

Title: Consultation on amending allergen information provisions contained within domestic food information legislation for food prepacked for direct sale IA No: RPC Reference No: RPC-4323(1)-DEFRA Lead department or agency: Defra Other departments or agencies: Food Standards Agency, Food Standards Scotland, Department for Health and Social Care	Impact Assessment (IA)
	Date: 25.01.19
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Secondary Legislation
	Contact for enquiries: Keith Forsyth

Summary: Intervention and options

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year	One-In, Three-Out	Business Impact Target Status
			Not in scope	Non qualifying provision

What is the problem under consideration? Why is government intervention necessary?

The primary issue under consideration is an imperfect information problem. A distinction is made in the regulations on food allergen information provision between foods that are prepacked and those that are prepacked for direct sale (PPDS). In the UK, foods that are prepacked are required to be labelled with full ingredients with any of the 14 specific food allergens (listed in Annex II of the EU Food Information for Consumers Regulation 1169/2011; FIC) in the ingredients emphasised, whereas with PPDS products it is permitted to provide information on the 14 food allergens in ingredients in writing or orally. It is often difficult for consumers to distinguish between prepacked and PPDS foods, and anecdotal evidence suggests that consumers assume that the absence of allergen information on packaged foods means food allergens are not contained in the product, which may not be the case for PPDS foods.

What are the policy objectives and the intended effects?

The overarching objective of the policy is to improve the provision of information to consumers about food allergens present in PPDS foods.

The intended effect of the Government’s intervention is to reduce the number of allergen-related incidents in which the provision of allergen information for PPDS foods is considered to be relevant.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Non-regulatory options

0. Do nothing.
1. Promote best practice.

Regulatory options

2. Mandate "ask the staff" labels on packages of PPDS foods, with supporting information for consumers in writing.
3. Mandate name of the food and allergen labelling (*i.e.* indicate which of the 14 allergens listed in Annex II of FIC are contained in the food) on packages of PPDS foods.

4. Mandate name of the food and full ingredient list labelling, with the 14 allergens listed in Annex II of FIC emphasised, on packages of PPDS foods.

All options are assessed relative to 'Do nothing' (Option 0).

Will the policy be reviewed? No, this IA is for a consultation only **If applicable, set review date:**

Does implementation go beyond minimum EU requirements?		Yes		
Are any of these organisations in scope?	Micro yes	Small yes	Medium yes	Large yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:_____ Date: _

Summary: Analysis and evidence - policy option 1

Description: Promote best practice

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate:
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate					
Description and scale of key monetised costs by ‘main affected groups’					
N/A					
Other key non-monetised costs by ‘main affected groups’					
The costs accrued will greatly depend on what is ultimately defined as best practice and on the activities that are undertaken to promote best practice. If there were to be new (or improved) guidance issued by government, then there would be costs to government in developing and distributing this. Similarly, if a public awareness campaign is launched (like the FSA’s #EasyToAsk campaign) then government will incur costs in developing and promoting this. Businesses then may incur familiarisation costs. This would not be a certainty as this is not a legislative change so not required.					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate	Optional		Optional		Optional
Description and scale of key monetised benefits by ‘main affected groups’					
N/A					
Other key non-monetised benefits by ‘main affected groups’					
The benefits of this option are difficult to define, as we cannot say how effective improved best practice would be (as businesses will have different base levels of performance). Furthermore as this is a non-regulatory option there is no guarantee that businesses will change their behaviour/practices. However we would expect an improvement in the provision of food allergen information to consumers as more businesses move towards best practice. This should therefore reduce the number of food allergen related incidents, and ultimately fatalities.					
Key assumptions/sensitivities/risks					Discount rate (%)
1) Lack of uptake by businesses. As there would be no legislative change, there is no guarantee (or requirement) that businesses would change how they operate. 2) Inconsistency in business practice. Some businesses would choose just to meet the regulatory minimum, some would adopt best practice, and others would do something in					

between. This inconsistent approach may confuse some consumers as it would not be clear where they need to look for allergen information.

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	Benefits: N/A	Net: N/A	N/A

Summary: Analysis and evidence - policy option 2

Description: “Ask the staff” labelling on packages of PPDS food, with supporting information for consumers in writing

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: -1.35	High: -2.26	Best Estimate: -1.96	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	1.20		0.0115		-1.35	
High	2.00		0.01939		-2.26	
Best Estimate	1.71		0.01814		-1.96	
Description and scale of key monetised costs by ‘main affected groups’						
We anticipate that there will be initial familiarisation costs for both businesses and government (local authorities). Furthermore we expect businesses will also face transitional labelling costs for this option. Government (local authorities/trading standards) will face on-going enforcement costs in assessing businesses compliance with the new regulations.						
Other key non-monetised costs by ‘main affected groups’						
Businesses may choose (as it is not necessary as part of this option) to improve (or run new) staff training practices.						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	Optional		Optional		Optional	
High	Optional		Optional		Optional	
Best Estimate	Optional		Optional		Optional	
Description and scale of key monetised benefits by ‘main affected groups’						
N/A						
Other key non-monetised benefits by ‘main affected groups’						
Improved provision of allergen information to consumers by increasing the likelihood of conversation between consumers and staff, and increased awareness amongst businesses of their obligation to provide information about the use of allergenic ingredients in their food. This should lead to improved consumer awareness of PPDS and confidence in businesses selling PPDS foods, and improve the choice of options where to shop (in terms of businesses) for those with food allergies. This ultimately should lead to a reduction in the number of allergen related incidents and fatalities. Businesses may receive increased footfall from consumers who previously avoided the PPDS market due to low confidence in the provision of information.						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
1) It requires the consumer to be proactive and sufficiently confident in asking the staff for allergen information. This may be difficult in busy retail environments, particularly for vulnerable groups (e.g. 16 – 24 year olds)						

- 2) It depends on staff being available and sufficiently trained to provide accurate information. Under current rules, businesses are required to provide information about the use of allergenic ingredients in a food.
- 3) If food is taken off the premises and given to a third party food allergic consumer, they may not have access to information on allergens contained within the product.

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.2	Benefits: N/A	Net: -0.2	N/A

Summary: Analysis and evidence - policy option 3

Description: Mandate name of the food and allergen labelling on packages of PPDS foods

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -6.79	High: -10.42	Best Estimate: -8.76
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low		6.73	0.0115		6.79
High		10.29	0.0194		10.42
Best Estimate		8.62	0.0181		8.76
Description and scale of key monetised costs by 'main affected groups'					
We anticipate that there will be initial familiarisation costs for both businesses and government (local authorities). Furthermore we expect businesses will also face transitional labelling costs for this option. Government (local authorities/trading standards) will face on-going enforcement costs in assessing businesses compliance with the new regulations.					
Other key non-monetised costs by 'main affected groups'					
Businesses may choose (as it is not necessary as part of this option) to improve (or run new) staff training on allergens. Businesses will also be restricted in their ability to substitute ingredients and the rate at which they change their products, without incurring additional costs (re-labelling).					
BENEFITS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low		Optional	Optional		Optional
High		Optional	Optional		Optional
Best Estimate		Optional	Optional		Optional
Description and scale of key monetised benefits by 'main affected groups'					
N/A.					
Other key non-monetised benefits by 'main affected groups'					
Improved provision of allergen information to consumers on PPDS food products. This should lead to improved consumer confidence in businesses selling PPDS foods and improved choice of options of where to shop (in terms of businesses) for those with food allergies. This ultimately should lead to a reduction in the number of allergen related incidents and fatalities. Businesses may receive increased footfall from consumers (particularly those allergic to foods on the EUs list of 14) who previously avoided the PPDS market due to low confidence in the provision of information.					
Key assumptions/sensitivities/risks					Discount rate (%)
					3.5
1) It may be challenging for some businesses to implement accurately, particularly micro and SMEs, and this may increase the risk of mislabelling incidents.					
2) It may result in businesses removing certain foods from their menu, thus reducing consumer choice in general.					

