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particular regarding enforcement costs and costs to industry, suggest this is likely to be a significant underestimate.

31. The mandatory introduction of full ingredients labelling for PPDS food will be a considerable challenge for industry to implement safely. It would likely involve a considerable programme of changes to be put in place by businesses and Government, as well as a suitable transition period to enable businesses to prepare.

**'Near-Miss' Reporting**

32. The consultation invited stakeholders' ideas on other changes to protect allergic consumers, including the development of a reporting mechanism for 'near-miss' non-fatal allergic reactions. Stakeholders indicated support for improvements in this area, and the FSA in England has already initiated work. Communication of risk information, training for food businesses and accreditation schemes were also raised and will be considered further as part of ongoing work.

**Conclusions**

33. The FSA is committed to improving the experience of food hypersensitive consumers and reducing the risks and limitations they face when making safe food choices. The priorities and actions we have identified will deliver continuing improvements for this community, whilst our research programme will deliver a better understanding of the severity and impact of food hypersensitivity, and shape further development of our strategy.
34. The consultation has shown food hypersensitive consumers have a strong desire to see rapid and demonstrable improvements in allergen labelling for PPDS foods, to deliver both better protection and increased choice and strongly favour the introduction of full ingredient labelling. The consultation responses indicate the significant challenge involved in moving to full ingredient labelling, for both businesses and Local Authorities.
35. The consultation has outlined potential changes to labelling which offer a range of benefits and limitations as described. The Board is asked to:
- **Review and endorse** the programme of work delivered and planned by the FSA to protect food hypersensitive consumers.
  - **Provide strategic direction** on the priorities for the FSA in protecting food hypersensitive people and **indicate** areas of particular importance to the Board.

Board meeting – 8 May 2019

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- **Consider** the analysis of responses to the Allergen Labelling Review on Pre-Packed for Direct Sale food, specifically:
  - The strong desire from allergic consumers for significantly more allergen information to be available to them, and their preference for full ingredients labelling.
  - The challenges involved in introducing mandating full ingredients labelling at this time, and range of actions required to deliver this.
  - The opportunities and limitations offered by other potential labelling changes and best practice measures.
- **Determine** the Board's advice to Ministers about acting on the outcome of the Review.



Board meeting – 8 May 2019

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**Annex A – Departmental responsibilities and the legislative framework on allergens**

The FSA is the lead government department for food allergy and intolerance policy and labelling in England, Wales and Northern Ireland. Food Standards Scotland (FSS) has a similar responsibility in Scotland.

There are separate food information regulations for England, Wales, Northern Ireland and Scotland. Defra is responsible government department for the Food Information Regulations that incorporates the allergy labelling provisions. The FSA is responsible for the FIR in Wales and Northern Ireland.

The Food Information to Consumers Regulation (EU) No 1169/2011 came into force on 13 December 2011. It brought together general, allergen and nutrition labelling regulation into a single legislative framework. The EU rules are enforced across the UK by the Food Information Regulations (FIR) Statutory Instruments. The FIR introduced a number of changes to allergy labelling and information provisions. These are set out below:

- The provision of allergen information is a requirement for all stages of the food chain, covering food intended for the final consumer, food supplied by mass caterers and foods supplied to mass caterers.
- Existing labelling provisions for prepacked foods to declare allergenic ingredients were maintained, but with an added requirement to emphasise allergens within the ingredients list.
- Allergenic ingredients must make a clear reference to the allergen (there are 14 major allergens listed).
- Where several ingredients in a food originate from a single allergen, labelling must make reference to the allergen for each ingredient.
- Allergen information must be clear, legible and marked in a conspicuous place and not obscured by written or pictorial matter.
- Allergen information was extended to non-prepacked foods on a national basis, including food sold pre-packed for direct sale (such as in bakeries, delis and sandwich bars).
- Allergen information must be clearly associated with the business providing the food via distance sales. Allergy information must be made available before the transaction is concluded and at point of delivery of the food.
- The voluntary use of '*may contain X*' type statements to indicate a risk of allergen contamination is still possible under the provisions, but there is a mechanism for the Commission to develop rules in this area at some point in the future.

