Review of allergen analytical testing methodologies: Executive summary and Introduction

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Authors: Helen H. Grundy, Lucy C. Brown, Mark Sykes, M. Rosario Romero, Dominic Anderson
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Executive Summary

The Food Information Regulation (FIR) states that accurate and understandable allergen information needs to be supplied to consumers for the 14 priority allergens. Food allergies affects between 1-2% of the UK population, with some allergens responsible for hospital admissions with anaphylaxis.

Food businesses have a legal responsibility to provide food that is safe, which means declaring allergens present as ingredients and warning consumers about their potential unintended presence due to cross-contact. A system needs to be implemented for testing allergens in foods, responding to incidents, and manage risks to protect consumers.

This review was prepared to inform FSA on the current state of the art of allergen testing methodologies and the remaining challenges. This project combined a critical literature review of testing methods with assessments of allergen proficiency testing data, consultation with stakeholders from the food industry, and consultation with industry experts regarding multiplex methodologies and the harmonisation of methods in an unbiased review of the current status of testing capabilities for the 14 EU-retained regulated food allergens.

Gaps in testing capabilities were highlighted in order to inform future direction, including a lack of transparent public data for the performance and applicability of commercial test kits. Cross-reactivities of kits were also highlighted along with the need for development of fast and accurate point-of-use tests to support food production. A review of allergen proficiency testing data revealed gaps in testing capabilities and variations between the outputs of different test kits when testing for the same allergen.

This review critically compares current testing methods to progress towards a suitable harmonised testing protocol that facilitates allergen risk management, and to mitigate limitations and evidence gaps. Suitable workflows outlining recommended testing protocols are presented for priority allergens to provide a resource for compliant testing and incident management.

Estimations of the cost of setting up new testing laboratories to support allergen workflows are also included in addition to detailing the cost of testing by established laboratories.

Introduction

The Food Information Regulation (FIR) states that accurate and understandable allergen information needs to be supplied to consumers for the 14 priority allergens. Food allergies affects between 1-2% of the UK population, with some allergens responsible for hospital admissions with anaphylaxis.

Food businesses have a legal responsibility to provide food that is safe, which means declaring allergens present as ingredients and warning consumers about their potential unintended presence due to cross-contact. A system needs to be implemented for testing allergens in foods, responding to incidents, and manage risks to protect consumers.

This project brings together literature review information, allergen proficiency testing data from testing laboratories around the world, along with details of consultation with experts involved in method development and standardisation and harmonisation of methods and stakeholders from the food industry, in an unbiased review of the current status of testing capabilities for the 14 EU-retained regulated food allergens. The project identifies strengths and limitations of current allergen testing capabilities and it complements ongoing Codex work and the current EFSA ThRAll project, that advises on threshold levels and harmonised methods of detection.

A wide range of routine and emerging methods are applied to food allergen testing. While certain methods are long-established and at various stages of validation and accreditation on a range of food matrices by their manufacturers, little or no cross-evaluation data are available to compare limitations, consider the potential to inter- convert reporting units and identify evidence gaps. There is much variation in the level of information provided with kits. Some kit manufacturers simply stating the limit of detection (LOD) and limit of quantitation (LOQ) of the kit. Other’s kits manuals provide much more kit validation data, such as that relating to applicability and also to recovery, precision, cross-reactivity when testing certain food matrices. Whether the food matrices were tested raw or incurred (the latter usually providing more suitable information due to the number of allergen-containing foods which are processed in some way prior to consumption. Another evidence gap involved both kits and data published in peer-reviewed manuscripts for which there is often little or no information as to whether the LOD and LOQ were determined by measuring the lowest levels at which an allergen can be detected when spiked in a buffer (the simplest scenario), whether it was spiked into a processed food, or whether it was an incurred product (the most challenging scenario, with allergen materials incorporated into the food formulation prior to relevant processing) to provide a ‘real life’ food matrix for testing.

This literature review investigates this, in addition to critically comparing current testing methods to progress towards a suitable harmonised testing protocol that facilitates allergen risk management, and to mitigate limitations including cross- reactivity and evidence gaps. Validation and standardisation data from UK, Europe or international initiatives are highlighted. The project also benefits from unique access to Fapas® proficiency testing data to review variability of inter- and intra- method data.

Alongside a literature review and expert consultations to align the project to the latest activities in allergen management, outputs include a comprehensive table (Table 1, Appendix 1) comparing and contrasting the commercial methods, highlighting limitations in testing methods, measurement parameters and evidence gaps.

Estimations of the cost of setting up testing laboratories to support allergen workflows are also included. Consultations with a range of industry stakeholders regarding allergen management in the supply chain have been conducted and the interview questionnaire and responses are included in this report.

Suitable workflows outlining the recommended testing protocols are presented for priority allergens to provide a resource for compliant testing and incident management.

The outcomes of this project can also be aligned to data issued by the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) regarding their review and establishment of threshold levels in foods for the priority allergens. The incidence and types of food allergy vary across the globe, with individuals in certain global populations showing sensitivity to food types for which other populations show little or no sensitivity. Different food commodities are also consumed at varying intake levels across different cultures and populations. The FAO/WHO Reference Doses (RFD), the maximum single day oral exposure which is anticipated to be without appreciable risk for the general population, are expressed in milligrams of total protein from the allergenic food. The Action Level (AL) relates to the reference dose divided by the mass of the food in kilograms, expressed as milligrames of total protein from the allergenic food per kilogram of food. The action level for a given allergen in foods will therefore differ depending on likely intake mass of that food type. Action levels for priority allergens, based on recommended reference doses and calculated for pre-defined intake categories, ranging from 10g to 1 kg, are detailed in the FAO/WHO Risk Assessment of Food Allergens Part Two (WHO, 2022).

This review compares and contrasts current testing methods to determine strengths and limitations of methods to inform FSA on the current state of the art of allergen testing methodologies.

A table detailing the various objectives for this project is shown below (Table of Objectives) along with an index of sections, each of which aligns with a project deliverable.

Table of Objectives

Objective number/Task number at project inception	Title of Deliverable or milestone	Status
01/01	Kick-off meeting with FSA to agree deliverables and search terms for the literature review.	Complete
02/01	Commencement of unbiased literature review and initial filtering.	Complete
02/02	Completion of filtering of literature.	Complete
02/03	Completion of unbiased review of literature.	Complete
03/01	Aligning project with Codex alimentarius activities and EFSA project ThRAll outcomes. Stakeholder engagement.	Complete
04/01	Assessment of variability of analysis from Fapas® proficiency testing data.	Complete
05/01	Review of Fapas® proficiency testing data.	Complete
06/01	Preparation of cost estimates to implement the required methods in a testing laboratory.	Complete
07/01	Delivery team project meetings and communications	Complete
08/01	Final report in draft	Complete
09/01	Final project meeting with FSA	Complete
10/01	Submission of final report	Complete
10/02	Submission of draft manuscript	Complete