- 3) It may reduce dialogue between consumers and staff, and businesses may become reliant on product labels. This will be particularly problematic for individuals that are allergic to foods that are not in Annex II of FIC
- 4) Businesses will have to improve their allergen management systems so that staff know how to label products accurately.

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 1.0	Benefits: N/A	Net: -1.0	

Summary: Analysis and evidence - policy option 4

Description: Mandate name of the food and full ingredient list labelling on packages of PPDS foods

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -6.79	High: -10.42	Best Estimate: 8.76
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	6.73		0.0115		6.79
High	10.29		0.0194		10.42
Best Estimate	8.62		0.0181		8.76
Description and scale of key monetised costs by 'main affected groups'					
We anticipate that there will be initial familiarisation costs for both businesses and government (local authorities). Furthermore we expect businesses will also face transitional labelling costs for this option. Government (local authorities/trading standards) will face on-going enforcement costs in assessing businesses compliance with the new regulations.					
Other key non-monetised costs by 'main affected groups'					
Businesses may choose (as it is not necessary as part of this option) to improve (or run new) staff training practices. Businesses will also be restricted in their ability to substitute ingredients as a mechanism to keep costs down, without incurring additional costs (re-labelling). Due to the specificity of the labelling it is anticipated that these restrictions will be greater than those experienced under Option 3, so therefore more costly to businesses.					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate	Optional		Optional		Optional
Description and scale of key monetised benefits by 'main affected groups'					
N/A					
Other key non-monetised benefits by 'main affected groups'					
Improved provision of allergen information on PPDS food products to consumers. This should lead to improved consumer confidence in businesses selling PPDS foods and improve the choice of options (in terms of businesses) for those with food allergies. This ultimately should lead to a reduction in the number of food allergen related incidents and fatalities. Businesses may receive increased footfall from consumers who previously avoided the PPDS market due to low confidence in the provision of information. Consistent provision of information on ingredients and allergens on all products that are prepacked and PPDS					

Key assumptions/sensitivities/risks	Discount rate	3.5
<p>1) It will be challenging for some businesses to implement accurately and safely, particularly micro and SMEs, and this may increase the risk of mislabelling incidents.</p> <p>2) It may result in businesses removing certain foods from their menu, thus reducing consumer choice in general.</p> <p>3) It may reduce dialogue between consumers and staff, and businesses may become reliant on product labels and divert resources away from providing staff with allergen training.</p>		

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:	
Costs:	1.0	Benefits:	Net:	-1.0
		N/A		
				N/A

Evidence base

Background and scope

General background on food allergens

In the UK, it is estimated that 1-2% of adults and 5-8% of children have a food allergy. This equates to around 2 million people living in the UK with a food allergy (this figure does not include those with food intolerances). This means the actual number of affected people living with food allergy and/or food intolerance is considerably more.

An allergic reaction can be produced by a tiny amount of a food ingredient that a person is sensitive to (for example a teaspoon of milk powder, a fragment of peanut or just one or two sesame seeds). Symptoms of an allergic reaction can range from mild symptoms such as itching around the mouth and rashes; and can progress to more severe symptoms such as vomiting, diarrhoea, wheezing and on occasion anaphylaxis (shock). Around ten people in the UK die from allergic reactions to food every year.

There is no cure for food allergy. The only way to manage the condition is to avoid food that makes the person ill. Therefore, it is very important that consumers are provided with accurate information about allergenic food ingredients in products to allow them to make safe food choices.

Legislative background

The legislative framework around the provision of food allergen information has evolved over many years. In 2011 The Food Information to Consumers Regulation (EU 1169/2011; FIC) introduced new rules for Food Business Operators (FBOs) relating to the labelling and provision of allergen information. FBOs are under a duty to ensure that all mandatory food allergen information must be accurate, available and easily accessible to the consumer. FIC allows for Member States to introduce national measures as to how information is to be made available for non-prepacked foods. The Food Information Regulations 2014 (FIR) and equivalent regulations in Wales, Scotland and Northern Ireland, are the domestic regulations that establish the enforcement measures for FIC in the UK.

In the UK, in recognition of the wide variety of out-of-home eating establishments, FIR introduced a flexibility for allergen information on non-prepacked foods, including food that is prepacked for direct sale (PPDS), to be made available by any means the food business chooses, including orally by a member of staff. Where the operator chooses not to provide food allergen ingredients information upfront on a menu for example, there must be an upfront indication to speak to a member of staff either on a label attached to the food itself or on a notice, menu, ticket or label that is readily discernible to the customer.

Prepacked foods

FIC allows Member States to make a distinction between prepacked foods, and non-prepacked foods, in how allergenic information should be provided to consumers. Article 2 (2) (e) of FIC defines what is and what isn't prepacked (Annex C) and the FSA's interpretation of this definition¹ is given below:

¹ <https://www.food.gov.uk/sites/default/files/media/document/food-allergen-labelling-technical-guidance.pdf>

Prepacked foods: *This refers to any food put into packaging before being offered for sale for example a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup. All the following must apply:*

- *the food is either fully or partly enclosed by the packaging;*
- *the food cannot be altered without opening or changing the packaging;*
- *the product is ready for sale to the final customer or to a mass caterer. (Adapted from the definition in Article 2 (2)(e) of EU FIC; Annex C).*

Under FIC, food which is prepacked, for example a ready meal sold in a supermarket, must be clearly labelled with allergenic ingredients from the list of 14 major allergens. Allergens must be emphasised to stand out from other ingredients within the mandatory ingredients list, for example in **bold** text.

Non-prepacked foods

Non-prepacked food includes:

- food not packed, such as loose items sold to the consumer without packing;
- food packed on the sales premises at the consumer's request, and
- food prepacked for direct sale (i.e. food prepared and wrapped for sale on the same premises in which they are made).

FIC defines prepacked food, and what is not prepacked, but it doesn't provide a specific definition of PPDS. In the absence of a definition in FIC we expect businesses and local authorities to use the definition set out in the FSA guidance².

For non-prepacked food, there is no requirement to label an individual product with the same mandatory information required for prepacked foods, however the allergen information must be readily available, including through indications to ask a member of staff, at the point where the intending purchaser chooses the product.

