In Autumn 2018, DEFRA committed to review the framework on allergen labelling in the UK. A consultation has now been launched, which proposes a number of options for amending allergen information provisions, specifically for food prepacked for direct sale (although respondents have also been asked whether the government should also review other types of food, as set out further below).

The consultation closes on 29 March. Individuals, businesses, consumer groups and enforcement authorities have been invited to respond and confirm which of the proposed four options (individually or in combination) are preferred. We summarise the current legal framework that applies to the provision of allergen information and the proposals under the consultation. We also consider whether other changes to allergen labelling are likely in coming months and the possible effects of Brexit.

Current Legal Framework

General Requirements for Information on Allergens Under EU and Domestic Legislation

The EU Food Information for Consumers Regulation (EU FIC) was adopted on 25 October 2011 (Regulation (EU) No 1169/2011) and has applied directly in member states, including the UK, since 13 December 2014 (except the mandatory nutrition declaration, which has applied since 13 December 2016). The EU FIC applies to food business operators at all stages of the food chain, with “food business” meaning any undertaking, whether for profit or not, carrying out any of the activities related to any stage of production, processing and distribution of food.

For prepacked foods, the requirements for labelling allergen information under the EU FIC are very specific. Allergen information must be provided in the required ingredient list of the product in a specified format (except where labels are not required to include an ingredient list, for example, in the UK, alcohol over 1.2% ABV). It must be in a different typeset, with the derivative followed by the allergen, for example: cheese (milk), prawns (crustacean), skinned milk.

There are 14 allergens specified under the EU FIC for these purposes:

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Alternative Allergens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten – wheat, rye, barley, oats, spelt, kamut or hybridised strains (and derivatives)</td>
<td>Crustaceans (and derivatives)</td>
</tr>
<tr>
<td>Eggs (and derivatives)</td>
<td>Fish (and derivatives)</td>
</tr>
<tr>
<td>Peanuts (and derivatives)</td>
<td>Soybeans (and derivatives)</td>
</tr>
<tr>
<td>Milk (and derivatives)</td>
<td>Nuts – almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts</td>
</tr>
<tr>
<td>Celery (and derivatives)</td>
<td>Mustard seeds (and derivatives)</td>
</tr>
<tr>
<td>Sesame Seeds (and derivatives)</td>
<td>Sulphur dioxide and sulphites (concentrations more than more than 10mg/kg or 10 mg/litre)</td>
</tr>
<tr>
<td>Lupin (and derivatives)</td>
<td>Molluscs (and derivatives)</td>
</tr>
</tbody>
</table>

It is a fairly common misconception amongst customers, as well as some food businesses, in relation to cereals containing gluten, that it is the gluten that is the allergen and which must be declared. This is incorrect. Although some people may choose to follow a gluten-free diet, it is actually the wheat, barley, rye etc. that is the allergen and which must be declared under the EU FIC.

Domestic legislation provides for the enforcement of the EU FIC in each member state. In the UK, regulations set offences and penalties for breach of the requirements, delegate competent authorities to inspect and enforce (typically environmental health or trading standards officers) and deal with matters where member states have discretion under the EU FIC. This includes a discretion for member states to determine the means by which allergen information should be made available for food that is not pre-packed.

In accordance with the definitions under the EU FIC, foods that are packed on the sales premises at the customer’s request (for example, a salad prepared in front of the customer, or cheese cut to size and sold at the delicatessen counter on request) are not prepacked (and therefore the allergen labelling requirements set out above do not apply), neither are foods which are prepacked for direct sale (PPDS), which are the main focus of the current consultation.
For PPDS foods, subject to any national provisions to the contrary, it is permissible to provide information on allergenic ingredients verbally or in writing. The consultation notes “concerns have been raised that it can be difficult for customers to distinguish between prepacked and PPDS foods and anecdotal evidence suggests that consumers assume that the absence of allergen information on food packaging means food allergens are not contained in the product, which may not be the case for PPDS foods.”

What Is Food Prepacked for Direct Sale?
There is no definition of PPDS food in the EU FIC. However, the Food Standards Agency (FSA) has produced technical guidance on allergen labelling which provides an interpretation (set out in the consultation document) as follows:

This applies to foods that have been packed on the same premises from which they are being sold. Foods prepared for direct sale are treated as 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: (1) it is expected that the customer is able to speak with the person who made or packaged the product to ask about ingredients; and/or (2) foods that fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made.

Within the consultation, further examples of PPDS are provided, including boxed salads, fresh pizza from the deli counter, 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. It is clear from these examples that the options proposed in the consultation for PPDS foods will potentially impact on the retail sector, as well as hospitality providers.

Other Liabilities and Consequences
If legal requirements on allergen information are not met, this may well mean that a product recall is required, particularly where a label does not include an allergen that is present as an ingredient, because it could render the food “unsafe” for consumers with allergies. Typically, this will apply to prepacked foods that are labelled incorrectly.

However, it is also worth remembering that in many jurisdictions, including the UK, in addition to potential liability for non-compliance with the EU FIC and national provisions in relation to allergen labelling/information, there are separate systems of civil liability, where a person who has suffered loss or damage (for example, an injury or illness) can make a claim for financial compensation from a person or company that has negligently breached a duty of care. As such, in the event of a consumer suffering an allergic reaction, such as anaphylaxis, from a product that was not properly labelled as to allergens, it is possible that the injured party will make a claim in the courts for money to compensate them for their losses; in addition to legal action by an enforcement authority, such as the police or food standards agency, for breach of criminal laws/food safety laws/the provisions of the EU FIC.