**Annex B – NIFAC and WFAC reports**

<b>Northern Ireland Food Advisory Committee: Themed Discussion</b>
Date of Meeting: 10 April 2019. Theme: Allergens
<b>Attendance</b>
<b>NIFAC Members:</b> Colm McKenna (Chair), Aodhan O'Donnell, Phelim O'Neill, Sara McCracken, Fiona Hanna, Lorraine Crawford, Greg Irwin. <b>FSA Officials:</b> Maria Jennings, Sharon Gilmore, Louise Connolly, Ross Yarham, Craig Leeman, Seth Chanas <b>Stakeholders:</b> Michael Walker (Chartered Chemist), Paula O'Neill (Armagh Banbridge and Craigavon Council), Helen Morrissey (Belfast City Council), Gary McFarlane (Chartered Institute of Environmental Health), Michael Bell (Executive Director of the Northern Ireland Food and Drink Association and Vice President of the Institute of Food Science and Technology).
<b>Presentations</b>
<b>Louise Connolly, FSA in NI Senior Adviser in Food Standards:</b> FSA work on food allergens. What is an allergy. Current Legislative Requirements. NI Allergen Incident Information. Consultation on amending allergen information provisions contained within domestic food information legislation for food prepacked for direct sale. The role of the FSA. Activity Specific to NI.  <b>Paula O'Neill, Armagh Banbridge and Craigavon Council:</b> Strategy to Improve Compliance with Allergen Requirements. Alleged Causes of Allergic Reactions. Formal Action. Current on-going serious investigations.  <b>Michael Walker (Consultant Science Manager and Nominated Officer with the Government Chemist Programme):</b> Development of Quality Control Materials for Food Allergen Analysis Funded by FSA. Food hypersensitivity. Quality of Life Issues.

Diagnosis, management, intervention and prevention. Food Law. Precautionary labelling. Thresholds and what we still need to know. The Biannual Public Attitudes Tracker.

#### **General Comments/Observations**

NIFAC received a wealth of information at this session, underlining the breadth of the work being done and the complexity of the issues involved.

NIFAC cautioned about the need for proportionality, noting the low statistics of a fatality occurring as the result of anaphylaxis but taking account of quality of life issues and the worrying increase in incidents. NIFAC acknowledged that the reason for that increase, whether from an increase in hypersensitivity, higher reporting rates, or an increasing use of allergenic ingredients, was unknown and that a better understanding of the causes would be key.

NIFAC received a recommendation from Vice President of the Institute of Food Science and Technology, Michael Bell, that working collaboratively with the Institute would be advantageous to both organisations as the Institute represents people with control over the contents of a high number of daily meals.

NIFAC noted the encouraging statistic from the presentations that consumers generally (and in NI in particular) are confident about asking about the allergen content of a food if they are uncertain. This was welcomed and the FSA should consider what might help these figures to become higher still, but a distinction should also be made about between having the confidence to ask and having confidence in the answer received. Encouraging allergy sufferers to ask in cases where suppliers have imperfect information could have unintended consequences.

NIFAC endorsed the principle that it was the Food Business Operator's responsibility to ensure that the food it produced was safe but heard several accounts of businesses being afraid to serve customers with allergies. It was

suggested that there was work to do in communicating to businesses that what was being asked of them was to provide information and for that information to be correct.

It was also noted at the meeting that many consumers may not have understood that, where a business had a high Food Hygiene Rating, food standards and allergen issues would not have been considered in awarding that rating. There was a suggestion that where allergens were concerned, it should cease to be considered a standards issue and be viewed in terms of food safety, which would bring it into the scope of the scheme. Given the original intention of FHRS, however, it was proposed that a parallel scheme for allergens, which could be practically assessed and rated at the same time, would be a preferable model.