Allergenic foods

There are 14 substances or products causing allergies or intolerances which (unless exempted) are legally considered to be mandatory information to consumers under the EU Food Information for Consumers Regulation (1169/2011; FIC). This requirement is extended to all foods provided to consumers and includes food that is not prepacked (e.g. restaurant meals); packed at the consumers' request (e.g. a deli sandwich prepared, wrapped and handed to the customer); or is prepacked for direct sale (PPDS; e.g. a sandwich prepacked before the customer chooses it). If a food product contains or uses an ingredient or processing aid derived from one of the substances or products listed below, it will need to be declared by the food business operator (FBO) to the consumer.

Namely,

1. Cereals containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof;
2. Crustaceans and products thereof;

² <https://www.food.gov.uk/sites/default/files/media/document/food-allergen-labelling-technical-guidance.pdf>

3. Eggs and products thereof;
4. Fish and products thereof;
5. Peanuts and products thereof;
6. Soybeans and products thereof;
7. Milk and products thereof (including lactose);
8. Nuts, namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof;
9. Celery and products thereof;
10. Mustard and products thereof;
11. Sesame seeds and products thereof;
12. Sulphur dioxide and sulphites >10mg/kg or 10mg/L;
13. Lupin and products thereof;
14. Molluscs and products thereof.

This list is consistent across the EU and cannot be amended by individual Member States.

Exemptions

Some ingredients made from the Annex II foods will not cause an allergic reaction because they have been highly processed (for example fully refined soya oil or wheat glucose syrups). This is because the allergen/protein has been removed and the product has been assessed by the European Food Safety Authority (EFSA) as not presenting an allergenic risk to the consumer. A full list of exemptions is available at Annex II of FIC.

Scope of the consultation

This consultation is focused on strengthening the provision of mandatory allergen information for foods prepacked for direct sale (PPDS).

PPDS is not defined in FIC, and it is not possible for the UK to define or clarify PPDS in regulation whilst we remain a member of the EU or during an implementation period. In the absence of a definition in FIC we expect businesses and local authorities to use the definition set out in the FSA guidance³:

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 (FSA interpretation of Article 2 (2)(e) of EU FIC; Annex C)*

³ <https://www.food.gov.uk/sites/default/files/media/document/food-allergen-labelling-technical-guidance.pdf>

Out of scope

The following issues fall outside the scope of this public consultation:

- The regulation of precautionary statements to indicate the unintentional presence of food allergens due to cross-contamination.

This consultation is concerned specifically with labelling of intentional allergenic ingredients.

- Allergen labelling provision for non-prepacked food ordered via distance selling, for example a takeaway pizza ordered over the phone or via the internet.

Under current rules, mandatory allergen information for non-prepacked food sold via distance selling must be provided to the consumer at the time of ordering on the material supporting the distance selling or through other appropriate means, and at the time the food is delivered. As the current rules are derived from EU FIC and do not allow for national measures, we cannot change the way distance sellers provide allergen information to consumers while we are a member of the EU or during an implementation period.

- Food not packed, and food packed on the sales premises at the consumer's request.

There is an expectation that in these circumstances, food allergic consumers will talk to staff about their allergy requirements so they can make safe food choices. The food business is legally required to provide accurate and clear information on food allergens making it a dual responsibility to help safe selection of foods.

Enforcement

Separate but parallel FIR enforcement regulations exist in each of the 4 countries of the UK. Enforcement of these regulations is undertaken by food enforcement officers within local authorities. Person(s) found guilty of an FIR offence may be liable to unlimited fines (England, Wales and Northern Ireland) and criminal sanctions. Breaches under FIR regarding allergens may also result in offences under the Food Safety Act (England, Wales and Scotland) or the Food Safety (Northern Ireland) Order which can result in fines or imprisonment.

Within Local Authorities enforcement is shared between Trading Standards and Environmental Health. Local Authorities ensure food businesses have an adequate level of allergen controls.

Problem under consideration and rationale for intervention

The primary issue under consideration is an imperfect information problem. A distinction is made in the regulations on food allergen information provision between foods that are prepacked and those that are prepacked for direct sale (PPDS). In the UK, foods that are prepacked are required to be labelled with full ingredients with any of the 14 specific food allergens (listed in Annex II of the EU Food Information for Consumers Regulation 1169/2011; FIC) in the ingredients emphasised, whereas with PPDS products it is permitted to provide information on the 14 food allergens in ingredients in writing or orally. It is often difficult for consumers to distinguish between prepacked and PPDS foods, and anecdotal evidence suggests that consumers assume that the absence of allergen information on packaged foods means food allergens are not contained in the product, and this is not the case for PPDS foods.

The overarching objective of the policy is to improve the provision of information to consumers about food allergens present in PPDS foods. The intended effect of the Government's intervention is to reduce the number of allergen-related incidents in which the provision of allergen information for PPDS foods is considered to be relevant.

Policy objective

The overarching objective of the policy is to improve the provision of information to consumers about food allergens present in PPDS foods.

In light of the overarching objective we have developed a spectrum of regulatory and non-regulatory policy options. Each option considers various measures that could be put in place to improve the provision of allergen information relating to PPDS foods. Options 1-4 represent a sliding scale moving from non-regulatory measures to increasingly prescriptive regulatory measures. Option 1 is a non regulatory approach intended to reduce the risk to consumers by encouraging changes to business practice. Options 2 to 4 consider leveraging regulatory measures in order to achieve the same objective of improving the provision of allergen information to consumers.

Description of options considered (including status-quo)

We have considered a wide range of policy options with stakeholders and can confirm that no potentially viable option has been ruled out of detailed appraisal without substantive reasoning. The policy options for strengthening the UK allergen information provision framework are summarised below; they can be broadly divided into non-regulatory and regulatory options. Note that each option need not be considered as exclusive; options may be combined, for example, non-regulatory options may build upon regulatory options in an escalating hierarchy, or options may be applied to different sizes of business.

Non-regulatory options

Policy Option 0. Do nothing.

This option retains the existing regulatory framework and continues with current public information campaigns to highlight the importance of allergen knowledge for businesses and general public. With this option, businesses continue to have a choice as to how they provide allergen information on PPDS foods and consumers will continue to be encouraged to take responsibility for safeguarding their own health. It is recognised that current policy is not satisfactory, and this option does not adequately address the main objective (see above).

Policy Option 1. Promote best practice.

This option would not require a legislative change, but to effect change would entail additional activity to promote best practice within the current framework to encourage businesses to review their knowledge, skills and actions to ensure a safer environment for consumers. Options for promoting best practice may include:

- Best practice guidance for the catering sector to be produced by FSA and FSS, and made available to all local authorities;
- Cross stakeholder conference with businesses hosted by Defra and FSA to discuss best practice and encourage change without legislative change;
- Public information campaign to highlight allergen knowledge and awareness for food businesses and the general public.

The main benefits of this option are that it has the potential to be designed and implemented in a shorter timescale than that required for a legislative change, and can be adapted to continue to be fit for purpose. It retains maximum flexibility for businesses to make allergen information available on PPDS foods in a way that best suits their business model whilst achieving the policy objective. Some businesses are already taking action to strengthen their allergen information provision. The FSA see a public awareness/ best practice campaign as essential, whatever the outcome of this review. In relation to this, FSA have launched a #EasytoAsk campaign and relevant businesses have indicated a willingness to directly support this in their approach to allergen labelling, which could significantly increase awareness.

