) AND [Terms for food allergen information provision:] (Advisory labelling) OR (Precautionary labelling) OR (PAL) OR (label*) (Written information) OR (Oral communication) OR (Verbal communication) OR (Sign*) OR (Menu) OR (Free from) OR (May contain) OR (Notice) **2. For allergy-related deaths and incidents** (Food) AND (Allerg*) OR (Coeliac) OR (hypersensitivit*) AND [Terms for deaths and incidents:] (Death) OR (Incident) OR (Reaction) OR (Accident) OR (Hospitali*) OR (Anaphylaxis)
Databases/sources	**Published/Academic Literature:** Web of Science, Scopus **Grey Literature:** • Government websites for each included country • Websites of international organisations related to food safety in each country such as Food Standards Agency (UK), International Association for Food Protection (USA), Food Federation Germany, Australian Food and Grocery Council • Websites of relevant voluntary and Third sector organisations in each country such as Allergy UK, Anaphylaxis Australia, Food Allergy Canada, Allergy Care India, National Allergy Strategy Group and Coeliac UK, and international equivalents like EFANET • Google search for published evaluations/ reviews of relevant legislation/ enforcement • Google search for news/campaigns/media reports • INSOFAN and RASFA for data on incidents recorded • Call for evidence amongst FSA stakeholders, advisors and their networks.

Stage 2. Screening of titles and abstracts

We will review the longlist of a maximum c.2,000 titles of published and unpublished studies, articles and reports (‘grey literature’) pertaining to the research questions on allergen-related information provision as specified above.

The table below sets out the first level inclusion/ exclusion criteria which we will apply to each title. We anticipate excluding 25% to 50% of titles at this point either because they are not of central relevance to allergen information in the non-prepacked food sector or they are duplicate studies in our sample.

1st level criteria	Inclusion criteria	Exclusion criteria
Allergens	Food allergens	Other allergens
Sector	Non-prepacked food sector	Pre-packed food sector; drinks and other consumables; other sources of allergen exposure.
Study size	<15 for qualitative studies <30 for quantitative studies	>15 for qualitative studies >30 for quantitative studies
Topic	Allergen labelling or provision of information; deaths and incidents related to food allergen	Deaths and incidents related to other food sector activities; Deaths or incidents related to non-food allergies
Countries	UK, Republic of Ireland, Netherlands, Belgium, Denmark, Norway, Germany, Lithuania, Sweden, Switzerland, Australia, Canada, India, Malta, New Zealand, Philippines, South Africa, and USA	All other countries.
Other		Duplicates (RSM to remove most during search stage, but some duplicates are likely to remain).

We will then review c.1000 abstracts, the second level inclusion/ exclusion criteria will then be applied to each abstract that passes the first level criteria. The second level criteria are listed

below and relate to the detailed research questions. These may need to be refined depending on the number of studies retrieved. Abstracts which do not meet any second level inclusion criteria will be discarded and the remaining abstracts will form the shortlist of relevant literature for further screening and quality assessment.

2nd level criteria	Inclusion criteria	Exclusion criteria
Topics based on research questions	Related to one or more these topics: • Current legislation and guidance, or its historical development, on provision of allergy-related information in non-prepacked foods • Non-prepacked food legislation compliance • Allergen labelling • Food allergen related deaths/ incidents • Non-prepacked food law enforcement	Not related to any of the topics related to the research questions.
Outcome	Outcomes and impact: • Compliance to legislation • Perceptions and outcomes of legislation for: a) Food businesses b) Consumers c) Enforcement officers • Risks of incident and death Effectiveness of approaches: • Confidence in purchasing food or eating out for consumers • Allergen information in the non-prepacked sector monitoring and enforcement practices • Reporting systems on deaths/ incidents	Does not have any of the outcomes/impacts/effectiveness of methods associated with the research questions.

Stage 3. Quality assessment of full texts

We expect to generate a shortlist of a maximum of 150 studies, with a minimum of 3 per country and a maximum of 15 per country. We will obtain and screen the full texts to identify the final list of the most relevant and pertinent studies to undergo full review. The selection will be based on tighter inclusion criteria including quality measures i.e. the extent to which methodologies/ evidence bases are robust following DEFRA guidance (footnote 2) using the following steps:

a) Score the relevance of the evidence for each research theme on a 3-point scale, (from 1=low to 3=high) considering:
- The relevancy of the method used;
- The relevancy of the evidence to the target subject/population;
- The relevancy of the intervention assessed;
- The relevancy of the outcome measured;
- The relevancy of the study to the latest legislation and/or practice of allergen information provision.

b) Score the robustness of the evidence on a 3-point scale (from 1=low to 3=high) where the following rating would apply:

Scale rating	Description
1	Few or no methodological criteria have been fulfilled. The conclusions of the study are thought likely or very likely to alter (high risk of bias)
2	Some of the methodological criteria appropriate for the study type have been fulfilled and those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions (risk of bias)
3	All or most of the methodological criteria appropriate for the study type have been fulfilled (low risk of bias)

c) Combine the two scores from a) and b) into one final measure of quality, i.e.. scored from 1 (1*1) up to 9 (3*3) and coded to result in a red-amber-green rating.
d) Present the process and results clearly to ensure transparency and replicability.

Stage 4. Full review and data extraction

We will complete a review of a maximum 90 articles, with a maximum of 5 articles per country, and extract information from the review literature into separate spreadsheets for each research theme and country, using the headings suggested below. The process for data extraction will be to start with legislation documents, thus getting an overview of the legally mandated approaches and then proceeding to systematic reviews and then individual studies.

We will specify the headings used to extract information into the data extraction spreadsheet. Headings will likely include title, author, date, country, study type, study aims, methods/ evidence base, findings, strengths and limitations reported in study, key themes/topics, relevant outcomes and a quality appraisal. For the data review, in addition we will develop headings such as incident type, number of deaths/ incidents, food business type/ size (if available).

Table for each research theme

Document title	Author(s)	Date of Publication	Source Country	Study Type	Aims	Method (Including key steps taken) (if relevant)	Summary of findings of allergen info approach/es	Strengths	Limitations	Evidence gaps	Quality Appraisal - Relevance	Quality Appraisal - Robustness	Relevant Research Question

For data extraction, depending on the datasets available we will undertake descriptive statistical analysis using MS Excel. Where possible, we will aim to conduct not only within-country but between-country comparisons, particularly for countries that share the same/similar legislative approach.

Quality appraisals will be completed concurrently with the extraction process. We will ensure that our work meets quality ratings according to AMSTAR (A Measurement Tool to Assess Systematic Reviews) (footnote 3).

Findings will be synthesised according to the research themes and research questions within each theme and written up into a report section and used to create country specific single-slide summaries.

1. PRESS 2015: checklist for search strategies | Karolinska Institutet University Library (ki.se)
2. The Production of Quick Scoping Reviews and Rapid Evidence Assessments
3. AMSTAR - Assessing the Methodological Quality of Systematic Reviews