NIFAC also noted that the NHS Guidance to allergy sufferers that “If you or your child have a severe food allergy, you need to be careful when you eat out” appeared at odds with FSA's message of “food you can trust”.

#### **County Specific Comments**

NIFAC thought that the profile of businesses in Northern Ireland and the good relationships between the FSA and the Councils, makes Northern Ireland an ideal place to pilot initiatives with an increased probability of effective buy-in from the relevant stakeholders.

Michael Bell also noted the importance to the NI economy that egg allergy had one of the lowest thresholds, egg consumption represented one of the UK's fastest growing protein sources and that NI was a significant supplier of egg to the UK.

It was noted at the meeting that there were several features of the way in which allergen issues were dealt with in Northern Ireland that were positive including the good cooperation between FSA in NI and Environmental Health Officers; good

## Board meeting – 8 May 2019

cross border relationships with FSAI and Safefood; District Council support for food standards work; good allergen awareness; local expertise; and good local allergy doctors and services. This was balanced against various negative factors such as the lack of local patient support following the closure of Allergy NI and Anaphylaxis Ireland; a lack of dialogue around the impact of physical activity levels and thresholds; and the possibility of further divergence in standards and labelling following EU Exit. Nevertheless, it was considered that the overall situation was a positive one that, were it to be replicated across England and Wales would see improvements there for allergy sufferers.

#### Actions for Secretariat

No actions arose from the discussion for FSA in NI staff to take forward.

#### Welsh Food Advisory Committee: Themed Discussion

Date of Meeting: 10/01/2019. Theme: Allergens

#### Attendance

**WFAC Members:** Dr R Hussey, Mr R Alexander, Mr D Peace, Dr N Barry, Mr J Wilson, Mrs Rebecca Lyne-Pirkis, Dr Philip Hollington

**FSA Officials:** Richard Bowen, Julie Pierce, Helen George

**Stakeholders:** Representatives from Coeliac UK, Zero2Five, Cardiff, Metropolitan University, the Chartered Institute Environmental Health (Wales) representatives from local authorities in Wales (including Caerphilly, Swansea, Blaenau Gwent and Monmouthshire)

#### Presentations

**Kerys James Palmer:** Overview of FSA's work on allergens including details on the allergen strategy proposed for 2019; the current legislative framework; proposals to review the legislation to consider whether it is effective in the light of recent tragedies; and details of FSA allergy communications campaigns.

**Ross Yarham:** Research studies being undertaken to underpin the FSA's food allergy and intolerance work programme. It covered the four key themes of the research programme, including the development of management thresholds for allergenic foods; the route and timing of exposure to food allergens in early life; the prevalence and characteristics of food allergy and intolerance; and, food allergen; labelling and consumer choice.

## Board meeting – 8 May 2019

**General Comments/Observations**

In commenting on the increased prevalence of allergens, the WFAC noted that there were a number of reasons for the increased prevalence including increased awareness, better diagnosis and a range of other factors, which could include the Western diet.

In commenting on the enforcement of the legislation, a local authority representative suggested that the highest prevalence of allergen incidents is linked to loose foods and contamination from unintentional ingredients. It was felt that food business operators had difficulty in managing these particular risks and that this often led to an over precautionary approach, with some business operators applying a blanket cautionary disclaimer. It was thought that this was having the effect of reducing consumer choice but this was considered a UK wide issue rather than one specific to Wales.

A representative from Coeliac UK commented that the blanket use of cautionary disclaimers was having a detrimental impact particularly in relation to gluten free products and that it was adversely affecting the range of products available to consumers suffering from Coeliac disease.

It was noted that the FSA's website was to be a main source of information for enquiries in relation to allergens and intolerances particularly in relation to the 14 foods specified in the Food Information Regulations (Wales) 2014. However, it was acknowledged that there were also some foods containing specific enzymes that may give rise to issues similar to those related to allergens and intolerances.

In relation to the catering industry there was a specific need for adequate training and information provision to ensure maximum consumer food choice. There was a need to ensure that all consumer and business information was kept up to date.