As this is a non-regulatory measure, there is no guarantee that businesses will change their practices.

Regulatory options

Policy Option 2. Mandate “ask the staff” labels on packages of food prepacked for direct sale, with supporting information for consumers in writing.

In the absence of a full list of ingredients, or list of allergens contained within the product on the packaging, PPDS foods would include a label/sticker on the packaging advising consumers to “ask the staff” about allergens. Upon request, consumers would also be provided with supporting information in writing before they purchase the food, and this information would include:

- A list of any of the 14 allergens contained within a specific product, or
- Full ingredient list with allergens emphasised

This sticker would be in addition to the signs that businesses are currently required to put in place prompting consumers to ask about allergens.

Of the regulatory options proposed, this option is the least costly to implement (see below) and is already being rolled out by bigger businesses. It would ensure that consumers are consistently prompted to be proactive in talking to staff about allergens when choosing PPDS foods. Anecdotal evidence indicates that it would normalise and encourage food allergic consumers to be proactive in talking to staff about their allergy requirements so they can make safe food choices. However, risks associated with this option include failure to provide sufficient information for those consumers who are not sufficiently confident to engage with staff, the availability of appropriately trained staff, and the risk which may ensue if food is taken off the premises and given to a third party food allergic consumer. Unlike the other regulatory options, this option does not carry the risk of mislabelling on the product packaging, but there is still a risk that the written information provided upon request may be incorrect.

Policy Option 3. Mandate name of the food and allergen labelling on packages of food prepacked for direct sale.

This option introduces a regulatory measure requiring PPDS foods to have a label on the packaging to tell the consumer the name of the food and which of the 14 allergenic ingredients in Annex II of FIC the product contains.

This option is less difficult for businesses to implement than full ingredient labelling, but more costly than option 2. It gives consumers clear product specific information on the food packaging, enabling food allergic consumers to make informed choices when purchasing food products. Also, when the consumer takes the food off the premises to eat later or to give to a third party, the information about food allergens is available on the packaging. This option also

allows businesses to make some ingredient substitutions without having to change the label on the packaging.

There may be risks associated with this option and it may be challenging to implement correctly, particularly for micro and SMEs, incurring additional administrative, equipment and training costs. For instance, it will increase costs to business as generic packaging would necessarily disappear or need to be supplemented with another label. As mislabelling is the most common source of product recall for prepacked goods, adding a label could introduce the risk of mislabelling incidents, particularly in busy kitchen environments where products containing different food allergens are made simultaneously. As consumers trust labels, this could cause more incidents as consumers may eat wrongly labelled packaged food, but overall, the risk of mislabelling is less for this option than the mislabelling risk associated with option 4. This options may also lead to businesses removing certain foods from their menu, thus reducing consumer choice in general. It would require strengthened training for all staff on allergens, to equip them with the knowledge and skills to implement allergen labelling procedures accurately.

Policy Option 4. Mandate name of the food and full ingredient⁴ list labelling, with allergens emphasised, on packages of food prepacked for direct sale.

This option requires that food prepacked for direct sale has a label with the name of the food and a list of full ingredients with allergens emphasised on the packaging.

Labelling will need to be compliant with Article 9 (1) a - c5 of FIC.

This option introduces a consistent approach to labelling of ingredients for food that is prepacked and prepacked for direct sale. It may give food allergic consumers more trust in the food they are eating and help consumers with food allergies and intolerances in addition to those mandatorily defined by FIC. It doesn't rely on staff having to provide accurate information on allergens, but staff will need to be sufficiently trained to implement allergen labelling procedures accurately. As with option 3, full ingredient labelling would increase costs to business as generic packaging would necessarily disappear or need to be supplemented with additional labelling. Adding a label may introduce the risk of mislabelling incidents, particularly in busy kitchen environments where products containing different allergens are made simultaneously, and this option carries the greatest mislabelling risk. As consumers trust labels, this could cause more incidents as consumers may eat wrongly labelled packaged food. This option may lead to businesses removing certain foods from their menu to avoid the costs of extra labelling, potentially reducing consumer choice in general. Additionally, the cost of full labelling may potentially stifle innovation and new product development and may constrain supply chain purchases and availability.

Composition of the PPDS market

The size of the PPDS market is difficult to establish, due to the complexity surrounding what is (and what is not) a PPDS food. This leads to a difficulty in determining which businesses sell

⁴ FIC Article 2 (2) (f):

'ingredient' means any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients';

⁵ In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:

(a) the name of the food;

(b) the list of ingredients;

(c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex 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;

PPDS foods and therefore who would be affected by any changes to regulations regarding PPDS foods. Moreover there is no data, that we are aware of, that sufficiently outlines the PPDS food sector. Therefore we need to make assumptions in order to set out what is in scope of this assessment.

For the assessment of costs and benefits in this document, only businesses that sell PPDS foods were considered. Businesses where goods which are packed at the consumers request (PCR), such as takeaways, are out of scope of this review and have not been considered for this analysis.

Businesses selling PPDS foods will be part of the wider 'Restaurants and mobile food service activities' sector (SIC code 56.1). Based on Government statistics⁶ we know that this wider sector has approximately 83,320 businesses, with 98% of these businesses being micro (less than 9 employees) or small (between 10 and 49 employees) businesses.

We have estimated that the number of businesses in the UK selling PPDS goods to be 7,785⁷ which represents approximately 9.3% of the sector. For our analysis we have also assumed that the proportion of businesses that were small or micro to be the same (approximately 98.2%⁶) as the wider sector (SIC 56.1).

Supermarkets have not been included in our analysis, although we are aware that they do sell PPDS foods in certain stores (e.g. rotisserie chicken can be sold as PPDS; and, in store bakeries in major retailers often sell PPDS foods), it is difficult to determine how many stores sell these goods as PPDS and how many as PCR. The decision to omit supermarkets from the analysis was taken, as it was assumed that they may choose to sell these goods as PCR (or remove them from sale altogether) to avoid incurring additional costs.

Costs and benefits of policy options

The main categories of impact to be considered are set out below and the analysis undertaken was carried out in accordance with guidance set out in the Green Book⁸.

If the policy is successful, benefits may accrue through:

- improved provision of allergen information to consumers;
- improved consumer confidence (particularly amongst those with food allergies) in the purchase of food products which are prepacked for direct sale;
- reduction in the number of incidents as a result of consumption of allergens in food; and
- reduction in fatalities due to allergic reaction.

The benefits have not been monetised in this assessment due to the overall uncertainty surrounding how effective each policy option would be. It is difficult to predict with any accuracy the effect of improved provision of information (either verbally or through labelling) on reducing allergy related incidents. Therefore benefits are discussed for each option but shall not receive any formal monetised evaluation.