This system of civil liability for damages is the reason that many businesses use “precautionary allergen labelling”, i.e. labelling as to allergens that may be present due to cross-contamination, as opposed to intentional inclusion in the food as an ingredient. In practice, precautionary allergen labelling is common for both prepacked and non-prepacked foods, despite the discouragement in FSA guidance from using such labelling, except where there is a genuine, assessed, unavoidable risk that good manufacturing practice cannot avoid. However, such labelling and potential civil liabilities are outside of the scope of the current consultation.

Options Proposed Under Consultation
The consultation seeks views on four options in relation to PPDS foods. It is clear that ultimately the government may adopt more than one of these options – for example, by combining option 1 (which is non-regulatory) with one of the options that would involve changes to the applicable legislation in the UK. The options are as follows:

1. Promotion of Best Practice – Additional activity to ensure a safer environment, including activity such as:
   - Best practice guidance for the catering sector produced by the FSA and Food Standards Scotland (FSS)
   - Cross-stakeholder conference between relevant government departments and businesses to discuss best practice and encourage change
   - A public information campaign to highlight allergen knowledge and awareness for food businesses and the public.

   The real advantage of this option is that it can be implemented relatively quickly and retains flexibility.

2. Requirement for obligatory “ask the staff” labels on PPDS food packaging, with supporting information available for consumers in writing, on request. The supporting information would be either a full list of any of the 14 allergens specified for prepacked foods under the EU FIC (see above) or a full ingredient list with allergens emphasised. This could be done by way of a sticker on packages, meaning that the cost would be limited.

3. Packaging of PPDS foods to be labelled with name of food and a list of any of the 14 allergens specified in the EU FIC and intentionally included in the product as an ingredient. This would have significant cost implications as “generic” packaging could not be used. The consultation notes that this option would still not help those consumers who are allergic to an ingredient that is not specified in the EU FIC.

4. Packaging to be labelled with name of food and full ingredient list, with allergens emphasised on the packaging of PPDS foods. This would, of course, be very similar to the position for prepacked foods under the EU FIC, so would likely assist with the perceived “confusion” claimed in the consultation, but again would have significant cost implications. The consultation also acknowledges that such an approach may prevent innovation and new product development, and affect supply chain purchases and availability.
The consultation recognises that all of the regulatory options will involve a degree of cost for the business and will involve risks of misinformation for customers, either due to mislabelling or to errors with the written list of allergens or ingredient list. Errors are perhaps more likely for foods prepared and packed on the premises where they are sold, because it is more likely that there will be regular substitutions of ingredients/recipe changes/“product of the day” (possibly dependant on seasonal availability) than a traditional prepacked food. However, it is at least arguable that such errors are equally likely if allergen information is provided verbally, as is currently permitted.

It is worth noting that in addition to opinions on the options proposed, the consultation requests feedback on proposed definitions of businesses sizes, either in terms of employees, or other criteria (such as number of outlets/branches, turnover or number of units sold). It also asks whether “small” and/or “micro” businesses should be exempt from some or all policy options. By implication therefore, any business ultimately defined as medium (current proposal 50-249 employees) or large (current proposal 250+ employees) will likely be required to comply with any proposals in relation to PPDS food allergen information.

Once the consultation responses have been collated, it is possible that any changes to the current system for PPDS foods may be implemented relatively quickly. The consultation asks respondents how long businesses should be allowed to implement any new policy, with timescales ranging from less than six months to five years for each option.

**Further Changes on the Horizon?**

As well as the proposed changes on allergen information for PPDS foods, the consultation notes that the FSA have been working with local authorities in Yorkshire on a pilot scheme to improve notification of incidents between businesses, local authorities and the NHS. It suggests that a requirement on businesses to report “near misses” related to their establishment could trigger a priority inspection of the businesses through the relevant local authority to ensure that non-compliances are identified and solved. A “near miss” would be an incident where a customer has an allergic reaction, after unknowingly eating a food containing an allergen, which becomes an anaphylactic shock, but is not fatal. Views are invited on this, which indicates that the government is considering introducing such a requirement in future.

In addition, respondents are also asked to comment on the other types of food which the government should review, including:

- Food packed on the sales premises at the consumer’s request
- Food not packed (such as loose items sold to the consumer without packing, or meals served in a restaurant)
- Non-prepacked food ordered via distance selling, for example a takeaway pizza ordered over the phone or via the internet
- Any other category

This suggests that other changes may be on the horizon and, if so, these will likely be in relation to other forms of non pre-packed foods (for which it is currently permissible to provide allergen information verbally).

The fact that Precautionary Allergen Labelling statements are specifically highlighted as being out-of-scope of this consultation may indicate that this will also be a focus area in future. Some countries do have more detailed provisions on “may contain” labels, such as the Australian “VITAL” risk-based threshold scheme for accidental cross-contamination, or the Swiss legal framework based on threshold levels.

**Impact of Brexit?**

The government explicitly states within the consultation document that, over the longer term, it will have an opportunity to review all food labelling when the UK has left the EU. Therefore, we may see further changes to allergen labelling in the UK after Brexit, which could extend to foods packed at the customer’s request, or even to prepacked foods. For example, the government could decide to review the list of 14 allergens and require additional or alternative ingredients to be highlighted to consumers, such as strawberry or kiwi. However, in the short term, the current EU laws will “carry over” into UK law on exit.

**Response to Consultation and Advice on Impact**

Please let us know if you want to understand more about the potential impact of the proposals on your organisation, either generally or in relation to your proposed response to the government. The survey itself can be completed online, or sent by email or post to DEFRA.

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