**County Specific Comments**

A local authority representative commented that it would be useful in any forthcoming Board discussions on allergens and intolerances, for data to be provided on the number and nature of incidents pre and post 2014 and for this to be made available on a country specific basis. It was also commented that it would be useful if the cost of the burden of the disease was provided at country specific level.

A representative of the Chartered Institute of Environmental Health (CIEH) commented that it would be helpful in developing any new strategy to understand the full pattern of the disease. It was suggested that it might be useful to consider hospital admission data to identify the scale of the problem and to explore any country specific dimension. It was also suggested that it would be useful to examine product recall and withdrawal data to understand if produce was having to be withdrawn as a consequence of ignorance on behalf of the food business

Board meeting – 8 May 2019

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operator, a disregard for the legal requirements, or as a result of cross contamination concerns.

An issue was raised in relation to the National Procurement Service in Wales. A number of local authority representatives commented that they had concerns in relation to how the procurement framework operated from a food hygiene perspective in respect of the public sector, particularly in relation to allergen and intolerant issues. It was considered that inadequate food standard and safety mechanisms were in place for the procurement of goods and services supplying a large part of the public sector including food to schools and hospitals. It was noted that the National Procurement Service was changing and might not continue in its current format.

**Actions for Secretariat**

In developing and improving data sets, it would be useful to explore regional and country differences to identify any demographic or epidemiological trends.

Provide a maximised analysis of data from product recalls and incident management information on a regional basis to establish if there are differences in the way food manufacturers work in the different countries.

Seek further information on food safety and standards controls and mechanisms built into procurement contracts negotiated to supply food and drink to the public sector

## Annexe C – FSA commissioned Science, Evidence and Research

The Food Allergy & Intolerance Research Programme was established in 1994 and since then has delivered a world leading portfolio of over 50 research projects, with leading organisations, that have had a significant impact on our understanding and have informed the Government's evolving policy and guidelines.

The programme has effectively responded to emerging issues in food allergy and has been at the forefront of new **research**, including:

- investigating how the timing of introduction of common allergenic foods into the infant diet influences the risk of infants developing food allergy. The Enquiring About Tolerance (EAT) Study was considered as part of a series of extensive FSA funded Systematic Literature Reviews looking at the influence of maternal and infant dietary practices on the development of allergy (and autoimmune disease). The implications of the associations revealed by these reviews were considered by wider government and resulted in a change in infant feeding recommendations to not delay the introduction of allergenic foods as stated in the Scientific Advisory Committee on Nutrition (SACN) report 'Feeding in the First Year of Life' which has been adopted by government. These and other impactful studies from the programme are having effects not just in the UK but around the world;
- the characterisation of kiwi fruit as a new and growing food allergy;
- identified the skin as a probable route of exposure to food allergens leading to sensitisation; and
- supported work to provide robust data on determining the prevalence of food allergy from birth to two years of age in the UK, which was part of a wider European collaborative approach. These investigations not only provide information about the history of food allergy in the UK but will also reveal different trends across Europe and the factors that influence the development of food allergy in children.

### Other evidence

As there is no cure for food allergy and intolerance our research outcomes look to improve the quality of life for those with a food hypersensitivity in a number of ways including work to support the **development of allergen management thresholds**, ultimately, reducing the need for unnecessary precautionary allergen labelling (PAL) e.g. 'May contain' being inappropriately used and only in situations where the risk cannot be managed. This is crucial in raising trust in PAL and is a high priority for consumers.



**Board meeting – 8 May 2019**

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The FSA is also developing new tracking measures for food allergy and intolerance to **monitor trends** in important areas such as quality of life and consumer behaviours, economic burden, as well as monitoring clinical data. The aim is to create a broader picture of food allergic consumers in the UK, especially following targeted interventions, to assess impact.