The main categories of costs to be considered are:

- the costs to businesses, including familiarisation costs, labelling costs, training costs, costs of determining allergens present in food products, costs of changing production lines and costs of determining the full list of ingredients of food products;

⁶ BEIS: Business Population Estimates (includes breakdown by size of business) - <https://www.gov.uk/government/statistics/business-population-estimates-2018>

⁷ The number of PPDS business (and the number of individual outlets) were estimated using data from Euromonitor. This is not based on any definition that Euromonitor use, but through a series of assumptions based on the businesses we expect to fall under the scope of these policy options.

⁸ The Green Book: appraisal and evaluation in central government - <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

- the costs to government, including familiarisation costs, development of new guidance (and similar materials) for businesses and the enforcement of new regulations.

The costs listed in this impact assessment do not reflect the complete picture of the policy options considered. Due to incomplete information and uncertainty over the extent/coverage of certain costs, we are unable to provide a full breakdown of all the costs that may occur. Similarly as we are unable to accurately establish the number of incidents caused by PPDS food products, we cannot make sensible estimations of the potential benefits that may be accrued.

Additionally we expect that any costs experienced will greatly outweigh any benefits that will be accrued.

In light of this we will look to consult on several aspects of our analysis to expand our understanding of the costs and benefits, in order for us to build upon and improve our costings of each policy option.

The net present values of the options have been assessed over a period of 10 years.

It is difficult to establish a baseline position from which we can assess. Currently businesses must be able to provide allergen information in written or verbal form. However we know that businesses may already do more than the minimum requirement, so some may already be carrying out what our policy options set out.

Option 0 (Do nothing - Baseline)

Option 0 is the 'do nothing' scenario against which all other options are measured. As such, the costs and benefits are defined to be 0.

Option 1 (Promoting best practice)

Costs to businesses

As this option does not involve a change in regulation, but improving on the actions that are already undertaken by businesses, it is difficult to quantify the change in costs relative to the baseline. Any costs here will very much depend on what businesses currently do with respect to the provision of allergen information (which will not be uniform across businesses due to the flexibility afforded by the current regulatory framework).

Moreover as there would be no legislative change, there is in turn no guarantee (or requirement) that businesses would change how they operate and thus incur additional costs.

If 'best practice' included the provision of new government guidance then there may be an associated familiarisation cost (someone within each business familiarising themselves with the new guidance).

Costs to consumers

We do not expect there to be any costs to consumers of this option. However, it is possible that businesses could choose to pass on any increase in costs that they experience (in meeting what is deemed to be best practice) on to consumers. This would not be an additional cost, simply the costs that are accrued by business may be passed on to consumers.

Costs to government

As what is defined as 'best practice' has not been fully defined at this stage, we are unable to quantify and monetise the associated costs to Government. However we can begin to anticipate where costs may arise based on the best practice suggestions that were listed in the options section:

- Best practice guidance for the catering sector to be produced by FSA and made available to all local authorities;

- Cross stakeholder conference with businesses hosted by Defra and FSA to discuss best practice and encourage change without legislative change;
- Public information campaign to highlight allergen knowledge and awareness for food businesses and the general public.

These are currently non-monetised costs.

If Government (more specifically the FSA) were required to produce new 'best practice guidance' or 'specific allergen training packs' there would be costs associated with these. The FSA would need to take time to develop the necessary information to produce these. This therefore would require people to develop and would have costs linked to the time taken to produce and the wage rate of those producing it. Similarly, if a public awareness campaign is developed, there would be costs associated with developing and running the campaign.

Benefits

The benefits have not been monetised. The benefits generated by this policy option will depend on several factors, including the level of awareness of the consumer of what allergen information is currently available to them.

We are unable to accurately quantify (and ultimately monetise) the associated benefits. This is due to uncertainty surrounding how effective this policy option will be in improving the provision of information to consumers.

However we would expect there to be an improvement in the provision of allergen information to consumers as more businesses move towards best practice. This should therefore reduce the number of allergen related incidents and risk of fatalities.

Option 2 ("Ask the staff" labelling on packages of PPDS food, with supporting information for consumers in writing)

Costs to businesses

Familiarisation costs

This cost has been monetised. There will be a one-off cost for businesses, associated with reading and familiarising themselves with the new regulations introduced. Time will be spent acquiring, reading and understanding the implications of the new legislation on their business.

Familiarisation costs are measured in terms of the time spent familiarising and are therefore calculated by multiplying the time it takes for a member of staff to read and understand the regulations, by their hourly wage rate. The relevant average hourly rate (from ONS Annual Survey of Hours and Earnings data⁹) has been up-lifted (by 30%) to take into account the non-wage labour costs and overheads (which is the standard methodology).

We assume that for small and micro businesses it would take one manager one hour to read and familiarise themselves with the new regulations. Similarly we assume for medium (50 to 249 employees) and large businesses (250 or more employees) that it would take one regulatory professional one hour to read and familiarise, followed by an additional hour to disseminate the relevant information to others (as they will have multiple outlets).

Although this policy is affecting businesses selling PPDS foods, we assume that all businesses that are part of SIC code 56.1 'Restaurants and mobile food service activities' (83,320 businesses¹⁰) will need to familiarise themselves with the new regulations. As businesses are

⁹ ONS Annual Survey of Hours and Earnings (ASHE) 2018 - <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010asheta/ble15>

¹⁰ BEIS: Business Population Estimates (includes breakdown by size of business) - <https://www.gov.uk/government/statistics/business-population-estimates-2018>

not defined by the goods that they sell, this means that all businesses in the wider sector will need to familiarise themselves with the new regulations.

The average hourly wage for ‘restaurant and catering establishment managers and proprietors’ is £11.93 according to the 2018 ONS: Annual Survey of Hours and Earnings (ASHE). This wage rate is then uprated by 30% to £15.51. Therefore we estimate the familiarisation cost per small and micro business to be £15.51.

The average hourly wage for ‘quality assurance and regulatory professionals’ is £24.13 according to 2018 ASHE data (see Annex A). This wage rate is then uprated to £31.37. Therefore we estimate the familiarisation cost per medium and large business to be £62.74.

The average hourly rate has been used to calculate a central estimate. In the ONS ASHE data there are lowest decile and highest decile wages, these have been used to produce low and high end estimates of familiarisation costs using the same methodology.

The total familiarisation cost to business is familiarisation cost per business multiplied by the relevant number of businesses.

	Low Estimate Familiarisation Costs	Central Estimate Familiarisation Costs	High Estimate Familiarisation Costs
England	£764,181	£1,136,343	£1,318,743
Scotland	£75,251	£111,899	£129,860
Wales	£46,739	£69,501	£80,657
Northern Ireland	£19,883	£29,566	£34,312
United Kingdom ¹¹	£906,053	£1,347,308	£1,563,571
Table 1: Estimated familiarisation costs to business under Option 2			

Labelling costs

This cost has been monetised.

Under this option all businesses will be required to include “ask the staff” as part of the labelling on all PPDS foods.

We assume this to be a transitional cost, with there being zero ongoing costs in subsequent years. This is due to packaging only requiring one redesign to account for the new requirements, after which it will be covered under business as usual labelling/packaging costs.

Based on previous research¹², we know that for minor labelling changes the range in cost per stock keeping unit (SKU) is £10 - £1,800¹³.

Uprating these to 2018 prices¹⁴, we then assume that the cost of re-labelling to be £10.99 per SKU for small and micro businesses, and £1978.59 per SKU for medium and large businesses.

¹¹ Country splits have been determined using FSA data outlining the number of Food Business Operators across the UK.

¹² Costs per SKU were converted to 2018 prices. Source: Developing a Framework for Assessing the Costs of Labelling Changes in the UK - <https://webarchive.nationalarchives.gov.uk/20130404011920/http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf>

¹³ The assumed range in the cost per SKU is due to a combination of both complexity (smaller businesses more likely to have simple labelling) and number of units of each product line (medium and large businesses will sell significantly more of a single PPDS product in a year).

¹⁴ Using ‘GDP deflators at market prices, and money GDP March 2018’ - <https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-march-2018-quarterly-national-accounts>

Our assumption is that an SKU can be equated to a distinct PPDS food product.

We assume that as the “ask the staff” label must be added to packaging of all PPDS foods, that we can treat the products sold in each business to be one line (i.e. we do not differentiate between products). Therefore the cost per business is simply the cost per SKU (according to business size).

In order to determine the total labelling costs to business, we have multiplied the cost per SKU by the number of businesses selling PPDS foods¹⁵.

A sensitivity analysis (+/- 20% on the cost per SKU) was used to estimate a lower and upper bound for labelling costs.

	Low Estimate Labelling Costs	Central Estimate Labelling Costs	High Estimate Labelling Costs
England	£245,425	£306,781	£368,137
Scotland	£24,168	£30,210	£36,251
Wales	£15,011	£18,763	£22,516
Northern Ireland	£6,386	£7,982	£9,578
UK	£290,989	£363,736	£436,483
Table 2: Estimated labelling costs to business under Option 2			

Training costs

This is currently a non-monetised cost.

Although not explicitly required, businesses may choose to improve staff training practices. The implementation of new or improved training will not be uniform across all businesses due to differences in the current level of training that they provide. Those who feel that they provide a very high level of training may feel they already meet what is deemed to be best practice, so would not change how they operate.

These cost could be incurred in one of two ways: providing training to staff members on the allergen content of PPDS foods on sale and/or providing guidance (documentation) to each outlet containing full allergen information.

Given the uncertainty around how this will be achieved, this cost has not been monetised at this current time.

Information provision costs

This is currently a non-monetised cost. Due to it being unclear the extent to which businesses already provide written allergen information on their premises, as current legislation states they must either already do this or provide the information verbally.

There would be a cost associated with producing written information, however that would depend on the number and complexity of PPDS food products that a business produces. This would also need to be amended/updated as new products were introduced (or current ones altered), the extent to which would depend on whether full ingredient information or simply allergen information was required.

¹⁵ The number of PPDS business were estimated using data from Euromonitor.

We intend to consult on this to gain an understanding of the extent to which businesses currently provide this information.

Costs to consumers

We do not expect there to be any costs to consumers of this policy. However, it is possible that businesses could choose to pass on any increase in costs they experience to consumers. This would not be an additional cost, simply the costs that are accrued by business may be passed on to consumers.

Costs to government

Familiarisation costs

Similar to familiarisation costs for business, there will be a one-off familiarisation cost to government. Time will be spent acquiring, reading and understanding the implications of the new legislation on their business.

We assume that for each local authority, it would take one Trading Standards Officer (TSO) or Environmental Health Officer¹⁶ (EHO) three hours to read, familiarise themselves with the new regulations and disseminate information to other TSOs/EHOs. According to 2018 ASHE data, the average wage rate for a Trading Standards Officer is £17.48 (Annex B). This is then uprated by 30% to £22.72. Therefore we estimate the familiarisation cost per local authority to be £68.17.

As with the familiarisation cost to businesses, low and high end hourly wages were used to produce low and high estimates for familiarisation costs.

The total familiarisation cost to government is cost per local authority multiplied by the relevant number of local authorities¹⁷ who would be carrying out checks on businesses.

	Low Estimate Familiarisation Cost	Central Estimate Familiarisation Cost	High Estimate Familiarisation Cost
England	£15,254	£24,065	£25,717
Scotland	£1,383	£2,182	£2,331
Wales	£951	£1500	£1,603
Northern Ireland	£475	£750	£801
United Kingdom	£18,063	£28,496	£30,452
Table 3: Estimated familiarisation costs to Government under Option 2			

Enforcement costs

This new legislation will be enforced during inspections by Trading Standards Officers or Environmental Health Officers. We estimate that the additional time required during an inspection of each outlet would be 15 minutes. It is our assumption that outlets selling PPDS foods are inspected once every 2 years¹⁸.

¹⁶ The costings in this analysis have been assessed using the hourly wage for TSOs rather than EHOs. We acknowledge that these roles are not identical. However we expect that the costs accrued due to familiarisation are expected to be similar for both roles.

¹⁷ Local authority split: England – 353, Scotland – 32, Wales – 22, Northern Ireland - 11

¹⁸ Trading Standards Wales (accessed 22/11/2018) - <https://www.tradingstandardswales.org.uk/help/foodinspect.cfm>

We will use the updated wage rate (£22.72) that we calculated for familiarisations cost as the time cost associated with inspections. Therefore the additional cost per inspection is £5.68.

The total enforcement cost is the cost per inspection multiplied by the number of inspections per year for each business, finally multiplied by the number of affected businesses (PPDS outlets).

	Low Estimate Enforcement Cost	Central Estimate Enforcement Cost	High Estimate Enforcement Cost
England	£16,445	£25,943	£27,724
Scotland	£1,619	£2,555	£2,730
Wales	£1,006	£1,587	£1,696
Northern Ireland	£428	£675	£721
United Kingdom	£19,498	£30,760	£32,871
Table 4: Estimated enforcement costs to Government under Option 2			

Benefits

The benefits have not been monetised. The benefits generated by this policy option will include those listed under Option 1, with there being an assumed improved success rate in reducing the likelihood of incidents due to allergic reactions.

It is believed that this policy option will lead to improved dialogue between consumers and food businesses (highlighted by both businesses and consumer groups as a key component of allergen information provision). This approach should raise public awareness of food allergies and empower individuals with a food allergy or intolerance to share their needs before making a food choice. This in turn should help to reduce the number of allergen related incidents further to that seen under Option 1.

This then also represents a benefit to consumers. The labelling of “ask the staff” (or equivalent) on each PPDS item signals to consumers (those with allergies in particular) that they can shop on those premises. As they will be able to speak with someone directly about allergen content of the foods on sale, to allow them to make an informed choice about what foods are safe for them to eat. Therefore, this option allows for food allergic consumers to have an improved choice of where to buy food.

This too implies a benefit for businesses. By improving the allergen information that they are able to provide, there may be the potential to grow their base of customers. Those with allergies who may have previously stayed away from the PPDS food market due to lack of clear allergen communication, may now choose to buy from the businesses selling these products.

This also presents a benefit for enforcement bodies in checking compliance. Assessing whether businesses are non-compliant is simple to detect, as they either have this on each product or they do not.

Option 3 (Mandate name of the food and allergen labelling on packages of PPDS foods)

Costs to businesses

Familiarisation costs

These are the same as those for Option 2.