Whilst continuing to utilise the outputs of previous research the focus has shifted to **Adult Food Allergy (AFA)** as this is an area of research with many gaps in knowledge and anecdotal evidence indicates this may be increasing issue. There are currently no robust prevalence data sets on adult food allergy in the UK which makes it difficult to gauge the scale of the issue and in identifying the most appropriate interventions. The recently commissioned AFA project, led by the University of Manchester, is an example of our extensive investment with a commitment of £1.82 million to find out the prevalence and patterns of adult food allergy. This is due to report in 2021.

The FSA will continue to be at the forefront of food allergy and intolerance research, delivering high quality research and evidence that underpins the FSA's policy and guidance in this area ensuring that food is safe and what it says it is so that the consumer can make informed choices.

**Board meeting – 8 May 2019**

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**Annexe D – Consultation**

The Government's consultation for amending allergen information provisions contained within domestic food information legislation for food prepacked for direct sale launched on 25 January and ran for nine weeks. Four options were presented for stakeholders to consider:

**Option One: Best Practice Measures:** This option does not involve a legislative change, but is instead about the delivery of multiple interventions to support a safer environment for consumers. The range of interventions (and their extent and duration) would need to be matched to particular issues and businesses but could include:

- Best practice guidance for the catering sector to be produced by the FSA and FSS in partnership with the food industry and made available to all local authorities.
- Production of training and educational material in different languages to raise awareness.
- Additional public awareness campaigns, including a focus on PPDS food to raise consumer awareness.
- Revised consumer advice on buying food.

**Option Two: 'Ask the staff' labelling with supporting information in writing.**

This option would mandate a label or sticker on the packaging advising consumers to "ask the staff" about allergens. When asked about allergens, staff would have to provide supporting information in writing upon request, before the food was purchased. This information would comprise either:

- A list of any of the 14 allergens contained within the specific product; or
- A full ingredient list with allergens emphasised.

**Option Three: Mandate name of the food and 14 allergens only on packaging.**

This option introduces a legislative change mandating the name of the food and a declaration of any of the 14 allergens in Annexe II of the FIC when used as an ingredient. The exact design of the label would need to be developed and consider issues such as extent of standardisation, use of a tick box approach, and default messaging for example indicating: "the above allergens were not used as an ingredient".

**Option Four: Mandate name of the food and full ingredient list labelling, with allergens emphasised.** This option introduces a legislative measure requiring a label

**Board meeting – 8 May 2019**

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naming the food and listing the full ingredients with allergens emphasised on the packaging, essentially fully aligning labelling for prepacked and PPDS foods.

Labelling will need to include: the name of the food, the list of ingredients and any ingredient or processing aid listed in FIC Annexe II or derived from a substance or product listed in Annexe II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, would be emphasised to stand out from the other ingredients in the list.

The following issues were out of scope:

- The regulation of Precautionary Allergen Labelling (PAL) regarding the unintentional presence of allergens due to cross-contact.
- Allergen labelling provision for non-prepacked food ordered via distance selling, for example a takeaway pizza ordered over the phone or internet.
- Food not packed (such as meals served in a restaurant or café), and food packed on the sales premises at the consumer's request.
- Allergen labelling provisions for prepacked food and loose food.
- The expansion of the EU regulatory list of allergens (the top 14 allergens of public health importance).

### Definition of PPDS

FIC does not provide a specific definition of PPDS. We expect businesses and Local Authorities to follow the interpretation set out in FSA's technical guidance on allergen labelling provided below.

**“Prepacked foods for direct sale:** This applies to foods that have been packed on the same premises from which they are being sold. Foods prepacked for direct sale are treated in the same way as non-prepacked foods in EU FIC's labelling provisions. For a product to be considered 'prepacked for direct sale' one or more of the following can apply:

- It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients.
- Foods that could fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made.”