Labelling costs

This cost has been monetised. The methodology used to calculate the labelling costs for this option builds upon the calculation of labelling costs for option 2.

We expect that PPDS foods will already be sold in some form of packaging. We therefore assume that once a business has made the change to their packaging/labelling due to this policy option, any further changes will occur under business as usual (i.e. businesses regularly redesign packaging/labelling for a number of different reasons¹⁹ such as rebranding).

For this option, we have made a pure assumption (not currently based on any evidence) that on average a business selling PPDS foods will have 20²⁰ different PPDS food products. Therefore the cost of re-labelling per business, is the cost per SKU multiplied by 20.

Then as in Option 2, multiplying the cost per business by the number of businesses.

A sensitivity analysis (+/- 20% on the cost per SKU) was used to estimate a lower and upper bound for labelling costs.

	Low Estimate Labelling Costs	Central Estimate Labelling Costs	High Estimate Labelling Costs
England	£4,908,499	£6,135,624	£7,362,748
Scotland	£483,353	£604,192	£725,030
Wales	£300,213	£375,266	£450,319
Northern Ireland	£127,711	£159,639	£191,567
UK	£5,819,776	£7,274,720	£8,729,664

Table 5: Estimated labelling costs to business under Option 3

Indirect costs associated with new labelling

This is a non-monetised cost. If businesses pre-print their packaging with the name and allergen information of a specific food, this then means that said business is restricted in what can be placed in that packaging.

Furthermore, it limits the extent to which a business can alter the ingredients of the product. They would be unable to add ingredients which would require the listing of another allergen (i.e. requiring another label change), or take an ingredient containing an allergen away (as this would then make the labelling inaccurate and again require a label change).

Training costs

This is currently a non-monetised cost.

Similar to option 2, although new (or additional) training is not explicitly required businesses may choose to improve staff training. This may become necessary as staff will need to be aware of what each product will need to be labelled with.

Alternatively, businesses may choose to provide guidance to each outlet as to what the content of each food is and how the product should be labelled, rather than relying on individual staff members to remember the allergen content of each PPDS food product.

¹⁹ Developing a Framework for Assessing the Costs of Labelling Changes in the UK - <https://webarchive.nationalarchives.gov.uk/20130404011920/http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf>

²⁰ This is not based on any evidence, purely an assumption. We will look to consult on this to establish a valid estimation of the number of distinct product lines that businesses currently have.

Due to the uncertainty around how businesses will approach this, we have not monetised this cost.

Costs of determining allergens.

We do not anticipate there being any costs associated with determining the allergens present in each PPDS product on sale.

Businesses should currently know what ingredients are in their food: including those they buy in their basic form (base ingredients such as fruit and vegetables) and the more complex ones that they buy from external suppliers (such as bread).

Costs to consumers

We do not expect there to be any costs to consumers of this policy. However, it is possible that businesses could choose to pass on any increase in costs they experience to consumers.

Costs to government

Familiarisation costs

These are the same as those for Option 2.

Enforcement costs

These are the same as those for Option 2.

Benefits

The benefits have not been monetised. The benefits generated by this policy option will include those listed under Option 2, with there being an assumed improved success rate in reducing the likelihood of incidents due to allergic reactions. This is because Option 2 merely promotes the conversation between consumers and staff (it does not guarantee one will take place), while this option guarantees that the 14 common allergens are always listed on the PPDS food product.

As with Option 2, it is expected that this will provide an improved provision of allergen information to consumers than the best practice option. However, we are unable to quantify to what extent this improvement will be.

Similar to Option 2, this option represents a benefit to consumers. Due to specific allergen information being visible on each PPDS food product, they can have increased confidence that what they are buying is safe for them to eat. Again this allows food allergic consumers to have an improved choice of where to eat and the number of goods from which to choose.

As stated in Option 2, those with allergies who may have stayed away from the PPDS food market due to lack of clear allergen communication, may now choose to buy from the businesses selling these products.

Option 4 (Mandate name of the food and full ingredient list labelling on packages of PPDS foods)

Costs to businesses

Despite our initial monetised costings indicating there to be no difference between Options 3 and 4, we wish to reinforce that we anticipate there to be substantial additional costs (with respect to Option 3) associated with Option 4 that we cannot fully monetise at this time. As highlighted, we will look to use the consultation to improve our understanding of the extent of the costs of this option.

Familiarisation costs

These are the same as those for Option 2.

Labelling costs

These are the same as those for Option 3.

Anecdotal evidence indicates that full ingredient labelling will be more costly to business than allergen labelling, but we were not able to obtain any figures to quantify these costs. We will seek to gather this information through the consultation.

Costs associated with new labelling

As highlighted in Option 3, this would place restrictions on a business's ability to substitute ingredients without requiring a label change. Businesses currently may look to change ingredients with close alternatives when prices rise as a means to keep costs low. Without this option to substitute for cheaper alternatives they may be forced to raise the price of their products. This restriction would be greater than that experienced under Option 3 where the policy only focuses on what allergens would need to be labelled, while this option would restrict the addition/subtraction of an ingredient.

Training costs

This is currently a non-monetised cost.

Similar to Options 2 and 3, although not explicitly required, businesses may choose to improve staff training. This may become necessary as staff will need to be aware of what each product will need to be labelled with.

Alternatively businesses may choose to provide guidance to each outlet as to what the content of each food is, rather than relying on individual staff members to remember the full ingredients as well as the allergen content of each PPDS product.

Due to the uncertainty around how businesses will approach this (may depend on size of business), we have not monetised this cost.

Costs of determining allergens.

We do not anticipate there being any costs associated with determining the full list of ingredients in each PPDS product on sale.

As stated in Option 3, businesses should know what ingredients are in their food. This information should not be difficult to attain and suppliers of more complex goods should include ingredients lists when supplying businesses selling PPDS foods.

Costs to consumers

We do not expect there to be any costs to consumers of this policy. However, it is possible that businesses could choose to pass on any increase in costs they experience to consumers. This would not be an additional cost, simply the costs that are accrued by business may be passed on to consumers.

Costs to government

Familiarisation costs

These are the same as those for Option 2.

Enforcement costs

These are the same as those for Option 2.

Benefits

The benefits have not been monetised. The benefits generated by this policy option will include those listed under Option 3, with there being an assumed better success rate in reducing the likelihood of incidents due to allergic reactions. We would expect that as full ingredients would

be listed, those who are allergic to foods/ingredients not included in the listed 14 would also benefit from this option. Therefore we would expect a further reduction in the likelihood (and ultimately number) of adverse reactions and fatalities with respect to Option 3.

As with Options 2 and 3, it is expected that this will provide an improved provision of allergen information to consumers than the best practice option. However we are unable to quantify to what extent this improvement will be.

Similar to Options 2 and 3, this option represents a benefit to consumers. Due to specific allergen information being visible on each PPDS food product, they can have increased confidence that what they are buying is safe for them to eat. Again this allows food allergic consumers to have an improved choice of where to eat and the number of goods from which to choose. As Option 3 only requires the labelling of the 14 allergens with the biggest public health impact in the EU, it does not account for those with allergies to foods other than those on the list of 14. Therefore full ingredient labelling can provide the same level of confidence to consumers with allergies not part of the listed 14.

As stated in Options 2 and 3, those with allergies who may have previously stayed away from the PPDS market due to lack of clear allergen communication, may now choose to buy from the businesses selling these products.

Consultation

We intend to gather data through the consultation to test the assumptions that we have made in this impact assessment.

In recognition of the disproportionate burden of any regulation on smaller businesses, we are looking to gather information through the consultation on potential thresholds to exempt smaller businesses from some obligations.

Enforcement officers have indicated that the existing micro or SME definitions would be difficult to use practically, as it will be difficult for an enforcement officer to determine whether a particular business is an SME or micro businesses. We will seek to gather views on the practicality of using SME definitions as exemption thresholds, and consider alternative proposals.

We also intend to gather views on combining options, for example, a two-tiered approach combining Option 2 (for smaller businesses) and Option 4 (for larger businesses).

Specific impact tests

Small and Micro Business Assessment

This section will consider the estimated impacts specifically on small and micro businesses (SMBs).

It is difficult to understand the extent to which SMBs feature in the PPDS market. As illustrated already in this document, the PPDS sector itself is difficult to establish.

According to the Government Business Population Estimates²¹, SMBs account for approximately 98% of all businesses in the 'Restaurants and mobile food service activities' sector that PPDS businesses are part of. Similarly these businesses account for approximately 53% of those employed in the same sector.

²¹ BEIS: Business Population Estimates - <https://www.gov.uk/government/statistics/business-population-estimates-2018>

From the same data source we know that SMBs contribute £17.6bn towards the £40.1bn total turnover of the sector. This equates to approximately £0.2m in turnover for each SMB in the sector.

In contrast Medium and Large businesses contribute £22.5bn towards the total turnover of the sector, equating to approximately £15m in turnover per business in the sector.

Non-quantifiable impact on small and micro businesses

We expect that mandating specific allergen or full ingredient labelling will disproportionately affect SMBs. Small changes in their cost or profit levels can affect SMBs sustainability and, therefore there is a risk that even a small impact on them could cause some to go out of business.

For example, a shortage of staff due to the time needed for familiarisation and implementation could lead to additional costs for SMBs, which naturally have fewer employees than larger businesses. Moreover larger businesses may (due to economies of scale) be large enough to warrant hiring those with specific legal expertise to interpret the new regulations (beyond familiarisation). So it could be argued that the degree of understanding and implementation of these new regulations could be better in larger businesses than smaller ones.

If additional (or improved) training was required, this too would disproportionately impact on SMBs. This would occur in a similar way to the impact from familiarisation (i.e. requiring to set aside time for training).

Quantifiable impacts on small and micro businesses

Familiarisation costs

In our analysis we expect the familiarisation costs incurred to be the same for Options 2, 3 and 4.

	Low Estimate Familiarisation Cost	Central Estimate Familiarisation Cost	High Estimate Familiarisation Cost
United Kingdom - SMBs	£854,239	£1,253,515	£1,563,571
% of familiarisation costs for all businesses borne by SMBs	94.3%	93.0%	92.3%
Table 6: Estimated familiarisation costs to Small and Micro businesses under Options 2,3 and 4			

Looking at the familiarisation cost per business, we see that familiarisation costs for individual SMBs is approximately 3-4 times smaller than larger businesses.

	Low Estimate Familiarisation Cost	Central Estimate Familiarisation Cost	High Estimate Familiarisation Cost
SMBs	£10.57	£15.57	£17.86
Medium and Large businesses	£34.66	£62.74	£80.18
Table 7: Estimated familiarisation costs per business under Options 2,3 and 4			

Labelling costs

		Low Estimate Labelling Costs	Central Estimate Labelling Costs	High Estimate Labelling Costs
Option 2	United Kingdom – SMBs	£67,212	£84,015	£100,818
Options 3 and 4	United Kingdom – SMBs	£1,344,241	£1,680,301	£2,016,361

Table 8: Estimated labelling costs to Small and Micro businesses under Options 2,3 and 4

Due to the nature of our calculations, the share of labelling costs borne by SMBs (23.1% of the total labelling costs) is consistent across both options and the range of estimates.

We assume that smaller businesses are less likely to have complex packaging for their PPDS products, therefore any labelling changes required are more likely to be less intrusive and therefore less costly than those experienced by larger businesses.

Competition test

The four questions of the competition assessment are as follows:

In any affected market, would the proposal:

1. Directly limit the number or range of suppliers?
 - The policy options proposed impose no direct limit on the number of suppliers/businesses that can operate in the PPDS food market.
2. Indirectly limit the number or range of suppliers?
 - The costs to individual business may vary, due to the current extent that they label their PPDS products and the number of items that they sell. The size of these variations between businesses are unlikely to be large enough to limit the number of businesses that are able to operate in the PPDS food sector.
 - The cost to businesses of the policy options considered are unlikely to prohibit the entry of new businesses in the PPDS food market.
3. Limit the ability of suppliers to compete?
 - There are currently businesses that are already voluntarily providing improved allergen labelling, which may be seen as a form of product/brand differentiation from their competitors. However we are not fully clear on the extent to which this is the case at this point in time.
 - The proposals do not limit businesses ability to compete on grounds of quality, geographic location, absolute price, advertisement and many other aspects on which businesses frequently compete.
4. Reduce suppliers' incentives to compete vigorously?
 - The policy options considered do not exempt suppliers/businesses from general competition law, introduce or amend intellectual property regime or increase the costs to customers of switching between suppliers.
 - Under current legislation businesses must be able to provide allergen information to consumers. Option 4 will require businesses to provide a list of full ingredients of each

PPDS food product, which may be of use to competitors. Disclosure of this information would potentially deter experimentation/innovation.

Sustainability test

There is no evidence to suggest that changes to the provision of allergen information will have an impact on sustainable development.

Environmental test

As this policy only deals with foods that are already being packaged, there is no environmental risk from increased packaging resulting in increased waste.

Justice impact test

A full justice impact test for this proposal will be carried out after the completion of the consultation and the details of each policy option have been finalised.

Rural proofing

We have considered the effects of the policy proposals on those living in rural areas. At present, there is no evidence to suggest that there would be a significant impact.

Annex A: Hourly wage for ‘Quality assurance and regulatory professionals’ (AHSE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Restaurant and Catering establishment managers and proprietors	Original Wage	£8.13	£11.93	£13.74
	Up-lifted Wage	£10.57	£15.51	£17.86
Quality assurance and regulatory professionals	Original Wage	£13.33	£24.13	£30.84
	Uplifted Wage	£17.33	£31.37	£40.09

Annex B: Average wage rate for a ‘Trading standards officer’ (AHSE, 2018)

		Low end hourly wage	Average hourly wage	High end hourly wage
Trading standards officer	Original Wage	£11.08	£17.48	£18.68
	Up-lifted Wage	£14.40	£22.72	£24.28

Annex C: Article 2 (2)(e) of FIC

‘prepacked food’ means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; ‘prepacked food’ does not cover foods packed on the sales premises at the consumer’s request or prepacked for direct sale;