PPDS foods may be available to consumers in out-of-home and retail environments. In an out-of-home environment such as a sandwich shop, café or burger bar, any food that is prepacked on the premises in anticipation of an order, before being

**Board meeting – 8 May 2019**

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offered for sale, would be considered to be PPDS. Examples may include foods which the consumer self-selects from a chiller cabinet or has to ask a member of staff for, for example, a sandwich or boxed salad on display behind a counter. Food ordered and collected in person by a consumer in a takeaway, may be PPDS if it was packed before it was offered for sale, for example, a wrapped burger, boxed fried chicken or wedges under a hot lamp

In a retail environment such as a supermarket, the following examples would also be considered to be PPDS, provided they are packed on the premises from which they are being sold before they are offered for sale:

- Fresh (uncooked) pizzas from the deli counter;
- Boxed salads;
- Hot foods such as rotisserie chicken or wedges; and
- Foods that are pre-weighed and packed such as cheese or meats from a delicatessen counter or baked goods from an in-store bakery

**Process**

We considered it important that we engaged directly with those all with an interest and crucial that we were able to hear from consumers who have allergies. The FSA and Defra held eight stakeholder engagement workshops in England and three in Wales. In Northern Ireland two workshops were held. FSS conducted their own stakeholder engagement. Approximately 150 individuals attended the workshops which were focussed on specific stakeholder groups: Allergen patient group and health care professionals, General food allergic consumers, young allergic consumers, Local Authorities, small businesses, large businesses and retailers. In parallel, stakeholders were able to submit views digitally and 1871 individual submissions were received.

**Response Demographics**

There were 1,887 respondents to the consultation. Respondents were asked to classify themselves as one of the following:

- An individual - responding with personal views, rather than as an official representative of a business / business association / other organisation.
- Business - in an official capacity representing the views of an individual business.

**Board meeting – 8 May 2019**

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- Non-governmental organisation - in an official capacity as the representative of a non-governmental organisation / trade union /academic institution / other organisations.
- Public sector body - in an official capacity as a representative of a local government organisation/public service provider/other public sector body in the UK or elsewhere.

It is pleasing that the consultation yielded 1,675 responses from individual consumers with approximately 9 out of 10 of them reporting that they or a relative had an allergy. Over half reported they were aged 35 to 54 with less than 1% being children aged 15 or below. The home nations of these respondents were roughly in proportion to the UK population.

There were 126 responses from businesses, 56% of businesses were small or micro businesses. Around two thirds of the businesses sold PPDS. About 30% of the 126 respondents reporting as businesses had more than 250 employees (Large) while 56% had 10 or fewer (Small and Micro). Of the large businesses, about 60% operated UK- or GB wide, whereas about 90% of the others were operated in a single nation of the UK. About two-thirds of the responding businesses reporting that they sold food pre-packed for direct sale (PPDS), although only 40% of microbusinesses did. Most large businesses that sold more than 50 lines whereas about half of micro businesses that reported selling PPDS sold 10 lines or less. Of those businesses stocking PPDS and providing the information, 77% said PPDS accounted for less than half of total units sold. All businesses were asked how they provided information about allergens to consumers. Of the 82 respondents to this question, providing written information upon request was the most common method (20 responses). Providing full ingredient labelling, allergen information on, or near, products and provided verbal information with visible prompts in store were also popular (12 or 13 respondents each).

There were 83 responses from Public Sector Bodies and 24 Non-Governmental Organisations (NGOs). Most were from local authorities (including trading standards and council catering). This group included local NHS organisations and universities. The 24 non-governmental organisations were varied including allergy campaign groups, food industry representatives, trading standards and universities.

**Near Miss Reporting**

Respondents from all groups suggested an online system to report near misses would be useful. Respondents across groups suggested that near misses should be reported by individuals and/or the NHS to the local authority or the FSA. Individuals

**Board meeting – 8 May 2019**

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suggested that there should be an easy to use reporting system that they could use to report incidents of near misses. Some suggested a centralized system that GPs and the NHS could report incidents on, to alert the FSA or Local authorities and trigger action. Businesses and NGO's noted that what constitutes a "near miss" needs to be defined. Respondents from businesses and NGOs and Public Sector Bodies suggested that the Reporting of Injuries Diseases and Dangerous Occurrences Regulations the (RIDDOR) should include allergic reactions.